

Health and Sport Committee Comataidh Slàinte is Spòrs

Supply and demand for medicines



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Health and Sport Committee

To consider and report on matters falling within the responsibility of the Cabinet Secretary for Health and Sport.



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Executive Summary

- In undertaking this inquiry into the supply and demand for medicines, we were anticipating exploring issues relating to the efficiency of the system and the levels of waste generated. However, in considering the themes raised with us a fundamental problem has become apparent the system of supply and demand for medicines in Scotland does not have a focus on patients.
- 2. Instead, the system is burdened by market forces, public sector administrative bureaucracyⁱ and reported under resourcingⁱⁱ, inconsistent leadership and a lack of comprehensive, strategic thinking and imaginationⁱⁱⁱ, allied to an almost complete absence of useable data^{iv}.
- 3. The lack of data collection and analysis on outcomes achieved via the prescriptions of medicines is of huge concern. The impact on individual patients of taking medicines is not being examined and worse, it is not routinely sought. Patients in primary care are not receiving follow up care to ensure the medicines prescribed were effective or even to ensure they were used.
- 4. We found the lack of care taken to understand people's experience of taking medicines impacted the system at every stage. We are clear that gathering, analysing and sharing this information in a comprehensive, systematic way across Scotland would be the single most beneficial action to result from this inquiry. This needs to be prioritised as a matter of urgency, which will require strong leadership.
- 5. Those we consider should have responsibility for solving problems or developing innovative solutions were often the very people who recounted the issues for us, but without accompanying ideas or impetus for change^v. The vague statements we heard of the utility or need to do something without accompanying detail on how it would be achieved are ineffective in driving forward innovation and change, particularly in reference to data and evidence collection^{vi}.
- 6. Little detail was offered as to how change might actually be brought about, let alone at a pace proportionate to the prize to be gained. Nobody seemed willing or able to take on responsibility for driving forward the change many identified as essential. These issues are not new and we heard little by way of solutions and strategies from senior leaders within the health service about what would actually be done to address them at the pace and scale required. We propose energetic, imaginative,

- iii Health and Sport Committee, Official Report, 21 January 2020, Col 4
- iv Health and Sport Committee, *Official Report*, 28 January 2020, Col 22 v Health and Sport Committee, *Official Report*, 10 March 2020, Col 11
- vi Health and Sport Committee, Official Report, 21 January 2020, Col 14

Letter from Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde, on Supply and Demand for Medicines, 28 February 2020

ii Letter from Dr Scott Jamieson of the Royal College of General Practitioners on the Supply and Demand for Medicines, 2 March 2020

accountable, focused leadership is required in order to achieve the changes required. We strongly recommend the Scottish Government examine the lack of accountability for improvement allied to the reasons why leaders at all levels are not proposing innovative, coherent and comprehensive solutions which many told us would deliver efficiencies and savings.

- 7. Given their responsibility for developing a plan to implement the National health and wellbeing outcomes framework, we were surprised to hear little of the role of Integrated Joint Boards (IJBs) in more cost and clinically effective use of medicines. For bodies with such a fundamental role to be notable by their absence in this inquiry again suggests a lack of strategic oversight in this area.
- 8. The relationship between prescriber and patient was stark throughout the inquiry. The power of the prescriber to determine the clinical and cost effectiveness of a patient's treatment was described as almost absolute, and it is clear prescribers are instinctively reaching for the prescription pad, and are not taking the time to discuss medicines with patients to a degree that ensures the clinical and cost effectiveness of the prescription. Nor are comprehensive reviews of polypharmacy or long-term prescriptions taking place and there is nothing in place to monitor, evaluate or mandate this, resulting in at best waste and at worst harm to the patient. It also appears to us there is not a strict adherence to the principles of realistic medicine, patients are not equal partners in discussions on their treatment. One of the areas this is most exposed is social prescribing and prescriptions for non-medicine alternatives.
- 9. We believe the Scottish Government's contract with GPs is failing to mandate these behaviours and actions and must be revised. In the long term, without systematic changes the Scottish Government should consider whether the system of GPs being external contractors works well for patients. An approach which pays GPs from the public purse with no monitoring or evaluation vii of their actions is not acceptable.
- 10. The role of community pharmacists in dispensing medicines was clear and well defined, however we heard a wealth of evidence on the other benefits community pharmacists could bring in ensuring the cost and clinical effectiveness of medicines in Scotland. However, the lack of structure surrounding their relationships with both patients and the rest of the health services means they are failing to exploit their skills, knowledge and position for the benefit of patients. Discussions on whether and how medicines were taken, and the effects of these, are at best being recorded on Post It Notes^{viii} and at worst disappearing without record^{ix}. Patients expect and deserve a better system than this.
- 11. We are extremely disappointed that once again all roads lead to the dismal failure of the NHS in Scotland to implement comprehensive IT systems which maximise the use of patient data to provide a better service^x. Comments^{xi} on patients' surprise at how badly information is handled, particularly at junctions of care, were casually made, once again exposing attitudes not focused on patient care. Worse

vii Scottish Government (2019). Primary care: national monitoring and evaluation strategy viii Health and Sport Committee, *Official Report*, *4 February 2020*, Col 11

ix Letter from Community Pharmacy Scotland on the Supply and Demand for Medicines, 20 February 2020

Health and Sport Committee

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- still, where a lack of patient focus was acknowledged^{xii}, this was not followed by a solution or plan to take action, but simply left hanging for us to add to the list of issues with medicine management.
- 12. We again urge the Scottish Government to consider the IT and data requirements of the NHS across the country in a strategic way and design systems with long term utility as a matter of urgency. We recognise this is a large undertaking but similarly, we cannot keep concluding in reports as we have for the last 4 years that savings, efficiencies and above all better patient care are possible with modern IT, capable of data gathering, analysing and sharing, without demanding urgent action in this area.

x Health and Sport Committee, Official Report, 21 January 2020, Col 14

xi Health and Sport Committee, Official Report, 4 February 2020, Col 19

xii Health and Sport Committee, Official Report, 4 February 2020, Col 17

Introduction

- 13. The Health and Sport Committee agreed to hold an inquiry into the supply and demand for medicines. This was in part based on the frequency of occasions the issue was raised with us by representatives of health boards and special health boards as part of our scrutiny of such bodies.
- 14. We agreed the inquiry would focus on four distinct areas—
 - Purchasing (including procurement and medicine price regulation, a reserved area undertaken at a UK level);
 - Prescribing (covering all licensed to write prescriptions);
 - Dispensing (covering hospital, pharmacy and GPs); and
 - Consumption (looking at effectiveness and wastage).
- 15. The overarching aim for our inquiry was to examine the management of the medicines budget, including the cost and clinical effectiveness of prescribing.
- 16. We also agreed that the purpose of the inquiry was not to consider the cost effectiveness of new medicines or whether particular medicines should be routinely available for prescribing by the NHS in Scotland. This issue arose in the written and oral evidence we received and we have limited our comments on these processes to their overall impact on the clinical and cost effectiveness of medicines throughout the system.

Engagement

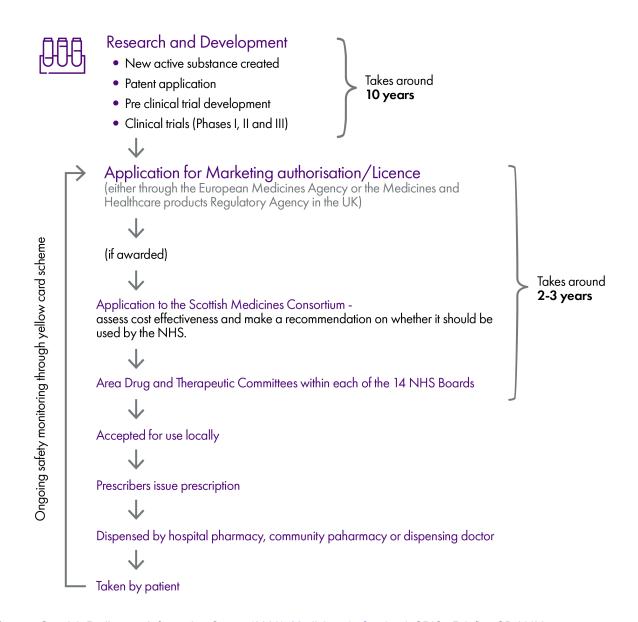
- We sought views from a wide range of bodies and individuals, and our call for submissions ran from September to November 2019. We requested comments on 4 areas—
 - 1. Does the system ensure patients receive the most clinically and cost effective treatments and, if not, how can this be improved?
 - 2. Does the NHS in Scotland achieve the most value from the money spent on medicines and, if not, how can this be improved?
 - 3. In what ways can the system be made more efficient?
 - 4. How can the medicines budget be controlled while maintaining clinical and cost effectiveness?
- 18. We received 58 written submissions. Further information was sought during our inquiry along with supplementary evidence from several witnesses who gave evidence. All correspondence and supplementary evidence can be found at Annexe B.

Supply and demand for medicines, 6th Report, 2020 (Session 5)

19. We are extremely grateful to all those who contributed to its inquiry, without the input we received, both written and oral, we would not have been able to undertake our work.

Structure of the report

Journey of a medicine - from research and development to Scottish patients



Source: Scottish Parliament Information Centre (2020). Medicines in Scotland. SPICe Briefing SB 20/08

- 20. Our inquiry was broad and wide ranging, covering the supply and demand for medicines in Scotland from the research and development of a drug, to the consumption by a patient. The report reflects the distinct areas we have examined and received evidence on—
 - Research and development
 - Licensing and acceptance for use in the NHS this includes how consideration of new medicines by the European Medicines Agency, the Medicines and

Healthcare products Regulatory Agency and the Scottish Medicines Consortium contributes or detracts from ensuring Scotland maximises spend on medicines

- Purchase and procurement
- Prescribing
- Dispensing
- Consumption
- Data and IT
- 21. A glossary of terms and acronyms has also been provided at the end of the report.

Background

- 22. Our inquiry took place against the back drop of the most recent Audit Scotland report on spending in the NHS in Scotland, which notes "drugs costs have stabilised" The report states—
 - "The NHS in Scotland spent almost £1.8 billion on drugs in 2017/18, a reduction of 0.2 per cent in real terms since 2016/17. Good progress continues to be made in the proportion of generic medicines prescribed. This increased from 83.9 per cent in 2017/18 to 84.3 per cent in 2018/19."xiv
- 23. The net expenditure on medicines by the NHS in Scotland in 2017/18 was 16.6%, down 0.1% on the year before. The majority of spending on drugs takes place in community and family health services and this was again reduced from the previous year.

Expenditure on drugs stabilised in real terms, in 2017/18



Spent on drugs in 2017/18 by the **NHS in Scotland**

0.2% less in real terms than 2016/17

Changes in spending varied by board from:

↓ 5% decrease for **NHS Borders**

↑ 5.8% increase for NHS Western Isles



Net expenditure in the NHS in 2017/18 was on drugs

0.1% less than in 2016/17



Spent on drugs in community and family health services

0.6% less in real terms than in 2016/17

The amount spent on drugs in hospitals was £438.4 million

0.9% increase since 2016/17



The Scottish Government, via the New Medicines Fund (NMF), provides additional funding to NHS boards to cover the costs of increasing access to some medicines for very rare conditions and endof-life care.

£42 million in 2017/18

Source: R600: pharmacy - drugs expenditure, ISD Scotland cost book data, November 2018; Volume and Cost (NHS Scotland), ISD Scotland, July 2019; Scottish Government NHS allocations, March 2019

Source: Audit Scotland (2019). NHS Scotland in 2019, Page 25

- 24. Stakeholders agreed medicines spend in Scotland is going in the right direction, with many telling us of the tightly controlled and meticulously scrutinised budget for spending on drugs, especially when compared to spending in other parts of the health service.
- 25. In relation to branded medicines, there are built in limits to spending increases as a result of the Voluntary Pricing and Access Scheme (VPAS) which it was noted provides a degree of predictability of spending. We were told^{xv} the UK compares favourably to other countries when it comes to prices paid for generic medicines^{XVI}.

Research and development



...within Europe, the UK has one of the highest spends on pharmaceutical research and development

SPICe Briefing (2020). Medicines in Scotland, SB 20-08

- 26. We heard there was potential for the NHS in Scotland to achieve better value from medicines based on activity at the research, development and manufacturing phases of a medicine's existence.
- 27. These included—
 - Use of data from real-world experience of using medicines as opposed to reliance on evidence gathered during clinical trials; and
 - Preparedness for personalised medicines, including within manufacturing.
- 28. Each are explored in turn.

Real-world experience and clinical trials

- 29. Submissions we received suggested the evidence gathered in clinical trials, and on which Scottish Medicine Consortium (SMC) and National Institute for Health and Care Excellence (NICE) appraisals are based, did not always match the data collected based on real-world use of a medicine. Several reasons were cited for this—
 - The "eligibility criteria" for clinical trials did not always match the groups to which a medicine was eventually prescribed;
 - Patients who eventually take medicines may have co-morbidities and this could affect the results^{xviii}; and
 - Smaller populations were available to participate in the trials for some drugs, resulting in a lack of economic information required for SMC assessment^{xix}.

- 30. Celgene UK^{xx} cited Cancer Research UK research showing clinical trials could prove a drug's safety and efficacy but did not always demonstrate the benefits to be derived for patients. They further noted "a greater emphasis on using real-world data of patients' treatment outcomes will be necessary to ensure, not only that outcomes for patients are personalised and optimal, but that the NHS can be confident it receives value for its medicines spend."^{xxi}
- 31. We recognise the value of knowing the wider benefits to be gained from medicines and the implications for clinical and cost effectiveness. As various stakeholders told us, medicines which are not having the desired effect are not good value for money.
- 32. Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland, said—
 - "Having that real-world evidence over time could greatly help us to evaluate what [medicine] is the most cost effective, once there is experience of using the medicine. However, to do that, we need much more efficient IT systems to collect outcomes data. As we have already heard, there are some great initiatives, such as the cancer medicines optimisation programme, but it is still early days and there is more work to be done."
- 33. The data on real-world application of medicines is important to both manufacturers and the NHS alike in terms of the value of medicines. As stated above, medicines which are not having the desired effect are not good value for money. This is a theme explored further in the VALUE AND OUTCOME BASED PRICING part of our report.

Personalised medicine

- 34. Personalised medicine involves tailoring drugs and treatment to the specific requirements of an individual's version of an illness and their biology.
- 35. The benefits include—
 - Increased efficacy of a drug (and therefore better value);
 - · Reduced adverse reactions (and therefore better clinical effectiveness); and
 - · Reduced waste.
- 36. Several themes were pursued in evidence on personalised medicine—
 - · Waste;

xvii Prostate Cancer UK. Written Submission

xviii Health and Sport Committee, Official Report, 21 January 2020, Col 5

xix Association of the British Pharmaceutical Industry. Written Submission.

xx Celgene UK. Written Submission.

xxi Celgene UK. Written Submission.

xxii Health and Sport Committee, Official Report, 21 January 2020, Col 54

- · Manufacturing technology; and
- Preparedness for personalised medicine in the healthcare system.

Waste

37. Several representations, including the Chief Pharmaceutical Officer^{xxiii} and the University of Strathclyde^{xxiv}, noted the potential for personalised medicine to reduce or even eradicate waste of medicines by ensuring maximum tailoring to the specific need of the patient.

Manufacturing technology

- 38. Alison Culpan of the Association of the British Pharmaceutical Industry (ABPI) suggested data enabling the identification of patients who could benefit from innovations in gene therapy was lacking, and this was squandering the opportunity to get the "right outcomes and value for money from what is spent on medicines."
- 39. The University of Strathclyde stated manufacturers were reliant on outdated technology and called for new production and supply chain technologies to "revolutionalise healthcare delivery" However, they said such a project was unlikely to be achieved by one company or group acting independently and called for cross sector and Government intervention.

Preparedness for personalised medicine in the healthcare system

- 40. Although it was clear to us the technology is in its infancy, a range of witnesses spoke of the need for current systems to adapt to the medicines of the future.
- 41. We received several representations urging the SMC to consider future proofing assessment processes. The Blood Cancer Alliance^{xxvii} welcomed approvals of chimeric antigen receptor T-cell (CAR T cell therapy^{xxviii}) but said challenges lay ahead in terms of greater demand and therefore budget impact. They called for further work with industry to "scope the likely challenges and financial impacts of these innovative treatments."^{xxix}

xxiii Health and Sport Committee, Official Report, 21 January 2020, Col 14

xxiv University of Strathclyde. Written Submission.

xxv Health and Sport Committee, Official Report, 21 January 2020, Col 26

xxvi University of Strathclyde. Written Submission.

xxvii Blood Cancer Alliance. Written Submission.

xxviii Further details on CAR T cell Therapy can be found here.

xxix Blood Cancer Alliance. Written Submission.

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- 42. It was noted personalised medicines would represent higher costs in some circumstances but this should be assessed and balanced against the likely benefits. There were calls for reform of the SMC assessment to accommodate personalised medicine and for a review similar to the work NICE are carrying out in this area.
- 43. Dr Alan MacDonald, Chair of the SMC, informed vs us about the SMC's horizon scanning activities (discussed further in the SCOTTISH MEDICINE CONSORTIUM HORIZON SCANNING section of this report) and preparations for the next generations of medicines. The ABPI noted the substantial evidence which would be required by the SMC for advanced therapies, indicating "the NHS needs to balance the risk of treatment failure with a manufacturer's need to recoup the enormous cost associated with development." xxxii
- 44. Technology in manufacturing was another area where stakeholders felt systems would require to be updated to accommodate innovations.
- 45. We note and welcome the ambitions in the area of personalised medicine described by the Chief Pharmaceutical Officer. We seek from the Scottish Government specific detail as to—
 - Which areas it currently considers require adaptation to embrace personalised medicine;
 - How this will link with other data and technology projects such as the National Digital Platform; and
 - Budgetary planning for the accommodation of personalised medicines within the health and social care service in Scotland.
- 46. We encourage the Scottish Government to consider the technology used by manufacturers and wholesalers in the creation and delivery of personalised medicines and consider what further incentives and support could be provided to develop these.
- 47. We recommend the Scottish Government make provision for the use of personalise medicine in the future, including data collection (a theme considered in detail in the DATA and IT section of this report).

Research and Development - conclusions

48. On the use of real-world data rather than clinical trials, we share the enthusiasm of stakeholders for better utilisation of such information. We also share their views on the data infrastructure required to achieve a system for proactively and comprehensively gathering this information.

xxx Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020

xxxi Association of the British Pharmaceutical Industry. Written Submission.

- 49. The advent of personalised medicines is an exciting prospect in terms of cost and clinical effectiveness according to many who spoke to us. Above all, the potential for personalised medicine to achieve positive impacts on budgets and waste, and improved clinical outcomes for patients, is clear. This is a theme we return to throughout the report.
- 50. We believe the Scottish Government should be doing all it can to support the use of personalised medicine, and encourage and support innovation in Scotland, while remaining mindful of the need to have in place appropriate systems and means of tracking and measuring outcomes.
- 51. However, we are clear such a development requires to be properly planned in terms of assessment processes, data and technology and budget required. In addition, we would expect cost implications along with measurement of effectiveness to be included in processes at the outset.

Licensing and acceptance for use in the NHS

All stakeholders have in common the aspiration that patients get prompt access to medicines likely to be of benefit to them in a way that is uncomplicated, timely and transparent. All stakeholders agreed that the aim was not to achieve universal access to all licensed medicines and that the system has to have the ability to give medicines not approved status if considered appropriate.

Scottish Government (2016). Review of Access to New Medicines, Page 10

- 52. The following sections cover how medicines are licensed and accepted for use within the NHS in Scotland. Products must first obtain a licence or marketing authorisation, before being assessed by the Scotlish Medicines Consortium (SMC) for use within the NHS in Scotland.
- 53. The impact of these processes on clinical and cost effectiveness was the subject of various representations to us as part of our inquiry.

Licensing

54. The Scottish Parliament Information Centre has described the licensing of drugs in the UK and the role of the Medicines and Healthcare products Regulatory Agency (MHRA)—

- "Before any medicine can be used in the UK, it usually has to receive a marketing authorisation from either the Medicines and Healthcare products Regulatory Agency (MHRA), or the European Medicines Agency (EMA). The MHRA is the UK's licensing and regulatory authority and its functions are reserved to Westminster. It therefore operates on behalf of the 4 UK countries. A marketing authorisation is often referred to as a 'licence' and can only be issued following the completion of clinical trials that show—
 - the medicine treats the condition it was developed for;
 - the medicine meets safety and quality standards; and
 - the medicine does not cause unacceptable side effects.

At the moment there are a number of routes for a medicine to obtain a marketing authorisation in the UK but at a very basic level this boils down to either applying via the EMA, or applying to the MHRA" xxxiii

- 55. We were particularly interested in two specific aspects of licensing and their impact on the use of medicines in Scotland—
 - · Licensing for more than one indication; and
 - Evidence provided by pharmaceutical companies to support licensing.

Licensing for more than one indication

- 56. We were interested in medicines which could have alternative uses to their original design and how this could achieve both savings and better results for patients (a current example which has arisen since our evidence sessions being the use of Remdesivir, an anti-viral drug, to shorten the recovery time from COVID-19). Given the complexities described to us, we were also keen to understand how applications could be encouraged for licences for existing medicines which could have an impact on conditions beyond that which they were originally designed for.
- 57. Representatives of the pharmaceutical industry suggested there was work going on from their perspective as to how this could be progressed.
- Warwick Smith, Director General, British Generic Manufacturers Association (BGMA), discussed the scope for looking "at older medicines that can be repurposed for new uses" He described discussions as "well advanced" on this. Alison Culpan of the Association of the British Pharmaceutical Industry (ABPI) said it was hard to quantify how much a licence application for an additional indication may cost. She provided detail on recommendations of an Association of Medical Research Charities report on ways to incentivise repurposing including research and development tax credits, creation of a fund, prescribing resources and support for clinicians. It also covered ways to enable the MHRA to communicate more easily with those seeking to research repurposing and for including repurposed medicines in the Accelerated Access Pathway.

- 59. She also highlighted work undertaken on this issue by the European Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP). She said the ABPI had been working on a draft framework with the Commission—
 - "This framework operates by improving communication between academia (who are often the first to identify medicines for repurposing), the regulator and industry partners. The process would enable an academic to contact the regulator for advice around the eligibility of a molecule, this advice would then enable the "academic champion" to take this project to an industry partner who can subsequently evaluate the risks and opportunities involved. A lack of awareness and communication between academia, the regulator and industry is often the first and largest barrier which prevents older drugs from being repurposed. This framework provides a template to de-risk and improve the process."
- 60. We were told of circumstances in which medicines were being used for indications for which they were not licensed and Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland, spoke^{xli} of legal challenges in this regard.
- 61. We were interested in whether there was a role for an organisation to encourage pharmaceutical companies to apply for licences for different indications for existing drugs. Both the MHRA^{xlii} and the SMC^{xliii} told us they could have no role in encouraging applications. Dr Alan MacDonald, Chair of the SMC, added—
 - "In certain circumstances HIS [Healthcare Improvement Scotland] can advise on the off-label/unlicensed use of cancer medicines. HIS hosts an Off-label Cancer Medicines Programme recently commissioned by Scottish Government's Cancer Division in response to its Beating Cancer: Ambition and Action strategy. This programme aims to provide advice to NHS Board Area Drug and Therapeutics Committees on the managed entry of off-label uses of cancer medicines. Through this advice the programme will facilitate equity of access to off-label uses of cancer medicines and reduce unwarranted variation for patients across NHSScotland. This programme is expected to deliver the first piece of advice to NHSScotland in summer 2020."

xxxiv Health and Sport Committee, Official Report, 21 January 2020, Col 37

xxxv Health and Sport Committee, Official Report, 21 January 2020, Col 37

xxxvi Health and Sport Committee, Official Report, 21 January 2020, Col 39

xxxvii Letter from the Association of the British Pharmaceutical Industry on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020

xxxviii Association of Medical Research Charities (2017). Facilitating adoption of off-patent, repurposed medicines into NHS Clinical Practice

xxxix A definition of repurposing in this context is provided in the Glossary of this report.

- xl Letter from the Association of the British Pharmaceutical Industry on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020
- xii Health and Sport Committee, Official Report, 21 January 2020, Col 60
- xiii Health and Sport Committee, Official Report, 21 January 2020, Col 11

- 62. Rose Marie Parr, Chief Pharmaceutical Officer, said the Scottish Government encouraged pharmaceutical companies to assess their licence. She added—
 - "We see some older medicines being repurposed and used for very different things. There needs to be some consideration of that huge burden on some parts of pharmaceutical industry to get their medicines to licence—that is very costly and takes time. Some of those processes could be shortened a bit, which would help."
- 63. Alison Strath, Principal Pharmaceutical Officer, Scottish Government, added "...we would need to work to understand what levers there might be to support repurposing" and although the Cabinet Secretary for Health and Sport, Jeane Freeman, foresaw challenges, she did not consider these to be "insurmountable". XIVIII
- 64. We request the Scottish Government provide details of what plans it has to respond to the suggestions provided by the Association of the British Pharmaceutical Industry (ABPI) on how applications for additional licences for medicines can be encouraged and incentivised.
- 65. We recommend the Scottish Government works with the UK Government and the MHRA to streamline and shorten the processes it described to us as causing barriers to pharmaceutical companies applying for additional licences and health care technology assessments for new indications for existing drugs.
- 66. We encourage the Scottish Government to provide details of how it will encourage pharmaceutical companies to apply for new licences for new indications for previously licensed medicines, including how timescales can be shortened to assist with this and the other levers proposed by the Scottish Government.
- 67. We also request the Scottish Government give consideration to commissioning and funding clinical trials on medicines for use in conditions of significant public health impact or where there is a significant lack of cost effective treatments.

Adaptive licensing

- 68. Alison Culpan, Scotland Director of the ABPI, highlighted the issue of adaptive licensing, which she described as "emerging"—
- xiiii Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020
- xliv Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020
- xIv Health and Sport Committee, Official Report, 10 March 2020, Col 11
- xIvi Health and Sport Committee, Official Report, 10 March 2020, Col 11
- xivii Health and Sport Committee, Official Report, 10 March 2020, Col 11
- xiviii Letter from the Association of the British Pharmaceutical Industry on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020

- "Adaptive licensing predominantly applies to new treatments where 'drug candidates' that meet a serious unmet medical need can be initially approved for use in a restricted patient group. This is then gradually expanded to broader patient populations as additional safety and efficacy data is generated. Whilst this doesn't apply to older molecules or those in limited indications, it does demonstrate that flexibility is required to ensure patients continue to benefit from fast access to new medicines."
- 69. We request details of whether adaptive licensing can be applied to new indications for existing drugs and the role the Scottish Government can play in encouraging this.

Evidence in support of licence applications

- Jonathan Mogford, Director of Policy, MHRA explained^I the process by which evidence to support licence applications was peer reviewed. He said the licensing process was "part of the important interaction with companies that ensures that the claims that are made for products are backed by clear scientific evidence" and noted in the agency's enthusiasm for the debate about using "real-world" evidence (please refer to the REAL-WORLD EXPERIENCE AND CLINICAL TRIALS section of this report) and suggested improved data on outcomes would fuel this further (this issue is considered fully in the OUTCOMES section of this report).
- 71. In correspondence with us, he further outlined the basis of decisions on evidence—
 - "All decisions on approval of medicines, wherever these are taken, are based on satisfactory demonstration by the applicant of the safety, quality and efficacy of new medicines. In the UK, the decisions are informed by independent advice from the Commission on Human Medicines. The MHRA does not plan to change the evidence standards for approval of new medicines and will use existing flexibilities, such as conditional approval and incentives for rare diseases to ensure that unmet clinical needs can be met by licensing of new products."
- 72. Dr Alan Macdonald, Chair of the SMC, outlined how the organisation treated medicines with less supporting evidence than they might otherwise expect and said "...if a medicine that is licensed by the EMA comes to us, we have to assume that it

- ii Health and Sport Committee, Official Report, 21 January 2020, Col 7
- iii Health and Sport Committee, Official Report, 21 January 2020, Col 20
- Letter from Jonathan Mogford, Director of Policy, Medicines and Healthcare products Regulatory Agency, on the supply and demand for medicines, 4 March 2020

xlix Letter from the Association of the British Pharmaceutical Industry on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020

Health and Sport Committee, Official Report, 21 January 2020, Col 19

has been shown that the benefits outweigh the risks. However, our job is different; it is to say whether the benefits justify the cost."

Licensing - conclusions

- 73. The opportunities presented by licensing medicines for more than one indication are currently being missed in our view, due to barriers described to us by stakeholders. We have recommended the Scottish Government consider how it can better encourage trials and expedite licensing for additional indications of existing drugs to maximise their use within the NHS.
- 74. On the standard of evidence required for new medicines, we are satisfied the processes are working although refer to our previous conclusion better use could be made of 'real-world' experience of using medicines, rather than relying solely on clinical trial data.

Access to new medicines

- 75. While the subject of access to new medicines does not form the focus of our inquiry^{lv}, many of the submissions received reflected on how new medicines are assessed in Scotland. Issues raised by work by the previous Health and Sport Committee in its session 4 inquiry^{lvi} on Access to New Medicines are relevant to this area.
- 76. In the period since that inquiry was undertaken, an independent review was held "to assess the impact of the new approach introduced in 2014 by [Scottish Medicines Consortium] SMC" and it reported^{lvii} to the Scottish Government in December 2016. The Scottish Government provided us with updates on progress towards delivery of the recommendations in the review in November 2017^{lviii}, February 2018^{lix}, May 2018^{lx}, June 2018^{lxi} and 13 January 2020^{lxii}.
- liv Health and Sport Committee, Official Report, 21 January 2020, Col 61
- Iv The Royal College of Physicians of Edinburgh suggested access to new medicines should have been revisited by the Committee as part of this inquiry in its written submission.
- Ivi Further information on the inquiry is available here.
- Ivii Scottish Government (2016). Review of Access to New Medicines
- Iviii Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 16 November 2017
- lix Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 2 February 2018
- Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 17 May 2018
- lxi Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 19 June 2018

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Supply and demand for medicines, 6th Report, 2020 (Session 5)

- 77. This section will consider evidence received on the following themes
 - Scottish Medicine Consortium (SMC) Assessments;
 - · Patient Access Schemes;
 - · Evidence Based Approvals; and
 - Interaction with the Pharmaceutical industry.

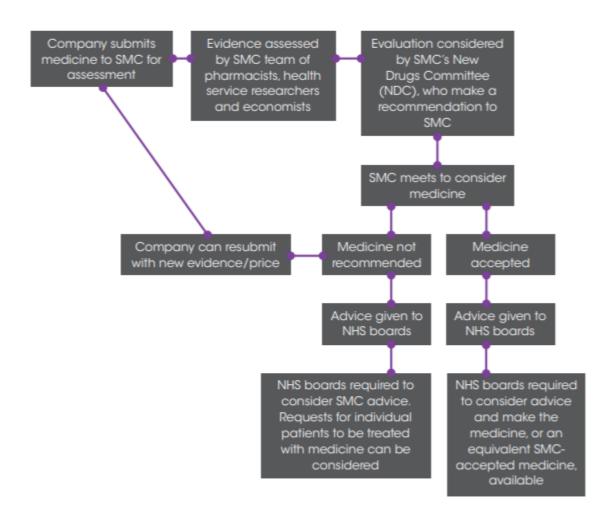
Scottish Medicines Consortium (SMC) assessments

- 78. The SMC is a branch of Healthcare Improvement Scotland (HIS) which carries out assessments on all new medicines for use in Scotland. It consists of a committee of "clinicians, pharmacists, NHS board representatives, the pharmaceutical industry and the public" It also has a horizon scanning function, which according to HIS "aims to support health boards with financial and service planning for new medicines in the pipeline that may be accepted into routine clinical use." As previously indicated, its primary role is to say whether the benefits of a new medicine justify the costs.
- 79. The following diagram describes the process by which drugs are assessed—

lxii Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 13 January 2020

Ixiii https://www.scottishmedicines.org.uk/about-us/who-we-are/

Process for medicines submitted to SMC (approximately 18 weeks)



Source: Scottish Medicines Consortium (2018). A Guide to the Scottish Medicines Consortium

Many, such as Celgene^{lxv} and the British Medical Association (BMA)^{lxvi} praised the efficacy of the assessment processes of the SMC and suggested these kept the budget under control while also allowing for access to new medicines. The Association of the British Pharmaceutical Industry (ABPI) said^{lxvii} the healthcare technology assessment conducted by the SMC was a "leader" in balancing cost and medical value, and said it made Scotland an attractive place for manufacturers to test new products.

Ixv Celgene. Written Submission.

Ixvi British Medical Association. Written Submission.

Ixvii Association of the British Pharmaceutical Industry. Written Submission.

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- 81. The Royal College of Physicians of Edinburgh^{lxviii} and others highlighted the potential waste from not using the most clinical and cost effective medicines available, stating the prescription of drugs of limited efficacy could "adversely apply pressure on the use of existing drugs of very good cost effectiveness, and on other treatments which provide better cost effectiveness". The difficulties in assessing cost effectiveness of medicines are discussed in the VALUE section of this report.
- 82. While many heralded the SMC assessment process and said their approval status inferred clinical and cost effectiveness, a number of questions were also raised.
- 83. We considered the following themes presented to us in evidence on the assessment processes of the SMC—
 - Speed of the assessment process compared with the rest of the UK;
 - Changes since the Review of Access to New Medicines^{lxix} (the Montgomery Review), including—
 - Review of assessment methods:
 - Peer Approved Clinical System (PACS) Tier 2;
 - Patient and Clinician Engagement (PACE);
 - Clinical and cost effectiveness of new medicines;
 - Access to end of life, orphan and ultra-orphan medicines; and
 - Interim acceptance.
 - The assessment of value; and
 - · Horizon scanning.

Speed of assessment compared with the rest of the UK

- Merck, Sharp and Dohme^{lxx}, Pfizer UK^{lxxi}, the Blood Cancer Alliance^{lxxii} and Roche^{lxxiii} suggested SMC assessments were slower than UK counterparts, thus denying availability of medicines to patients and the cost benefits to the NHS for longer.
- Others such as Prostate Cancer UK^{lxxiv} expressed their concerns about delays and Janssen^{lxxv} were among those who called for investment of "money and resource" to allow the SMC to deal with delays in assessment.

Ixviii Royal College of Physicians of Edinburgh. Written Submission.

lxix Scottish Government (2016). Review of Access to New Medicines

lxx Merck, Sharp and Dohme. Written Submission.

Ixxi Pfizer UK. Written Submission.

Ixxii Blood Cancer Alliance. Written Submission.

Ixxiii Roche Products Ltd. Written Submission.

86. While noting the issues raised with us were predominantly from bodies with an interest in seeing medicines becoming available quickly, we would welcome the view of the Scottish Government as to the reasons for potential differences in assessment speeds throughout the UK and what, if any, action is required by the Government or the SMC to rectify this.

Assessment of licensed medicines for cost effectiveness

- 87. We note the process of approval by the SMC starts with companies submitting medicines for assessment. The MS Society Scotland suggested there should be a more effective system for accessing medicines which were licensed but had not yet been assessed by the SMC in order to ensure patients can access the most effective treatments. We concur with this view.
- 88. We recommend the Scottish Government work with the SMC to develop a more effective system for accessing medicines which have not been submitted for assessment to the SMC based on the premise every newly licensed medicine should be assessed for cost effectiveness regardless of whether the manufacturer applies.

Changes since the Montgomery Review - review of assessment methods

- 89. In the Review of Access to New Medicines, Dr Brian Montgomery, Chair of the Review, wrote "...the overwhelming sense encountered was that there was a high level of satisfaction with SMC and that its processes remain robust."
- 90. Dr Alan MacDonald, Chair of the SMC, said—
 - "The process has changed to allow greater access to medicines for cancer and rare conditions, which was a specific policy intent." IXXVIII
- 91. Nonetheless, there were several areas highlighted to us where stakeholders felt improvements could go further—
 - The BMA implied there is still an imbalance in the system based on the difficulties in prescribing off-formulary or unlicensed medicines contrasted with the high approvals for drugs approved at speed for small groups of patients;

Ixxiv Prostate Cancer UK. Written Submission.

Ixxv Janssen. Written Submission.

Ixxvi The MS Society Scotland. Written Submission.

Ixxvii Scottish Government (2016). Review of Access to New Medicines, Page 9

Ixxviii Health and Sport Committee, Official Report, 21 January 2020, Col 57

IXXIX British Medical Association. Written Submission.

- The ABPI^{lxxx}, Janssen^{lxxxi} and the Blood Cancer Alliance^{lxxxii} suggested
 assessments for combination therapies should be considered, noting the
 difficulty in demonstrating value and the financial barriers to companies to
 bringing these forward for assessment, meaning patients were missing out on
 clinically effective treatments. The ABPI also said the SMC should maintain an
 awareness of other assessment bodies' approach to consideration of
 combination therapies;
- Roche Products Ltd said "Whilst robust, Roche believes that current methods
 of value assessment are becoming restrictive and patients in Scotland are not
 getting access to some clinically and cost-effective medicines when compared
 to the rest of the UK. Evolution of process must be seen as a priority to ensure
 delivery of best value and equitable access to cost-effective treatments across
 the UK. "Ixxxiiii They suggested further reforms to Patient Access Schemes and
 Genomic Profiling.
- Merck Sharp and Dohme note^{lxxxiv} a lack of commitment to review assessment processes for specialised medicines for which the quality adjusted life year (QALY) and Institute for Clinical and Economic Review (ICER) measures are not appropriate, resulting they say in patients missing out on medicines for specialised conditions. They believed such assessments were not suitable for every medicine.
- Cancer Research UK suggested assessment of clinical and cost effectiveness was becoming more challenging and new "commercial and commissioning approaches are required in response to this trend, to ensure effective management of the medicines budget".
- 92. When questioned, Dr Alan MacDonald, Chair of the SMC, defended the "rigour" of the SMC appraisals process, acknowledging there may still be debate around access levels. He described the SMC function of comprehensive consideration of new medicines as compared with existing options as unique. Dr Brian Montgomery outlined in views on how changes implemented since his review of access to new medicines in Scotland had ensured the SMC had more flexibility which meant less circumvention of the process for patients to gain access to new medicines, therefore improving the robustness of the SMC appraisal system.

IXXX Association of the British Pharmaceutical Industry. Written Submission.

Ixxxi Janssen. Written Submission.

IXXXII Blood Cancer Alliance. Written Submission.

IXXXIII Roche Products Ltd. Written Submission.

Ixxxiv Merck, Sharp and Dohme. Written Submission.

IXXXV Cancer Research UK. Written Submission.

Ixxxvi Health and Sport Committee, Official Report, 21 January 2020, Col 44

IXXXVII Health and Sport Committee, Official Report, 21 January 2020, Col 44

Ixxxviii Health and Sport Committee, Official Report, 21 January 2020, Col 45

93. The BMA^{lxxxix}, the Royal College of Physicians of Edinburgh^{xc} and the Royal College of GPs^{xci} were critical of the approval of medicines following political pressure and the importance of evidence based assessments and prescribing was emphasised by many throughout the inquiry.

Changes since the Montgomery Review - Peer Approved Clinical System (PACS) Tier 2

- 94. While the SMC assesses and takes decisions on medicines for routine use in the NHS as a whole, there are routes for patients and clinicians to access rarer medicines. Prior to the Review of Access to New Medicines^{xcii}, the Peer Approved Clinical System (PACS) and the Individual Patient Treatment Request (ITPR) systems were available.
- 95. The review recommended the Scottish Government should—
 - "Review and evaluate the experience of PACS to date with a view to deciding on any required modifications and thereafter agree the final model and timescales for implementation in NHSScotland." xciii
- 96. In response to this, a review of PACS Tier 1 was undertaken and a second tier was developed to replace the ITPR process. In June 2018, the Peer Approved Clinical System (PACS) Tier 2 was introduced to provide a new route for patients to access rarer medicines.
- 97. The advent of PACS Tier 2 was welcomed by respondents to our call for evidence such as Celgene^{xciv}, who said it strengthened the system, Cancer Research UK^{xcv} and Pfizer UK^{xcvi}.
- 98. NHS Fife Area Drug and Therapeutic Committee (ADTC)^{xcvii}, NHS Lothian ADTC^{xcviii} and NHS Borders^{xcix} said PACS removed a health board's ability to consider cost or affordability where the SMC had already deemed a medicine not to be cost effective and more patients would access them as a result (as PACS facilitates access and does not allow boards to consider the cost). We sought the view of the Cabinet Secretary for Health and Sport on this issue in correspondence^c and also her view of when the second stage of the review of PACS would be completed.

IXXXIX British Medical Association. Written Submission.

xc Royal College of Physicians of Edinburgh. Written Submission.

xci Royal College of GPs. Written Submission.

xcii Scottish Government (2016). Review of Access to New Medicines

xciii Scottish Government (2016). Review of Access to New Medicines, Page 35

xciv Celgene. Written Submission.

xcv Cancer Research UK, Written Submission.

xcvi Pfizer UK. Written Submission.

xcvii NHS Fife Area Drug and Therapeutics Committee. Written Submission.

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99. However, others identified areas for further consideration including consistency of application and review of PACS Tier 2.

Postcode lottery

- 100. We were keen to explore the operation of PACS Tier 2 and whether this had created a uniformity of access across the country.
- 101. The Cabinet Secretary for Health and Sport stated "Guidance issued offered health boards a framework that aimed to enhance consistency among boards in the ways that they consider clinicians' requests to prescribe certain medicines that are not recommended by the SMC for routine use in NHS Scotland."^{ci}
- 102. Dr Alan MacDonald, Chair of the SMC, suggested^{cii} the operation of the SMC should prevent postcode lotteries but yielded^{ciii} each health board may apply PACS differently. He noted the National Review Panel's role was to respond to that but both he^{civ} and the Cabinet Secretary said there had been only one appeal to the Panel so far. The Cabinet Secretary believed this was too few to analyse but said "the small number of cases referred does suggest that the Government's core objective of the PACS Tier Two system, to provide greater consistency across the country, is being achieved."^{cv}
- 103. Dr Brian Montgomery told us "The reality is that, although the system is often portrayed as postcode prescribing, health boards apply the same principles to a completely different set of individuals, and therefore we see differing consequences." CVI
- 104. We are heartened to hear of the few appeals to the National Review Panel although share the Cabinet Secretary's opinion on the conclusions which can be drawn from this. We note the Area Drug and Therapeutic Committee (ADTC) Collaborative will "ensure the ongoing review and development" of the guidance issued to boards on PACS Tier 2.

xcviii NHS Lothian Area Drug and Therapeutic Committee. Written Submission.

xcix NHS Borders. Written Submission.

- c Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020
- ci Letter from the Cabinet Secretary for Health and Sport on the Review of Access to Medicines, 13 January 2020
- cii Health and Sport Committee, Official Report, 21 January 2020, Col 48
- ciii Health and Sport Committee, Official Report, 21 January 2020, Col 48
- civ Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020
- cv Letter from the Cabinet Secretary for Health and Sport on the Review of Access to Medicines, 13 January 2020
- cvi Health and Sport Committee, Official Report, 21 January 2020, Col 49

105. We recommend the Scottish Government provide details of how it will reduce inconsistency in the application of PACS Tier 2.

Review of the implementation of PACS Tier 2

- 106. The Cabinet Secretary for Health and Sport told^{cviii} us the Scottish Government committed to review the new system 6 and 12 months after introduction. She said the first review was undertaken in January 2019 and said feedback (though limited) focused on the administration of the new system, consolidation of board application processes and when applications were admissible. A 12 month review took place from June to September 2019 and responses/conclusions are due for publication in "early 2020".
- 107. We are keen to receive data to enable comparison between the operation of PACS Tier 2 and individual patient treatment requests (IPTR) as soon as possible.
- 108. We recommend the results of the review of the implementation of PACS Tier 2 be made available at the earliest possible opportunity and include details of the impact of the implementation of PACS Tier 2 on the budgets of all health boards for medicines, including comparison with the spend under the previous IPTR system.

Changes since the Montgomery Review - Patient and Clinician Engagement (PACE)

- 109. Celgene^{cix} were supportive of the Patient and Clinician Engagement (PACE) process and the Cabinet Secretary for Health and Sport, Jeane Freeman, informed us of both the fulfilment of the recommendations on PACE but also of the next steps to "explore how PACE actually shapes decision-making"^{cx}.
- 110. We welcome this work and look forward to receiving details of developments.

cvii Letter from the Chief Medical Officer and Chief Pharmaceutical Officer to Chief Executives, Medical Directors, Directors of Pharmacy and Directors of Finance within NHS Boards on Guidance on the Implementation of the Peer Approved Clinical System (PACS) Tier Two, 29 March 2018

cviii Letter from the Cabinet Secretary for Health and Sport on the Review of Access to Medicines, 13 January 2020

cix Celgene. Written Submission.

cx Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 13 January 2020

Changes since the Montgomery Review - Clinical and cost effectiveness of new medicines

- 111. While recognising the welcome outcome of increased access to new medicines as a result of changes implemented since the Review of Access to New Medicines, we were disappointed to hear some thought this was at the expense of clinical and cost effectiveness.
- The Royal College of GPs expressed^{cxi} the view changes in policy had seen medicines approved which may not have been previously and said "the clinical effectiveness of new medicines as a result may not be to the same level as they were historically". NHS Grampian ADTC^{cxii} said medicines were approved with less evidence of clinical or cost effectiveness than would previously have been the case while Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde said "Through the changes to the policy position in Scotland, boards are now making available medicines that we would consider to be no longer cost effective. That has an impact in that it diverts resources away from other interventions that we might consider to be cost effective."^{cxiii}
- 113. The views of NHS Grampian ADTC and Gail Caldwell provide an example of a frustration experienced throughout this inquiry on the role of NHS leaders, although we sympathise with the predicament.
- 114. If an ADTC does not have control over items for inclusion on a formulary, what is their purpose? Senior pharmacists we heard from throughout the inquiry helpfully identified a number of issues within health boards for us, but provided no solutions to these. If a Director of Pharmacy is not in a position or empowered to ensure resources are being applied to the most effective interventions, this is a larger problem than ineffective medicine prescription.
- 115. We recommend the Scottish Government consider the role of health boards within PACS decision making processes to make clear what the role of ADTCs, directors of pharmacy and other senior leaders is.

Changes since the Montgomery Review - access to end-of-life, orphan and ultraorphan medicines

116. Rarer medicines defined as end-of-life, orphan and ultra-orphan can be defined as follows—

cxi Royal College of General Practitioners. Written Submission.

cxii NHS Grampian Area Drug and Therapeutic Committee. Written Submission.

cxiii Health and Sport Committee, Official Report, 4 February 2020, Col 26

End-of-
Life
Medicine

"A medicine used to treat a condition at a stage that usually leads to death within 3 years with currently available treatments." CXiV

Orphan Medicine

"A medicine with European Medicines Agency (EMA) designated orphan status (i.e. conditions affecting fewer than 2,500 people in a population of 5 million) or a medicine to treat an equivalent size of populations irrespective of whether it has designated orphan status."

Ultra-Orphan Medicine

"To be considered as an ultra-orphan medicine all criteria listed should be met—

- the condition* has a prevalence of 1 in 50,000 or less in Scotland,
- the medicine has an EMA orphan designation for the condition and this is maintained at time of marketing authorisation,
- · the condition is chronic and severely disabling, and
- · the condition requires highly specialised management.
- * SMC uses the description of the condition within the European Medicines Agency's (EMA) Orphan Maintenance Assessment Report (OMAR) as a reference (or the description within the original orphan designation if the OMAR is not available). Submissions for medicines that are validated as ultra-orphan according to this definition will be assessed by SMC and will then be available to prescribers for a period of up to three years while further clinical effectiveness data are gathered. After this period the company will be asked to provide an updated submission for reassessment and SMC will make a decision on routine use of the medicine in NHSScotland."CXVI
- 117. Recommendations 6 and 7 in the Review of Access to New Medicines were—
 - "Review the definitions for end-of-life, orphan and ultra-orphan medicines to
 ensure that the definitions used remain suitable to deal with the assessment of
 anticipated new treatments such as targeted medicines, increasing use of
 combination therapies and the impact of genomics.
 - Develop, agree and implement a new definition of "true ultra-orphan medicine" to take account of low-volume, high-cost medicines for very rare conditions."
- 118. Recommendation 11 called on the Scottish Government to "Develop and implement a new assessment and approval pathway for true ultra-orphan medicines that restricts the role of SMC to health technology assessment and places the responsibility for the final decision on availability elsewhere."
- In January 2020, the Cabinet Secretary informed us all three recommendations had been implemented. While the definitions for end-of-life and orphan medicines were deemed suitable, a new definition for ultra-orphan medicines was devised. As of January 2020, the new definition had tested "more than twenty medicines". We were interested in whether new definitions had posed any issues thus far and the Cabinet Secretary said positive feedback had been received by pharmaceutical companies. This tallied with responses to our call for views, with organisations such as Celgene praising the strength and adaptiveness of Scotland's healthcare technology assessment processes, which it said "are ensuring Scotland receives good value for the money it spends" cxxi.

cxiv Scottish Government (2016). Review of Access to New Medicines cxv Scottish Government (2016). Review of Access to New Medicines

cxvi Scottish Medicines Consortium Revised process - ultra-orphan medicines for extremely rare conditions cxvii Scottish Government (2016). Review of Access to New Medicines, Page 17 cxviii Scottish Government (2016). Review of Access to New Medicines, Page 22

cxix Letter from the Cabinet Secretary for Health and Sport on the Review of Access to Medicines, 13 January 2020

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- 120. However, others were reserved about the success of the new processes, with companies such as Chiesi Ltd saying it was "early days" for the new pathway. The European Medicines Group called for "similar energy to be put behind access to medicines for common conditions as well as orphan and end-of-life conditions". CXXIII
- 121. We recognise it is still early days for the new definitions and pathways, and request the Scottish Government publish reports on evaluations.

Changes since the Montgomery Review - interim acceptance

..recognising that the clinical evidence base for new medicines is often uncertain, and while the data capabilities are being improved, SMC has begun to develop its assessment process by introducing an option of conditional (interim) acceptance for some medicines. This new approach will support earlier patient access with the reassurance that the medicine's clinical effectiveness will be revisited in around 2-3 years. If a medicine that has been accepted on an interim basis is subsequently not recommended by the SMC, then that medicine will no longer be routinely available in NHS Scotland. Patients taking the medicine who are deriving clinical benefit will, however, be able to remain on the treatment until the patient and clinician consider it appropriate to stop.

Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, 26 February 2020

- 122. The SMC said it was working on extending interim acceptance to more new medicines. The notion of conditional approval was welcomed by stakeholders including the European Medicines Group^{cxxiv} and we were told of several areas where the new interim acceptance would be beneficial.
- 123. Dr Alan MacDonald, Chair of the SMC, said the debate on outcome based pricing (see the VALUE AND OUTCOME BASED PRICING section for further analysis) would be one the SMC would have to consider as its interim acceptance option

cxx Letter from the Cabinet Secretary for Health and Sport on the Review of Access to Medicines, 13 January 2020

cxxi Celgene. Written Submission. cxxii Chiesi Ltd. Written Submission.

cxxiii European Medicines Group. Written Submission. cxxiv European Medicines Group. Written Submission.

- became more "mature" noting there was a grey area for medicines which worked, but not quite as well as originally claimed.
- 124. The ABPI^{cxxvi} described challenges ahead for the SMC, including evidence from trials based on decreasing participant samples, and suggested expansion of the number of medicines accepted under the "interim acceptance" status could help. Bristol-Myers Squibb^{cxxvii} said this route should be available for a "wider group of medicines not just those with conditional marketing authorisation."
- 125. The Cabinet Secretary for Health and Sport told us the SMC was "....now exploring extending the use of the conditional acceptance option, specifically in the context of clinical uncertainty whether further data is likely to [be] forthcoming at a relatively early stage as a consequence of ongoing clinical trials."

Value

- 126. The concept of value was highlighted to us in several written submissions. Stakeholders suggested this was a subjective assessment and could have multiple meanings what is good value for an individual may not be good value for the population. It was also argued the value of a medicine could change depending on its age or its successors. The question of the efficacy of a cheaper medicine and whether this was worth the spend in comparison to better clinical results from more expensive medicines was also raised.
- 127. Matt Barclay of Community Pharmacy Scotland said "The cost of medicines should also be seen in terms of value, rather than in terms only of cost. When they are used appropriately, most medical interventions using medicines are perfectly good value for money. The situation has to be looked at in that light." Similar points were made by a number of pharmaceutical manufacturers.
- 128. Prostate Cancer UK^{cxxx} were among those who asserted the use of medicines which may carry a high price tag, but which achieve huge savings in other forms of treatment, should be considered good value. The European Medicine Group^{cxxxi} and Healthcare Improvement Scotland (HIS)^{cxxxii} suggested medicines spend should not be considered in isolation from the health and social care budget as it risked discounting savings to be achieved across a pathway. Pfizer UK^{cxxxiii} also suggested wider societal costs, including to the economy, should be accounted for when considering the value of medicines, while the MS Society Scotland^{cxxxiv} called for consideration of the impact on the welfare budget. HIS noted the "cost effectiveness analysis to drive value for money is not used uniformly across all areas of medicines spend."^{cxxxv} and the Cabinet Secretary for Health and Sport,

cxxv Health and Sport Committee, *Official Report, 21 January 2020,* Col 53 cxxvi Association of the British Pharmaceutical Industry. Written Submission.

cxxvii Bristol-Myers Squibb. Written Submission.

cxxviii Letter from the Cabinet Secretary for Health and Sport on the Review of New Medicines, 13 January 2020

cxxix Health and Sport Committee, Official Report, 28 January 2020, Col 16

- Jeane Freeman^{cxxxvi}, suggested evidence gathering in this area was hard and there was not a Scotland wide approach.
- 129. Many believed the SMC processes achieve good value for money and praised the system.

Scottish Medicine Consortium horizon scanning

- 130. The Scottish Medicines Consortium (SMC) described its horizon scanning functions as—
 - "SMC provides Health Boards with early intelligence on new medicines in development to support their financial and service planning. SMC is involved in the use and development of UK PharmaScan, a UK-wide horizon scanning database that provides information on new medicines, indications and formulations in the pharmaceutical pipeline. Forward Look, the SMC's annual horizon scanning report, is published in October each year, it provides concise information on new medicines/indications that are expected to impact Boards over the following financial year. The report is accompanied by a financial planning tool describing estimated uptake and potential budget impact. SMC provides biannual updates to allow Boards to adjust their financial plans within year. We know that Forward Look reports are highly valued by Boards."
- 131. In terms of recent activity to prepare for the next generation of medicines, the SMC told us it had issued briefings recently on "advanced therapy medicinal products and medicines with histology-independent indications" and anticipated more personalised medicines for patients with specific biomarkers, regenerative cell therapies and "complex combination regimes for cancer medicines" cxxxviii
- 132. We were interested in whether the horizon scanning function of the SMC was working effectively.
- 133. Dr Scott Jamieson of the Royal College of GPs^{cxxxix} posed the question of whether the SMC was assessing medicines against the qualities of value to patients and

cxxx Prostate Cancer UK. Written Submission.

cxxxi European Medicine Group. Written Submission.

cxxxii Healthcare Improvement Scotland. Written Submission.

cxxxiii Pfizer UK. Written Submission.

cxxxiv The MS Society Scotland. Written Submission.

cxxxv Healthcare Improvement Scotland. Written Submission.

cxxxvi Health and Sport Committee, Official Report, 10 March, 2020, Col 18

cxxxvii Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020

cxxxviii Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020

suggested it was not. David Coulson, Assistant Director of Pharmacy, NHS Tayside cxl said the SMC's work was vital to ensure there were no surprises and emphasised the importance of a good evidence based to ensure value from medicines. Dr Jamieson^{cxli} also stressed the need to collect good outcomes data to achieve this (see the OUTCOMES section of this report for further detail).

- 134. Many stakeholders believed the SMC processes for horizon scanning would have to be updated to accommodate personalised medicines (discussed fully in the PREPAREDNESS FOR PERSONALISED MEDICINE IN THE HEALTHCARE SYSTEM section of this report). Roche^{cxlii} called for a consultation, akin to a review undertaken by the National Institute for Health and Care Excellence (NICE), on SMC processes and preparedness for assessing personalised medicine and updated horizon scanning. Pfizer UK^{cxliii} suggested there was room for ongoing review in this area also to ensure patients could gain early access to new innovations.
- 135. The Cabinet Secretary for Health and Sport, Jeane Freeman, said—
 - "The new medicines fund is vital, but we need to parallel the work that the SMC is doing in considering its processes in anticipation of precision medicine and coming innovations. We need to consider how we fund and whether we should alter our approach in the light of innovative and important developments for patients."

 California in the light of innovative and important developments for patients.
- 136. We request detail of how and the planned timescale in which the Scottish Medicines Consortium processes will be reviewed and updated to accommodate innovations in medicines.
- 137. We recommend the Scottish Government review how it intends to fund this work, as well as the innovative medicines of the future to ensure Scottish patients are world leaders in receiving the best possible pharmaceutical treatment.

SMC assessment processes - conclusions

138. The healthcare technology assessments of the SMC were lauded as world leaders and the processes, as well as recent updates to these, were welcomed in the main for their contribution to the clinical and cost effectiveness of medicines used by the NHS in Scotland. There was general consensus improvements had been achieved through the Review of Access to New Medicines, but that the programme of reform

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cxxxix Health and Sport Committee, Official Report, 28 January 2020, Col 28 cxl Health and Sport Committee, Official Report, 28 January 2020, Col 28 cxli Health and Sport Committee, Official Report, 28 January 2020, Col 28 cxlii Pfizer UK. Written Submission.
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cxliv Health and Sport Committee, Official Report, 10 March 2020, Col 19

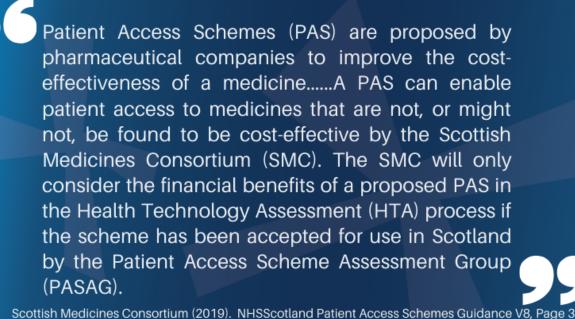
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and review must continue to ensure processes remain able to accommodate innovation.

- 139. There were calls for updates to assessment methods and measures to speed up assessments and we suggest the Scottish Government and the Scottish Medicines Consortium consider these suggestions. We also look forward to seeing how measures such as interim acceptance and the new definitions of end-of-life, orphan and ultra-orphan medicines progress.
- 140. Finally, we are in full agreement with evidence suggesting the value of medicines should be considered as well as the cost, and the full range of benefits and savings medicines could provide, both in health and across the economy, should be accounted for in decisions (see the VALUE section of this report for further detail).

Patient Access Schemes



- 141. According to Janssen^{cxlv}, 54% of the medicines for which the Scottish Medicines Consortium (SMC) published review advice between 1 January 2018 and 31 October 2019 had a Patient Access Scheme (PAS) discount and Celgene^{cxlvi} noted a steady increase in their use also. Patient Access Schemes are used to discount the cost of new drugs in the early years of their use.
- 142. Roche Products Ltd proposed revisions could be made to the criteria for PAS to "drive further value" and Pfizer UK called for revisions to the system.

cxly Janssen. Written Submission.

cxlvi Celgene. Written Submission.

cxlvii Roche Products Ltd. Written Submission.

- 143. The Blood Cancer Alliance noted two types of PAS are available: a simple scheme and a complex scheme cxlviii. The group called for a more "flexible and transparent commercial framework" referring to the use of complex discount schemes and the difficulties these could bring. The group called for the guidance to be "revised to deliver a more mature, flexible and transparent framework for commercial discussion, focused on overcoming identifiable barriers to access and incentivising early engagement and flexibility on the part of industry."
- 144. The Blood Cancer Alliance^{cli} described the dichotomy between the commercial confidentiality of the schemes and the need for transparency in decision making for the public, noting the former helped ensure good value for the NHS. They further added—
 - "In Scotland a further complexity exists in that some treatments do not have a formally approved PAS, although they are reimbursed by NHS Scotland at a discounted price. Where this is the case, the SMC will not take into account the discount price for the purpose of assessing the cost effectiveness and instead apply the full list price. This means that cost effectiveness decisions are not being based on the true cost of the combination to NHS Scotland. This is leading to inefficient decisions."

145. Bristol-Myers Squibb said—

- "Any scheme not presented as a simple discount is regarded as complex and PASAG assessment is made with their established view that these schemes introduce cumulative administrative burden for the NHS and that their perceived financial benefits may not be fully realised in practice. They therefore tend to be rejected. The Committee should investigate the proportion of SMC submissions that include a PAS, what proportion are regarded as simple or complex and what proportion of complex PAS are accepted."
- 146. We recommend the Scottish Government should review, along with the Scottish Medicines Consortium and the Patient Access Scheme Assessment Group, how the actual cost to be charged to the NHS on approval of medicines can be "assessed in the absence of a formal [Patient Access Scheme] PAS" Cliv.
- 147. We would welcome the view of the Scottish Government on how confidentiality in the negotiation of Patient Access Schemes can ensure best value for the NHS.

cxIviii Scottish Medicines Consortium (2019). NHSScotland Patient Access Schemes Guidance V8, page 3

cxlix Blood Cancer Alliance. Written Submission.

- cl Blood Cancer Alliance. Written Submission.
- cli Blood Cancer Alliance. Written Submission.
- clii Blood Cancer Alliance. Written Submission.
- cliii Bristol-Myers Squibb. Written Submission.
- cliv Blood Cancer Alliance. Written Submission.

148. We recommend the Scottish Government provide detail of "...the proportion of Scottish Medicine Consortium submissions that include a PAS, what proportion are regarded as simple or complex and what proportion of complex PAS are accepted."

Interaction with the pharmaceutical industry

- 149. In the Review of Access to New Medicines, Dr Brian Montgomery stated—
 - "To date the interaction between the various players, and certainly that between NHSScotland and the pharmaceutical industry has tended to begin only once a medicine has been granted a license and a submission to SMC is being considered. All spoken to consider this to be too late, missing as it does the opportunity to collaborate on issues such as horizon scanning, the optimal use of specific medicines, wider assessments of impact and value and more pragmatic pricing strategies."
- 150. We also heard there was still a case for review of interaction with the pharmaceutical industry, with groups such as the European Medicines Group^{clvii}, Merck, Sharp and Dohme^{clviii} and Janssens^{clix} calling for further engagement with companies. The Blood Cancer Alliance suggested a "more flexible, better resourced and transparent commercial framework for negotiation with the industry is essential if the most clinically effective medicines are to be made cost effective in the future."
- 151. The British Dental Association clxi called for stronger negotiations with drug companies in order to save money. The role of the SMC is not to negotiate on price, merely to assess whether the benefits of the medicine offered are worth the stated cost. This left us wondering where the room for negotiations on price are within the tendering and national procurement systems.
- 152. We recommend the Scottish Government and the Scottish Medicines Consortium consider the views on interactions with the pharmaceutical industry during assessment of new medicines we received and what benefits could accrue for the NHS in Scotland from improvement in this area.

clviii Merck, Sharp and Dohme. Written Submission.

clix Janssen. Written Submission.

clx Blood Cancer Alliance. Written Submission.

clxi British Dental Association. Written Submission.

clv Bristol-Myers Squibb. Written Submission.

clvi Scottish Government (2016). Review of Access to New Medicines, Page 48

civii European Medicines Group. Written Submission.

Access to new medicines - conclusions

153. Although consideration of access to new medicines did not form part of the inquiry, we have considered views presented on the role of the SMC in as far as this impacts on the clinical and cost effectiveness of medicines used in the NHS. While we believe advances have been made in light of the recommendations of the Montgomery Review, we urge the Scottish Government to consider the views proposed to us on further potential improvements. We also suggest there is scope to consider the operation of Patient Access Schemes further to ensure these are best serving the NHS and to look at interactions with the pharmaceutical industry during assessment of medicines.

Scrutiny of non-medicine interventions

- 154. Throughout the inquiry, we heard a general theme there is inequality of scrutiny between medicines compared to other healthcare interventions.
- 155. Other interventions such as medical devices, appliances, technology, and procedures do not receive the same robust level of scrutiny as medicines before being used on patients. It is also not clear to us how the potential benefits of medicines are assessed against the benefits of non-medicine interventions.
- 156. On licensing, the Cabinet Secretary for Health and Sport, Jeane Freeman, told us "We continue to press the [Medicines & Healthcare products Regulatory Agency] MHRA to make its process for medical devices comparable with the process that we all expect for clinical trials, licensing and so on of medicines." She suggested the Medicines and Medical Devices Bill at Westminster may be a vehicle for discussions on improving the MHRA's processes. We requested the discussions which have taken place on this issue with the MHRA and look forward to considering a legislative consent memorandum on the Bill.
- 157. Dr Ewan Bell, National Clinical Lead, Area Drug and Therapeutics Committee Collaborative, Healthcare Improvement Scotland, said—
 - "..there are other interventions that are non-medical but are not social prescribing, such as bariatric surgery, which is much more effective for the treatment of type 2 diabetes than any medicine. There has not been sufficient evaluation of different interventions outwith medicines in NHS Scotland......The health boards have a variety of inputs—from the Scottish Medicines Consortium, the Scottish health technologies group, clinical guidelines, patient support groups and targets—and there is no national, once-for-Scotland comparison or health technology-type evaluation of those different inputs. There is no comparison of all those different interventions, and no ranking—I do not want to use the word "prioritisation"—of what NHS Scotland believes that it is important to deliver on."

clxii Health and Sport Committee, Official Report, 10 March 2020, Col 16

clxiii Letter to the Cabinet Secretary for Health and Sport on Supply and Demand for Medicines, 23 March 2020

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- 158. This issue is further discussed at length in the NON-PHARMACEUTICAL INTERVENTIONS and SOCIAL PRESCRIBING sections of this report.
- 159. David Coulson, Assistant Director of Pharmacy, NHS Tayside^{clxv} suggested the single national formulary (considered fully at the FORMULARY section of this report) may be a way to consider national governance for the prescription of non-medicine interventions.
- 160. In June 2018, the then Cabinet Secretary for Health and Sport, Shona Robison, told us—
 - "A policy team for medical devices within the Scottish Government is in the process of being set up which will consider, with stakeholders, the need for further policies and strategies on medical devices' use in Scotland."
- 161. We ask the Scottish Government to provide detail as to how the assessment process for new medicines compares the benefits of medicines with non-medicine interventions (such as surgery, digital technology and lifestyle changes).
- 162. We ask the Scottish Government to provide an update on the work of the established policy team within the Scottish Government considering use of medical devices in Scotland, including remit, timescales for work, engagement activities with stakeholders to date, the outcomes of this work and plans, including timescales, for further scrutiny and governance in the area of medical devices.

Purchase and Procurement



...the challenge is how to best manage the interface between NHSScotland and the pharmaceutical industry. A situation where NHSScotland seeks to optimise its use of a finite resource subject to ever-increasing demands while the pharmaceutical industry operates in a competitive commercial environment and seeks to maximise return on its investment and meet the expectations of its shareholders.

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Scottish Government (2016). Review of Access to New Medicines, Page 36

- 163. The process of purchase and procurement was one of the four central pillars of our inquiry.
- 164. Several submissions, predominantly from the pharmaceutical industry, focused on how budgets were already well managed and predictable due to pricing schemes and the close scrutiny of the drugs budget. The Association of the British Pharmaceutical Industry (ABPI) observed the "...percentage cost of what we spend on medicines in 2020 is only 1 per cent more than what was spent on medicines in 1948."

 They also note "...and yet we have made great advances in this area over the past 40 years."
- 165. To put this in a different perspective, Spending on medicines constitutes 13.1% of the overall health budget^{clxix} totalling £1.76bn.
- 166. The wealth of evidence on spending on medicines we received will be considered in the following sections of this report—
 - 1. Achieving best value in procurement;
 - 2. International pricing markets;
 - 3. Wholesale Supply Chains;
 - 4. Pricing branded medicines;

clxvii Health and Sport Committee, Official Report, 21 January 2020, Col 21

clxviii Health and Sport Committee, *Official Report, 21 January 2020*, Col 21 clxix Scottish Parliament Information Centre (2020). Medicines in Scotland. SPICe Briefing SB 20/08, Page 3

- 5. Pricing generic medicines;
- 6. Purchasing in secondary care; and
- 7. Purchasing in primary care.

A. Achieving best value in procurement

- 167. In the previous chapter of this report, we considered aspects of the Review of Access to New Medicines which said—
 - "During evidence gathering from stakeholders much was made of the need to take a more sophisticated approach to benefits that includes patient reported outcomes, wider societal benefits such as the ability to continue working or a reduction in care or support requirements. The term "overall budget impact" was used on several occasions and requires the application of sophisticated health economic modelling which takes account not just of medicine costs but of whole system value and impact and introduces the concept of multiple "currencies" not just financial cost. The integration of health and social care presents Scotland with a particular opportunity in this regard."
- 168. That report's author, Dr Brian Montgomery, explained clxxi to us how the options in terms of new diseases and how to treat them were exceeding the increasing budget being made available in healthcare. He noted savings may be achieved from disinvestment in a particular drug but these may not be monetary, but the "currency" of "capacity".
- 169. David Coulson, Assistant Director of Pharmacy, NHS Tayside, and Rose Marie Parr, Chief Pharmaceutical Officer^{clxxiii}, also warned against considering medicines in terms of their cost alone, with the former telling us—
 - "We need to consider the whole-system cost of medicines, which involves the issues you mention, such as the phlebotomist's time, lab time and the use of reagents, and not just the procurement cost. We need to take that considered approach to medicines to ensure that we are making the right choices. We must make decisions that are based on sound clinical evidence."

B. International pricing markets

170. We were interested in how the UK's decision to leave the European Union would impact on pricing in the UK and Scotland of medicines.

clxx Scottish Government (2016). Review of Access to New Medicines, Page 49 clxxi Health and Sport Committee, <u>Official Report</u>, <u>21 January 2020</u>, Col 42

clxxii Health and Sport Committee, *Official Report*, 21 January 2020, Col 57 clxxiii Health and Sport Committee, *Official Report*, 21 January 2020, Col 2 clxxiv Health and Sport Committee, *Official Report*, 28 January 2020, Col 22

- 171. Warwick Smith, Director General, British Generic Manufacturers Association (BGMA) was supportive of the regulatory landscape in the UK, which he said allowed the market to thrive, emphasising the importance of market forces in maintaining attractive prices when compared with more interventionist regimes in the rest of Europe. clxxv
- 172. While Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of Health and Social Care, said clxvi the UK Government had been clear the price of medicines would not be an issue for discussion in future trade negotiations, there was concern about potential regulatory or licensing provisions which could be part of trade negotiations with the United States of America. The Cabinet Secretary for Health and Sport, Jeane Freeman, said it was too early to tell whether the outcomes of trade negotiations conducted by the UK Government would impact on price preferring to focus on "standards of governance, patient safety, and regulations that we want to see replicated" clxxviii.

C. Wholesale Supply Chains

- 173. We heard how the supply chain of medicines impacts on their cost effectiveness.
- 174. NHS Ayrshire and Arran^{clxxix} and NHS Scotland Directors of Pharmacy^{clxxx} each stressed the challenges posed by complexities and the time taken for procurement of medicines in both primary and secondary care. Community pharmacists also outlined the least efficient areas of interaction with the supply chain from their perspective although they were at pains to note how they did not allow challenges to impact on the service provided to patients (this is further explored in the COMMUNITY PHARMACY PROCUREMENT section of this report).
- 175. Warwick Smith, Director General, British Generic Manufacturers Association (BGMA), told^{clxxxi} us delays in the supply chain could arise from issues such as availability of raw materials and active pharmaceutical ingredients (APIs), price competition, regulatory change, increased cost of goods, tender processes or penalties for non-supply.
- 176. The main points raised with us in terms of the supply chain were related to shortages.

clxxv Health and Sport Committee, *Official Report, 21 January 2020,* Col 22 clxxvi Health and Sport Committee, *Official Report, 21 January 2020,* Col 19

clxxvii Health and Sport Committee, Official Report, 21 January 2020, Col 35

clxxviii Health and Sport Committee, *Official Report, 10 March 2020,* Col 11 clxxix NHS Ayrshire and Arran. Written Submission.

clxxx NHS Scotland Directors of Pharmacy. Written Submission.

clxxxi Letter from the British Generic Manufacturers Association on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020

Supply and demand for medicines, 6th Report, 2020 (Session 5)

Shortages

- 177. Warwick Smith (BGMA) provided^{clxxxii} us with examples of why shortages of medicines occur, such as manufacturing changes abroad and reduced capacity due to adherence to regulatory requirements for packaging. He also noted^{clxxxiii} how this could impact on individual ingredients and how safety concerns could contribute to shortages.
- 178. Martin Sawer, Executive Director, Healthcare Distribution Association, defended the current approach suggesting clxxxiv the decision to leave the European Union had caused the NHS to become better at analysing shortages and horizon scanning, stating there was a "much better understanding of how much stock is around" He further described steps taken by wholesalers to improve efficiency within the system, such as updated communication systems to provide better intelligence to pharmacists as to when they may expect stock to be available. He also advocated working with the private sector who he said were incentivised to prevent or plug gaps, rather than establish centralised supply management.
- 179. Both Warwick Smith^{clxxxvii} and Martin Sawer^{clxxxviii} noted ongoing European wide strategic discussions on resilience in the supply chain and the geographical centralisation of production of certain medicines and chemicals. We were also interested in the impact of leaving the European Union in terms of the current 'just in time' approach to drug supply and how potential border checks would affect this.
- 180. Similarly, Martin Sawer expressed concern about any potential barriers which could impact on price. Alison Culpan, Scotland Director, Association of the British Pharmaceutical Industry (ABPI), said the organisation wanted a "frictionless border so that our medicines can come straight in" Angela Timoney, Director of Pharmacy, NHS Lothian xex, spoke of the impact of the 'just in time' approach and said where the normal rate of shortages was around 80, there were currently around 120-130 shortages. She praised the efforts of national procurement to mitigate shortages.

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clxxxiii Health and Sport Committee, Official Report, 21 January 2020, Col 30 clxxxiv Health and Sport Committee, Official Report, 21 January 2020, Col 29 clxxxv Health and Sport Committee, Official Report, 21 January 2020, Col 31 clxxxvii Health and Sport Committee, Official Report, 21 January 2020, Col 31 clxxxviii Health and Sport Committee, Official Report, 21 January 2020, Col 30 clxxxviii Health and Sport Committee, Official Report, 21 January 2020, Col 30 clxxxix Health and Sport Committee, Official Report, 21 January 2020, Col 34 cxc Health and Sport Committee, Official Report, 4 February 2020, Col 22
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clxxxii Health and Sport Committee, Official Report, 21 January 2020, Col 28

181. Despite assurances to the contrary from industry the number of shortages is steadily increasing and we recommend the Scottish Government discuss this with industry representatives as a matter of urgency.

D. Pricing - Branded Medicines

Voluntary Pricing and Access Scheme (VPAS)

- 182. Spending on branded medicines is partly controlled by the Voluntary Pricing and Access Scheme (VPAS) which "caps the rate of growth in spend on branded medicines at 2 per cent. Spend above that is reimbursed; payments are made by industry to the NHS in England—and in Scotland, through the arrangements that we have to repay the devolved Administrations." It is "expected to save the NHS in Scotland around £90 million in 2019" Both the UK Government and industry were enthusiastic about collaboration and negotiation between them in establishing the scheme.
- 183. The advantages of the scheme with regard to spending and cost effectiveness for the Scottish NHS are—
 - **Predictability of budgets** several stakeholders were keen to emphasise how the scheme ensured predictability by capping rises in spending at 2%.
 - Applies to a significant proportion of medicines the ABPI noted "In 2018, 58% of medicines accepted for use by the [Scottish Medicines Consortium] SMC were discounted and of the top 300 branded products used in the NHS, 90% had a patient access scheme discount attached." CXCV
 - Accelerates and streamlines access to medicines Merck, Sharp and
 Dohme suggested^{cxcvi} this was particularly helpful in the context of the UK
 leaving the European Union and it suggested the pricing scheme was a "crucial
 element of securing global confidence in the UK as a market post-Brexit".
 - A good model Roche Products Ltd said^{cxcvii} the principle of a pricing agreement should be replicated across other areas of NHS spending to ensure "stability and surety for the overall finances of the NHS in Scotland".
 - Allows for commercial flexibility Kwoya Kirin International highlighted how
 this allowed for flexibility regarding pricing for different indications (the specific
 use for a medicine where there may be more than one see the MULTI
 INDICATION PRICING section of this report for further details).

exci Health and Sport Committee, Official Report, 21 January 2020, Col 2

cxcii Health and Sport Committee, Official Report, 21 January 2020, Col 4

cxciii Health and Sport Committee, Official Report, 21 January 2020, Col 2

cxciv Health and Sport Committee, Official Report, 21 January 2020, Col 22

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184. However, there were also notes of caution in accepting the virtues of VPAS. The Blood Cancer Alliance advocated managing budgets was not the same as delivering value, and this was determined by the SMC.

Efficacy of the Voluntary Pricing and Access Scheme (VPAS)

185. Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of Health and Social Care, UK Government, told us the UK Government believed "VPAS is an effective mechanism for capping the rate of growth in branded medicine spend, which is, by far, the bulk of expenditure on medicines" cxcix.

Transparency in pricing around the UK

- 186. The VPAS includes a clause stating—
 - "The details of national commercial arrangements agreed with the purchasing authority in one UK country will be made available on a confidential basis to purchasing authorities in any part of the UK. Scheme Members will work with purchasing authorities to achieve comparable arrangements that provide an acceptable value proposition in each part of the UK."
- 187. Written submissions we received were supportive of the ability to share such information and Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government, noted^{cci} transparency of pricing had been a Scottish Government priority in the 2018 negotiations.
- 188. However, others noted there was still discrepancy in pricing around the UK, despite this clause. In its written submission, Cancer Research UK^{ccii} noted these existed despite the VPAS commitment which should drive value for money in future commercial negotiations with medicines manufacturers.
- 189. NHS National Services Scotland (NHS NSS) agreed, observing instances where the price offered in Scotland has been higher than the price offered in England, adding—

cxcv Association of the British Pharmaceutical Industry. Written Submission.

cxcvi Merck, Sharp and Dohme. Written Submission.

cxcvii Roche Products Limited. Written Submission.

cxcviii Blood Cancer Alliance. Written Submission.

cxcix Health and Sport Committee, Official Report, 21 January 2020, Col 2

- cc UK Government (Department of Health and Social Care) and ABPI (2018). The 2019 Voluntary Scheme for Branded Medicines Pricing and Access Chapters and Glossary, page 28
- cci Letter from Rose Marie Parr, Chief Pharmaceutical Officer on Supply and Demand for Medicine, 26 February 2020

ccii Cancer Research UK. Written Submission

- "This is directly linked to differences in health technology assessment (HTA) processes." cciii
- 190. Elizabeth Woodeson said the aim of the scheme was to achieve transparency in pricing across the UK but that this "does not necessarily mean that each country is required to agree the same price."
- 191. Alison Culpan, Scotland Director, ABPI, expanded on this by stating the organisation "encourages its members to give each of the four nations the same arrangement" and described how other elements may impact on the price paid for a medicine in each country (such as the collection of data). Merck, Sharp and Dohme cevi elaborated, comparing the lack of provision for innovative pricing provided through the Commercial Framework and the data collection requirements of the Cancer Drugs Fund in England. They said "The Scottish system requests equitable pricing but equitable pricing does not mean equitable access for Scottish patients. Scotland cannot expect equity on one parameter without providing it in another". Alison Strath, Principal Pharmaceutical Officer, Scottish Government, added "We need to consider the different parameters that are sometimes attached to deals."
- 192. Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS NSS^{ccix}, said provision to share pricing information among purchasing authorities was in the process of being implemented and her organisation was "delighted" to see "provision for comparable arrangements to be offered to other home countries" in the VPAS agreement. She added work was ongoing to implement the VPAS provision on ensuring comparable arrangements around the UK.
- 193. We were surprised to hear UK wide pricing information was not collected, seeing this as a potential source of savings by learning from the approach of comparable countries and sought to discover if the Scottish Government was monitoring whether counterparts received better prices for the same products and if so, on what basis this was achieved. Alison Strath, Principal Pharmaceutical Officer, told us the Scottish Government was "setting up arrangements that will allow information sharing between the organisations that are involved in pricing and negotiations on price, so that we have sight of the prices and can enter negotiations about them." We were also surprised to hear from NHS National Services Scotland purchasing and stock holding data would assist in the secondary care procurement process, but this is not currently gathered.

cciii Letter from NHS National Services Scotland on Supply and Demand for Medicines, 24 February 2020.

cciv Health and Sport Committee, *Official Report, 21 January 2020,* Col 3 ccv Health and Sport Committee, *Official Report, 21 January 2020,* Col 24

ccvi Merck, Sharp and Dohme. Written Submission.

ccvii Merck, Sharp and Dohme. Written Submission.

ccviii Health and Sport Committee, *Official Report, 10 March 2020,* Col 15 ccix Health and Sport Committee, *Official Report, 21 January 2020,* Col 45 ccx Health and Sport Committee, *Official Report, 10 March 2020,* Col 15

- 194. The issue of how pricing around the UK was monitored and shared was at best unclear to us, meaning it is hard to see how Scotland can be comparing the price paid and the arrangements on which these are based to achieve best value.
- 195. We recommend the Scottish Government routinely collect information on pricing around the UK along with the arrangements on which those prices were agreed, with a view to maximising the opportunity to obtain the best price for medicines.
- 196. We recommend the Scottish Government ensure the NHS is gathering data on purchasing and stock holding by individual boards to improve procurement processes.

Rebate to Scotland and the New Medicines Fund

- 197. The ABPI noted that while spending on medicines in 2017/18 was stated at £1.8bn^{ccxii}, the actual cost would be lower thanks to rebates and confidential discounts offered by the industry through VPAS.
- 198. The Scottish Government has chosen to allocate most of the funding received from the rebate to the New Medicines Fund which Rose Marie Parr, Chief Pharmaceutical Officer, described as "a really positive policy" She continued—
 - "People can see the increase in medicines and the increase in medicines use, but they can also see that rebate being used transparently for the new medicines fund. Boards have gained over the past five years and they are due to gain up to £90 million or so in the current year."
- 199. She later noted "To date, around £200 million has been made available to Boards in Scotland through the New Medicines Fund which is a significant contribution to achieving value based pricing itself." However, representations from pharmaceutical companies and others highlighted the VPAS scheme and rebates returned £258m to the NHS in Scotland in the last five years. Bristol-Myers Squibb^{ccxvi} also suggested the fund was not transparent and called for more data on how this was used by boards.
- 200. We were also interested in the extent to which the New Medicine Fund met boards' need with regards to spend on new medicines. David Coulson, Assistant Director of Pharmacy^{ccxvii}, said affordability of new medicines was challenging and boards

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ccxi NHS National Services Scotland. Written Submission.
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ccxii Audit Scotland (2019). NHS Scotland in 2019, Page 25

ccxiii Health and Sport Committee, Official Report, 21 January 2020, Col 4

ccxiv Health and Sport Committee, Official Report, 21 January 2020, Col 4

ccxv Letter from Rose Marie Parr, Chief Pharmaceutical Officer on Supply and Demand for Medicines, 26 February 2020

ccxvi Bristol-Myers Squibb. Written Submission.

ccxvii Health and Sport Committee, Official Report, 28 January 2020, Col 27

relied on the advice of the SMC as to whether a medicine was worth the resource. The Cabinet Secretary for Health and Sport, Jeane Freeman, said—

- "My suspicion is that, in truth, the fund will never be big enough, because pharmaceutical companies will continue to introduce new medicines that people will want to access." CCXVIII
- 201. We are interested in what happens to applications for end of life, orphan and ultraorphan medicines when the fund is exhausted. The Cabinet Secretary also suggested there was a need to consider how personalised medicines would be funded in the future. ccxix
 - "The new medicines fund is vital, but we need to parallel the work that the SMC is doing in considering its processes in anticipation of precision medicine and coming innovations. We need to consider how we fund and whether we should alter our approach in the light of innovative and important developments for patients."
- 202. We ask the Scottish Government to clarify the significant discrepancy in the level of rebate received and the amount allocated to the New Medicines Fund.
- 203. We request a detailed breakdown by Board of the spend on new medicines each year and the amount they have received from the New Medicines Fund.

Voluntary Pricing and Access Scheme - conclusions

204. While we welcome the principle of a cap on the cost paid by the NHS for branded medicines and the willingness of the both the UK Government and pharmaceutical companies in negotiations on this, it is unclear why the cost is simply not capped, rather than a system of overpayment and rebate. We are of the view this must lead at the very least to inefficiency and unnecessary spend in terms of time and administration.

Pricing based on other considerations

Value and outcome based pricing

205. Several submissions proposed pricing systems based on outcomes and value. Community Pharmacy Scotland proposed^{ccxxi} a system of weightings to reflect the benefits of a medicine in pricing. Others described the various benefits of and values of an outcome based approach to pricing, including reducing investment risk for the NHS while rewarding the pharmaceutical industry for innovation and therapeutic breakthroughs.

- 206. Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of the Health and Social Care, UK Government, detailed the role of the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) in assessing new medicines and said they look at the benefit a medicine delivers as well as its price.
- 207. However, it was clear to us "benefit" was not the same as the outcomes from taking the medicine and Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government, noted ccxxiii the potential differences between the reactions to medicines, and benefits, demonstrated during clinical trials and the "real-world" application.
- 208. Throughout our inquiry, we have consistently been told data on outcomes is not collected. We therefore asked for further information about outcome based pricing from the Scottish Government.
- 209. We were told—
 - "The Committee also asked for my view on what should happen if the outcome, once assessed, differ from the original claims by the company. As you will know, there is a greater interest from the pharmaceutical industry to explore outcomes-based pricing and commercial agreements and we are actively considering how the VPAS might provide new opportunities in relation to innovative and flexible approaches to pricing. Critical to the delivery of novel pricing approaches will be the NHS capability to collect outcome data, which is why our strategic approach to data collection and the interdependency with the Digital Health and Care Strategy is important. I would imagine that in the event that the outcomes are different there would be the opportunity to consider a number of options, including whether to reconsider the reimbursement price, review and/or its place in any prescribing guidance."
- 210. We were previously told the Scottish Government was testing a proof of concept outcome based pricing approach and sought details of other innovative and flexible approaches to pricing being considered in correspondence to the Cabinet Secretary.

Support for value and outcome based pricing

211. Notwithstanding the absence of any data, there is support for value and outcome based pricing from both the NHS and the pharmaceutical industry.

ccxxi Letter from Community Pharmacy Scotland on the Supply and Demand for Medicines, 20 February 2020

ccxxii Health and Sport Committee, *Official Report, 21 January 2020,* Col 5 ccxxiii Health and Sport Committee, *Official Report, 21 January 2020,* Col 5

ccxxiv Health and Sport Committee, *Official Report*, *21 January 2020*, Col 5 ccxxv Letter from the Cabinet Secretary for Health and Sport on the Review of New Medicines, 13 January 2020

ccxxvi Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

- 212. Rose Marie Parr highlighted^{ccxxviii} interest from the pharmaceutical industry in outcome and value based pricing, while NHS Grampian Area Drug and Therapeutic Committee said^{ccxxviii} the prices paid for medicines should reflect the evidence based potential of those medicines, and where risk was taken this should be in conjunction with the pharmaceutical industry.
- 213. Alison Culpan, Scotland Director, Association of the British Pharmaceutical Industry (ABPI), said "both the industry and patients believe this represents the future road of travel when it comes to ensuring patient access to innovative medicines." She suggested such pricing measures had merit where medicine was curative, as opposed to helping manage conditions, and further exploration was required for those which managed conditions. NHS National Services Scotland (NHS NSS) suggested there was already an "established route" for companies to provide outcomes based schemes via the Patient Access Scheme Assessment Group (PASAG)—
 - "New regulatory approaches that speed up medicines access from a regulatory perspective are increasing the number of products where there is uncertainty surrounding cost-effectiveness at the point of market access and where outcomes-based pricing could offer a solution. PASAG is working with the SMC to consider lessons learned from recent assessments and to consider how the review of outcomes-based pricing proposals could be better aligned with the Scottish Medicines Consortium] process."
- 214. Community Pharmacy Scotland^{ccxxxiii} highlighted a number of challenges associated with the introduction of value based pricing, such as assessment of value may be cumbersome and difficulties associated with rare diseases and lack of evidence.
- 215. The SMC said "as SMC was set up to ensure that the prescribing of new medicines across NHS Scotland is clinically and cost-effective, we are committed to the principle of value based pricing." CCXXXIV
- ccxxvii Letter from Rose Marie Parr, Chief Pharmaceutical Officer on Supply and Demand for Medicines, 26 February 2020
- ccxxviii NHS Grampian Area Drug and Therapeutic Committee. Written Submission.

 ccxxix Letter from the Association of the British Pharmaceutical Industry on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020
 - ccxxx Letter from the Association of the British Pharmaceutical Industry on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020
- ccxxxi Letter from NHS National Services Scotland on the Supply and Demand for Medicines, 24 February 2020
- ccxxxii Letter from NHS National Services Scotland on the Supply and Demand for Medicines, 24 February 2020
- ccxxxiii Letter from Community Pharmacy Scotland on the Supply and Demand for Medicines, 20 February 2020
- ccxxxiv Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020

Outcome based pricing and improved access to medicines

216. Dr Alan MacDonald, Chair of the SMC, indicated ccxxxv support for outcome based pricing but noted the data gathering challenges associated with this. As noted in the CHANGES SINCE THE MONTGOMERY REVIEW - INTERIM ACCEPTANCE section of this report, he said the debate on outcome based pricing would be one the SMC would have to consider as its interim acceptance option became more "mature" noting there was a grey area for medicines which worked, but not quite as well as originally claimed.

Collection of outcomes data to support value based pricing

- 217. The importance of collecting data on outcomes was emphasised to us throughout our inquiry, not least to facilitate proposed outcomes based pricing.
- 218. Alison Culpan, Scotland Director of the ABPI, said data collection to provide outcome information was required "desperately" by the pharmaceutical industry and called on the Scottish Government to implement the outcomes of the data scoping task force ccxxviii. She suggested other areas of the UK were further ahead in their collection of data on outcomes and were therefore able to offer more advanced pricing schemes based on outcomes.
- 219. Celgene^{ccxl} cited the Review of Access to New Medicines to suggest a reluctance on the part of the NHS to enter into outcomes based payments due to the onerous nature of the data collection required. We agree with Merck, Sharp and Dohme who said "For Scotland to achieve real value for money we need leadership to put Scotland at the forefront of assessing value, collecting data and working in collaboration with researchers, academia and industry rather than in isolation". ccxli They also called for better sharing of data on outcomes, including with the pharmaceutical industry. Pfizer UK^{ccxlii} were keen to help support the design of data architecture, which Kwoya Kirin International ccxliii were optimistic about given the size of Scotland and its unique patient identifiers (although we note the Community Health Index Number is to be replaced ccxliv). Community Pharmacy Scotland ccxlv suggested pharmacy was ideally placed to collect outcomes data but said this was not currently gathered as it was not mandated. We find this frustrating, from both the perspective of lack of proactivity from pharmacy but also as it is a missed opportunity in contracts with pharmacy on the part of Government, who also recognise the significance of outcomes data.

ccxxxv Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020

ccxxxvi Health and Sport Committee, *Official Report, 21 January 2020,* Col 53 ccxxxvii Health and Sport Committee, *Official Report, 21 January 2020,* Col 25

ccxxxviii Health and Sport Committee, Official Report, 21 January 2020, Col 26

ccxxxix Letter from the Association of the British Pharmaceutical Industry on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020 ccxl Celgene. Written Submission.

- 220. Area drug and therapeutic committees and Dr Alan MacDonald, Chair of the SMC^{ccxlvi}, indicated support for outcome based pricing but noted the data gathering challenges associated with this. NHS National Services Scotland^{ccxlvii} suggested the work undertaken on the back of the recommendations of the Data Scoping Taskforce may change this. We have considered the work and timescales for implementations of the recommendations of the taskforce further in the DATA SCOPING TASKFORCE AND DIGITAL HEALTH AND CARE STRATEGY section of this report.
- 221. Rose Marie Parr, Chief Pharmaceutical Officer, told us the Scottish Government was actively considering how the Voluntary Pricing and Access Scheme (VPAS) could provide new opportunities with regard to innovative pricing, but said "NHS capability to collect outcome data" would be "critical" to this. We agree with the Chief Pharmaceutical Officer about the importance of having the data in the first place and highlight this as another example of leadership not being or feeling empowered to deliver.
- 222. The issue of collection of data on outcomes derived from the use of medicines is explored extensively in the DATA AND IT OUTCOMES section of this report. At this point, we note the emphasis and importance placed on the collection of data to support more innovative and cost effective pricing based on value and outcome.
- 223. We ask the Scottish Government to provide detail of a plan to routinely and comprehensively collect outcome data from taking medicines at all points of the healthcare system, including in care homes, community pharmacy and general practice, and the proposed timescales for implementation.

ccxli Merck, Sharp and Dohme. Written Submission.

ccxlii Pfizer UK. Written Submission.

ccxliii Kwoya Kirin International. Written Submission.

- ccxliv Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, on technology and innovation in health and social care, 23 May 2019
- ccxIv Letter from Community Pharmacy Scotland on the Supply and Demand for Medicines, 20 February 2020
- ccxlvi Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium, on the Supply and Demand for Medicines, 26 February 2020
- ccxlvii Letter from NHS National Services Scotland on the Supply and Demand for Medicines, 24 February 2020
- ccxIviii Letter from Rose Marie Parr, Chief Pharmaceutical Officer on Supply and Demand for Medicines, 26 February 2020
- ccxlix Letter from Rose Marie Parr, Chief Pharmaceutical Officer on Supply and Demand for Medicines, 26 February 2020

Health and Sport Committee

Supply and demand for medicines, 6th Report, 2020 (Session 5)

Where outcomes differ from those anticipated

- 224. Alison Culpan of the ABPI called on the Scottish Government to implement the outcomes of the data scoping task force on indications and outcomes to allow the industry to "see whether our medicines are doing what we say they will do and whether the right patients are getting them" ccl.
- 225. She provided^{ccli} us with a number of suggestions as to how pricing rebates could operate in a scenario where outcomes did not match manufacturers' claims—
 - Cost sharing arrangements prices would be reduced until a response from a patient had been verified;
 - Payment by results rebates would be offered based on a comparison of the real-world results of medicines versus the trial claims. APBI suggest this represents "genuine risk sharing";
 - Coverage with evidence development evidence would be collected in realworld settings to demonstrate efficacy (similar to current "ultra-orphan pathway);
 - Risk sharing Manufacturers reimburse a proportion of the cost when the patient fails to respond;
 - Outcomes guarantees/pay for performance a rebate is provided if individual patients do not respond; and
 - Conditional treatment continuation use of drug and payment is monitored at certain points throughout patient experience of taking the medicine.

She said there should also be mechanisms where manufacturers could be reimbursed where outcomes exceeded what was advertised.

- 226. Jonathan Mogford, Director of Policy, Medicines and Healthcare products Regulatory Agency (MHRA) described the role of the organisation, telling us—
 - "As discussed during the session, the remit of MHRA is evaluation of the safety, quality and efficacy of new medicines. The benefit/risk profile is kept under review following approval of the medicine and MHRA will act on emerging new data to include further information for prescribers and patients in product literature and amend the claims that can be made by manufacturers or to suspend or revoke the marketing authorisation, as necessary."
- 227. We seek detail on what happens to the price paid to manufacturers in the event of the MHRA suspending or revoking a license for medicines for which the NHS in Scotland has already paid.

Multi-indication pricing

- ²²⁸. The European Medicines Group^{cclii}, Roche Products Ltd^{ccliii}, ABPI^{ccliv} and Kwoya Kirin International^{cclv} noted pricing for medicines could depend on the indication for which they were proposed to treat, with the latter saying—
 - "A single price cannot reflect all these values thus to provide all these options in a cost effective manner, some flexibility on pricing is essential". cclvi
- 229. This would represent a savings potential by ensuring costs paid for use for one indication were not dictated by the potential higher costs which could be demanded for use to treat another indication.

Pricing based on other considerations - conclusions

- 230. We heard overwhelming support from a variety of stakeholders for innovations in pricing on value and outcomes, but this served to highlight the lack of collection and utilisation of this valuable information. Bristol-Myers Squibb^{cclvii} proposed a working group should be established to consider Managed Access Schemes, including innovative pricing.
- 231. We recommend the Scottish Government consider establishing a group to consider innovative pricing schemes in the round, notwithstanding the urgent need for outcome data collection to be considered across the system for various purposes.

E. Pricing - generic medicine

232. Audit Scotland describe generic medicine as "cheaper, sometimes significantly, compared to branded medicine" and note cost saving measures implemented by boards included increased use of generic medicine in secondary care, reviews of prescriptions in primary care to allow for cheaper options to be used and use of biosimilars (which again may be cheaper). A recent report by Oxera demonstrates the potential savings to be made by prescribing generic version of drugs, noting—

cclii European Medicines Group. Written Submission.

ccliii Roche Products Ltd. Written Submission.

ccliv Association of the British Pharmaceutical Industry. Written Submission.

cclv Kwoya Kirin International. Written Submission.

cclvi Kwoya Kirin International. Written Submission.

cclvii Bristol-Myers Squibb. Written Submission.

cclviii Audit Scotland (2019). NHS Scotland in 2019, Page 24

- "While there is variation in the extent and speed of price changes across different products, on average, the generic price in the six months after loss of exclusivity is 70% lower, falling to 80–90% lower over a four-year period."
- 233. The report also describes the UK as an attractive market for manufacturers of generic medicines due to "large size and low regulatory barriers" and analysis in the report uncovers the cost of generic medicines in the UK is generally lower than in other European countries. We also heard about fewer barriers to entry compared to other European countries.

Cost of generics - price increases

- 234. Oxera describes how market conditions can impact on the price of generic medicines—
 - "...manufacturers have the ability to change their production levels and prices relatively easily to react to changes in market conditions. In the short term, manufacturers generally avoid exiting entirely, instead decreasing production if market conditions are adverse and increasing production if market conditions improve. This creates a self-correcting mechanism whereby short-term and significant price increases are often met with additional supply followed by a decrease in price."
- The Royal Pharmaceutical Society in Scotland told^{cclxii} us the prices of generic medicines represented good value for money, but that these were more susceptible to price fluctuations than other drugs. One of the reasons offered for this was shortages in the global supply chain and the sudden impact this could have on the cost of generic medicine. Janssen^{cclxiii} and AstraZeneca^{cclxiv} cited NHS figures showing the biggest price rises reported by ISD Scotland^{cclxv} over the last two years had been for generic medicines, with the former suggesting this may be due to "paying more for items in short supply". The British Generic Manufacturers Association (BGMA)^{cclxvi} suggested a longer lead in time of 4 months in secondary care procurement could lessen the impact of shortages.

cclxii Royal Pharmaceutical Society in Scotland. Written Submission.

cclxiii Janssens. Written Submission.

cclxiv AstraZeneca. Written Submission.

cclxv ISD Scotland Top 10 increases and decreases (Financial year 2018/19)

cclxvi British Generics Manufacturers Association. Written Submission.

cclix Oxera (2019). The supply of generic medicines in the UK: A study by Oxera - Prepared for the British Generic Manufacturers Association, Page 2

ccix Oxera (2019). The supply of generic medicines in the UK: A study by Oxera - Prepared for the British Generic Manufacturers Association, Page 2

cclxi Oxera (2019). The supply of generic medicines in the UK: A study by Oxera - Prepared for the British Generic Manufacturers Association, Page 2

- 236. Martin Sawer, Executive Director, Healthcare Distribution Association, expressed colevii concern about any potential barriers caused by border arrangements which could impact on price.
- 237. NHS Grampian Area Drug and Therapeutic Committee gave an example of the power and actions of drug companies in relation to price indicating—
 - "Value is also undermined when elements of the pharmaceutical industry hike prices of niche products with little competition. Often these products are older established medicines or medicines that have a significant use as unlicensed medicines from specialist suppliers. These medicines require little in the way of return on investment for research and development but are able to be priced high on the basis of little or no market competition. These practices can impact significantly on NHS spend with no improvement in patient outcomes." CCIXVIII

Cost of generics - UK Government price setting powers

- 238. In 2017, the Health Service Medical Supplies (Costs) Act 2017 gave ministers the power to intervene to control the price of generics when there is insufficient competition. To date those powers have not been used. We queried this with Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of Health and Social Care, UK Government, who told colvix us the Government had simultaneously taken powers to require pharmaceutical companies to justify any price increases. She said it was hoped agreements on price could be reached with companies prior to requiring the price setting power and she described this move as a "significant intervention in a marketplace" Colvix. She also noted despite the Government having legislated that work was being done to consider how the power could be used and a forthcoming consultation was expected. She also confirmed the price setting powers, once exercised by a UK Secretary of State, would apply around the UK.
- 239. The BGMA, while welcoming the powers of the UK Government to investigate and act, said cclxxii price rises for generic medicines were justified in some instances but they also suggested cclxxiii that where demand was low competitive pricing could not work. The BGMA suggested streamlining of the MHRA approvals process would be preferable to "intervention in the market" as a means of improving access. Their overarching view being that it "is wrong to have different pricing and reimbursement mechanisms for unbranded and branded medicines competition and those that don't."cclxxvi

cclxvii Health and Sport Committee, *Official Report, 21 January 2020,* Col 34 cclxviii NHS Grampian Area Drug and Therapeutic Committee. Written Submission. cclxix Health and Sport Committee, *Official Report, 21 January 2020,* Col 10

cclxx Health and Sport Committee, Official Report, 21 January 2020, Col 10

cclxxi Letter from Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of Health and Social Care, UK Government, on the Price Setting Powers under the NHS Act 2006, 24 January 2020

F. Purchasing in Secondary Care



- 240. There are separate procurement routes for medicines depending on whether these are prescribed in primary or secondary care. Roughly, the latter tend to be more expensive using more branded medicines to treat more serious ailments.
- 241. According to the Scottish Parliament Information Centre—
 - "Medicines expenditure in Scotland has risen steadily over the last decade and it now accounts for 13.1% of the total health budget. Most prescribing takes place in the community but recent trends show that prescribing costs in this sector have reduced. However, drugs expenditure in the community and hospitals has been growing at a higher rate than overall expenditure."
- 242. Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland (NHS NSS), informed supply us the previous year had seen a slight "deflation" in the centrally procured medicine spend for secondary care. Of a £400m spend, £58m of savings elsewhere had been achieved and she

cclxxii Health and Sport Committee, Official Report, 21 January 2020, Col 24

cclxxiii Health and Sport Committee, Official Report, 21 January 2020, Col 37

cclxxiv Letter from the British Generic Manufacturers Association on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020

cclxxv Letter from the British Generic Manufacturers Association on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020

cclxxvi Letter from the British Generic Manufacturers Association on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020

cclxxvii Scottish Parliament Information Centre (2020). Medicines in Scotland. SPICe Briefing SB 20/08, Page 3

- demonstrated this with examples of procurement of hepatitis C drugs and use of biosimilars (which Dr Alan MacDonald, Chair of the Scottish Medicines Consortium also described as a "good news story").
- Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde^{cclxxx} told us medicines represented 17% of board expenditure in Scotland. She said a major challenge for controlling spend was increased access to medicines which had been developed as a result of the Montgomery Review. Both she^{cclxxxi} and Angela Timoney, Director of Pharmacy, NHS Lothian^{cclxxxii}, provided examples of best practice where boards had been able to significantly reduce their overall spend on the medicines, but suggested there were likely to be incidences of use of branded or more expensive medicines in hospitals by the nature of their work.
- 244. NHS Ayrshire and Arran said "The increasing availability of very high cost medicines in acute care has resulted in a percentage rise in hospital spend that exceeds Board's annual uplift. A large part of offsetting these costs has to be met by targeting savings in other areas of care."
- 245. Community Pharmacy Scotland proposed that—
 - "products' list prices in secondary care (which are set by manufacturers and sometimes known as ex-factory prices) do not always reflect theNHS net price because confidential discounts are agreed, including via patient access schemes. Consequently, spending measured by list prices could overstate the total cost of medicines in secondary care."
- 246. Roche Products Ltd also asserted cclxxxv the advertised list price of a drug did not always reflect what was ultimately paid by the NHS.

cclxxviii Health and Sport Committee, Official Report, 21 January 2020, Col 41

cclxxix Health and Sport Committee, *Official Report*, 21 January 2020, Col 42 cclxxx Health and Sport Committee, *Official Report*, 4 February 2020, Col 26

cclxxxi Health and Sport Committee, Official Report, 4 February 2020, Col 27

cclxxxii Health and Sport Committee, *Official Report, 4 February 2020,* Col 27 cclxxxiii NHS Ayrshire and Arran. Written Submission. cclxxxiv Community Pharmacy Scotland. Written Submission. cclxxxv Roche Products Ltd. Written Submission.

G. Purchasing in primary care

...talking for primary care, it is difficult to envisage how the supply chain could become more efficient and crucially person centred, at its endpoint, than the 1257 strong community pharmacy network in terms of procurement

- 247. According to the Scottish Parliament Information Centre—
 - "The vast majority of medicines are dispensed to patients in the community using a prescription issued by a General Practitioner (GP) or another prescriber such as a dentists or nurse. These prescriptions are usually taken to a community pharmacy and dispensed by a pharmacist. Like GPs, community pharmacists are not employees of the NHS but instead they operate as independent businesses contracted by the NHS. There are currently 1257 pharmacies providing pharmaceutical care services in Scotland......Each community pharmacist procures medicines to fulfil prescriptions on behalf of their patients. This is generally done by procuring the required medicine from wholesalers who effectively act as a middleman between the pharmaceutical companies and pharmacists. Some manufacturers may offer a direct to pharmacy arrangement for the procurement of medicines (i.e. bypassing the wholesaler)."
- 248. We were surprised to hear from Community Pharmacy Scotland they could see no improvements to the efficiency of procurement in primary care, as evidence presented to us suggested there are areas, not least in terms of pharmacist time, where they system could be streamlined. This is further explored in the following sections.

Community Pharmacy Procurement

249. In the main, those pharmacists and NHS National Services Scotland (NHS NSS), who all worked within the system were supportive of the existing processes of procurement of medicine in primary care. This is done via community pharmacy seeking to obtain the best prices from wholesalers.

- 250. However, challenges for community pharmacists were noted—
 - The efficiency of community pharmacy procurement; and
 - Movement of prescriptions traditionally administered in secondary care settings to primary care settings (the example cited most commonly was the ability for patients to take hepatitis C drugs in the community);
- 251. Martin Sawer, Executive Director, Healthcare Distribution Association, supported the current schemes, saying—
 - "We support the flexibility that has been created to enable generic prices to rise. It allows for a bit more resilience, because new manufacturers will enter the market, and it creates incentives to purchase in the supply chain. As wholesalers, we try to get the best deal from manufacturers because we own most of the products that we distribute. Likewise, pharmacies use wholesaler competition to try to buy and purchase in the most attractive way, based on the reimbursement prices that they will get. We certainly think that incentives in the supply chain provide a lot of competition across the UK, and that volume is important to keep supply going." CCIXXXVIII

Efficiency of Community Pharmacy Procurement

- 252. Stakeholders such as Community Pharmacy Scotland cclxxxviii and the National Pharmacy Association were at pains to promote the efficiency of procurement through community pharmacies and, although they noted challenges, emphasised the lack of impact these had on the end result for the patient and the NHS.
- 253. While promoting their efficiency, they also took every opportunity to tell us of the time spent by senior pharmacists in procuring pharmacy stock. Evidence focused on—
 - The wholesale model and how this impacts on the efficiency of community pharmacy procurement; and
 - The seniority of staff involved in procurement within community pharmacies

Community pharmacy procurement from wholesalers

- 254. Community Pharmacy Scotland told us of the complexities introduced for pharmacy procurement through the Direct to Pharmacy distribution schemes introduced by some drug manufacturers in 2007.
- 255. The model is described as—

- "...pharma companies retain ownership of their products further through the supply chain. They use traditional wholesalers to hold their stock on a consignment or agency basis rather than transferring title of the goods. This provides them [pharmaceutical companies] with greater control and benefits, however for community pharmacy teams this can add to the workload to ensure they order the right stock, for the patient in a timely manner."
- 256. Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland, expressed frustration at the direct to pharmacy approach, saying—
 - "Our supply chain is very spidery; it is more complex than it has ever been. We have some frustrations with direct supply models, whereby companies in effect trade their medicines directly to us rather than through a wholesaler, which means more phone calls, more emails, more websites to visit and more methods of communication. However, our having wholesalers who supply a myriad of different medications and our having pharmacies all over the country means that the system is fairly bullet-proof and we have a bit of a cushion when things go wrong."
- 257. He noted^{ccxcii} the guidance from Community Pharmacy Scotland and said this was interpreted in such a way as to give Scotland a lot more flexibility in dealing with supply chain issues than in other devolved nations.
- 258. Matt Barclay, Director of Operations at Community Pharmacy Scotland, also described how pharmacy teams were now required to purchase medicines from multiple wholesalers. He said time taken to do this took pharmacists away from care for patients. However, he said pharmacists dealt with the challenge efficiently and he did not believe medicines were taking longer to reach patients as a result. ccxciv
- 259. We were also interested in the issue of quotas (a limit placed on the amount of any one drug which a community pharmacy can procure in one batch), which can result in community pharmacists spending more time than necessary obtaining drugs where quota limits are less than the amount a patient has been prescribed. Matt Barclay^{ccxcv} and the National Pharmacy Association^{ccxcvi} said quota systems placed considerable demands on the time of community pharmacists and the latter added these were not "intuitive nor responsive, inflexible and we believe inequitable."

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ccxc Community Pharmacy Scotland. Written Submission.
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ccxcii Health and Sport Committee, Official Report, 4 February 2020, Col 23

ccxciii Health and Sport Committee, Official Report, 21 January 2020, Col 46

ccxciv Community Pharmacy Scotland. Written Submission.

ccxcv Health and Sport Committee, Official Report, 21 January 2020, Col 48

ccxcvi National Pharmacy Association. Written Submission.

ccxcvii National Pharmacy Association. Written Submission.

ccxci Health and Sport Committee, Official Report, 4 February 2020, Col 23

Martin Sawer of the Healthcare Distribution Association, described why wholesalers may impose quotas on the amount of medicines which can be purchased by organisations, suggesting this was due to the allocation of too many wholesaler licenses and noting the lack of transparency in the chain.

Movement of prescriptions from secondary to primary care

- 261. The Cabinet Secretary for Health and Sport, Jeane Freeman, said—
 - "More people with complex conditions are being treated at home or in their communities with medicines that historically were used only in hospitals. That is because we know that that care location provides the best outcomes for patients."
- 262. Matt Barclay of Community Pharmacy Scotland^{ccc}, McKesson UK^{ccci}, NHS
 Grampian Area Drug and Therapeutic Committee (ADTC)^{cccii}, the Royal
 Pharmaceutical Society in Scotland^{ccciii} and the Company Chemists Association^{ccciv}
 highlighted the challenge posed for community pharmacists from medicine
 developments which meant treatment could be provided in a primary setting rather
 than secondary and used the example of hepatitis C to demonstrate this.
- 263. Matt Barclay described the procurement problem for pharmacists of obtaining expensive medicines previously available through secondary care (and thus different procurement system), which may not be required. It was proposed the community pharmacy contract and the remuneration model for community pharmacists should address this issue. In contrast, Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS NSS, noted cccv issues with supply chains and ensuring the NHS did not end up paying more by moving the procurement of such drugs from centrally for secondary care to the hands of community pharmacists for primary care.
- 264. This suggested to us there could be an issue with drugs being more expensive in a primary care setting where the VPAS and bulk buying options open to the NHS centrally were not available to community pharmacists.

ccxcviii Health and Sport Committee, *Official Report, 21 January 2020,* Col 32 ccxcix Health and Sport Committee, *Official Report, 10 March 2020,* Col 2 ccc Health and Sport Committee, *Official Report, 21 January 2020,* Col 43

ccci McKesson UK, Written Submission.

cccii NHS Grampian Area Drug and Therapeutic Committee. Written Submission.

ccciii Royal Pharmaceutical Society in Scotland. Written Submission.

ccciv Company Chemists Association. Written Submission. cccv Health and Sport Committee, *Official Report*, *21 January* 2020, Col 47

Staff

- 265. Recognising the issue arising above in relation to the time pharmacists are dedicating to procurement at the expense of directly interacting with patients, we were keen to understand why this task was being undertaken by senior staff.
- 266. The Royal Pharmaceutical Society in Scotland (RPS) cccvi noted there could be a greater role for pharmacy technicians, particularly in dispensing, but said a more formalised career path was required. The RPS also suggested cccvii the correct level of qualified personnel should be assigned to the correct tasks to ensure efficiency, best value and more patient facing time for pharmacists. When asked how they were progressing this, the RPS responded they had "advocated extensively for improvements in the career pathways of pharmacy staff"cccviii but noted, without offering proactive solutions themselves, there was still much to be done. Matt Barclay, of Community Pharmacy Scotland, said "Technicians and other pharmacy team members can generally deal with this although...the pharmacist should have oversight around the supply chain, training for pharmacy team members on how to source medicines and may have to step in at times to ensure supply or source alternatives for patients." Angela Timoney, Director of Pharmacy, NHS Lothian, told^{cccx} us of work undertaken within the board to maximise the skills of all levels of staff.
- She also^{cccxi} said there was a need to ensure technicians were doing some of the tasks currently fulfilled by pharmacists, but also involving support workers and administration staff in that. Scottish Government Chief Pharmaceutical Officer, Rose Marie Parr^{cccxii}, agreed there was a need to work flexibly across job roles in the future which would be a new way of working and we sought details of this from the Cabinet Secretary for Health and Sport in correspondence^{cccxiii}.
- 268. We consider this to be one of many examples of evidence presented to us of inefficiencies and issues with spending on medicines in the Scottish NHS by senior leaders, with no corresponding proposal of how to address it or recognition of the role they could play. We are clear the issue of how pharmacy staff time is used in

cccvi The Royal Pharmaceutical Society in Scotland. Written Submission.

cccvii The Royal Pharmaceutical Society in Scotland. Written Submission.

CCCVIII Letter from the Royal Pharmaceutical Society in Scotland on the Supply and Demand for Medicines, 25 March 2020

cccix Letter from Community Pharmacy Scotland on the Supply and Demand for Medicines, 20 February 2020

cccx Letter from Angela Timoney, Director of Pharmacy, NHS Lothian, on Supply and Demand for Medicines, 24 February 2020

cccxi Health and Sport Committee, Official Report, 4 February 2020, Col 14

cccxii Health and Sport Committee, Official Report, 10 March 2020, Col 25

CCCXIII Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

primary care is inefficient and needs to be addressed as a matter of urgency. In community pharmacy settings, we suggest this includes removing the role of sourcing the cheapest medicines from pharmacists who, to improve efficiency, ought to be spending time sharing clinical expertise with patients.

- 269. We recommend the procurement of medicines become part of the formalised training for pharmacy technicians, including how to manage other staff to assist. We seek details from the Scottish Government as to how it will work with pharmacy bodies, such as the Royal Pharmaceutical Society in Scotland and Community Pharmacy Scotland, to effect this in primary care settings.
- 270. We also seek detail from the Cabinet Secretary as to any action the Scottish Government can take to implement more flexible working and formalised career pathways for pharmacy staff as a matter of urgency, including if appropriate using the community pharmacy contract.

Community pharmacy procurement versus central procurement

- 271. NHS National Services Scotland (NHS NSS) described the current system—
 - "The NHS reimburses pharmacies for medicines dispensed at a price higher than the cost to the pharmacy of purchasing the product...this is by design and a key reason for the effectiveness of the current arrangements. Community pharmacies retain the difference between the pharmacy purchase price for a medicine and the fixed Drug Tariff reimbursement price; this incentivises pharmacies to source medicines at the lowest available prices which creates the price competition that drives down prices being charged by wholesalers and manufacturers."
- 272. If medicines cost more than the tariff price, pharmacists are also able to claim the surplus.
- 273. We were interested in whether it was more cost effective for the NHS to be reimbursing community pharmacists for medicines purchased than to be purchasing those centrally at the lower price offered by the drug company. The element of competition introduced by community pharmacy purchasing in a free market was key, according to NHS NSS.
 - "The current arrangements in place in Scotland and central procurement are both 'free-market' approaches that create a pro-competitive environment for generic medicines. The focus on competition through both methods is believed to be why the recent Oxera report into generic medicines prices found that UK prices were closer to countries in the study that made use of centralised tendering than those countries that applied regulatory approaches to control pricing."

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- 274. Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS NSS said^{cccxv} she believed the current system worked well and it can "achieve the same results as central tendering could achieve". She also informed us of comparative countries in Europe where central tendering took place and cited recent studies which suggested—
 - "...moving to a single central purchaser could lead to concentration of supply; risks associated with reducing the number of suppliers in a market include increasing the risk of supply problems and reducing price competition. These are both factors which can lead to higher prices over the long-term. Tender conditions (e.g. number of suppliers; length of award etc.) would need to be designed to manage this risk with the desire for low prices balanced with the need to ensure continuity of supply of medicines. A key benefit of the established approach in primary care is that it encourages plurality of supply."
- 275. She also highlighted examples of where central procurement would or had been be preferable, such as for flu vaccines cccxviii and off patent 'speciality' generics such as those for treating cancer and HIV cccxviii. She said the benefit of this would be allowing such drugs to be dispensed in community settings by bringing prices in line with those achieved in secondary care procurement.

The Scottish Drugs Tariff

- 276. The Scottish Drug Tariff stipulates the price a community pharmacist will be reimbursed for a drug and this is a set price regardless of what is paid for the medicine by the pharmacist. It is—
 - "...published for and on behalf of the Primary and Community Care Directorate, Scottish Government. The Tariff contains information regarding the prescribing, dispensing and reimbursement of medicines and appliances on primary care NHS prescriptions."
- 277. Community Pharmacy Scotland noted "The method of determination of prices is according to a general protocol established by the Scotlish Ministers after consultation with Community Pharmacy Scotland."
- 278. They provided^{cccxxi} a detailed description of the operation of the tariff, including their view it is designed to encourage competition in the generics market, the nature of which meant it was robust and working well in the main.

cccxv Health and Sport Committee, Official Report, 21 January 2020, Col 47

cccxvi Letter from NHS National Services Scotland on the Supply and Demand for Medicines, 24 February 2020

cccxvii Health and Sport Committee, Official Report, 21 January 2020, Col 47

CCCXVIII Letter from NHS National Services Scotland on the Supply and Demand for Medicines, 24 February 2020

cccxix Public Health Scotland. Scottish Drug Tariff

cccxx Community Pharmacy Scotland. Written Submission.

cccxxi Community Pharmacy Scotland. Written Submission.

- 279. Community Pharmacy Scotland added—
 - "Maintaining the delicate balance of the Drug Tariff supports existing competition and the positive impact of this competition on NHS pricing. Squeezing tariff prices too far could lead to generic manufacturers exiting the UK marketplace. The Tariff can occasionally be subverted at a local level through the practice of 'branded generic' prescribing. This is instigated by Health Boards looking for short term savings through certain companies offering cheaper 'brands' that the generic tariff price. This practice is fraught with challenges for patients, pharmacy and issues around sustainability of supply."
- 280. The Royal Pharmaceutical Society in Scotland said drugs should be included in the tariff in so far as possible to avoid fluctuations in price and to provide a continuity of supply.
- 281. The National Pharmacy Association said the Scottish Drug Tariff "has a more timely response process to medicines shortages and the resultant price increases than the rest of the UK, although it was recognised that on rare occasions contractors may still be out of pocket for dispensing prescriptions to patients."

Financial Risk

- Matt Barclay of Community Pharmacy Scotland described cccxxv the financial risks for community pharmacists of procuring more expensive treatments. He said cccxxvi the shift of delivery of treatments from primary to secondary care contributed to this. He noted cccxxvii wholesalers payment terms were 30 days, but the NHS did not reimburse for 2-3 months, and described systems to apply for funding in advance as "clunky". Both he cccxxviii and Lindsay McClure of NHS National Services Scotland referenced work underway on how the reimbursement system could remove the financial risk for community pharmacists.
- 283. We recommend the NHS pay community pharmacy on the same payment terms as have been requested by wholesalers.

cccxxii Community Pharmacy Scotland. Written Submission.
cccxxiii Royal Pharmaceutical Society in Scotland. Written Submission.
cccxxiv National Pharmacy Association. Written Submission.

cccxxv Health and Sport Committee, Official Report, 21 January 2020, Col 46

cccxxvi Health and Sport Committee, Official Report, 21 January 2020, Col 43

cccxxvii Health and Sport Committee, Official Report, 21 January 2020, Col 47

cccxxviii Health and Sport Committee, Official Report, 21 January 2020, Col 47

cccxxix Health and Sport Committee, Official Report, 21 January 2020, Col 47

Over the counter medicines

- 284. In the age of free prescriptions in Scotland, there has been controversy over the prescription of drugs like paracetamol and ibuprofen which can be purchased either over the counter or in other settings such as supermarkets.
- 285. We found consensus around the issue from many witnesses.
- 286. Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government suggested prescriptions for such drugs were often to manage long-term chronic conditions and it would not be cost effective or time efficient for a patient to purchase these over the counter as the amount they would be supplied would be very high. She also said cccxxxi the availability of drugs through the tariff was less important than how use of those drugs was reviewed, and suggested denying someone a prescription for a drug like paracetamol could require them to take something more harmful or more expensive cccxxxii.
- 287. Dr Scott Jamieson of the Royal College of GPs^{cccxxxiii} suggested spending on drugs available over the counter had reduced in his area and proposed this could be due to "realistic value conversations...along with polypharmacy reviews and the support of our wider multidisciplinary teams". He was at a loss to explain why prescribing of paracetamol had reduced but suggested it could be concerned with health literacy or quantity.

Purchasing and procurement - conclusions

- 288. We started by considering—
 - "...the challenge is how to best manage the interface between NHSScotland and the pharmaceutical industry. A situation where NHSScotland seeks to optimise its use of a finite resource subject to ever-increasing demands while the pharmaceutical industry operates in a competitive commercial environment and seeks to maximise return on its investment and meet the expectations of its shareholders."
- 289. While agreeing with the sentiment of this, we believe a vital component has been omitted the patient. We questioned whether it is in their best interest to allow market economics to determine the purchase and procurement of medicines.
- 290. We heard of the complexities of the international supply chain and the subsequent impact on the NHS, including the effect of leaving the European Union and the issue of shortages. We also considered the pricing of both branded and generic drugs.

cccxxx Health and Sport Committee, Official Report, 21 January 2020, Col 13

cccxxxi Health and Sport Committee, Official Report, 21 January 2020, Col 13

cccxxxii Health and Sport Committee, Official Report, 21 January 2020, Col 13 cccxxxiii Health and Sport Committee, Official Report, 28 January 2020, Col 24

cccxxxiv Scottish Government (2016). Review of Access to New Medicines, Page 36

- 291. Those involved in the industry were keen to emphasise the helpful nature of competition to pricing, but we were surprised to hear this echoed by those responsible for purchasing in the NHS, especially where it appeared to mean higher prices paid through procurement via the Scottish Drugs Tariff and community pharmacies.
- 292. We were pleased to hear of the successes of the Voluntary Price Access Scheme (VPAS) but lament the lack of information gathering on pricing around the UK to ensure Scotland is performing well in negotiations. We also question why the system of rebates is used, rather than simply restricting the amount which can be paid in the first place as this must lead to leakage. In our view, the New Medicines Fund is a welcome way to spend the rebates, however are not clear as to how boards fund access to new medicines once the allocation from the fund is depleted. The Scottish Government should ensure boards have sufficient, and if required ringfenced, funding to cover this. There also appeared to be a discrepancy in the rebate figure quoted and the amount being allocated to the fund.
- 293. Much of the evidence we received proposed innovative pricing schemes which would help reduce the cost and risk associated with medicines procurement in Scotland. Some proposals would also lead to better health outcomes for patients. However, the lack of information about the outcomes of use of medicines is preventing the introduction of such pricing mechanisms and as we discuss in the DATA AND IT section of our report, the time to comprehensively and uniformly update and improve data and technology use in the NHS is long since past.
- 294. Evidence received from pharmacists served to highlight the inefficiency of senior staff procuring medicines in primary care and we have suggested this be addressed as a matter of urgency. We have also proposed the NHS should pay suppliers on the terms they are subjected to.
- 295. However, our main concern is the difference in procurement systems for primary and secondary care and we don't understand why one organisation, the NHS, has two concurrent methods operating. We question whether assessment has taken place to compare the prices achieved for the NHS via the two methods.
- 296. We recommend the Scottish Government assess the costs of procurement of all drugs purchased for use in Scotland via both primary and secondary care based prescriptions and produce comparative figures showing the costs of equivalent products purchased through the different routes.
- 297. We recommend the Scottish Government keep the Committee up to date with progress of discussions with the UK Government on Brexit negotiations and trade, as well as the outcomes of the negotiations with the EU, in the context of the likely impact on the cost of drugs in Scotland.

Prescribing

- 298. The next stage in the supply and demand for medicines is for NHS boards to decide which medicines they will make available to patients in their area.
- 299. The first step is the assessment by local Area Drug and Therapeutic Committees (ADTCs) for inclusion in local formularies. Prescribers then create prescriptions based on the medicines available on the formulary, among various other factors.
- 300. This chapter of the report will consider the various factors involved in the prescriptions of medicines and their influence on the clinical and cost effectiveness of treatments—
 - The freedom of the prescriber, including the main influences on prescribing behaviour;
 - Prescriptions in primary care;
 - · Prescriptions in secondary care;
 - · Non-medicine prescribing;
 - · Social prescribing;
 - · Realistic medicine:
 - · Prescribing generics and biosimilars;
 - · Prescription charges;
 - Prescribing non-licensed medicines;
 - Polypharmacy; and
 - Non-medical prescribers.

Freedom of the prescriber



Prescribers have a significant degree of clinical independence to respond to patients' needs and therefore the 'system' cannot 'ensure' patients receive the most clinically and cost effective treatments, only promote their adoption and provide advice or challenge where adoption does not take place.

NHS Grampian Area Drug and Therapeutic Committee. Written Submission.

301. The freedom of a prescriber in Scotland to prescribe what they consider appropriate was stated as one of the biggest influences on cost and clinical effectiveness in the system of supply and demand for medicines. Both the private and public sector submissions made similar points around this.

Factors which may influence prescribing

- 302. Audit Scotland described the main factors which can influence prescribing in its 2013 report "Prescribing in general practice in Scotland" Lt suggested these included—
 - 1. The Quality and Outcomes Framework (QOF) (now replaced in the General Medical Services (GMS) Contract);
 - 2. NHS Board formularies: and
 - 3. Clinical guidelines.

A. The Quality and Outcomes Framework and the General Medical Services Contract (GMS Contract)

- 303. Audit Scotland described the Quality and Outcomes Framework (QOF) as—
 - "...a voluntary incentive scheme for GPs which uses financial incentives to encourage high quality care. The QOF has had considerable influence on the way GPs work, including their prescribing. For example, it includes targets for managing particular conditions, such as hypertension, which have an effect on prescribing."

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- 304. NHS Grampian A^{cccxxxvii} suggested QOF criteria on prescribing behaviour were not replicated in the new GMS contract and it is not clear what has replaced this mechanism. NHS Tayside^{cccxxxviii} said in the absence of the QOF, the role of Health and Social Care Partnerships "to support and drive the sense of urgency regarding medicines spend" was vital in good medicine management.
- 305. We have further commented on the monitoring and accountability of the GMS contract in the GENERAL MEDICAL SERVICES (GMS) CONTRACT section of this report.

B. Formulary

- 306. A formulary is a list of medicines and medical devices which are available to prescribe. In his review of access to medicines, Dr Brian Montgomery said—
 - "Formularies perform two primary functions. They can be a comprehensive compendium of all medicines available for use or they can be decision-support tools which promote and support the safe and effective use of medicines in the management of medical conditions."
- 307. Every health board has an ADTC which fulfils a number of functions with regard to the formulary—
 - Generate local formularies;
 - · Provide an education function;
 - Take responsibility for prescribing decisions; and
 - Create local guidance and governance of medicines.
- 308. Once approved by the Scottish Medicines Consortium (SMC), local ADTCs will consider whether to add drugs to local formularies. As NHS Lothian ADTC^{cccxli} told us, not all drugs will automatically be added if there is already a range of choice on the formulary.
- 309. A number of issues were raised with us in relation to formularies—
 - Adding items to local formularies;
 - The value of a formulary with fewer options;
 - · Formulary compliance;
 - Disinvestment/investment;

cccxxxvii NHS Grampian Area Drug and Therapeutic Committee. Written Submission.

cccxxxviii NHS Tayside. Written Submission.

cccxxxix Scottish Government (2016). *Review of Access to New Medicines*, Page 33 cccxl Healthcare Improvement Scotland. Written Submission.

coxi i lealthcare improvement ocoliana. Written oubinission.

cccxli NHS Lothian Area Drug and Therapeutic Committee. Written Submission.

- · Competition; and
- A Single National Formulary (SNF).

Adding items to the formulary following SMC decisions

- 310. We were interested in whether new drugs were automatically added to board formularies once approved by the SMC. Dr Alan McDonald, Chair of the SMC, said cccxlii the introduction of a new drug would not render the previous one obsolete. Roche Products Ltd and Cancer Research UK raised concerns at the lack of monitoring of health boards adhering to guidance, stating SMC approved medicines should be available within 90 days and proposing examination of the uptake of medicines across all health boards. Merck, Sharp and Dohme suggested mandating all health boards to adopt SMC regulations.

 AstraZeneca cccxivi called for guidelines to be developed which did not automatically include the cheapest options in the formulary, but to ensure the best long-term solutions were included (the issue of assessment, value from medicines and the cost of medicines is explored further in the VALUE section of this report).
- 311. We recommend the Scottish Government consider options for monitoring the uptake by health boards of new medicines approved for use by the SMC, including the speed at which these are available and the value and outcomes generated and whether this information can be made publicly available.

Value from a formulary with fewer options

- 312. The Royal College of Psychiatrists said "value could be improved by having a tighter formulary led by both medical and pharmacy staff but this relies on a reliable supply of medications. Intermittent supplies increase inefficiencies as clinical staff are pulled into repeated changes of medications." NHS Fife ADTC cccxlvii said waste could be avoided by having a more limited choice in a formulary to avoid having to stock everything.
- 313. We would welcome the view of the Scottish Government on whether a "tighter" formulary, with a narrower range of choices, is preferable.

cccxlii Health and Sport Committee, Official Report, 21 January 2020, Col 54

cccxliii Roche Products Ltd. Written Submission.

cccxliv Cancer Research UK. Written Submission.

cccxlv Merck, Sharp and Dohme. Written Submission.

cccxlvi AstraZeneca. Written Submission.

cccxIvii NHS Fife Area Drug and Therapeutic Committee. Written Submission.

Supply and demand for medicines, 6th Report, 2020 (Session 5)

Formulary compliance

- 314. The ADTCs who contacted us spoke of the importance of compliance with the formulary and how this was a rough and "crude" measurement of the effectiveness of a system. Most suggested this was above 85% for most health boards, exceeding the target of 80%. They described how electronic prescribing in primary care made this relatively easy and anticipated the Hospital Electronic Prescribing and Administration System (HEPMA) supporting this further in secondary care. The British Medical Association (BMA) cccxlix described the occurrence of doctors prescribing off formulary as "rare".
- 315. McKesson UK^{cccl} noted the plans for the new Pharmacy First service (formerly the minor ailment service) would improve formulary compliance and bring a national uniformity to what was available to patients.

Disinvestment/investment

- 316. It was not clear to us how drugs, once added to the formulary, were reviewed, if at all, and how decisions to disinvest in medicines were taken where there is little evidence of effectiveness or cost-effectiveness.
- 317. The main examples of this presented to us in evidence included—
 - patients maintained on medicines where there is evidence of more costeffective alternatives:
 - · homoeopathy and herbal remedies; and
 - older medicines which have not been reviewed in the same way as new medicines.
- 318. The question of who should be responsible for reviews and disinvestment in formularies was discussed with us.
- 319. Healthcare Improvement Scotland (HIS) wrote in their submission—
 - "In the medicines arena, much of the focus is on the investment in new treatments but there may be a role for the identification of areas for disinvestment to free up resources for use in treatments that deliver more value."
- 320. Along with Pfizer UK^{ccclii}, they said there was a need to focus on disinvestment as much as investment in new medicines, and Dr Ewan Bell, National Clinical Lead, ADTC Collaborative, at HIS said^{cccliii} there was a role for the organisation in national

cccxIviii NHS Lothian Area Drug and Therapeutic Committee. Written Submission.

cccxlix British Medical Association. Written Submission.

cccl McKesson UK. Written Submission.

cccli Healthcare Improvement Scotland. Written Submission.

ccclii Pfizer UK. Written Submission.

- disinvestment in medicines. We sought further detail on this role in correspondence cocliv to the Cabinet Secretary.
- 321. The role of the ADTCs was also highlighted to us by Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland (NHS NSS), who said ccclv they should "indicate the most cost effective products to be prescribed at any point in time". However, we are not clear on the assessment processes used by ADTCs to decide whether to include a drug or not, given we have heard this may depend on factors such as the number of other drugs fulfilling the same role, and that the advent of PACS Tier 2 meant boards may not always be able to take decisions based on cost effectiveness. In the absence of data on outcomes, it is also hard to see how retrospective cost effectiveness is measured.
- 322. Lindsay McClure used biosimilars as an example ccclvi of how changes were made, noting a lot of work went into changing from an established product to a new one and informing us of national support available for local change. It does not appear this national support is offered in a comprehensive or systematic manner however.
- Dr Brian Montgomery suggested ccclvii investment and disinvestment tended to be reactive, rather than strategic, and this resulted in any savings achieved quickly dissipating. Chiesi Ltd called for a review of medicines currently prescribed which are of limited clinical value and Cancer Research UK suggested the NHS in Scotland had to ensure optimal use of medicines in routine clinical use, to get the best value from prescription of these medicines. We are of the view the best way to achieve this would be routine review of formularies to ensure the drugs contained therein are the ones which will achieve best value, but again it is hard to see how this can be achieved without comprehensive information on the outcomes of taking medicines. There is clearly a prize to be won in terms of savings by disinvesting.
- 324. Removal of drugs from formularies could also face challenges from patients.
- 325. We were told how patient choice impacted on decisions to disinvest and it was perceived to be particularly difficult to change prescribing in patients who had been on medicines for a long time.
- 326. Dr Scott Jamieson of the Royal College of GPs in Scotland spoke^{ccclx} of the dichotomy between a national decision to disinvest in a particular drug and patient assuredness it was the cure for them. He spoke of the emotive nature of medicine

cccliii Health and Sport Committee, Official Report, 28 January 2020, Col 21

cccliv Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

ccclv Health and Sport Committee, Official Report, 21 January 2020, Col 52 ccclvi Health and Sport Committee, Official Report, 21 January 2020, Col 52 ccclvii Health and Sport Committee, Official Report, 21 January 2020, Col 53

ccclviii Chiesi Ltd. Written Submission.

ccclix Cancer Research UK. Written Submission. ccclx Health and Sport Committee, *Official Report, 28 January 2020,* Col 21

Supply and demand for medicines, 6th Report, 2020 (Session 5)

for some patients and said a prescriptive list of what could and could not be prescribed would be unhelpful.

327. We recommend the Scottish Government work with Healthcare Improvement Scotland to establish a system for routine and comprehensive review of local formularies, including in relation to the use of biosimilars, accounting for issues such as equity of access regardless of postcode.

Competition

328. Both Dr Alan MacDonald, Chair of the SMC^{ccclxi}, and Lindsay McClure of NHS NSS^{ccclxii} suggested there were mechanisms by which the most cost effective product would be used where options and competition exist, using the example of hepatitis C drugs.

Single National Formulary

- 329. In its Programme for Government in 2016^{ccclxiii}, 2017^{ccclxiv} and 2018^{ccclxv}, the Scottish Government included a commitment to introduce a single national formulary (SNF) with the latter suggesting this would be in place in 2019. However, the Programme for Government in 2019-20 did not contain reference to this work.
- 330. In correspondence ccclxvi in January 2020, the Cabinet Secretary for Health and Sport, Jeane Freeman, said a web platform to host the SNF and a governance model for cooperation is currently being tested between NHS Lothian, NHS Fife and NHS Borders (which Alison Strath, Principal Pharmaceutical Officer, Scottish Government, suggested would link well with HEPMA) and said the whole system would be in place in 2021. We were interested in how the new platform would communicate with the like of HEPMA and sought the view of the Cabinet Secretary for Health and Sport on this issue in correspondence ccclxviii.
- 331. We also asked—

ccclxi Health and Sport Committee, Official Report, 21 January 2020, Col 53

ccclxii Health and Sport Committee, *Official Report, 21 January 2020,* Col 41 ccclxiii Scottish Government (2016). *A Plan for Scotland, The Government's Programme for Scotland 2016-17*, Page 62

- ccclxiv Scottish Government (2017). A Nation with Ambition, the Government's Programme for Scotland 2017-18, Page 98
- ccclxv Scottish Government (2018). *Delivering for Today, Investing in Tomorrow, the Government's Programme for Scotland 2018-19,* Page 71
- ccclxvi Letter from the Cabinet Secretary for Health and Sport on the Review of New Medicines, 13 January 2020

ccclxvii Health and Sport Committee, Official Report, 10 March 2020, Col 25

- When a single national formulary is anticipated to be put in place;
- How this will interact with local formularies;
- How can best practice across individual formularies be shared; and
- How will information about the medicines spending of each health board be recorded and published and how will it be used to improve value across the country.
- 332. We have received mixed views on the introduction of the national formulary. It was thought this would bring many benefits, including consistency around the country and unwanted variation ccclxix, information sharing ccclxx, nationalised governance on the prescription of non-medicines ccclxxi, work better for patients ccclxxii, reduce duplication ccclxxiii and be more cost effective ccclxxiv.
- 333. Equally, a number of challenges and disadvantages were proposed. Dr Ewan Bell, National Clinical Lead, ADTC Collaborative, HIS, questioned the definition of an SNF and whether this would merely be a "list of drugs that is developed centrally" He proposed "Another approach, which would be more value-added, would be to develop intelligent national therapeutics pathways that were condition specific" and added this approach would still allow for local decision making within the parameters of a national approach. Dr Scott Jamieson of the Royal College of GPs CCCIXXVII was supportive of this.
- 334. There were also concerns from various stakeholders about the potential lack of local decision making, the education role and local perspectives on pathways into formularies. The opportunity to share best practice was also feared to be a casualty of the introduction of an SNF^{ccclxxviii}. It was proposed clinicians may find it difficult to support an SNF^{ccclxxix} and keeping local versions of national formularies stocked could prove challenging^{ccclxxx}, particularly if there were shortages^{ccclxxxi}. There were also suggestions an SNF may not be clinically or cost effective^{ccclxxxii}.

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ccclxviii Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020
ccclxix Health and Sport Committee, Official Report, 28 January 2020, Col 12
ccclxx Health and Sport Committee, Official Report, 28 January 2020, Col 13
ccclxxii Health and Sport Committee, Official Report, 28 January 2020, Col 14
ccclxxii National Pharmacy Association. Written Submission.
ccclxxiii European Medicines Group. Written Submission.
ccclxxiv Royal College of Psychiatrists. Written Submission.
ccclxxvi Health and Sport Committee, Official Report, 28 January 2020, Col 12
ccclxxvi Health and Sport Committee, Official Report, 28 January 2020, Col 12
ccclxxvii Health and Sport Committee, Official Report, 28 January 2020, Col 13
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The Royal College of GPs told us a further downside would be the time taken to 335. implement it and Dr Scott Jamieson ccclxxxiii thought one aspect of this could be every health board currently using a different system to operate their formulary. He noted Greater Manchester has a similarly sized population to Scotland but only has one formulary because it uses a single IT system. We note a board working with a similarly population size to Scotland operates without the concerns of the loss of local knowledge and decision making cited to us in evidence. It also serves to further highlight the opportunities where uniform IT systems are used.

336. Alison Strath said—

- "For me, the point on the formulary is that we are thinking about how medicines sit in the treatment care pathways. There is a need for us to continue to ensure, as the cabinet secretary has mentioned, that there is flexibility where there is a need for that. We need a national solution, but we must ensure that there is still flexibility to allow things to work around a local system where that is needed. Focusing on clinical pathways and where the medicine sits in the pathway is the key to doing that. That would probably allow us to think about social prescribing as well as the medicines." CCCIXXXIV
- 337. We recommend the Scottish Government clarify the purpose of the Single National Formulary in the context of the suggestions this should be more than a "list of drugs that is developed centrally" and include condition specific pathways.
- 338. We ask the Scottish Government provide clarity as to their intentions with a Single National Formulary including others options considered (such as condition specific pathways) and timescales, and how it will address the concerns raised with us on the transition from local systems. We are keen to hear the extent to which the Scottish Government envisages a national system allowing for local flexibility and clinical input.
- 339. We ask the Scottish Government to provide detail as to how a Single National Formulary technical system will be developed in a way which integrates with the various other systems required to better manage medicines in Scotland, such as HEPMA and the National Digital Platform.

ccclxxviii The Royal College of GPs. Written Submission.

ccclxxix Health and Sport Committee, Official Report, 28 January 2020, Col 13

ccclxxx Royal College of Physicians of Edinburgh. Written Submission.

ccclxxxi The Royal College of GPs. Written Submission.

ccclxxxii The Royal College of GPs. Written Submission.

ccclxxxiii Health and Sport Committee, Official Report, 28 January 2020, Col 13 ccclxxxiv Health and Sport Committee, Official Report, 10 March 2020, Col 25

ccclxxxv Health and Sport Committee, Official Report, 28 January 2020, Col 12

The inclusion of non-medicines in a single national formulary (SNF)

- 340. A further advantage relayed to us was the use of a SNF to govern the use of non-medicines in Scotland. Dr David Coulson, Assistant Director of Pharmacy, NHS Tayside^{ccclxxxvi}, Dr Scott Jamieson of the Royal College of GPs^{ccclxxxvii}, and the Royal College of Psychiatrists^{ccclxxxviii} were among proponents of the idea.
- 341. Dr Ewan Bell, HIS, suggested the way non-medical items were recommended to health boards was probably inconsistent but was non-committal as to whether improved governance should be at a local or national level. ccclxxxix
- 342. We recommend the Scottish Government use the opportunity to strengthen governance of non-medicine prescribing in Scotland and propose an SNF should include non-medicines.

C. Clinical Guidelines

- 343. According to the Scottish Parliament Information Centre—
 - "Professional guidance to clinicians on prescribing states that they must 'provide effective treatments based on the best available evidence'. Doctors are expected to work within the limits of their competence and keep their knowledge and skills up to date. One of the ways in which they do this, is by using clinical guidance. There are a number of sources of clinical guidance, including professional bodies such as the Royal Colleges, the Scottish Intercollegiate Guidelines Network (SIGN) and the National Institute for health and Care Excellence (NICE)."

Freedom of the prescriber - conclusions

- 344. We are of the view the prescriber in Scotland does indeed wield immense power when it comes to making clinically and cost effective decisions as to which medicines to prescribe and opportunities to improve their prescribing should be maximised.
- 345. The most prevalent current opportunity to influence behaviour presented to us in evidence was formularies. We concur these should be under constant review and Boards should take strategic decisions to disinvest where medicines are no longer the most clinically or cost effective options. We agree governance of non-medicine prescribing should be strengthened.

ccclxxxvi Health and Sport Committee, Official Report, 28 January 2020, Col 14

ccclxxxvii Health and Sport Committee, Official Report, 28 January 2020, Col 14

ccclxxxviii Royal College of Psychiatrists. Written Submission.

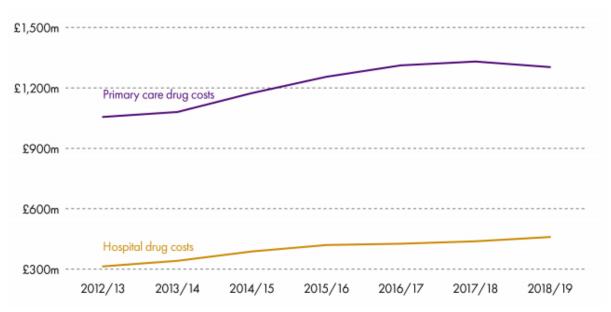
ccclxxxix Health and Sport Committee, Official Report, 28 January 2020, Col 15

cccxc Scottish Parliament Information Centre (2020). Medicines in Scotland SB 20/08

346. The biggest opportunity to influence behaviour which we believe is currently being missed is the use of the GMS contract to reward or incentivise prescribing of medicines which represent the best value for the patient.

Prescribing in primary care

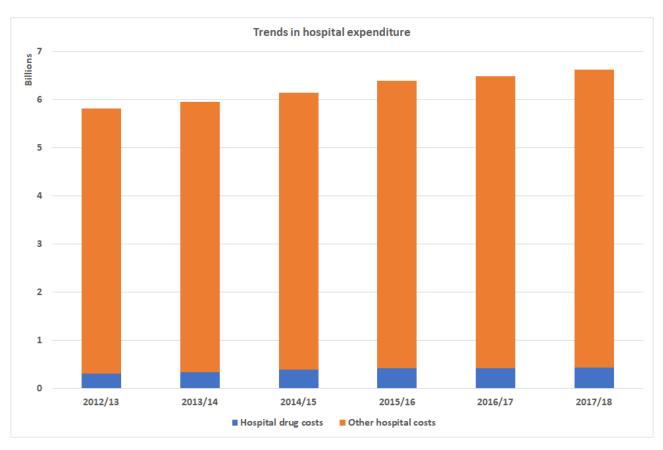
347. Medicines prescribed in the community far outweigh those prescribed in hospital settings and the costs of this are shown below.



ISD Scotland - Health Service Costs Book

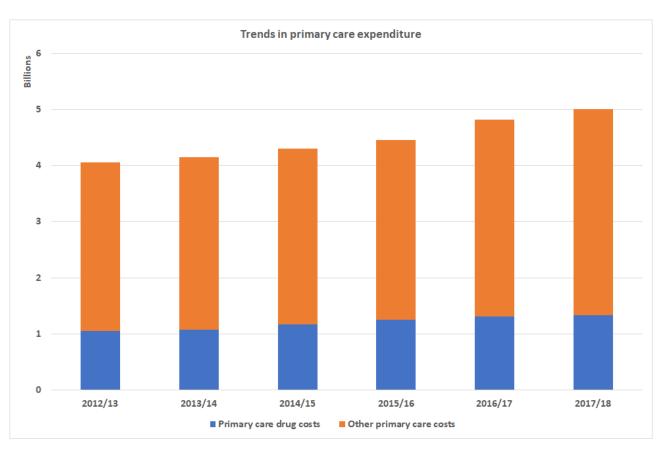
Source: Scottish Parliament Information Centre (2020). Medicines in Scotland SB 20/08

Trends in hospital expenditure



Source: Scottish Parliament Information Centre (2020)

Trends in primary care expenditure



Source: Scottish Parliament Information Centre (2020)

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- 348. According to the Scottish Parliament Information Centre—
 - "The number of items issued in the community has steadily increased over the past decade, from 89.3 million items in 2009/10 to 103.4 million items in 2018/19 (+15.8%). However, the numbers have plateaued since 2016."
- 349. It was also noted in "2018/19, the total cost of providing medicines and pharmacy services in the community decreased by 0.5%." Audit Scotland suggested this drop was due to better reviews of prescriptions, increasing the use of generic medicines in secondary care and switching to biosimilars.

Reviews of prescriptions

- 350. The issue of whether repeat or long-term prescriptions were being reviewed was prevalent throughout our inquiry. Several reasons for the importance of reviews were given—
 - Improved safety by addressing any misunderstandings about medication cccxciv;
 - Provide an opportunity to discuss medicines with patients;
 - Reduce waste by avoiding patients remaining on medicines which are no longer effective for them; and
 - Prevent harm from taking medicines which are no longer suitable.
- 351. Audit Scotland said the Scottish Government Effective Prescribing team had helped boards reduce costs on medicines by "emphasising the importance of carrying out medicines reviews, to safely reduce the number of medications being taken at the same time."
- 352. However, from the evidence presented to us, it appears these are not happening comprehensively or systematically. NHS Tayside told us " Our current systems for review and discontinuation of medication fail to make significant inroads into those patients who are prescribed potentially inappropriate medicines."

Comprehensive reviews of prescriptions are not routinely taking place

- 353. Several reasons were outlined to us as to why reviews may not be taking place—
 - A reluctance to change medicines, both on the part of the patient and the prescriber; and
 - Resources required to undertake reviews, including GP time and the pharmacotherapy aspects of the GMS contract.

cccxci Scottish Parliament Information Centre (2020). Medicines in Scotland SB 20/08 cccxcii Scottish Parliament Information Centre (2020). Medicines in Scotland SB 20/08

cccxciii Audit Scotland. (2019). *NHS in Scotland 2019* cccxciv Royal College of Physicians of Edinburgh. Written Submission. cccxcv Audit Scotland. (2019). *NHS in Scotland 2019*, page 25 cccxcvi NHS Tayside. Written Submission.

354. In addition, we were interested in how the General Medical Services contract covers reviews of medication.

Reluctance to switch

355. Several stakeholders observed prescribers were generally good at proposing the most cost and clinically effective solutions in the first instance but there was a reluctance to review prescriptions on both the part of the prescriber and the patient, with the latter "assumed" to be unwilling to switch medications particularly based on a reduced cost.

Resources required to review prescriptions

- 356. Some suggested GP time with patients was a constraint, an issue comprehensively discussed further in the SOCIAL PRESCRIBING section of this report. Others called for further resources to support a better system of reviews.
- 357. The new General Medical Services contract introduces a new pharmacotherapy service, designed to integrate the work of GPs, pharmacists and other health professionals in one practice. This approach is described as "crucial to reducing GP workload" and includes transferring responsibilities for work such as medicines reviews and repeat prescribing to pharmacists cccxcviii. The contract stipulates all GP practices will be serviced by pharmacy support by April 2021.
- The Chief Pharmaceutical Officer, Rose Marie Parr, outlined cccxcix the Scottish Government's ambitions with regard to the GP contract and the new roles for pharmacists working within surgeries to take on roles relating to reviews, deprescribing and polypharmacy. While she emphasised the importance of reviews, she did not specify how these would become systematically embedded in the culture of prescribing, nor how the contract would influence such behaviour.
- 359. The Royal Pharmaceutical Society in Scotland^{cd} noted the demands on GP time and said making use of the pharmacists working within GP practices to carry out patient reviews would be an efficient use of resources. They also suggested^{cdi} pharmacists took a holistic view which helped with achieving cost and clinical effectiveness. They said pharmacists could reduce "inappropriate polypharmacy" and medicines not being taken properly, if at all, and called for time to be built into pharmacotherapy contractual models to allow for "meaningful clinical and cost effectiveness interventions. This would include deprescribing".
- The contract notes^{cdii} pharmacists will not be directly employed by the GP practices, but they will coordinate their work load. Local Health and Social Care Partnerships

cccxcvii Scottish Government (2017). The 2018 General Medical Services Contract in Scotland

cccxcviii A table containing the services which will be provided is included at Annexe C. cccxcix Health and Sport Committee, *Official Report, 10 March 2020,* Col 17 cd Royal Pharmaceutical Society in Scotland. Written Submission.

cdi The Royal Pharmaceutical Society in Scotland. Written Submission. cdii Scottish Government (2017). The 2018 General Medical Services Contract in Scotland

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- will commission services and health boards will employ nursing and healthcare assistant staff. It is not clear who will employ pharmacists.
- 361. Pharmacists in the community were also seen as a resource to help support medication reviews.
- 362. Rose Marie Parr said patients "might be harmed by their medicine and receive no benefit, so we need better medication review systems, as well as the capacity to review. In "Achieving excellence in pharmaceutical care: a strategy for Scotland", we say that community pharmacists could potentially look at long-term conditions and medication review for people in society who are worried or perhaps need a review of their medicines. Cdiiiu
- 363. Pharmacists themselves are in favour, with both Community Pharmacy Scotland and the Royal Pharmaceutical Society in Scotland championing the role. Matt Barclay, Director of Operations, Community Pharmacy Scotland^{cdiv} said part of "Achieving excellence in pharmaceutical care: a strategy for Scotland"^{cdv} was embedding conversations with patients about their needs and requests. How this could be done in a community pharmacy setting was being considered as part of the Medicines Care Review^{cdvi} (MCR).
- 364. He further added "...from Community Pharmacy Scotland's perspective, there is a need to look at the Medicines Care Review and, potentially, to contractualise that slightly better in order that we focus on a proper medicines review so that we have conversations with patients and record the outcomes. At present, we have the conversations, but we do not record the outcomes. Our doing so would allow us to cement our place." We were interested in why the gathering of outcome data requires to be contractualised and what leadership organisations such as Community Pharmacy Scotland could provide in ensuring this happened. The organisation said colviii it was committed to examining this through the MCR framework but further funding and addressing IT issues would be required.
- 365. A source of frustration throughout our deliberations on medicines has been the assertion from pharmacists of the valuable work taking place at community level which is not recorded or shared effectively. It appears without mandating this contractually, information which could improve patient outcomes and save the NHS money is being lost.
- 366. We were pleased to hear a greater role for pharmacists is being considered, particularly in the longer term. Rose Marie Parr said "In the longer term, we want to consider how pharmacists in primary care or in community pharmacy can help to

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cdiii Health and Sport Committee, Official Report, 21 January 2020, Col 7 cdiv Health and Sport Committee, Official Report, 28 January 2020, Col 23
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cdv Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland

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cdvi Further detail on the medicines care review is available here. cdvii Health and Sport Committee, Official Report, 28 January 2020, Col 16
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cdviii Letter from Community Pharmacy Scotland on Supply and Demand for Medicines, 4
March 2020

- reduce polypharmacy and help people with long-term conditions who are taking way too many medicines that have not been reviewed over an appropriate timescale. cdix
- 367. While we welcome this ambition, we would welcome clarification as to why this is a long-term goal, rather than an area for immediate action.
- 368. We ask the Scottish Government to provide detail of progress towards the 2021 deadline for all GP practices (either directly or through GP clusters) to include pharmacy staff, including—
 - If this target will be met;
 - · Who employs these pharmacists and is accountable for their performance;
 - Whether responsibility and accountability for delivery of this target lies with boards or with the Scottish Government, and if boards, what action will the Scottish Government take if it is not achieved;
 - · If the target will not be met which areas will fail to do so and why; and
 - If the target will not be met, current estimates of timescales for doing so.

The General Medical Services (GMS Contract)

- 369. We are interested in how the new GMS contract will evaluate the work of GPs and the extent to which they are accountable for delivering the desired outcomes, such as prescription reviews. In March 2019, the Primary Care: National Monitoring and Evaluation Strategy^{cdx} was published which stipulates its focus is on "national" or "macro" level policies. It also says—
 - "It is also not for central government to decide how evidence is used to inform local or cluster-level decision-making, and service delivery or clinical practice (the 'micro' level), or how learning is captured from those and then acted on. This strategy, however, offers transferable principles, methods and core research questions, and we have a responsibility to encourage the development of a more intelligence-informed primary care system, to support an improved data infrastructure, and to work with national partners to promote evidence and appropriate methods."
- 370. We are concerned by the apparent ambiguity between the Scottish Government's "responsibility to encourage the development of a more intelligence-informed primary care" and the Government suggestion it is not its place to decide how evidence should inform decision making, especially in light of evidence we have received on the importance of data. We also have concerns this lever of encouragement will prove insufficient to produce the actions we are told are essential, particularly on data gathering.

cdix Health and Sport Committee, *Official Report, 21 January 2020,* Col 13 cdx Scottish Government (2019). Primary care: national monitoring and evaluation strategy cdxi Scottish Government (2019). Primary care: national monitoring and evaluation strategy

- 371. Dr Scott Jamieson of the Royal College of GPs^{cdxiii} told us no national data is collected on medicines reviews, although he was confident those with long-term conditions received regular reviews of their medications. He welcomed changes in the GMS contract to allow for such conversations with patients, which he said would be less restrictive than the previous QOF approach. Dr David Shackles of the Royal College of GPs noted^{cdxiv} however the occupation had faced workforce challenges since the removal of the QOF approach and said "significant pressures on GPs' workload has adversely affected the ability of GPs to carry out as many in-depth medication reviews as they would hope to." He also suggested the pharmacotherapy aspects of the contract were not as helpful as they could be due to workforce issues experienced by pharmacists.
- 372. Alpana Mair, Head of Effective Prescribing and Therapeutics, Scottish Government, noted the existence of the 7 steps process for reviewing medications with people and suggested this took the approach of "Before prescribing, a GP or a non-medical prescriber has the conversation with the patient and gets them to ask what they would do rather than take a tablet." Claire Fernie, Public Partner Volunteer, NHS Fife^{cdxvi} suggested people were willing to be prescribed alternatives, but this required the prescriber to have the skills to manage the conversation differently. Scottish Care^{cdxvii} said a greater role for social workers in 7 Step reviews should be accommodated.
- 373. Again, there does not seem to be a correlation between the Government's expectation these conversations are occurring and the reality in the GP surgery.
- 374. The Scottish Government's Primary Care: National Monitoring and Evaluation Strategy states—
 - "A three-year period of significant transition for transformative service redesign, described in the 2018 GMS Contract, will shape national priorities for monitoring and evaluating in the early years of this Strategy."
- 375. It goes on to describe long-term strategies for incorporating data gathering before adding—
 - "Clearly, we will not have sufficient resources to monitor and evaluate all changes with the same intensity. The Scottish Government will, in close consultation with the Primary Care Monitoring and Evaluation Steering Group and our national partners, prioritise activity, taking account of developments across the health and social care system (e.g., the new framework for community based integrated services initiated this year), and will take the long view beyond 2021."

cdxii Scottish Government (2019). Primary care: national monitoring and evaluation strategy cdxiii Health and Sport Committee, *Official Report*, 28 January 2020, Col 22

cdxiv Letter from the Royal College of GPs on the Supply and Demand for Medicine, 9 March 2020

cdxv Health and Sport Committee, Official Report, 10 March 2020, Col 23

cdxvi Health and Sport Committee, Official Report, 18 February 2020, Col 4

cdxvii Scottish Care. Written Submission.

- 376. We are not satisfied with this approach to data collection and evaluation. It appears the new GMS contract has been initiated with no interim monitoring and evaluation processes in place, with the first three years of operation being used to inform a longer-term piece of work. It is also not clear what weighting will be given to elements of primary care delivery in evaluation.
- 377. We are not convinced the contract adequately requires GPs to carry out reviews of medicines or to ensure these are carried out by the other health care professionals coming within their sphere of management.
- 378. We consider the GMS contract to be an ideal tool for the Scottish Government to "encourage" the behaviours and outcomes required from its relationship with GPs, including regular reviews of patients' medication. Allowing three years to elapse before even developing an evaluation strategy represents at best a wasted opportunity and at worst potential harm for patients left languishing on inappropriate medication regimes.
- 379. This approach also suggests GPs are receiving payment for services, regardless of outcomes, in the first three years of the contract.
- 380. We recommend the Scottish Government review how the General Medical Services (GMS) contract can be updated to ensure patient medication reviews are taking place at suitable intervals with the review outcomes monitored and recorded to demonstrate the value they provide.
- 381. We request the Scottish Government provide detail of—
 - Progress on development of the evaluation and reporting mechanism for the GMS;
 - How GP performance is measured now the Quality and Outcomes
 Framework element of the GMS contract has been removed, including in the
 first three years of operation;
 - When the GMS contract is next to be reviewed;
 - The anticipated proportion of the primary care budget to be spent on the GMS in the first three years of operation (broken down by year); and
 - The consequences of a GP failing to meet the expectations of the contract in terms of delivery of national strategies and policies.

Patients' Views

- 382. The need for open conversations with patients on their medicines was emphasised throughout the inquiry, including on whether or not to change their prescriptions and prescription regimes.
- 383. Dr Scott Jamieson of the Royal College of GPs in Scotland spoke^{cdxviii} of the balance required between national decisions and individual patient preferences.

Other forms of support as part of reviews

384. Adam Stachura, Head of Policy and Communications, Age Scotland, cdxix spoke of how reviews should not just be about medicines but should encompass other forms of care which may represent savings and better clinical outcomes for patients using the example of good podiatry services to enable better mobility.

Digitisation of reviews of medicines

- 385. The University of Strathclyde^{cdxx} proposed using technology to ensure reviews of medicines were maximised, suggesting an app which could monitor adherence, patient response to medicines and the optimal time for switching to a cheaper alternative.
- 386. NHS Tayside^{cdxxi} suggested a solution was to ensure all NHS boards were using ScriptSwitch^{cdxxii}, prescribing software designed to suggest cost saving alternatives, and the Pharmacist and Data-Driven Quality Improvement in Primary Care (P-DQIP) intervention^{cdxxiii}, which aims to identify patients at risk from harm from polypharmacy and provide decisions support making functions.

Reviews of prescriptions - conclusions

- 387. The Chief Pharmaceutical Officer, Rose Marie Parr, told us people may be taking medicines from which they are no longer deriving benefit or may be now causing harm, and "better medication review systems as well as the capacity to review" were required.
- 388. We agree with this and wonder what the Scottish Government, pharmacists and the NHS are doing to ensure this happens. Such reviews should also be used to encompass other forms of care which may represent savings and better clinical outcomes for patients, using the example of good podiatry services to enable better mobility.
- 389. The need for open conversations with patients on their medicines was emphasised to us throughout the inquiry, including on whether or not to change their prescriptions and prescription regimes. While we recognise there are challenges involved, none seem insurmountable in comparison to the prize to be won of better clinical outcomes for patients and cost effective use of medicines. It has been

cdxviii Health and Sport Committee, *Official Report, 28 January 2020,* Col 21 cdxix Health and Sport Committee, *Official Report, 18 February 2020,* Col 11 cdxx University of Strathclyde. Written Submission cdxxi NHS Tayside. Written Submission.

cdxxii Further detail on ScriptSwitch can be found here.

cdxxiii Further details on the Pharmacist and Data-Driven Quality Improvement in Primary Care (P-DQIP) can be found here.

cdxxiv Health and Sport Committee, Official Report, 21 January 2020, Col 7

frustrating to hear of ambition in this area without associated action planning and of another area where GPs act unchecked.

Repeat prescribing

390. The management of repeat prescribing was an area of interest to us due to the obvious potential for waste to occur.

Medicines Care Review Service

- One of the main solutions cited was the Medicines Care Review (MCR) service cdxxv offered by community pharmacies. This is a three stage process, whereby patients with long-term conditions can register with their local pharmacy and undergo an assessment by the pharmacist to create a pharmaceutical care plan. The patient's GP then produces a repeat prescription for a period of time, which the pharmacist fulfils. Regular updates are sent to the GP after each episode of dispensing and at the end of the prescription period, a full report is submitted back to the GP.
- 392. Gail Caldwell, Director of Pharmacy at NHS Greater Glasgow and Clyde^{cdxxvi}, told us this was an incredibly important tool for boards to avoid waste in repeat prescribing. She said the system—
 - "...does not have the same risks as managed repeats, because each time the patient presents for a prescription, the pharmacist checks that the patient requires the medicine, which reduces the number of times that a medicine is dispensed. As part of that service, in order that we support patients to get the most from their medicines, patients get a medicines review. That is important, because it means that any inappropriate polypharmacy can be assessed and changes can be made."
- 393. Community Pharmacy Scotland suggested GP practices should engage with the MCR^{cdxxviii} and the repeat prescribing system could reduce the workload for doctors. We were also told^{cdxxix} the MCR service provided a "feedback loop" from community pharmacy to prescriber but this did not have a high uptake in the majority of areas. Technical issues with operation were also noted^{cdxxx}. Their ambition^{cdxxxi} was for the service to provide a care summary akin to the patient treatment summary provided upon discharge from hospital. The benefit of this was cited as giving patients control over their own information and care.

cdxxv Further detail on the Medicines Care Review (MCR) service can be found here: https://nhsnss.org/services/practitioner/pharmacy/pharmacy-services/medicines-care-review-mcr/

cdxxvi Health and Sport Committee, Official Report, 4 February 2020, Col 2

cdxxvii Health and Sport Committee, Official Report, 4 February 2020, Col 2

cdxxviii Further detail on the Medicines Care Review (MCR) service can be found here: https://nhsnss.org/services/practitioner/pharmacy/pharmacy-services/medicines-care-review-mcr/

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- 394. Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland spoke of the pharmacist as a "spotter" who could identify irregularities with repeat prescriptions and emphasised the importance of conversations with patients and passing on that information to pharmacists and GPs working within practices. Gail Caldwell also spoke of the inbuilt design to encourage discussion with patients.
- 395. Again however, we were concerned by the lack of formality and structure surrounding the sharing of information as a result of these conversations.

Pharmacotherapy and repeat prescriptions

396. While Community Pharmacy Scotland and the Company Chemists
Association suggested pharmacists within GP practices could assist with repeat prescribing, Jonathan Burton warned dealing with the administration of this exclusively would not make the best use of pharmacists' skills.

Delivery of repeat prescriptions

- 397. Jonathan Burton of the Royal Pharmaceutical Society in Scotland said patient involvement in delivery of repeat prescriptions was key to ensuring they were still getting medicines they were expecting and needing, although he did not elaborate on how this came about and our experience is of no patient input being sought.
- 398. Gail Caldwell of NHS Greater Glasgow and Clyde^{cdxxxvii} noted medicines could also be delivered to people's homes through the homecare system, which was how some manufacturers preferred their medicines to be supplied.
- 399. Campbell Shimmins of Community Pharmacy Scotland also extolled the benefits of having pharmacists in communities saying this meant they knew their patients and said changes to arrangements for getting medicines would result in direct contact with the patient.

cdxxx Letter from Community Pharmacy Scotland on Supply and Demand for Medicines, 4 April 2020

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cdxxxi Health and Sport Committee, Official Report, 18 February 2020, Col 36 cdxxxii Health and Sport Committee, Official Report, 28 January 2020, Col 47
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cdxxxiii Health and Sport Committee, *Official Report, 4 February 2020,* Col 36 cdxxxiv Company Chemists Association. Written Submission.

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cdxxxv Health and Sport Committee, Official Report, 4 February 2020, Col 4 cdxxxvi Health and Sport Committee, Official Report, 4 February 2020, Col 4 cdxxxviii Health and Sport Committee, Official Report, 4 February 2020, Col 5 cdxxxviii Health and Sport Committee, Official Report, 4 February 2020, Col 5
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400. We recommend the pharmacist role in repeat prescriptions be examined and, if required, included in the community pharmacy contract to ensure they are demonstrating value from the service provided and going beyond packaging and delivering medicines.

Prescribing in secondary care

- 401. The main themes of the evidence presented on prescribing in secondary care settings were—
 - · Delaying discharge; and
 - The collection of prescribing data in secondary care and the Hospital Electronic Prescribing and Administration (HEPMA) System.

Delaying discharge

- 402. The issue of delayed discharge caused by the time taken to fulfil prescriptions for people leaving hospital arose.
- 403. Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde^{cdxxxix}, and Angela Timoney, Director of Pharmacy, NHS Lothian^{cdxl}, said delays could be caused by—
 - time taken to create the prescription;
 - Accuracy checking; and
 - For the collaboration required between staff from various disciplines.
- 404. Gail Caldwell caused some Members of the Committee concern by indicating cdxli it takes 3 hours from receipt of a prescription to prepare it in hospitals and said there was a need to keep challenges posed by this, and the systems to mitigate it, under review as it was not person centred. When questioned as to why it takes so long, she indicated the doctor responsible for discharging patients would have to complete an Immediate Discharge Letter (IDL). However, we note this is concerned with the prescription and not dispensing of the drugs, and does not explain the time taken from receipt of the prescription in a pharmacy to leaving hospital. We were disappointed a Director of Pharmacy did not present plans seeking to eradicate such delays.

cdxxxix Health and Sport Committee, Official Report, 4 February 2020, Col 16

cdxl Letter from Angela Timoney, Director of Pharmacy, NHS Lothian, on Supply and Demand for Medicines, 24 February 2020

cdxli Health and Sport Committee, Official Report, 4 February 2020, Col 16

cdxlii Letter from Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde, on Supply and Demand for Medicines, 28 February 2020

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- She suggested one solution to this could be transferring the prescription to a 405. community pharmacist to fulfil, a proposition supported by Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland Cdxliii. Graeme Bryson, Director of Pharmacy, NHS Dumfries and Galloway cdxliv provided an example of a pilot being scoped in Dumfries and Galloway to use an electronic immediate discharge letter to communicate with community pharmacy.
- 406. Angela Timoney, Director of Pharmacy, NHS Lothian thought HEPMA would assist (further detail on the implementation of HEPMA can be found in the HOSPITAL ELECTRONIC PRESCRIBING AND ADMINISTRATION SYSTEM section of this report) and also highlighted measures taken to ensure there was a full staffing compliment, noting shortages in the pharmacy profession as well as different qualification levels for different posts. She proposed pharmacists should be on the Shortages Occupation List (SOL).
- 407. We consider the time indicated for fulfilment of a prescription within hospital settings when compared with community counterparts is excessive and suggests inefficiency in the system. We are concerned this may be replicated across Scotland in other health board areas. We note the solutions to this being trialled in NHS Dumfries and Galloway and propose the outcomes of this may result in good practice which should be shared.
- 408. We ask the Scottish Government to assess how long prescriptions are taking in hospital settings in each health board across the country and the reasons for this.
- 409. We recommend the Scottish Government ensures the results of the trials taking place within NHS Dumfries and Galloway are shared among health boards as a starting point for addressing this inefficiency across the country.

Collection of prescribing data in secondary care

410. In general, we heard the ability and practice of capturing prescribing data in primary care works well thanks to e-prescribing, but this was not mirrored in secondary care. Evidence from various stakeholders, including Dr David Coulson, Assistant Director of Pharmacy at NHS Tayside and Dr Scott Jamieson, Royal College of GPs^{cdxlviii} praised data collection in primary care, with a notable caveat from the British Medical Association in Scotland suggesting electronic prescribing in primary care would improve data capture.

cdxliii Health and Sport Committee, Official Report, 4 February 2020, Col 20

cdxliv Health and Sport Committee, Official Report, 18 February 2020, Col 36 cdxlv Health and Sport Committee, Official Report, 4 February 2020, Col 17

cdxlvi Letter from Angela Timoney, Director of Pharmacy, NHS Lothian, on Supply and Demand for Medicines, 24 February 2020

cdxIvii Health and Sport Committee, Official Report, 28 January 2020, Col 8

cdxIviii Health and Sport Committee, Official Report, 28 January 2020, Col 10

- 411. In secondary care however, the position is quite different.
- 412. Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government, told us—
 - "We can quite easily track the amount of drugs that are prescribed and who they are prescribed to on an individual patient basis. However, we do not have as good ways of tracking data in hospital and secondary care. We need to get prescribing decisions that are based on good data and good evidence and, in the longer term, we also need to think about outcomes or health gain in relation to those medicines. Cdlin
- 413. The Chief Pharmaceutical Officer was optimistic regarding progress in collecting data, noting good examples in relation to cancer, and when discussing the roll out of the Hospital Electronic Prescribing and Administration system (HEPMA).

Hospital Electronic Prescribing and Administration System (HEPMA)

- 414. Throughout this inquiry we have been interested in the implementation of the Hospital Electronic Prescribing and Administration System (HEPMA).
- 415. The benefits of a system which collects and shares data on prescribing are clear. Witnesses and written submissions detailed the advantages and efficiencies to be gained from implementation, including—
 - Allowing hospital discharge letters to be pre-populated with prescription information^{cdliii};
 - Supporting ease of medicine reconciliation cdliv;
 - "Improving the quality of prescribing" cdlv;
 - "Reducing medicine information errors between primary and secondary care" care
 - "Reducing missed doses of medicines" cdlvii;
 - "...better insight into prescribing and other medicine related activities through data analytics at different levels" cdlviii;
 - Removing the need for manual audits of prescriptions of medicines which are resource intensive for staff^{cdlix};
 - Allowing for comparison of data across all hospitals in Scotland^{cdlx};
 - Facilitating analysis of variation in prescribing cdlxi;

cdxlix British Medical Association Scotland. Written Submission.

cdl Health and Sport Committee, Official Report, 21 January 2020, Col 4

cdli Health and Sport Committee, Official Report, 21 January 2020, Col 14

- Increasing accountability for spending of prescribers and medicine management teams^{cdlxii};
- Increasing prescribing from the formulary cdlxiii;
- Improving safety by removing written prescriptions^{cdlxiv};
- Introducing electronic reminders as found in primary care into secondary care^{cdlxv}:
- Facilitating the end of faxing of prescriptions^{cdlxvi};
- Mitigating delays in discharge caused by waiting for prescriptions to be dispensed in hospitals^{cdlxvii};
- Means only available medicines can be dispensed, reducing administration errors and delays^{cdlxviii};
- Introducing small time efficiencies for nurses which add up to more time with patients^{cdlxix}; and
- Requires all information to be included at the point of prescription, saving staff time in not having to go back and check detail with the prescriber^{cdlxx}.
- 416. Despite all the advantages, Dr Lewis Morrison, Chair of BMA Scotland^{cdlxxi}, focused on the impact on the prescriber when he questioned whether the system would take
- cdliii Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 5
- colliv Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 25
- cdlv Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 39
- cdlvi Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 39
- cdlvii Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 39
- cdlviii Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 39
- cdlix Health and Sport Committee, Official Report, 28 January 2020, Col 19
- cdlx Health and Sport Committee, Official Report, 28 January 2020, Col 19
- cdlxi Health and Sport Committee, Official Report, 28 January 2020, Col 19
- cdixii Health and Sport Committee, Official Report, 28 January 2020, Col 19
- cdlxiii Royal Pharmaceutical Society in Scotland. Written Submission.
- cdlxiv Royal Pharmaceutical Society in Scotland. Written Submission.
- cdlxv NHS Grampian Area Drug and Therapeutic Committee. Written Submission.
- cdlxvi National Pharmacy Association. Written Submission.
- cdlxvii Health and Sport Committee, Official Report, 4 February 2020, Col 17
- cdlxviii Health and Sport Committee, Official Report, 18 February 2020, Col 38
- cdlxix Health and Sport Committee, Official Report, 18 February 2020, Col 38
- cdixx Health and Sport Committee, Official Report, 18 February 2020, Col 38

- longer to create a prescription than writing one by hand, although he acknowledged^{cdlxxii} electronic prescribing was safer.
- 417. Set against that concern, the Directors of Pharmacy for both NHS Lothian and NHS Greater Glasgow and Clyde cdlxxiv, were clear HEPMA would deliver efficiency into the system by removing the need to hand write documents.
- 418. In August 2017, the Scottish Government published "Achieving excellence in pharmaceutical care: a strategy for Scotland" which included a recognition of the need to transform delivery of services through use of technology. In relation to HEPMA it—
 - "...committed to... implementation of Hospital Electronic Prescribing and Medicines Administration (HEPMA) in every NHS Board across Scotland. cdlxxvi
- 419. In August 2017, three health boards had implemented HEPMA. We sought an update on progress^{cdlxxvii} in December 2019, and in January 2020 were told—
 - "...NHS Lanarkshire is due to complete implementation in 2020. During 2019, NHS Lothian, NHS GGC and the North Region Consortium (NHS Grampian, NHS Highland, NHS Orkney, NHS Shetland, NHS Tayside and NHS Western Isles) all commenced their implementation, with the remaining Health Boards due to start in 2020-21. We will continue to work with Health Boards to ensure a local and regional approach to delivery across all the remaining Boards over the next three to five years and to support this we have established a national HEPMA Implementation Oversight Board." Cdlxxviii
- 420. We are concerned no new health boards have fully implemented the system in the 2 year period since the Achieving Excellence strategy document was published with no new health boards using the fully integrated system. That some boards have not yet started, and a 5 year timescale to implement a system commissioned in other areas, appears excessive.
- 421. Progress is disappointing and does not reflect the assertion the strategy for data collection "includes gaining traction and pace in terms of the implementation of Hospital Electronic Prescribing and Medicines Administration (HEPMA) across Scotland" cdlxxix.

cdlxxi Health and Sport Committee, Official Report, 28 January 2020, Col 48

cdlxxiii Health and Sport Committee, *Official Report*, 28 January 2020, Col 51 cdlxxiii Health and Sport Committee, *Official Report*, 4 February 2020, Col 17

cdlxxiv Health and Sport Committee, Official Report, 4 February 2020, Col 18

cdlxxv Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland

cdlxxvi Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 21

cdlxxvii Letter from the Convener of the Health and Sport Committee to the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 13 December 2019

cdlxxviii Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 13 January 2020

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- 422. In evidence, the Chief Pharmaceutical Officer said the Scottish Government is at "start of that journey" with regard to data collection in secondary care.
- 423. An update on implementation of HEPMA was committed to cdlxxx in the first quarter of 2020 and we were promised cdlxxxi a copy of this report when available. This remains outstanding.

Challenges of introducing HEPMA

- 424. We heard implementation of HEPMA was difficult and that the behaviour change required in order to use it could be more challenging than the physical roll out.
- 425. Stakeholders recognised HEPMA should be more than a tool for administering medicines, it should also support essential data collection including clinical outcomes.
- 426. The Chief Pharmaceutical Officer, Rose Marie Parr told us she saw it as a two-stage project—
 - "Once we have electronic prescribing, we will be in a much better position to get better data and outcomes." cdlxxxiii
- 427. Stage 2 being to create a national digital platform which was planned for in the national digital strategy (see the DATA SCOPING TASKFORCE AND DIGITAL HEALTH AND CARE STRATEGY section of this report for further consideration of this strategy). That would allow not only prescribing but outcomes and data to be looked at. She added "Other countries across the world are able to look at their population and at the health gains from medicines and other healthcare interventions."
- 428. Alison Strath, Principal Pharmaceutical Officer, Scottish Government, told us the size of Scotland means that we should be able to bring in primary care data and roll it out quite quickly. She added—
 - "We will probably want to focus on specific areas initially in order to gain experience, then we will think about how we spread that out." "cdlxxxiv"
- 429. While we agree with the need to include data collection and analysis at both secondary and primary care, we are concerned the approach to development of HEPMA has not taken into account wider strategic goals. This is exemplified by the approach to procurement.

cdlxxix Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 13 January 2020

cdlxxx Health and Sport Committee, Official Report, 4 February 2020, Col 31

cdlxxxi Letter from Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde, on Supply and Demand for Medicines, 28 February 2020

cdlxxxii Health and Sport Committee, Official Report, 21 January 2020, Col 8

cdlxxxiii Health and Sport Committee, *Official Report, 21 January 2020,* Col 8 cdlxxxiv Health and Sport Committee, *Official Report, 10 March 2020,* Col 19

Procurement of HEPMA

- 430. We heard it is open to each individual health board to procure and implement its own version of HEPMA, rather than a single system across the country. We believe there are several issues with this—
 - It does not facilitate either the easy movement of staff or patients from one health board to another;
 - It contradicts information provided to us on the Digital Health and Care Strategy, where the previous Cabinet Secretary, Shona Robison, said "it is our intention that a new more national 'once' approach will indeed remove many of the concerns that were rightly raised..."
 - It does not seem conducive to developing the data gathering systems which would assist nationally; and
 - It contributes to the piecemeal approach to development of technology which disenfranchises parts of the system.
- 431. While acknowledging boards may wish to adapt national policies to suit local needs where these can be "evidenced", the Cabinet Secretary for Health and Sport, Jeane Freeman, told us "every board having a different approach will not work."
- 432. Yet all boards are potentially developing separate versions of the system, although some are taking a more collaborative approach. cdlxxxvii
- 433. Overall responsibility for the implementation of HEPMA is not clear although there exists a National Implementation Oversight Board.
- 434. Alison Strath told us about this group and data—
 - "There was a question earlier about how we make sure all the parts are aligned. Our HEPMA oversight group is co-chaired by one of the clinical advisers to the NES digital service. We made that link straight away: we think about what data can come from HEPMA, what data locks into national digital platforms—it is a bit like plug and play—and how we can bring in primary care data. We definitely have the building blocks. The size of Scotland means that we should be able to get traction and be able to establish that and roll it out quite quickly. We will probably want to focus on specific areas initially in order to gain experience, then we will think about how we spread that out." cdlxxxviii
- 435. In light of the benefits, it is disappointing to learn roll out of this system across Scotland is patchy, slow and proceeding at a snail's pace with a variety of systems being considered and individually designed and procured.

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- 436. The Scottish Government should clarify ownership of this project as a matter of urgency. Several written submissions called on the Government to make its commitment to HEPMA clear and we concur.
- 437. We recommend the Scottish Government clarify who is responsible and who is accountable for the delivery and implementation of HEPMA.
- 438. We remain unclear as to the working of the Oversight Board and the oversight group and their respective roles and remits and would welcome this detail along with their accountability, governance and timescales for delivery and implementation.
- 439. We also request detail of actions being taken to communicate the benefits of the use of HEPMA to NHS staff and the training available to support staff in learning to adapt to the new system. We are also interested in development and sharing of training techniques and best practice across boards.

Is there a role for HEPMA in the movement of records between primary, secondary care and social care?

- 440. We also looked at linkages between primary and secondary care as well as social care. Rose Marie Parr, Chief Pharmaceutical Officer, told cdlxxxix us they did not exist at present although there is ambition to get single patient records that are data driven. This area is one considered by us in some depth during the Primary Care inquiry during which we became clear these records belonged to patients and existing barriers to sharing were ill-conceived and required to be removed.
- 441. She told us about good connections with community pharmacy and general practice, and that there has been the electronic transfer of prescribing data for some time. She highlighted there were "issues relating to the fall-down in care between different areas of care. When people are discharged from hospital and go back into their community, some of the boundaries are not as seamless as they should be."
- She further explained the difficulties in medicines reconciliation when using a paper system and said she wanted to look at new technologies which would allow for the electronic transfer of this.
- 443. Rose Marie Parr said "We want to allow people in secondary care who are able to be stabilised on their medicines to come into primary care and to live more at home or in a homely setting, but we need the systems to be able to do that" cdxcii.
- 444. We were concerned to hear the processes and systems being blamed for such delays, and question the extent to which the lack of system actually prevents movement into primary care settings.

cdlxxxix Health and Sport Committee, *Official Report, 21 January 2020,* Col 8 cdxc Health and Sport Committee, *Official Report, 21 January 2020,* Col 8 cdxci Health and Sport Committee, *Official Report, 21 January 2020,* Col 9

cdxcii Health and Sport Committee, Official Report, 21 January 2020, Col 9

- 445. We agree with Rose Marie Parr that "We need the transfer of prescriptions to be safe and effective" and the "need for community pharmacies to allow us to get secondary care prescriptions that might be more complex than they have been used to "cdxciv" although we are concerned at the suggestion pharmacists are unable to handle all prescriptions.
- 446. Dr David Shackles of the Royal College of GPs^{cdxcv} emphasised the value in the patient treatment summary issued upon discharge from hospital which he said could aid conversations with other healthcare professionals, although we are aware of limitations in what it contains and delays in its delivery impacting on continuing care in the community.
- 447. We were also interested in the role of HEPMA in communicating with the electronic systems in place in in primary care. The Association of the British Pharmaceutical Industry (ABPI)^{cdxcvi} said a better interface such as HEPMA between primary and secondary care would allow for "an overview of the whole patient journey with safety at the heart of care".
- 448. However, organisations such as the Royal College of Physicians of Edinburgh^{cdxcvii} stated there was a lack of joined up working between primary and secondary care when it came to medicines, which Claire Fernie, Public Partner Volunteer, NHS Fife^{cdxcviii} highlighted could pose a safety issue.
- 449. Professor Angela Timoney, Director of Pharmacy, NHS Lothian said the linking of HEPMA with primary care services was the "next step" and spoke of the lack of medicines governance systems in place to accommodate such communication currently. She said—
 - "We hope that our prescribers, as part of their continuing professional development and attention to detail, will share that information so that we can see what is happening. At the moment, those systems are not there, but they have to be."
- 450. We are concerned that after all this time senior management are still "hoping" prescribers, who are all funded from the public purse, will share information, nor why systems, and particularly governance, are not already in place. We are impatient about the progress and engagement from senior management.
- 451. The Cabinet Secretary assured^d us it was the intention for HEPMA to communicate with primary care and community pharmacy systems.

cdxciii Health and Sport Committee, Official Report, 21 January 2020, Col 9

cdxciv Health and Sport Committee, *Official Report, 21 January 2020,* Col 9 cdxcv Health and Sport Committee, *Official Report, 18 February 2020,* Col 36 cdxcvi Association of the British Pharmaceutical Industry. Written Submission. cdxcvii Royal College of Physicians of Edinburgh. Written Submission.

cdxcviii Health and Sport Committee, *Official Report, 18 February 2020,* Col 13 cdxcix Health and Sport Committee, *Official Report, 4 February 2020,* Col 19

- 452. Matt Barclay, Director of Operations at Community Pharmacy Scotland said "Data is really important for the safe transfer of information between secondary care, primary care and community pharmacy, and for things such as medicines reconciliation. Getting the HEPMA programme right in secondary care is also crucial to improving the safety element in primary care."
- 453. Rose Marie Parr, the Chief Pharmaceutical Officer, Scottish Government^{dii} said the ability for HEPMA to talk to other systems was dependent on the development of the national digital platform and a shared medication record, which were currently being worked on. She continued—
 - "We should also look at the discharge programme and what happens when people come out of hospital and secondary care and go into the community. We should look at innovative ways of making that move a bit more seamless."
- 454. We are also concerned about the role of the Chief Pharmaceutical Officer who was indicating a need for innovative ways of making the move for people coming out of hospital and secondary care into the community a bit more seamless but does not appear to have initiated any action to do just that. We were given no indication the ideas and ambitions behind this assertion are backed up by action and strategy.
- 455. We are also concerned a key point of transition within health care does not currently have systems in place for sharing information on medicines assigned to patients beyond the mere "hope" this will happen. This is particularly worrying in light of the Chief Pharmaceutical Officer's statement^{div} the transition between secondary and primary care is when the most harm from medicines occurs and the view this is a major opportunity for waste^{dv}. We are further concerned this has not been built into the initial design of HEPMA, once again betraying a lack of strategic oversight, both within the implementation of this project, and culturally with technological solution development for the NHS.
- 456. Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland^{dvi} spoke of the benefits of pharmacy receiving an admissions note in NHS Forth Valley when patients enter hospital which prevented repeat prescriptions being sent. He also spoke of receipt of discharge letters as in some other health boards, which he said were stored together with admission information in the community pharmacy online database.

d Health and Sport Committee, *Official Report*, 10 March 2020, Col 5 di Health and Sport Committee, *Official Report*, 21 January 2020, Col 59 dii Health and Sport Committee, *Official Report*, 10 March 2020, Col 5 dii Health and Sport Committee, *Official Report*, 10 March 2020, Col 6 div Health and Sport Committee, *Official Report*, 10 March 2020, Col 5

dv Health and Sport Committee, Official Report, 18 February 2020, Col 34 dvi Health and Sport Committee, Official Report, 18 February 2020, Col 40

- 457. We recommend the system of preventing repeat prescriptions being sent automatically which is used in NHS Forth Valley is instituted in all health boards without delay.
- 458. We believe it is essential HEPMA systems can facilitate the movement of data between primary and secondary care to ensure a smooth transition for patients and request detail from the Scottish Government on who will take on a leadership role in that respect and when this will be in place.

Funding for HEPMA

- 459. Various written submissions called for commitment to funding of HEPMA.
- 460. Angela Timoney, Director of Pharmacy, NHS Lothian, said the Scottish Government did not provide the full funding for HEPMA, and boards were required to "address the gap", suggesting there is an issue with paying for systems.
- 461. It is not clear to us from the most recent Scottish Government Budget where the funding for HEPMA lies although we have been assured it has been provided for and we sought^{dvii} clarification of this from the Cabinet Secretary for Health and Sport.

Data Collection

462. We were dismayed to hear from Graeme Bryson, Director of Pharmacy, NHS Dumfries and Galloway^{dviii} that despite HEPMA being introduced in Dumfries and Galloway 4 years ago, the board was only just at the point of considering looking at the information generated. He also noted^{dix} HEPMA had been designed with administration in mind and was not capable of the analysis required to maximise the information it could produce. Angela Timoney, Director of Pharmacy at NHS Lothian, said^{dx} she believed a better understanding of medicines use was key to system efficiency and called for further investment in this from the Scottish Government.

Hospital Electronic Prescribing and Administration System (HEPMA) - conclusions

- 463. The Cabinet Secretary told us "Our expectation is that the majority of boards will have concluded the implementation of HEPMA by the end of this year, with perhaps
- dvii Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines Inquiry, 23 March 2020
- dviii Health and Sport Committee, Official Report, 18 February 2020, Col 38
- dix Health and Sport Committee, Official Report, 18 February 2020, Col 39
- dx Letter from Angela Timoney, Director of Pharmacy, NHS Lothian, on Supply and Demand for Medicines, 24 February 2020

- only one or two of the smaller boards still having to complete that work." She was also confident HEPMA would be running across the country by March 2021.
- 464. We very much welcome this commitment and consider these timescales to be in line with the pace which has both been called for by stakeholders and the Scottish Government alike. However, we have heard from NHS Greater Glasgow and Clyde^{dxiii} (whose Director of Pharmacy co-chairs the implementation oversight board) their current plan anticipates delivery in 2022 and 2023. NHS Tayside^{dxiv} told us they anticipated the system would go live on wards by spring 2021.
- 465. We are concerned at the differences in the commitments made by the Cabinet Secretary and the plans of health boards, and question whether this shows a lack of communication and oversight.
- 466. We ask the Scottish Government to provide detail as to what the pre-COVID-19 timescales for delivery were for each health board and whether these matched the Cabinet Secretary's statement delivery would be complete by March 2021.
- 467. We ask the Scottish Government to provide detail as to whether the implementation of HEPMA is still on track for delivery by the end of 2020 as stated by the Cabinet Secretary and the extent to which the system will be similar enough across the country to allow data to be exchanged as well as detail about the ability of the system to generate and share data.
- 468. If it is no longer on track, we would welcome an indication of the likely timescales for implementation in each health board in Scotland.
- 469. We recommend the Scottish Government provide the funding required to ensure the delivery of not only the HEPMA systems in all health boards, but also the infrastructure required to maximise the outcomes data the system is capable of producing. We also seek assurances funding provided for HEPMA is ringfenced for the purpose.

Non-pharmaceutical interventions

- 470. We received a wealth of evidence suggesting prescription of medicines was not always the most clinically or cost effective course of action, and that medicines should be seen only as part of a menu of options available.
- 471. The main points made to us were—

dxi Health and Sport Committee, Official Report, 10 March 2020, Col 4

dxii Health and Sport Committee, *Official Report, 10 March 2020,* Col 8 dxiii Letter from Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde, on Supply and Demand for Medicines, 28 February 2020

dxiv Letter from David Coulson, Assistant Director of Pharmacy, NHS Tayside, on Supply and Demand for Medicines, 2 March 2020

- Assessment and governance of non-pharmaceutical interventions was not equal to that of medicines;
- Medicines were not always the most clinically or cost effective course of action, with the example of diabetes cited on several occasions;
- Meaningful discussions with patients are a vital part of the picture;
- GPs and other prescribers need to have sufficient knowledge of nonpharmaceutical options in order to confidently suggest these to patients; and
- · Non-pharmaceutical interventions could be safer.

Assessment and governance of non-medicine prescribing

- 472. The assessment of some non-pharmaceutical interventions has been discussed in the SCRUTINY OF NON-PHARMACEUTICAL INTERVENTIONS section of this report. However, we cover it further here in the context of the improved governance called for. Stakeholders told us the assessment and scrutiny of non-pharmaceutical interventions was not of the same standard as that of medicines. This is despite the potential for similar or improved outcomes. Part of this relates to the standard of evidence prescribers seek of their effectiveness.
- 473. Dr Scott Jamieson of the Royal College of GPs told^{dxv} us the provision of non-medicines represented the biggest opportunity for review of governance and improvement in effective, and therefore cost effective, prescribing and told us of work undertaken in NHS Tayside to create good formulary processes for non-medicines underpinned by good review and governance structures.
- 474. We now understand the scrutiny of medicines is extremely robust in comparison to "other areas of NHS spending such as medical devices, procedures, IT infrastructure or contracted out services." Dr Jamieson suggested non-medicines are an area of "extremely high cost but without the regulatory supports that are in place for medicines" In addition, direct marketing to patients is permissible with non-medicines.
- 475. Dr Jamieson told us-
 - "chronic pain is a good example of an area in which there is pretty universal agreement that non-drug options should be more widely explored, because they are far safer to use and the evidence for them is as good as it is for medicine for chronic pain."

dxv Health and Sport Committee, *Official Report, 28 January 2020,* Col 18 dxvi Association of the British Pharmaceutical Industry. Written Submission.

dxvii Health and Sport Committee, Official Report, 28 January 2020, Col 14

dxviii Health and Sport Committee, *Official Report*, 28 January 2020, Col 15 dxix Health and Sport Committee, *Official Report*, 28 January 2020, Col 3

- 476. Although adding a significant caveat, he said "Nonetheless, it is hard to get tangible evidence that is specific to a patient. With a multimorbid 85-year-old with five other diseases, for example, what are the caveats to the evidence that I need to present? It is really complicated and difficult to try to show that in an intelligent way that is accessible to me at the point of prescribing, and it is not yet being done."
- 477. Dr Lewis Morrison, Chair of the British Medical Association (BMA) in Scotland^{dxxi}, highlighted the difficulties in providing equal levels of evidence and suggested this may hinder, rather than help, the provision of non-pharmaceutical interventions, cautioning^{dxxii} that having to apply a similar standard of evidence might mean certain things never get done.

Medicines are not the only or even the most cost or clinically effective way forward

- 478. Many used diabetes as an example of where non-medicine forms of treatment may be the most effective. Dr Ewan Bell, National Clinical Lead, Area Drug and Therapeutics Committee Collaborative, Healthcare Improvement Scotland, proposed^{dxxiii} bariatric surgery, the success rate of which he said could not be beaten by medicines in reducing diabetes, saying insufficient was being carried out in Scotland. He pointed to SIGN guidelines as being overly restrictive.
- 479. Dr Scott Jamieson, Royal College of GPs, said conversations as to the best course of treatment (be they surgical, lifestyle choices or medicines) should be taking place with patients, as per SIGN guidance, but noted misunderstanding of guidance could cause practitioners to reach for the prescription pad.
- 480. We are concerned SIGN guidelines could be misconstrued and recommend the Scottish Government work with SIGN to assess where ambiguity exists and update SIGN guidance to ensure full conversations with patients are not being hindered.
- 481. Several submissions discussed how the prescribing of medicines was wasteful where these are not the most clinical and/or cost effective treatment. Yet a number of witnesses described reasons why this was still happening.
- 482. The British Dental Association^{dxxv} said changes required to persuade the public to adopt lifestyle changes which would produce better health outcomes would require a level of Government intervention which may clash with other political priorities such as the economy. The organisation also suggested a monetary incentive for patients akin to that available for smoking cessation in pregnancy.

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dxx Health and Sport Committee, Official Report, 28 January 2020, Col 6 dxxi Health and Sport Committee, Official Report, 28 January 2020, Col 39
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dxxii Health and Sport Committee, *Official Report*, 28 January 2020, Col 39 dxxiii Health and Sport Committee, *Official Report*, 28 January 2020, Col 5 dxxiv Health and Sport Committee, *Official Report*, 28 January 2020, Col 5

- NHS Fife Area Drug and Therapeutic Committee dxxvi noted non-medical interventions may be the most clinically effective but assessment of this was difficult, adding access to the resources required were also challenging and limited. Dr Jamieson outlined work on decision making aids for patients, both internationally and within the Scottish Government. He spoke of the difficulties in finding evidence to support courses of action in specific cases and although he described information on conversations needed with patients as "binary and crude" he was supportive of Scottish Government action in this area. This topic is further discussed in the SOCIAL PRESCRIBING section of this report.
- 484. Several submissions noted the success of other lifestyle change policies such as smoking cessation and alcohol consumption and suggested these models should be looked at for other forms of healthy living which would improve health.
- ⁴⁸⁵. Dr Lewis Morrison, Chair of BMA Scotland^{dxxviii} and Eileen McKenna, Associate Director Professional Practice, Royal College of Nursing Scotland^{dxxix}, both highlighted the role multidisciplinary teams have in keeping people well and in their homes, away from formal healthcare settings.
- 486. Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde^{dxxx} saw a need for medicines to be part of a pathway of care alongside other interventions which may be more suitable, such as smoking cessation and flu vaccinations in the case of Chronic Obstructive Pulmonary Disease. She also spoke^{dxxxi} of the savings using more expensive anaesthetic drugs in some cases may have elsewhere in the system as part of a pathway of care.
- Dr Jamieson suggested^{dxxxii} there was not currently sufficient time within a 10 minute appointment for GPs to consider non-medicine options comprehensively.
- 488. NHS Grampian Area Drug and Therapeutic Committee (ADTC)^{dxxxiii} suggested that where medicines were used this should be complimented by appropriate lifestyle changes, but noted this required a different type of conversation with patients.
- 489. We understand there are challenges involved in prescribing the best course of treatment where this is not a medicine but are unwilling to accept this is a reason not to do it. Conversations with patients regarding treatment options do not appear to be taking place and appointment times are too restrictive. There is also no assessment or monitoring of ailments presented and treatments prescribed. We

dxxv British Dental Association. Written Submission.
dxxvi NHS Fife Area Drug and Therapeutic Committee. Written Submission.

dxxvii Health and Sport Committee, *Official Report, 28 January 2020,* Col 6 dxxviii Health and Sport Committee, *Official Report, 28 January 2020,* Col 37

dxxix Health and Sport Committee, *Official Report, 28 January 2020,* Col 37 dxxx Health and Sport Committee, *Official Report, 4 February 2020,* Col 26

dxxxi Health and Sport Committee, Official Report, 4 February 2020, Col 29

dxxxii Letter from Dr Scott Jamieson of the Royal College of General Practitioners on the Supply and Demand for Medicines, 2 March 2020

dxxxiii NHS Grampian Area Drug and Therapeutic Committee. Written Submission.

have considered these issues fully in the SOCIAL PRESCRIBING section of this report.

Communication with the public

490. Dr David Coulson, Assistant Director of Pharmacy, NHS Tayside was supportive dxxxiv of campaigns around lifestyle changes and use of non-medicine interventions, and agreed community pharmacies would be a key player in dispersal of information.

GP knowledge

- 491. Dr Scott Jamieson of the Royal College of GPs^{dxxxv} said GPs did not have the expertise to prescribe non-medical items, calling for further investment, and acknowledged as much time should be spent on such interventions with patients as medicines. He proposed the single national formulary model could help in this regard.
- 492. Other parts of the health service could be called upon to help in this regard. The Royal College of Occupational Therapists dxxxvi cited the results of a pilot in NHS Lanarkshire of occupational therapists (OT) working directly within GP practices and taking direct referrals. Working with an OT had produced a 55% reduction in the number of patients requiring further appointments with the GP with examples of where patients also had been removed from medicine regimes as a result of the changes.

Non-pharmaceutical interventions - conclusions

493. The area of non-medicine governance and prescription is one that needs to be further considered and there should be parity of scrutiny afforded to medicines and non-pharmaceutical interventions. We recognise the gaps in evidence but believe that all treatment decisions should be based on the best available evidence. We recommend this is an area for urgent strategic review, from procurement, through prescription, to consumption and request detail of how the Scottish Government intends to achieve parity.

Social prescribing

- We have recently reported dxxxvii on our separate inquiry into social prescribing, and this subject has been prevalent during our work on medicines. A lot of submissions suggested a culture of instinctively reaching for a prescription pad while failing to explore alternative options, which could be safer for patients and represent cost savings for the NHS.
- 495. It was suggested to us not all GPs support the concept of social prescribing. Various reasons were cited including "time constraints, not perceiving it as part of their role, and a lack of strong evidence demonstrating the long-term effectiveness of social prescribing "dxxxix".

Culture change needed

- 496. Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government said "We can educate people to not think that a prescription is the first thing. We have to look at not just self-care but aspects of talking therapies and social prescribing. That involves a mindset change for patients and the public, and a discussion about that needs to happen."
- 497. She and the Cabinet Secretary for Health and Sport, Jeane Freeman, both spoke on patient expectation with regard to prescribing medicines over other healthcare interventions. The Cabinet Secretary stated "We need to shift our mindset so that we see social prescribing as being at least of equal value to prescription of medicines."
- 498. We are encouraged the Scottish Government is supportive in principle of the recommendation social prescriptions should be treated on an equal basis to medical prescriptions and we note the commitment in the Scottish Government response^{dxlii} to our report "Social Prescribing: Physical Activity is an Investment, Not a Cost" to explore how Scotland might achieve this aim.

dxxxvii Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)

dxxxviii Argyll and Bute Health and Social care Partnership. Written Submission (Social Prescribing Inquiry)

dxxxix Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639), Page 7

dxl Health and Sport Committee, Official Report, 21 January 2020, Col 7

dxii Health and Sport Committee, Official Report, 10 March 2020, Col 22

dxlii Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

dxliii Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)

499. We would welcome detail of the remit and timescales for this piece of work. We would also welcome further updates from Scottish Government as work progresses.

Evidence on the benefits and outcomes of social prescribing

- 500. In our report "Social Prescribing: Physical Activity is an Investment, Not a Cost" we concluded—
 - "We are agreed and are clear that we do not require any further evidence in relation to the efficacy of physical activity on improving health and wellbeing. Direct correlation and causation has been proven and should be accepted by all sectors"
- 501. The Cabinet Secretary for Health and Sport, Jeane Freeman, agreed dxlvi.
- 502. We were therefore disappointed to hear this view is not shared by general practitioners. Dr Scott Jamieson of the Royal College of GPs told us "We need to show evidence for them [social prescribing and non medicine options] that is as good as the evidence for the drug options, and we need to put as much investment into them so as to help our patients and to help our clinicians to make their decisions."
- Dr Brian Montgomery called dxlviii for data to be available on social prescribing to "convince us" the offering was "having the desired effect and it actually a worthwhile alternative". We profoundly disagree. We are of the view this evidence exists, and as we stated in our report and agreed by Parliament, the time for collection of information about the benefits of sporting and cultural activities has passed and we have entered an era of focus on delivery.

dxliv Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)

dxlv Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)

dxlvi Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

dxlvii Health and Sport Committee, *Official Report*, 28 January 2020, Col 9 dxlviii Health and Sport Committee, *Official Report*, 21 January 2020, Col 51

dxlix Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)

An instinct to prescribe medicines

- 504. Dr Alan MacDonald, Chair of the Scottish Medicines Consortium (SMC), said^{dl} SMC was "permissive" meaning an approval meant a medicine had been approved, not mandated, for use. He said prescribers should be aware of medicines available but were also free to choose other options. Dr Brian Montgomery expressed^{dli} the view the system was "skewed" towards the prescription of medicines and Dr David Coulson, Assistant Director of Pharmacy at NHS Tayside, suggested^{dlii} it was easy to follow the pathway of a prescription of a medicine in comparison to alternative options.
- 505. The Cabinet Secretary for Health and Sport, Jeane Freeman, diii said there was a need to overcome the instinct to prescribe medicines, noting how the support of pharmacotherapy services and anticipatory care planning would contribute to this.

A pill for every ill - patient expectation

- 506. Several witnesses, including the Cabinet Secretary for Health and Sport^{dliv}, spoke of the culture of a "pill for every ill" and suggested the patient expectation of being prescribed a pill was a hurdle to overcome in the path to full adoption of social prescribing and realistic medicine.
- 507. Dr Lewis Morrison, Chair of British Medical Association Scotland, ^{dlv}, said there were better levels of understanding and health literacy in Europe than here. He noted the risks of overloading patients with data when all they were interested in was outcomes and said patients "tend to focus on medication because it is quick". Adam Stachura, Head of Policy and Communications, Age Scotland ^{dlvi} noted the pressure which could be applied on health professionals by patients to prescribe a pill, using the example of a complete change in diet to cure acid reflux versus taking a pill.
- 508. We were also interested in whether the community pharmacy contract created an incentive for them to dispense medicine rather than discuss alternatives as they will be recompensed for the drugs dispensed. Campbell Shimmins of Community Pharmacy Scotland suggested it may previously have been the case but the nature of the contract was changing to include more service delivery elements such as Pharmacy First.

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dli Health and Sport Committee, Official Report, 21 January 2020, Col 50 dlii Health and Sport Committee, Official Report, 21 January 2020, Col 51 dliii Health and Sport Committee, Official Report, 28 January 2020, Col 4 dliii Health and Sport Committee, Official Report, 10 March 2020, Col 22 dliv Health and Sport Committee, Official Report, 10 March 2020, Col 22 dlv Health and Sport Committee, Official Report, 28 January 2020, Col 41 dlvi Health and Sport Committee, Official Report, 18 February 2020, Col 5 dlvii Health and Sport Committee, Official Report, 4 February 2020, Col 32
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Supply and demand for medicines, 6th Report, 2020 (Session 5)

- 509. The Cabinet Secretary for Health and Sport, Jeane Freeman, said "We need to help people to understand that even though they might not get those [medicines], they will still have been treated. We need to shift our mindset so that we see social prescribing as being at least of equal value to prescription of medicines."
- 510. We welcome the Scottish Government's attitude to addressing the assumption of patients that medicines will be prescribed, but the evidence provided raised further questions. We are interested both in what the Scottish Government is doing to address the culture with the public but also how it is monitoring the conversations highlighted by Alpana Mair, Head of Effective Prescribing and Therapeutics, Scottish Government, involving the 7 Step Process are taking place (see the GENERAL MEDICAL SERVICES (GMS) CONTRACT section of this report for further detail). We sought the view of the Cabinet Secretary for Health and Sport on this issue in correspondence dlix.
- 511. We would welcome detail of precisely how the Scottish Government proposes to change the culture and perception of the public that where the prescription of a medicine is expected during consultations and how it intends to support primary care providers to access social prescribing.

New General Medical Services (GMS) Contract and support from other health professionals

- 512. The new General Medical Services (GMS) contract introduces a new pharmacotherapy service, designed to integrate the work of GPs, pharmacists and other health professionals in one practice. This approach is described as "crucial to reducing GP workload" and includes transferring responsibilities for work to pharmacists of the contract stipulates all GP practices will be serviced by pharmacy support by April 2021.
- 513. Dr Scott Jamieson of the Royal College of GPs^{dlxii} and the British Medical Association (BMA)^{dlxiii} suggested the new GMS contract would increase the capacity for GPs to assess more complex patients by making better use of other primary care colleagues. He said this would allow for consideration of non-drug options and Matt Barclay of Community Pharmacy Scotland^{dlxiv} agreed other health professionals could support non-pharmaceutical prescriptions.

diviii Health and Sport Committee, Official Report, 10 March 2020, Col 22

dlix Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

dlx Scottish Government (2017). The 2018 General Medical Services Contract in Scotland

dixi A table containing the services which will be provided is included at Annexe C dixii Health and Sport Committee, *Official Report*, 28 January 2020, Col 2

dixiii British Medical Association. Written Submission.

- 514. The Cabinet Secretary for Health and Sport, Jeane Freeman, said the new pharmacotherapy service represented an opportunity for progressing the social prescribing agenda, noting the conversations pharmacists have with patients and citing evidence people "find it easier to be honest with the pharmacist". dlxv She suggested the pharmacist, in discussion with the GP, was best placed to introduce the concept of alternative prescribing.
- 515. This raises several questions for the Committee regarding the sequence of events involved and the circumstances under which a patient would speak to a pharmacist at a GP practice in advance of speaking to a GP. We are of the view this approach would rely on a carefully managed triage system within GP practices in order to ensure the patient spoke to the right healthcare professional within a practice and is therefore dependent on the relationship of trust between a patient and the individual ascertaining their needs.
- 516. We would welcome further detail from the Cabinet Secretary on precisely how the new pharmacotherapy aspect of the GMS contract will promote social prescribing and how this will be evaluated and monitored.
- 517. It also raises the question, once again, of what happens to the information patients provide to community pharmacists regarding their attitudes to medicines. We sought the view of the Cabinet Secretary for Health and Sport on this issue in correspondence^{dlxvi}.
- 518. The Cabinet Secretary also indicated the "opportunity to use community link workers". We previously welcomed the commitment to employ 250 community link workers throughout Scotland by 2021 and in the Cabinet Secretary's response to our report on social prescribing dlxviii, she said—
 - "The number of Community Links Workers in post as at March 2019, based on October returns, is 116."
- 519. We ask the Scottish Government to provide detail of the number of community link workers currently employed and a progress update towards meeting the target of 250 by March 2021.

dixiv Health and Sport Committee, Official Report, 28 January 2020, Col 4

dlxv Health and Sport Committee, Official Report, 10 March 2020, Col 20

dlxvi Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

dixvii Health and Sport Committee, Official Report, 10 March 2020, Col 20

dlxviii Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)

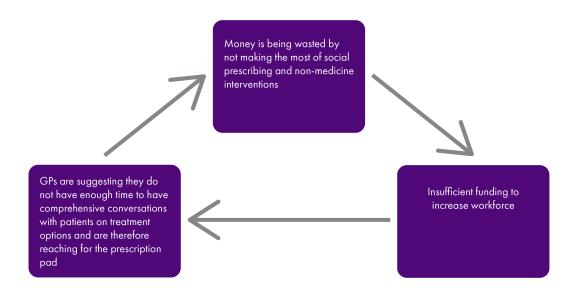
dlxix Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

- 520. In the Scottish Government's response dlxx to our report "Social Prescribing:

 Physical Activity is an Investment, Not a Cost" it was indicated that Community

 Link Workers are allocated to practices based on an assessment of local need and in line with strategic priorities.
- 521. We would welcome an outline of how this supply and demand is determined. It would be helpful to see detail of any guidance on this for Integration Authorities.

Longer Appointment Times



- 522. We recognise the pressures on GPs, but also note their self-employed status as business owners. It is entirely within their gift to ensure the social prescribing and realistic medicine agendas expected by the Scottish Government and mandated by the GMS contract, are delivered. Accompanying documents to the contract, such as the policy memorandum^{dlxxii} to the regulations and the accessible version^{dlxxiii} of the regulations, make clear holistic and comprehensive care for patients' body and mind is an underlying principle of the contract.
- 523. Eileen McKenna, Associate Director Professional Practice, Royal College of Nursing Scotland said "There is an issue with time: many professionals are time
- dlxx Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020
- dlxxi Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)
- dlxxii The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018 SSI 2018/66. Policy Memorandum.
- dixxiii Scottish Government (2017). The 2018 General Medical Services Contract in Scotland

constrained. There is some evidence of nurse prescribers having longer appointment times, promoting non-medicine interventions, doing reviews and listening to individuals with regard to their compliance and whether they take their medicines. That is multifactorial: as you have heard, it is about multidisciplinary reviews, polypharmacy reviews, people having time and patients being empowered."

- 524. The Cabinet Secretary for Health and Sport, Jeane Freeman, said—
 - "....we need to find a way to actively promote social prescribing in a way that is practicable for the prescribers."
- 525. We once again return to the issue of evaluation of the contract and how the Scottish Government is ensuring GPs are meeting expectations set out in national strategies (as discussed in the REVIEWS OF PRESCRIPTIONS section of this report).
- 526. We ask the Scottish Government to provide its view on the appointment length of GPs and in light of the changes made in the GP contract, along with those for pharmacy, provide an assessment of the impact on GP time.
- 527. We reiterate our recommendation the Scottish Government provide full detail of how it intends to evaluate the GMS contract, including how GPs deliver policy priorities such as social prescribing and realistic medicine, and when the contract will next be reviewed to ensure it is maximising its power to encourage in prescribers the behaviours desired by the Scottish Government.

Awareness of referral pathways and activities to prescribe

- 528. We heard evidence on the lack of available referral pathways and awareness among prescribers of the options for activities to prescribe. Dr David Coulson, Assistant Director of Pharmacy at NHS Tayside, said "We are not good at making it easy to access other pathways, which do not involve medicines. dlxxviii and NHS Tayside dlxxviii also called for further investment in public health initiatives to move from cure to prevention.
- Dr Scott Jamieson of the Royal College of GPs suggested alack of knowledge among GPs and lack of a formulary style system made it hard for doctors to socially prescribe and suggested this should be done by others with more awareness of the options. However, this suggests the onus would be on the patient to present their symptoms to the professional with expertise in the solution, inferring they would already have to know how to cure their ailment and thus rendering the need for medical intervention obsolete. We believe health professionals, and in particular GPs, need to have a better awareness of social prescribing.

dlxxiv Health and Sport Committee, *Official Report, 28 January 2020,* Col 40 dlxxv Health and Sport Committee, *Official Report, 10 March 2020,* Col 21 dlxxvi Health and Sport Committee, *Official Report, 28 January 2020,* Col 4

- 530. Indeed, in our report "Social Prescribing: Physical Activity is an Investment, Not a Cost" we suggested there is a lack of comprehensive awareness of initiatives which can be prescribed. We made the following recommendations—
 - "We recommend Scottish Government supports NHS Boards and Integration Authorities (IAs) to invest in engagement work to raise awareness and understanding of social prescribing, and other primary prevention activities round promoting physical activity, and their benefits to the public.
 - We recommend IAs develop and roll-out awareness and education work of social prescribing and other primary prevention activities around promoting physical activity, across all heath and social care professionals."
- 531. Matt Barclay, Director of Operations at Community Pharmacy Scotland, said "Other practitioners in the multidisciplinary team can support that direction of travel by being aware of the options." The Cabinet Secretary for Health and Sport, Jeane Freeman, said "We need to ensure that everyone in a general practice—the pharmacist, the GPs, the advanced nurse practitioners and practice nurses—knows about all the opportunities in the community that people can be pointed towards and helped to join; for example, book clubs, walking football groups, walking groups and lunch clubs."
- 532. In the Cabinet Secretary's response to our report, she said this was being achieved—
 - The Scottish Government was "Supporting NHS Boards and Integration Authorities to implement physical activity social prescribing by embedding the National Physical Activity Pathway (NPAP) into existing practice."
 - NHS Scotland was working with academics to produce Quality Standards for Physical Activity Referral and NHS Scotland would "continue to raise awareness amongst health and social care professionals of the NPAP implementation guidance, e-learning opportunities such as Raising the Issue of Physical Activity, and resources such as Moving Medicine."
- dlxxviii Letter from Dr Scott Jamieson of the Royal College of General Practitioners on the Supply and Demand for Medicines, 2 March 2020
- dlxxix Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)
- dlxxx Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639), Page 8
- dlxxxi Health and Sport Committee, Official Report, 28 January 2020, Col 3
- dlxxxiii Health and Sport Committee, Official Report, 10 March 2020, Col 20
- dlxxxiii Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020
- dlxxxiv Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

- 533. However, no specific detail was offered on how health boards and integration authorities are being supported to embed NPAP into existing practice, nor how awareness of physical activity prescription routes would be raised.
- 534. The Cabinet Secretary's response further described the NPAP process as an "evidence based pathway through which health and social care professionals can deliver structured physical activity brief advice to those within their care" and provided a list of how this might be achieved, including signposting to local physical activity opportunities and "refer to a structured Physical Activity Referral Scheme where such opportunities exist" dixxxv.
- 535. However, the NPAP delivers structured physical activity brief advice to those already receiving care and we believe there are two issues with achieving this—
 - 1. There is a lack of awareness among prescribers as to the opportunities which exist and no detail as to how this is being addressed; and
 - 2. The lack of comprehensive coverage of Physical Activity Referral Schemes.
- 536. We request detail of how reliance on the National Physical Activity Pathway addresses both primary prevention, alongside reactive interventions from health and social care professionals.
- 537. We are concerned at the gap between the Scottish Government's expectations and impression of what is being delivered regarding social prescribing and realistic medicine and what is happening in GP practices.
- 538. We recommend the Scottish Government develop and implement a monitoring framework for the evaluation of NPAP. This should include regular reporting and provide comparable information across Health Boards.
- 539. We ask the Scottish Government to provide full detail of how boards are being supported to implement NPAP and how they are raising awareness of NPAP, "elearning opportunities such as Raising the Issue of Physical Activity, and resources such as Moving Medicine" dixxxvi.
- 540. We ask the Scottish Government to provide specific details as to how awareness of social prescribing options will be raised with GPs and other primary care health care professionals to ensure they are aware of and utilising existing evidence on the benefits of specific activities for specific ailments, combined with access to detail of local initiatives.
- 541. In the Cabinet Secretary's response dixxviii to our report on social prescribing, she indicated resources are being allocated to build capacity and expertise within healthcare to improve referral routes and breakdown barrier to referral. She said
- dlxxxv Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020
- dlxxxvi Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

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NHS Health Scotland was working to co-produce Quality Standards for Physical Activity Referral with academics and providers, and highlighted the work of the European funded mPower project to develop wellbeing plans for people over the age of 65. She added this project would also allocate funding to examining how access to activities in rural areas could be improved.

- 542. We would welcome more detail on how the European-funded mPower project can lead to increased capacity in the voluntary sector and improve access in rural areas.
- 543. She also referred to a community scheme run in collaboration with the British Heart Foundation on blood pressure management.
- 544. We were pleased to hear of the preventative action being undertaken as part of this project and request detail of whether this work will be rolled out across other areas. We note that "From 2020 the project will also explore how small pockets of funding can lead to increased capacity in the voluntary sector and support community transport options to improve rural access to activities."
- 545. We seek confirmation of when the Quality Standards for Physical Activity Referral will be complete and in use by practitioners.
- 546. We were pleased to learn of the preventative action being undertaken as part of the mPower project and request further detail of whether this work will be rolled out across other areas. We also seek clarification of the funding for this project post 2020 and whether the Scottish Government will commit to matching funding that would previously have come from the European Union. Furthermore, we request details of how this project can lead to increased capacity in the voluntary sector and improve access in rural areas.
- 547. We would welcome more detail on how the Scottish Government is measuring or assessing effectiveness of the initiative on blood pressure management in the community, including if there are plans to introduce it in other areas.
- 548. We are also aware coverage of activities across the country is not uniform, as highlighted by Adam Stachura, Head of Policy and Communications, Age Scotland Sco

dixxxvii Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

dlxxxviii Health and Sport Committee. 14th Report, 2019 (Session 5). Social Prescribing: Physical Activity is an Investment, Not a Cost (SP Paper 639)

dlxxxix Health and Sport Committee, Official Report, 18 February 2020, Col 3

dxc Health and Sport Committee, Official Report, 28 January 2020, Col 3

- 549. The response from the Cabinet Secretary to our report highlighted a number of examples of work intended to build capacity and capability of community organisations. However, we are unclear if there is a plan or planned approach to ensure this happens. The response also highlighted the work underway on the ALISS database. However, evidence received as part of our inquiry indicated that this database is out of date, under-resourced and not fit for purpose.
- 550. We would welcome more detail of action plans to increase or prioritise activity in community organisations. In particular, we are interested to hear more about what targets there are to achieve this and how they will be monitored and evaluated.
- 551. We would appreciate further detail on what plans and timescales are in place to address issues identified with the ALISS database, including what the process is to involve local people and Integration Authorities in this work and how the information contained in this database fits into the proposed health and social care digital platform.
- The Cabinet Secretary for Health and Sport^{dxcii} was keen to emphasise the balance required to be struck between national policy and the local initiatives on which success would depend, but said a "national drive" was needed^{dxciii}.
- 553. We recommend the Scottish Government provide detail of how social prescribing can be uniformly and comprehensively embedded across the country, without detriment the local initiatives on which success may depend.

Inequality

- 554. A prevalent theme in our inquiry on social prescribing was inequality of access, both to preventative schemes and to social prescribing as a cure.
- 555. We are encouraged by the Scottish Government's commitment to make sport and physical activity accessible to all. The response dxciv to our report indicated a range of activities to tackle inequalities, including work with sportscotland.

dxci Health and Sport Committee, *Official Report, 18 February 2020,* Col 4 dxcii Health and Sport Committee, *Official Report, 10 March 2020,* Col 20

dxciii Health and Sport Committee, Official Report, 10 March 2020, Col 22

dxciv Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

- 556. We would appreciate further detail on the aims and targets the Scottish Government is hoping to achieve through this work, alongside how the Scottish Government is measuring if this work is making a difference to people's lives.
- 557. In our report we recommended a significant proportion of each Integration Authority budget be spent on commissioning local services to increase physical activity levels. We further recommended most of this investment is spent in the most deprived areas. In the Scottish Government's response dxcv, steps were highlighted which all Integration Authorities are required to undertake to ensure resources are spent in a way that improves the health and wellbeing of their community.
- 558. We would appreciate detail on how the Scottish Government are measuring and evaluating whether the resource allocation by Integration Authorities is leading to improvements in health and wellbeing in communities. We wonder whether this will be monitored through the Fairer Scotland Duty and seek clarification on whether there are any plans to issue guidance to Integration Authorities in this regard.
- 559. The response^{dxcvi} set out the commitment in the Programme for Government 2019-20 to develop community wellbeing services and supports across Scotland for 5-24 year olds.
- 560. We would welcome further detail on the timescales for this work, plans for how it will be achieved and what further action Scottish Government is taking to promote social environments, community assets and local connectedness.

Inquiry into Social Prescribing

In the Scottish Government response dxcvii to our report following our inquiry onto social prescribing, a number of questions arose for us. While not directly linked with medicines, they do represent important factors in the wider social prescribing agenda and we take the opportunity of this section of this report to seek further details.

- dxcv Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020
- dxcvi Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020
- dxcvii Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

- The response detailed how the A More Active Scotland action plan decix demonstrates how this evidence is recognised and informs action across Ministerial portfolios, setting out how the Scottish Government and a range of partners...are working together to achieve our shared vision of a Scotland where people are more active, more often decided.
- 563. The Plan outlines that the data for new indicators within the set that will become available from autumn 2018. It also outlines that these will be published on the Scottish Government Active Scotland Outcomes Framework web pages.
- 564. We would welcome an outline of how Scottish Government are monitoring and measuring results of the More Active Scotland action plan, and the outcomes this has achieved to date.
- We were informed dci sportscotland undertook an audit of community access to school sport facilities in 2013. This audit found that while 89% of school sport facilities were available for public use, there was considerable variation in actual levels of utilisation. Available for use is irrelevant if not actually used, accessible or affordable and we question what action is being taken to ensure public facilities are all of these things.
- 566. We would welcome a more recent update on this since 2013 as well as confirmation if there has been any research, examination or reason why there was considerable variation in actual levels of utilisation.
- 567. We are pleased to hear that the Scottish Government has committed to seek to offer three-year rolling funding for third sector organisations. We are aware that three-year contracts are a welcome start to providing stability for organisations.
- 568. We would welcome further detail on when the Scottish Government will start allocating three-year contracts, and timescales for ensuring this happens for all organisations.
- dxcviii Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020
- dxcix Scottish Government (2018). A More Active Scotland: Scotland's Physical Activity Delivery Plan
 - dc Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020
 - dci Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

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- 569. We were informed the "Scottish Government is aware of and welcomes a number of positive examples where Integration Authorities are investing in physical activity programmes and working with local communities." The response goes on to cite several examples of work where this is happening. However, the recommendation in our report referred to involving community and voluntary organisations in strategic commissioning.
- 570. Strategic commissioning is about planning and delivering services and support for people. It includes identifying the needs of individuals and communities, enabling people to decide what will best address those needs and working together with agencies to put the right services and support in place.
- 571. We are unclear whether the examples given came about through a strategic commissioning or a regular commissioning process and would welcome further detail on how these initiatives were planned and implemented. We would also welcome further detail on whether investment/provision and strategic planning processes can be reviewed as part of Integration Authority strategic plans going forward.

Social Prescribing - conclusions

- 572. We believe the case has been repeatedly made for social prescribing to have parity with medicine prescribing and are of the view it is just a case of making it happen.
- 573. The response to our report on our inquiry on social prescribing from the Cabinet Secretary said—
 - "I agree with the Committee that there is significant potential to increase the pace and scale of this work across Scotland, building on examples of best practice in delivery. We will therefore establish a Working Group to identify and communicate such examples of best practice, and coproduce resources for practitioners in the many roles which make up the overall system."
- 574. We request further detail on timescales, proposed membership and remit for the Working Group.

dcii Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, in response to the Committee's report "Social Prescribing: Physical Activity is an Investment, not a cost", 4 February 2020

Realistic Medicine



One of the main aims of Realistic Medicine is for people using healthcare services and their families to feel empowered to discuss their treatment fully with healthcare professionals, including the possibility that a suggested treatment might come with side effects – or even negative outcomes. Everyone should feel able to ask their healthcare professional why they've suggested a test, treatment or procedure, and all decisions about a person's care should be made jointly between the individual and their healthcare team. By 2025, everyone who provides healthcare in Scotland will demonstrate their professionalism through the approaches, behaviours and attitudes of Realistic Medicine.

Former Chief Medical Officer, Dr Catherine Calderwood

- 575. The concept of realistic medicine was supported by those who responded to our call for views and they highlighted the reasons why this approach to healthcare, including use of the 5 questions^{dciii}, can help improve the clinical and cost effectiveness of medicines prescribed.
- 576. The questions are—
 - Is this test, treatment or procedure really needed?
 - What are the potential benefits and risks?
 - What are the possible side effects?
 - Are there simpler, safer or alternative treatment options?
 - What would happen if I did nothing?
- Dr Scott Jamieson of the Royal College of GPs^{dciv}, the University of Strathclyde^{dcv} and several other responses to our call for evidence suggested conversations with patients to explain and discuss the value of medicines were vitally important, and there was widespread support for the use of the realistic medicine 5 questions^{dcvi}. Reasons for this included—
 - To maximise the effectiveness of a medicine or a switch to another medicine, a
 patient must be invested in it. This included ensuring they were comfortable
 with multiple switches as more cost effective products became available
 (including generics or biosimilars, the benefits of which are described in the
 PRESCRIBING GENERICS AND BIOSIMILARS section of this report);

dciii Realistic Medicine - the Five Questions - available at https://realisticmedicine.scot/the-five-questions/

- Avoiding situations where patients request medicines which are not the most cost or clinically effective;
- Failure to have meaningful discussions with patients on their medicines results in waste, as patients are not engaged with the process and may not adhere correctly to the prescription. The importance of health literacy to adherence was emphasised to us from several sources. Dr Scott Jamieson of the Royal College of GPs said "If a patient does not know why they are taking a medicine or what its intended benefit is, that is a failure of the system. When we have time to ensure that realistic conversations are being had with patients, and the positives of taking their medicine are being explained to them, they will be more likely to value the medicines and take them."
- · No medication or an alternative may be the better options; and
- Good knowledge and understanding of ailments and medicines taken could help those with long-term conditions manage them better, and Dr Jamieson discussed^{dcviii} software options in this regard.
- Matt Barclay of Community Pharmacy Scotland spoke^{dcix} of the need to be natural with patients and root the conversation within their realm of experience in order to secure better outcomes. The British Medical Association (BMA) called for a "national conversation" with patients on realistic medicine. Adam Stachura, Head of Policy and Communications, Age Scotland and people may not know they have the "right or are empowered" to be involved in discussions on their treatment. Claire Fernie, Public Partner Volunteer, NHS Fife said those with long-term conditions may be more involved in discussions on their care. She added some respondents to questions on the realistic medicines programme had an expectation the doctor would know best.
- We also heard views^{dcxiii} that prescribers could be doing more to ensure patients had the time to process information provided by prescribers.
- 580. On training in having realistic medicine discussions with patients, Dr David Shackles of the Royal College of GPs told us—

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dciv Health and Sport Committee, Official Report, 28 January 2020, Col 17
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dcv University of Strathclyde. Written Submission.

devi Realistic Medicine - the Five Questions - available at https://realisticmedicine.scot/the-five-questions/

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devii Health and Sport Committee, Official Report, 28 January 2020, Col 18 deviii Health and Sport Committee, Official Report, 28 January 2020, Col 19 deix Health and Sport Committee, Official Report, 28 January 2020, Col 20
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dcx British Medical Association. Written Submission.

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dexi Health and Sport Committee, Official Report, 18 February 2020, Col 1
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dexii Health and Sport Committee, *Official Report, 18 February 2020,* Col 2 dexiii Health and Sport Committee, *Official Report, 18 February 2020,* Col 2

"Given the time pressures, patient enablement is difficult to do, but it is something that we need to encourage our trainees to manage. However, the pressure on training means that elements such as patient enablement or motivational interviewing to help our patients are being squeezed out of already busy training schedules."

581. He later told us—

- "RCGP will continue to support clinicians to carry out medication reviews through the provision of high-quality training which focuses on medicines management" dcxv
- 582. We inquired as to the training provided in this area and the General Medical Council informed^{dcxvi} us of how this is carried out, including guidance currently being developed and plans to "help" GPs to follow this. The Royal College of GPs suggested training for GPs was not long enough in comparison with other medical specialities and said—
 - "RCGP would also like to see an increased proportion of training during this time spent in frontline general practice, where trainees will be able to gain greater experience of core general practice, including medicines management."
- 583. Although Dr Jamieson of the Royal College of GPs^{dcxviii} said he felt "tick box" exercises such as the quality outcomes framework (QOF) (which required GPs to fulfil certain tasks and demonstrate that) undermined the discussions with patients, we consider there needs to be a way to ensure this is happening and has proposed in the REVIEW OF PRESCRIPTIONS section of this report this should be through the GMS contract.
- 584. We are also not clear as to how in-depth the training in this area is. The Royal College of GPs have suggested there is not enough GP training time dedicated to a patient focused approach to issues such as reviews of medicines according to the principles of realistic medicine. The General Medical Council have stated doctors must demonstrate skills in history taking, diagnosis and medical management, as well as communication with patients and others. The emphasis placed on this element of GP training is not clear. The body had also noted it has produced guidance on the realistic medicine agenda which they encourage clinicians to follow.
- 585. We are once again struck by the void between the expectations of the Scottish Government and what GPs are actually delivering.

dcxiv Health and Sport Committee, Official Report, 18 February 2020, Col 26

dcxv Letter from the Royal College of GPs on the Supply and Demand for Medicines, 9 March 2020

dcxvi Letter from the General Medical Council on the Supply and Demand for Medicines, 4
March 2020

dcxvii Letter from the Royal College of GPs on the Supply and Demand for Medicines, 9 March 2020

dcxviii Health and Sport Committee, Official Report, 28 January 2020, Col 11

586. We recommend the Scottish Government consider use of the GMS contract as a tool to go beyond mere encouragement of its realistic medicine agenda.

Prescribing generics and biosimilars

Generic medicine



Prescribers are strongly encouraged and it is Scottish Government policy to write prescriptions by generic name where clinically appropriate. Generic medicines are equally effective, but generally less expensive than proprietary products (particularly those in the Scottish Drug Tariff...).

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Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland

- 587. In its 2013 report, Audit Scotland noted there was "scope to make potential annual savings of up to £26 million without affecting patient care" and one of the ways to achieve this was to increase prescription of generic drugs.
- 588. Audit Scotland said the Scottish Government Effective Prescribing team had helped boards reduce costs on medicines by "implementing electronic prompts for prescribers, to encourage them to use generic medicines and lower-cost alternatives."

Biosimilars

589. Biosimilars were described to us as—

"...copies of biologic medicines. Biologic medicines are made from living organisms, so they are inherently a bit variable as they are from different cell lines. The regulator reviewed and scrutinised those medicines and said that they have comparable quality, safety and efficacy. The benefit of biosimilars is that, because they are a copy of a product that was on patent and had no competition, we now have competition and significant savings for the first time. In that area, we work closely with boards to ensure implementation and uptake of the most cost-effective biologic products. Over the next few years, more of those products will be coming off patent and we will have to continue to work to control spend."

Benefits of prescribing generic medicines and biosimilars

- 590. Generic prescribing rates have been increasing each year in Scotland since 2009/ 10 according to NHS National Services Scotland Information Services Division (ISD). In 2018/19, 84.3% of prescriptions were generic drugs^{dcxxii}.
- 591. Audit Scotland highlight the cost effectiveness of prescribing generic medicine and biosimilars in the organisation's report "NHS Scotland in 2019" By way of example, the report notes NHS Grampian achieved a saving of £3.5m in 2017/18 compared with the year before through increased prescription switches to biosimilars.
- 592. Rose Marie Parr, the Chief Pharmaceutical Officer, Scottish Government, said "Across Scotland, millions of pounds have been saved by changing people not just to generics but to biosimilars, which are similar to the active ingredients that the patients used previously. There are areas in Scotland in which we can be nimble about getting the best price for the NHS." Dr Brian Montgomery used dcxxvi the example of switching from branded statins to generic versions used by other health boards to illustrate how a £1m saving could be achieved in one move.

Governance of generic and biosimilar prescribing

593. Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland (NHS NSS) said—

dcxxii Health and Sport Committee, *Official Report, 21 January 2020,* Col 41 dcxxii NHS National Services Scotland Information Services Division (2019). Prescribing and Medicines: Dispenser Payments and Prescription Cost Analysis, page 19 dcxxiii Audit Scotland (2019). NHS Scotland in 2019, Page 24

dcxxiv Audit Scotland (2019). NHS Scotland in 2019, Page 25 dcxxv Health and Sport Committee, *Official Report*, 21 January 2020, Col 11

dcxxvi Health and Sport Committee, Official Report, 21 January 2020, Col 54

- "The regulator reviewed and scrutinised those medicines and said that they have comparable quality, safety and efficacy. The benefit of biosimilars is that, because they are a copy of a product that was on patent and had no competition, we now have competition and significant savings for the first time. In that area, we work closely with boards to ensure implementation and uptake of the most cost-effective biologic products. Over the next few years, more of those products will be coming off patent and we will have to continue to work to control spend."
- Dr Ewan Bell, National Clinical Lead, Area Drug and Therapeutics Committee (ADTC) Collaborative, Healthcare Improvement Scotland (HIS), said "There is a good news story. The ADTC collaborative, which sits within HIS, was responsible for developing a prescribing framework for moving patients from biologics to biosimilars. The framework tries to ensure consistency of approach throughout NHS Scotland, and has saved tens of millions of pounds. There is an opportunity, as biologics come to the end of their patents, to move patients from biologics to biosimilars that have the same effect. There is a high rate of generic prescribing within NHS Scotland, and that needs continued vigilance. There are good things happening, supported by stakeholders including the ADTC collaborative."
- 595. Cancer Research UK^{dcxxix} proposed a drive to increase use of biosimilars, akin to that being undertaken in NHS England and the British Generics Manufacturers

 Association^{dcxxx} said programmes to encourage switching to biosimilars should be prioritised.
- 596. While welcoming the progress made in prescription of generic medicine and biosimilars, we urge the Scottish Government to maintain momentum and explore all opportunities for sharing of best practice and further savings in this area.

Prescription charges

- 597. Charges for prescriptions were removed in Scotland in 2011. There has been a 20.5% increase in the number of items dispensed in the first 10 years of operation^{dcxxxi}.
- 598. We were interested in how removal of prescription charges had altered perceptions of prescriptions for low cost items such as paracetamol. In general, responses to this query suggested the removal of prescription charges was in the main a good thing, including when measuring cost effectiveness.

dcxxviii Health and Sport Committee, *Official Report, 21 January 2020,* Col 41 dcxxviii Health and Sport Committee, *Official Report, 28 January 2020,* Col 18 dcxxix Cancer Research UK. Written Submission.

dcxxx British Generics Manufacturers Association. Written Submission.
dcxxxi NHS National Services Scotland Information Services Division (2018). Prescribing and Medicines: Dispenser payments and prescription cost analysis

- 599. Matt Barclay, Director of Operations at Community Pharmacy Scotland noted prescribed paracetamol was used by patients to manage chronic pain conditions, and if prescriptions for this were not available, the alternative would be more expensive. He added "....with regard to patients who need analgesia for significant acute conditions or chronic pain, I would focus more on the overall value than the individual cost of the medicine, although I appreciate that the differences in cost could be significant."
- 600. We were interested in whether prescriptions for low cost items could be removed altogether and prescribers could hand out medicine on the spot. The British Dental Association dexxxiii noted the advent of removal of prescription charges had seen more demand for specialist toothpaste and suggest savings could be made if it could be purchased directly from the dentist. They also proposed limiting the amount of prescriptions of toothpaste per patient to achieve savings.
- 601. The idea of including the cost of medicines on prescriptions was also of interest to us. NHS Grampian Area Drug and Therapeutic Committee (ADTC)^{dcxxxiv} said there was a need to communicate the value of medicines to patients, as free at the point of receipt did not mean cost neutral.

Prescribing non-licensed medicines

- 602. We were interested in prescriptions for unlicensed medicines.
- 603. There is however a difference between prescribing a medicine which has no licence at all, and prescribing one which has a licence for a different indication, known as 'off-label' prescribing. Alison Strath, Principal Pharmaceutical Officer, Scottish Government^{dcxxxv} and David Coulson, Assistant Director of Pharmacy, NHS Tayside^{dcxxxvi} described 'off-label' prescribing, with the latter saying—
 - "It means that we have a medicine that has been licensed through our regulatory body, but the prescriber is not using it for that particular indication."
- There appeared to be confusion as to whether medicines with no licence could be prescribed. Dr Brian Montgomery said dexxxvii the General Medical Council (GMC) required doctors to prescribe licensed medicines. The British Medical Association (BMA) said twas "rare" to find a doctor who would prescribe off formulary or suggest unlicensed medicines. Dr Scott Jamieson of the Royal College of GPs dexxxix noted the guidance on such prescribing highlighted the crux of the issue the most efficacious and cost effective drugs to treat a particular ailment may not be licensed for that indication, leaving the prescriber exposed to risk in taking an individual judgement.

dcxxxiii Health and Sport Committee, *Official Report, 21 January 2020,* Col 56 dcxxxiii British Dental Association. Written Submission.

dcxxxiv NHS Grampian Area Drug and Therapeutic Committee. Written Submission.

dcxxxv Health and Sport Committee, Official Report, 10 March 2020, Col 9

dcxxxvi Health and Sport Committee, *Official Report, 28 January 2020,* Col 31 dcxxxvii Health and Sport Committee, *Official Report, 21 January 2020,* Col 60

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- 605. Faced with various views, we sought clarification from the Scottish Government.
- 606. The Chief Pharmaceutical Officer, Rose Marie Parr, dexl told us each health board had its own governance system and guidance for prescribers on use of unlicensed drugs, which came from area drug and therapeutic committees (ADTCs). The Cabinet Secretary for Health and Sport, Jeane Freeman, noted there may be confused or varied interpretation of governance and said "we might need to look at how well understood the current governance process is dexli. She also undertook to ask the ADTC collaborative—
 - "...to see whether there is any way for us to streamline the process in any way, and to ensure that prescribing clinicians know what the current route is and what they have to do in order to prescribe off-label—they are not forbidden from doing that."
- 607. Alison Strath, Principal Pharmaceutical Officer, Scottish Government, informed us of work being funded by the Scottish Government and supported by Healthcare Improvement Scotland (HIS) to "test how we might use some medicines off-label and how we might create a governance structure for that. We have started by looking at cancer medicines because a number of those fell into that category. What we learn from that will help us to think about how we link our policies."
- 608. We sought details of the work, including the remit of the project, intended outcomes and timescales for completion in correspondence^{dcxliii} to the Cabinet Secretary.
- 609. Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland (NHS NSS), told^{dcxliv} us NHS NSS was able to procure unlicensed medicines for use within the NHS in Scotland.
- 610. We welcome the commitment from the Cabinet Secretary to liaise with the Area Drug and Therapeutic Committee collaborative on how guidance for off label prescribing could be developed and shared with prescribers to ensure they are aware of how to achieve the most clinical and cost effective outcomes, and look forward to an update on how this is progressed.

dcxxxviii British Medical Association. Written Submission.

dcxxxix Health and Sport Committee, *Official Report*, 28 January 2020, Col 32 dcxl Health and Sport Committee, *Official Report*, 10 March 2020, Col 8

dexli Health and Sport Committee, Official Report, 10 March 2020, Col 9 dexlii Health and Sport Committee, Official Report, 10 March 2020, Col 9

dexiiii Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

dexliv Health and Sport Committee, Official Report, 21 January 2020, Col 41.

Polypharmacy

- 611. Dr David Coulson, Assistant Director of Pharmacy, NHS Tayside, said "It is also about understanding the polypharmacy challenge. Why a patient is taking 10 medicines should be questioned; it might be absolutely fine for one patient but inappropriate for another. From community pharmacy, to pharmacies working in general practice, to nursing teams, we all have a responsibility for that, and for managing the pill burden and the value that we get from resources."
- 612. The Royal College of Physicians of Edinburgh said opportunities to address polypharmacy were not always taken and in some circumstances deprescribing could save money and improve outcomes.
- 613. The Cabinet Secretary for Health and Sport, Jeane Freeman, said—
 - "Until 2012-13, there was an annual volume increase of 3 per cent. Since the introduction of the first polypharmacy guidance in 2012, the rate of volume increase has fallen each year."

Non-medical prescribers

614. Eileen McKenna, Associate Director Professional Practice, Royal College of Nursing Scotland^{dcxlviii} and Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland^{dcxlix} spoke of the benefits of non-medical prescribers, including nurses and pharmacists respectively. They identified issues surrounding education and qualifications in this regard. Campbell Shimmins of Community Pharmacy Scotland spoke of a scheme in NHS Ayrshire and Arran, details of which were sent^{dcl} to us by the health board, aiming to have independent prescribers in every pharmacy. This service has been a pre-curser to the Pharmacy First scheme and has seen patients present at their pharmacy, rather than GP surgery for common ailments.

Prescribing - conclusions

- 615. The influence of prescribers on the clinical and cost effectiveness of medicines was a prominent theme throughout evidence received on prescribing.
- 616. The use of and adherence to a formulary is key to this and we look forward to hearing more on the Government's vision for a single national formulary or an

dcxlv Health and Sport Committee, *Official Report*, 28 January 2020, Col 17 dcxlvi Royal College of Physicians of Edinburgh. Written Submission. dcxlvii Health and Sport Committee, *Official Report*, 10 March 2020, Col 3 dcxlviii Health and Sport Committee, *Official Report*, 28 January 2020, Col 44

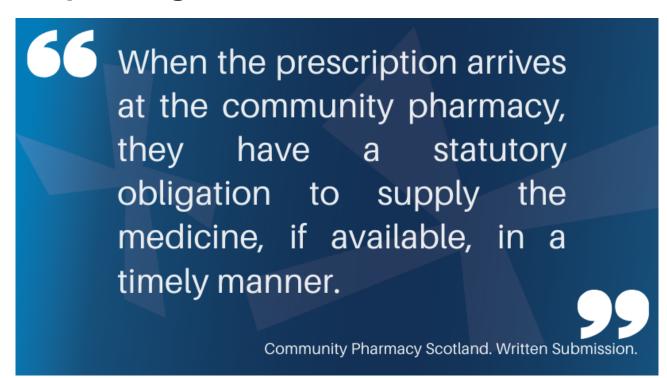
dexlix Health and Sport Committee, Official Report, 28 January 2020, Col 45

dcl Letter from NHS Ayrshire and Arran on Supply and Demand for Medicines, 2 March 2020

alternative formulary approach such as a condition specific pathway (as indicated previously in the report). We also want to see the opportunity taken to improve governance surrounding non-pharmaceutical interventions. We caveat this by suggesting a national formulary must address concerns about the loss of benefits provided by a local system.

- 617. We believe the GMS contract should be used to ensure strategies on medicines and non-pharmaceutical interventions, such as social prescribing, are achieved and carried out in practice. Social prescribing remains a huge missed opportunity and we look forward to further details as to how the Scottish Government will make the urgent progress needed in this area.
- 618. Reviews of prescriptions were a further area where we have recommended prompt attention is required, and again we have sought detail from the Scottish Government as to how the new aspects of the GMS contract will assist with ensuring regular and comprehensive reviews are taking place for those on long-term prescriptions. Repeat prescription management could be similarly improved.
- 619. We were disappointed prescribing in secondary care has fallen behind and by the evidence regarding the implementation of the HEPMA, suggesting there is no leadership or strategic oversight of this project. Again, we have recommended this cannot continue. We are also concerned at evidence suggesting prescriptions in secondary care were leading to delays in patient discharge from hospital and suggest this requires urgent consideration.
- 620. Non-pharmaceutical interventions, including social prescribing, require more scrutiny and given greater parity with medicines governance.
- 621. Prescriptions of generic drugs and biosimilars represents a large proportion of prescribing in Scotland and therefore achieves savings. We have suggested momentum in this area be maintained by promoting best practice. Similarly, we have suggested governance surrounding prescriptions of unlicensed medications could be improved to ensure opportunities are being maximised to make the best cost and clinically effective decisions.

Dispensing



- 622. Once a prescription has been provided for a patient, it is then presented to a pharmacist to dispense the medicine.
- 623. According to the Scottish Parliament Information Centre—
 - "In Scotland, patients may have their medicines dispensed in hospital by a hospital pharmacist employed by the NHS, or in the community by a community pharmacist or dispensing doctor practice. In order to dispense NHS prescriptions, a pharmacy must be entered onto the NHS board's pharmaceutical list. This involves an application to the board and consideration by its Pharmacy Practices Committee. Pharmacies are included on the list when it is considered necessary or desirable in order to secure adequate provision of pharmaceutical services."
- 624. This section of the report will consider evidence presented to us on the best way to ensure clinical and cost effectiveness as this stage. We have examined—
 - The role of community pharmacy, including the new Pharmacy First Initiative;
 - · Automated dispensing;
 - · Dispensing in care homes; and
 - Online pharmacy.

Community pharmacy contract

- 625. We are interested in how the community pharmacy contract can influence the clinical and cost effectiveness of medicine interventions.
- 626. Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland said—
 - "We are always talking to the committee about the additional value that pharmacists bring through their conversations with patients, oversight activities and so on. Up to this point, it has been difficult, because of lack of IT and how the contract is developed over time, to prove that added value by quantifying and recording it. However, we are getting closer to the point at which we can build a really good evidence base, ensure that there is good visibility for the great work that goes on around dispensing, and incentivise pharmacists to engage with that and be consistent in it."
- 627. We look forward to the Royal Pharmaceutical Society in Scotland presenting evidence to support its claims of added value. We are sympathetic these should exist but recommend the profession start collecting the necessary evidence which we imagine would, if substantiated, be positively received by the Scottish Government in future contract discussions.
- 628. We are interested in plans to evaluate and monitor the first year of operation of the community pharmacy contract, especially in light that this will not be renegotiated for three years, rather than the previous annual renewal. We sought the view of the Cabinet Secretary for Health and Sport on this issue in correspondence deliii. We also asked whether there were plans to include further incentives to drive better pharmaceutical care, including data retention.
- 629. We were also interested in whether the community pharmacy contract created a perverse incentive for community pharmacists to dispense medicine rather than discuss alternatives as they will be recompensed for the drugs. Campbell Shimmins of Community Pharmacy Scotland suggested that may previously have been the case but the nature of the contract was changing to include more service delivery elements such as Pharmacy First. Angela Timoney, Director of Pharmacy, NHS Lothian said the contract was moving towards "professional fees for their services". The Chief Pharmaceutical Officer, Rose Marie Parr, said—
 - "We want community pharmacists to make a wider range of patient-focused interventions and come away from supply dispensing, although not completely, to perhaps look at other ways to do that and be much more up front with the patient in talking about their medicines and trying to reduce some of the harm that can happen."

dclii Health and Sport Committee, *Official Report, 4 February 2020,* Col 34 dcliii Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

- 630. She suggested there were two "streams" to that work—
 - · Pharmacy First; and
 - Support for patients with long-term conditions

Minor Ailment Scheme and Pharmacy First

- 631. Pharmacy First is the new title for the Minor Ailment Scheme, which "sees community pharmacists able to give advice to and if necessary treat or refer patients..." with uncomplicated conditions.
- 632. Where previously the eligibility criteria for the minor ailments scheme was limited, the scheme will be widened to cover everyone and the original April 2020 launch for this has been delayed due to the COVID-19 crisis.
- 633. Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government, emphasised the shift in the contract from simply remunerating dispensing to a focus on other services provided by pharmacists—
 - "We have to think about what the Scottish drug tariff is there for. It reimburses our community pharmacists for the drugs that they have already bought—they have taken the risk of buying them—but it also pays for aspects of the community pharmacy service. We have a contract agreement with Scottish pharmacy contractors around acute prescribing—everyone will see that when they take a prescription to a pharmacist—and around the pharmacy first service, which will be rolled out in April 2020. Pharmacists will be able not just to focus on self-care, but to look at pharmacy first treatment, which will include antibiotics for urinary tract infections and some skin problems. The point is to avoid having to go to a prescriber—a GP or someone in accident and emergency—and to allow community pharmacy to take on some of that burden. The issue for me is less about what drugs are within the tariff and more about how they are used and reviewed. dclviiin
- G34. Jonathan Burton of the Royal Pharmaceutical Society in Scotland delix, was enthusiastic about the new Pharmacy First service and highlighted the role community pharmacists could play in providing a consultancy service which may mitigate the need for people to make a GP appointment.
- 635. Campbell Shimmins of Community Pharmacy Scotland cited research into the impact of the minor ailment service which he described as "overwhelmingly positive" Along with Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clydedclxi and Jonathan Burtondclxii, hedclxiii suggested more publicity, education and communication with the public will be required when the scheme is extended to all.

dclv Health and Sport Committee, Official Report, 4 February 2020, Col 34

dclvi Health and Sport Committee, Official Report, 10 March 2020, Col 23

dclvii Community Pharmacy Scotland - retrieved from https://www.cps.scot/nhs-services/ national/pharmacy-first/

dclviii Health and Sport Committee, Official Report, 21 January 2020, Col 13

dclix Health and Sport Committee, Official Report, 28 January 2020, Col 37

- 636. We are interested in how the Pharmacy First initiative will be evaluated and monitored and sought the view of the Cabinet Secretary for Health and Sport on this issue in correspondence delxiv.
- 637. We support this development although we are unclear whether positivity and enthusiasm for the Pharmacy First scheme among professionals may not match with public awareness of the scheme as was reflected in discussions^{dclxv} with stakeholders. We are interested in how the new Pharmacy First scheme will be advertised and sought the view of the Cabinet Secretary for Health and Sport on this issue in correspondence^{dclxvi}. We also sought details of the expected demand.

Pharmacy and the General Medical Services Contract

Community Pharmacy in GP surgeries - Pharmacotherapy

- 638. The new GMS contract^{dclxvii} has introduced co-location of community pharmacists within GP surgeries to provide advice and prescribe and dispense medicine, although it was highlighted to us this form of working is not new.
- 639. The University of Strathclyde said dclxix access to pharmacists in GP practices was currently limited—
 - "An evaluation of the GP practice-based pharmacists programme has been commissioned to capture the learning and inform any models for future practice developments."
- 640. The Chief Pharmaceutical Officer, Rose Marie Parr^{dclxxi}, said job roles would have to be more flexible in the future.

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dclx Health and Sport Committee, Official Report, 4 February 2020, Col 36
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dclxi Health and Sport Committee, Official Report, 4 February 2020, Col 37

dclxii Health and Sport Committee, Official Report, 4 February 2020, Col 37

dclxiii Health and Sport Committee, Official Report, 4 February 2020, Col 37

dclxiv Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

dclxv Health and Sport Committee, Official Report, 18 February 2020, Col 17

dclxvi Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

dclxvii Scottish Government (2017). The 2018 General Medical Services Contract in Scotland

dclxviii Health and Sport Committee, Official Report, 28 January 2020, Col 55

dclxix University of Strathclyde. Written Submission.

dclxx Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 16

dclxxi Health and Sport Committee, Official Report, 10 March 2020, Col 25

- 641. The Cabinet Secretary for Health and Sport, said—
 - "The introduction of the pharmacotherapy service in around 70 per cent of our general practices as a result of phase 1 of the GP contract means that pharmacists and pharmacy technicians are now embedded in the general practice team, who can provide medication management systems, including formulary compliance, hospital out-patient requests, medicine reconciliation and repeat prescribing management. They can also provide polypharmacy and medication reviews, including of high-risk medicines, and take on the management of people with more complex multiple conditions, which involves taking decisions with individuals on the use of their medication and, where appropriate, monitoring and adjusting treatment prescriptions. By taking on that role, those pharmacists are improving clinical outcomes for people, reducing the workload of GPs and freeing up the capacity of others to focus on people with undifferentiated illness or other complex needs."
- 642. The impact of the pharmacotherapy aspect of the contract was discussed in several representations to us throughout the inquiry and themes arising included—
 - Relationship between pharmacist and community;
 - · Impact on the pharmacy workforce;
 - · Skills and training; and
 - Ability to work remotely.

Relationship between pharmacist and the community

- 643. The Company Chemists Association delxxiii suggested "pharmacists within community pharmacy settings are ideally placed to work in collaboration with GP teams" noting the enhanced relationship between those working in the community and the public. The theme of community pharmacy work with the public was prevalent throughout our work, with several organisations extolling the benefits of the discussions people have with their pharmacist, including—
 - Development of a relationship of trust dclxxiv
 - Ensuring patients know how to take their medicine and what the benefits are, as this helps with safety, adherence and waste reduction; and
 - Allowing patients to make an informed decision about whether to take a prescription.
- 644. While much was made of the importance of conversations between pharmacist and patients, and the benefits of the close relationship which can form, it was unclear to us the extent to which—

- pharmacists will contradict the advice of prescribers and what influence such discussions may have on whether people take their prescriptions; and
- Information gleaned from such conversations is recorded and put to use.
- Campbell Shimmins of Community Pharmacy Scotland^{dclxxv} said there was not a conflict between the advice of prescribers. Both Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde^{dclxxvi} and Angela Timoney, Director of Pharmacy, NHS Lothian^{dclxxvii}, spoke of the good working relationships between GPs and pharmacists. Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland^{dclxxviii} quoted^{dclxxviii} a study suggesting around 5% of prescriptions were technically inaccurate to highlight an area in which the pharmacist was an important safety net.
- 646. However, we were concerned that in all the evidence we have taken on the importance of discussions between community pharmacists and patients at the point of dispensing, there is no route for processing the information offered by patients. Nor is there any indication of the extent to which these conversations are happening. Jonathan Burton delxxx stated recording of discussions was down to the professional judgement of the pharmacist but, in describing situations where he sent Post It Notes to GPs, felt communication could be improved. We question the professional judgement involved in recording important information relating to patient health in such an ad hoc informal manner.
- 647. Community Pharmacy Scotland dclxxxi highlighted the use of paper forms for this purpose adding uptake was not comprehensive. The Royal Pharmaceutical Society in Scotland later provided us with its view that in order for information to be recorded, it would have to be mandated dclxxxii. We are concerned at professional people and bodies adopting such a position.
- 648. We are also surprised the gathering of data on interactions with patients within community pharmacy is not a condition of the community pharmacy contract.
- 649. Campbell Shimmins^{dclxxxiii} suggested visiting people's homes was a key way to understand how they were taking their medicines. Although he acknowledged this is not a regular occurrence, he also said^{dclxxxiv} there was no formal process for doing

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dclxxvi Health and Sport Committee, Official Report, 4 February 2020, Col 9

dclxxvi Health and Sport Committee, Official Report, 4 February 2020, Col 10

dclxxviii Health and Sport Committee, Official Report, 4 February 2020, Col 10

dclxxviii Health and Sport Committee, Official Report, 4 February 2020, Col 11

dclxxix Health and Sport Committee, Official Report, 4 February 2020, Col 12

dclxxx Health and Sport Committee, Official Report, 4 February 2020, Col 11

dclxxxi Letter from Community Pharmacy Scotland on Supply and Demand for Medicines, 4

March 2020
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dclxxxii Letter from the Royal Pharmaceutical Society in Scotland on the Supply and Demand for Medicines, 25 March 2020

- so. Dr David Shackles of the Royal College of GPs^{dclxxxv} spoke of initiatives where pharmacy technicians visited the homes of patients.
- 650. We are keen to understand more about the governance of community pharmacists visiting the homes of patients. Community Pharmacy Scotland suggested the more pertinent issue was the absence of a pharmacist from a pharmacy which impeded the normal business of a chemist from being carried out. While according to CPS, the regulations covering this are reserved, we are interested in whether such practice is safe and covered by suitable governance structures such as the PVG scheme.
- 651. We ask the Scottish Government for full details of the governance structures surrounding pharmacists work in the homes of private individuals, recognising this is an infrequent occurrence, and how this is covered in the Community Pharmacy Contract.
- 652. We also ask the Scottish Government to advise what aspects of data collection are covered in the new pharmacy contract.
- 653. We recommend the Scottish Government, as a matter of urgency, formalise the systems for sharing information between prescribers and dispensers. This should be done in collaboration with GPs and pharmacists.
- 654. We heard much from pharmacists about the personalised services they offer from the heart of communities, including making house calls and ensuring people received their medicines in extreme weather.
- 655. However, we are also aware some pharmacists have started charging for deliveries although these charges can be avoided if prescriptions are booked online. Adam Stachura, Head of Policy and Communications, Age Scotland suggested this was detrimental to the care of the 0.5m people in Scotland who do not have access to the internet. Claire Fernie, Public Partner Volunteer, NHS Fife described this as a barrier to access.
- 656. We recommend the Scottish Government consider the impacts of charges such as this from private companies in preparation of the next Community Pharmacy contract and in the meantime liaise with the organisations as to how these could be mitigated and removed.

dclxxxiii Health and Sport Committee, Official Report, 4 February 2020, Col 6

dclxxxiv Health and Sport Committee, Official Report, 4 February 2020, Col 6

dclxxxv Health and Sport Committee, Official Report, 18 February 2020, Col 23

dclxxxvi Letter from Community Pharmacy Scotland on Supply and Demand for Medicines, 4
March 2020

dclxxxvii Health and Sport Committee, Official Report, 18 February 2020, Col 9

dclxxxviii Health and Sport Committee, Official Report, 18 February 2020, Col 9

657. We recommend the next iteration of the Community Pharmacy contract takes account of compensation for pharmacist delivery of prescriptions.

Impact on the pharmacy workforce

- 658. Several organisations, such as the Company Chemist's Association delaxxix, McKesson UK he Royal Pharmaceutical Society in Scotland and Community Pharmacy Scotland noted the impact of pharmacists integrating within GP surgeries, which caused a reduced workforce pool to be available to the community pharmacy service. It was proposed the speed of this had compounded the issue and we heard calls for further work force planning to ensure adequate numbers of both pharmacists and pharmacy technicians.
- 659. Community Pharmacy Scotland suggested the inclusion of pharmacists within GP practices was welcome, but the key benefit was communication which they felt could be improved between GPs and pharmacists working in the community. They also proposed that different models were available indicating future discussions on this were imminent. The Chief Pharmaceutical Officer, Rose Marie Parr^{dcxciv}, said there was a need to work flexibly across job roles in the future which would be a new way of working and we sought details of this from the Cabinet Secretary for Health and Sport in correspondence^{dcxcv}.
- 660. When questioned on the impact of the GMS contract on the pool of personnel on which community pharmacy had to draw, Bryan Lamb, Head of Pharmacy Branch, Scottish Government said—
 - "As part of the three-year agreement that we have entered into with Community Pharmacy Scotland, we are looking to introduce a new independent prescribing career pathway as well as a foundation programme, which is about encouraging people to come back into community pharmacy to practise. They will be able to maximise not only their patient interaction skills but their medicines knowledge, and they will be able to provide patients with long-term treatment. That is a key change in how we are bringing people into the network to sustain community pharmacy."

dclxxxix Company Chemists Association. Written Submission.

dcxc McKesson UK. Written Submission.

dexci The Royal Pharmaceutical Society in Scotland. Written Submission.

dexcii Community Pharmacy Scotland. Written Submission.

dexciii Health and Sport Committee, *Official Report, 28 January 2020,* Col 56 dexciv Health and Sport Committee, *Official Report, 10 March 2020,* Col 25

dcxcv Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

- 661. The Scottish Government stated that in order to deliver the new GMS contract, it would—
 - "...increase the pool of qualified pharmacists to provide the pharmacotherapy service, additional funding has been secured to increase the number of pharmacist training posts from 170 to 200 per year from 2018/19. This will ensure that there is sufficient capacity to deliver the pharmacotherapy service within the proposed timescales."
- 662. However, in light of the concerns heard throughout the inquiry from stakeholders, we are concerned as to whether there are sufficient trained numbers of personnel available to deliver this. Indeed, Angela Timoney, Director of Pharmacy, NHS Lothian proposed adding pharmacists to the Shortages Occupation List (SOL).
- 663. In the REVIEWS OF PRESCRIPTIONS section of this report, we sought an update on progress towards delivering pharmacy support services in every GP practice in Scotland and we are also interested in whether the support for training programmes has been sufficient to "ensure" delivery of the "pharmacotherapy service within the proposed timescales" delivery.
- 664. We ask the Scottish Government to provide an update on the training programmes which have been supported for pharmacists since the start of the current GMS contract. To include the numbers of students taking up places as compared to the numbers of pharmacists the Scottish Government envisaged were needed to "ensure that there is sufficient capacity to deliver the pharmacotherapy service within the proposed timescales" dcc.

Skills and Training

- 665. Skills and training were raised with us throughout the inquiry.
- 666. The Royal Pharmaceutical Society^{dcci} noted there could be a greater role for Pharmacy Technicians, particularly in dispensing, but said a more formalised career path was required. The Royal Pharmaceutical Society in Scotland also suggested^{dccii} the correct level of qualified personnel should be assigned to the correct tasks to ensure efficiency, best value and more patient facing time for pharmacists.

dexevi Health and Sport Committee, *Official Report, 10 March 2020,* Col 25 dexevii Scottish Government (2017). The 2018 General Medical Services Contract in Scotland

dcxcviii Scottish Government (2017). The 2018 General Medical Services Contract in Scotland

dcxcix Scottish Government (2017). The 2018 General Medical Services Contract in Scotland dcc Scottish Government (2017). The 2018 General Medical Services Contract in Scotland dcci The Royal Pharmaceutical Society in Scotland. Written Submission.

dccii The Royal Pharmaceutical Society in Scotland. Written Submission.

- 667. It was also suggested dcciii investment in digital skills for pharmacists would be required as systems moved online and an increase in the number of pharmacists working in data scientists and clinical informatics roles. Angela Timoney, Director of Pharmacy, NHS Lothian dcciv, said the board had invested in developing its own workforce to combat shortages by funding places at Edinburgh college for technicians.
- 668. The Chief Pharmaceutical Officer, Rose Marie Parr^{dccv}, indicated funding had been made available for pre-registration training and there were ongoing discussions with training providers on this.

Automation

- 669. In August 2017, the Scottish Government published "Achieving excellence in pharmaceutical care: a strategy for Scotland" which included a recognition of the need to transform delivery of services through use of technology. They stated—
 - "We are committed to this transformative programme of work which includes automated technologies. dccvii"
- 670. Advocates of automation suggested greater use of technology to dispense at scale would—
 - Improve safety and accuracy dccviii;
 - Save time allowing community pharmacists more time with patients;
 - Create "capacity within the system and specifically within GP practice" by reducing GP workload on repeat prescriptions;
 - "Optimise space available in the dispensary" dccx;
 - "Avoid duplication" dccxi;
 - "Increase distribution safety standards" dccxii;
 - "Create safe and efficient repeat prescribing" dccxiii;
 - Reduce the number of errors in the dispensing process; and
 - Save nursing time^{dccxiv}.

dcciii The Royal Pharmaceutical Society in Scotland. Written Submission.

dcciv Health and Sport Committee, Official Report, 4 February 2020, Col 14

dccv Health and Sport Committee, Official Report, 10 March 2020, Col 25

dccvi Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland

dccvii Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 5

- Omnicell provided us with a detailed submission extolling the virtues of introducing technology into the dispensing process with a strong focus on reducing errors and improving efficiency. As well as the many benefits for staff and the NHS, they cite the following issues which can arise for patients if errors occur—
 - "Medication errors can result in adverse drug reactions, drug-to-drug interactions, a lack of efficacy, sub-optimal patient adherence, impaired quality of life and a poor patient experience."
- 672. In response to questions on the Omnicell submission, Adam Osprey, Policy and Development Pharmacist, Community Pharmacy Scotland said "a computer is only as intelligent as what somebody tells it to do"dccxvii. He also said one solution might not suit all types of pharmacy, noting robotic solutions may work in hospitals but not in community pharmacies.
- 673. On robotic dispensing, Omnicell said—
 - "Robots have the potential to manage stock rotation reducing medicines wastage, handle high volumes of dispensing in community pharmacies, or dispensing "hubs", and release pharmacists to develop and deliver patient-centred services."
- 674. Adam Osprey^{dccxix}, suggested robotic dispensing required huge scale in order to produce efficiencies. He proposed, however, other interventions such as barcoding on medicines could help ensure accuracy of dispensing.
- 675. While recognising the potential automation has to revolutionise dispensing, we question how much has been achieved so far in trials in Scotland. "Achieving Excellence in Pharmaceutical Care A Strategy for Scotland" states—

dccviii Omnicell. Written Submission.

dccix Company Chemists Association. Written Submission.

dccx McKesson UK. Written Submission.

dccxi McKesson UK. Written Submission.

dccxii McKesson UK. Written Submission.

dccxiii McKesson UK. Written Submission.

dccxiv Omnicell. Written Submission.

dccxv Omnicell. Written Submission.

dccxvi Omnicell. Written Submission.

dccxvii Health and Sport Committee, Official Report, 18 February 2020, Col 43

dccxviii Omnicell. Written Submission.

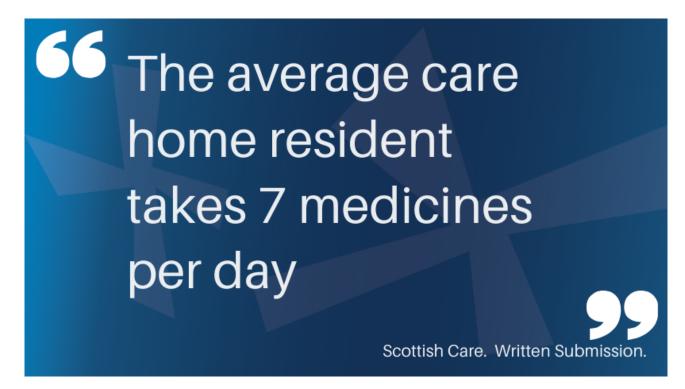
dccxix Health and Sport Committee, Official Report, 18 February 2020, Col 42

- "Within NHS Greater Glasgow and Clyde (NHS GG&C) the largest hospital pharmacy robotic installation in the world exists within a Pharmacy Distribution Centre and distributes nine million packs of medicines to 4000 destination points from the eastern boundary of Glasgow to Argyll in the west Highlands. The main hospitals within NHS GG&C also have dispensing robots which dispense medicines for individual people. The use of this technology has enabled a very much smaller pharmacy to be built in the new Queen Elizabeth University Hospital than would otherwise have been required and has enabled pharmacy staff working in that hospital, freed from dispensing, to be available at the bedside to assist people to achieve the best outcomes from their treatment with medicines. In addition, semi-automated medicines cabinets are being installed within hospital wards and departments. The Golden Jubilee has recently invested in this technology for the whole hospital and the benefits include releasing time for nurses to care for people and guicker access to stored medicines meaning that people can receive for example pain relief as required more quickly. Typically wards can store 20% less medication through use of these cabinets while still providing medicines to meet the people's needs."dccxx
- 676. The Scottish Government indicated evaluation of trials highlighted in the "Achieving Excellence in Pharmaceutical Care A Strategy for Scotland" were underway and we would welcome detail of these. Graeme Bryson, Director of Pharmacy, NHS Dumfries and Galloway ccxxii, noted a Scottish Government commissioned report on robotics in community pharmacies is due to report in the middle of the year.
- 677. We ask the Scottish Government to provide detail on the evaluations of pilots and trials undertaken by both the Scottish Government and health boards of automated dispensing so far in Scotland and details of the current work due to report in the middle of the year.

dccxx Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 41

dccxxi Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 41

Care Homes



- 678. The issue of prescribing and dispensing medicines in care homes and the potential for reducing waste and improving efficiency was raised with us by several sources.
- 679. Researchers from the University of Edinburgh provided a detailed account of the potential for reduced waste and more efficient dispensing of medicines in care homes covering—
 - Consideration of the use of 'Just in Case' boxes;
 - Include a stock of medicines in care homes in the way hospitals and hospices do; and
 - Allow bulk prescribing in care homes.
- 680. Others were keen to see pharmacists have a direct role working within care home settings. We look at these suggestions in turn.

Use of 'Just in Case' boxes

681. The University of Edinburgh researchers provided the following explanation of 'Just in Case' boxes—

- "Anticipatory prescribing in the community, known as 'Just in Case' boxes, were traditionally set up for people dying in their own home, using individualised patient prescriptions with the person's name typed on each medication. They are recommended by the Scottish Palliative Care guidelines, and became part of policy in case of distress in the last days of life and saved calling out a GP at weekends/OOHs. Each 'Just in Case Box' contains ten ampoules of each anticipatory medication. The above best practice in end-of-life medication provision then became popular within the care home setting in order to save the care home organisation having to pay a 'home office licence' in order to have controlled drugs in the care home 'as stock'."
- 682. The researchers suggest the boxes result in a lot of waste, and pose problems with storage and pharmacist and staff time in preparing and checking the boxes.

 Medications which are not taken prior to a patient's death are returned and cannot be used again. Fife Area Drug and Therapeutic Committee (ADTC)^{dccxxiv} told us it was working with care homes to reduce avoidable returns.
- 683. A comparison of the two different approaches was provided—

Summary comparison of 'just in case' boxes versus medications 'as stock'University of Edinburgh. Written Submission.

Just in Case Boxes	Stock
JiCBs are issued for use during last days of life	'as stock' can be used during last days of life + for any 'acute' issue once prescribed by a GP/OOHs
JiCB are for individual people only	Used for any resident
JiCB for each resident includes following medication: • s/c morphine 10 ampoules • s/c hysocine 10 ampoules	'as stock' medication would include just one box of each medication i.e. s/c morphine; s/c hyoscine; s/c midazolam; s/c levomeprazine.
 s/c midazolam 10 ampoules s/c levomepromazine 10 ampoules 	
Time wastage for pharmacists creating JiCBs for each resident	Less time wastage for pharmacists as only supplying one box of each medication per care home
It is rare that more than two or three JiCB medications used - all remaining ampoules then returned/destroyed by pharmacist once resident dies	No names on 'stock' medication so don't need to be destroyed unless 'out of date'
Between 30-50% of residents in a nursing care home will have JiCB prescribed – so need of checking each JiCB twice a day + need for large storage cupboards.	Simple checking of four boxes of 'as stock' medication twice a day. No need of large storage cupboards.
Don't have to pay for Home Office Licence	Currently independent care home organisations have to pay for a Home Office Licence to hold medications 'as stock' but independent hospices don't

Stock of Medicines

- Or David Shackles of the Royal College of GPs^{dccxxv} suggested there were circumstances, such as care homes, where stocking medicines may be a good way to reduce waste, a notion supported by Scottish Care^{dccxxvi}.
- 685. It was suggested that care homes use 'Just in Case' boxes to circumvent the requirement to pay to hold a licence from the Home Office to have a stock of medicines. We wrote to the Home Secretary, Priti Patel, to inquire as to why this was the case and received a response dccxxvii from the Minister of State for Crime and Policing, Kit Malthouse. This notes the area is regulated by the Misuse of Drugs Regulations 2001 and highlights exemptions to the requirement to hold a licence—
 - "Care homes which are wholly or mainly maintained either by a public authority out of public funds or by a charity or by voluntary subscriptions
 - Care homes not satisfying these requirements are also able to hold controlled drugs in Schedule 3 to 5 (inclusive) without a Home Office licence, but they will need a controlled drugs licence for drugs in Schedule 2."
- 686. He stated there are no plans to review this legislation.
- 687. The Chief Pharmaceutical Officer, Rose Marie Parr, stated dccxxx the Scottish Government suggested it was for each home to advocate to the Home Office for exemptions to the requirement to hold a licence. She explained the regulatory burden this would place on the individual home, as well as the governance and risk challenges such as lack of nursing staff and general workforce challenges faced by the sector, and improved margin for error when selecting from stock rather than individual patient's medicines.
- 688. Recognising the challenges associated with the proposed alternative to 'Just in Case' boxes, we believe this is an area worthy of further consideration as to how to reduce the associated waste.
- 689. We ask the Scottish Government how much wastage is produced from care homes returning medicine and at what cost to the NHS?

dccxxv Health and Sport Committee, Official Report, 18 February 2020, Col 26

dccxxvi Scottish Care. Written Submission.

dccxxvii Letter from the Minister of State for Crime and Policing Kit Malthouse MP on the Supply and Demand for Medicines in Scotland: Licensing of Medicines in Care Homes, 3 March 2020

dccxxviii Misuse of Drugs Regulations 2001

dccxxix Letter from the Minister of State for Crime and Policing Kit Malthouse MP on the Supply and Demand for Medicines in Scotland: Licensing of Medicines in Care Homes, 3 March 2020

dccxxx Letter from Rose Marie Parr, Chief Pharmaceutical Officer on Supply and Demand for Medicines, 26 February 2020

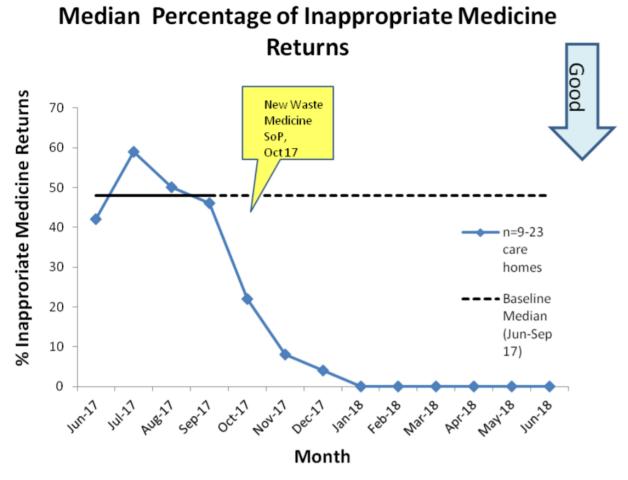
- 690. We recommend the Scottish Government consider how medicines could be held in care homes in a manner which does not produce the levels of waste caused by 'Just in Case' boxes.
- 691. We recommend the Scottish Government work with the Home Office to consider further the approach to licensing in care homes as well as the fees payable for licences for different types of organisation.

Bulk prescribing in care homes

- 692. The Royal Pharmaceutical Society in Scotland suggested bulk prescribing could be a way to eliminate waste, citing an example of nutritional drinks which if prescribed for one patient but not used, cannot then be kept by the care home for use by another patient.
- 693. NHS Tayside provided^{dccxxxii} us with detail of the model used by the board, in collaboration with care providers, to reduce medicines waste arising in care homes. A new protocol and pathway was developed, ensuring only appropriate medicines were returned to pharmacists and the results are shown below—

dccxxxi Letter from the Royal Pharmaceutical Society in Scotland on the Supply and Demand for Medicine, 25 March 2020

dccxxxii Letter from David Coulson, Assistant Director of Pharmacy, NHS Tayside, on Supply and Demand for Medicines, 2 March 2020



Source: Letter from David Coulson, Assistant Director of Pharmacy, NHS Tayside, on Supply and Demand for Medicines. 2 March 2020

Pharmacists reported seeing a huge reduction in returned medicines, which they previously said had amounted to tens of thousands of pounds of waste every month. NHS Tayside suggested to us "If there are opportunities to influence and develop government policy related to medicines management within care homes, based on this effective work, there would be a significant and positive impact across the whole of Scotland." This approach was praised by Community Pharmacy Scotland.

695. We recommend all Health Boards consider the results of the work undertaken in NHS Tayside and we ask the Scottish Government who would be responsible for facilitating the roll out of similar schemes in every health board in Scotland.

dccxxxiii Video by the Care Inspectorate outlining detail of the NHS Tayside project, available at https://www.careinspectorate.com/index.php/guidance/9-professional/4752-medicine-waste-in-care-homes

dccxxxiv Letter from David Coulson, Assistant Director of Pharmacy, NHS Tayside, on Supply and Demand for Medicines, 2 March 2020

dccxxxv Health and Sport Committee, Official Report, 28 January 2020, Col 29

Other health care staff's presence in care homes

- 696. According to the Scottish Government "There is also an important role for GP practice-based pharmacists, at the interfaces of the profession, working closely with hospital pharmacists, community pharmacists and care homes to ensure seamless care and reduce potential medication related problems and errors."
- 697. Others, including Scottish Care dccxxxvii, also emphasised the role pharmacists could be playing directly in care homes.
- 698. AstraZeneca^{dccxxxviii} called for investment to allow community and GP pharmacists to work in care homes. The Royal Pharmaceutical Society in Scotland felt care homes should have more dedicated services from pharmacists^{dccxxxix}. The organisation proposed this would—
 - · Reduce waste through more effective, evidence based prescribing;
 - Address inappropriate polypharmacy in care homes
- 699. They also called for consideration to be given to bulk prescribing in care homes to make efficient use of resources and Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland thought this would help reduce waste by allowing care homes to draw on a supply rather than have items prescribed for individual patients. Community Pharmacy Scotland sides said pharmacists should be working within care homes and suggested guidance from the professional body would be helpful. Jonthan Burton suggested pharmacists should be permanent members of staff within care homes in order to optimise impact and support areas like polypharmacy review and training support for the pharmaceutical aspects of tasks undertaken by care assistants.
- 700. Dr Lewis Morrison, Chair of BMA Scotland, British Medical Association (BMA)^{dccxliii}, advocated those in care homes were entitled to the same levels of care as others and said this would be achieved through a multidisciplinary approach.
- 701. Eileen McKenna, Associate Director Professional Practice, Royal College of Nursing Scotland^{dccxliv}, said there was an opportunity through the Transforming Roles programme to examine the role of nurses in nursing homes. Claire Fernie, Public Partner Volunteer, NHS Fife^{dccxlv}, spoke of a pilot in Fife where GPs and

dccxxxvi Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 16

dccxxxvii Scottish Care. Written Submission.

dccxxxviii AstraZeneca. Written Submission.

dccxxxix Royal Pharmaceutical Society in Scotland. Written Submission.
dccxl Health and Sport Committee, *Official Report, 4 February 2020,* Col 7

dccxli Community Pharmacy Scotland. Written Submission.

dccxlii Health and Sport Committee, *Official Report*, 28 January 2020, Col 60 dccxliii Health and Sport Committee, *Official Report*, 28 January 2020, Col 59 dccxliv Health and Sport Committee, *Official Report*, 28 January 2020, Col 59

- Pharmacists went into care homes together, which she said reduced waste but also improved safety and wellbeing through formal reviews of medicines.
- 702. Scottish Care dccxlvi proposed each care home should have a link pharmacist, noting recent work on linking dentists with care homes and suggesting a similar model should be considered by the Scottish Government.
- 703. We request detail from the Scottish Government on what learning from good practice elsewhere is undertaken in this area and how that is encouraged.
- 704. We seek the view of the Scottish Government on the views presented to us on making greater use of the skills of nurses in care homes.
- 705. We agree pharmacists should have similar roles in care homes to those in GP practices and seek detail of what the Scottish Government can do to make this a reality.

Scottish Government consideration of dispensing in care homes

- 706. The Chief Pharmaceutical Officer, Rose Marie Parr, detailed decxivii further work on how medication is used in care homes in correspondence. She wrote—
 - "One of our five Pharmacy Clinical Leadership Fellows is undertaking work on improving the pharmaceutical care of residents in care homes, in line with Achieving Excellence in Pharmaceutical Care. Along with taking forward examples of best practice of pharmaceutical care in care homes for national implementation they are exploring—

The development of a care home specialist interest group.

The greater use of electronic Medicine Administration Record (eMAR) in a care homes.

The use the Medicines: Care and Review (M:CR) service in care home residents.

Examine the use of a palliative care assessment tool in care homes, and

Address the issue of improving waste reduction of medicines in care homes." dccxlviii

dccxlvii Health and Sport Committee, Official Report, 21 January 2020, Col 15

dccxlviii Letter from Rose Marie Parr, Chief Pharmaceutical Officer on Supply and Demand for Medicines, 26 February 2020

707. We note the exploration going on and would like to see that turned into action with the benefits that would accrue being delivered to patients and budgets. We request an update on when these proposed changes will be delivered in practice in care homes.

Online Pharmacy

- 708. We were interested in the regulation and operation of online pharmacy, although it was suggested by various witnesses this was not a prevalent issue in Scotland.
- 709. Campbell Shimmins of Community Pharmacy Scotland dccxlix and Adam Stachura, Head of Policy and Communications, Age Scotland both believed there was a place for online pharmacy, but that at the moment the best way to deliver the services expected was within communities where discussions and review could take place. Claire Fernie, Public Partner Volunteer, NHS Fife cccli raised the issue of data sharing when using online services.
- 710. We are of the view some of the face to face work carried out in communities could be undertaken digitally, akin to the engagements through the attend anywhere service^{dcclii}.
- 711. The Cabinet Secretary for Health and Sport, Jeane Freeman, said—
 - "...we would have some concern if we were seeing significant evidence of online prescribing having an impact on community pharmacy."
- 712. We believe the profession is perhaps underestimating the potentially disruptive effect of online pharmacies. We ask what consideration the Scottish Government has given to the potential threat of online pharmacies and how it can future proof the contract and associated regulations to protect the network.

dccxlix Health and Sport Committee, Official Report, 4 February 2020, Col 39

dccl Health and Sport Committee, Official Report, 18 February 2020, Col 21

dccli Health and Sport Committee, Official Report, 18 February 2020, Col 21

dcclii Further detail on the use of the video Attend Anywhere platform is available here: https://nhs.attendanywhere.com/resourcecentre/Content/Home.htm

dccliii Health and Sport Committee, Official Report, 10 March 2020, Col 26

Consumption

Waste



The biggest waste occurs when a medicine is prescribed that is expected to have a therapeutic benefit, but the patient does not get that benefit. There is a real issue around ensuring that patients understand and take their medicines. A medicine that is prescribed but which goes to waste is, in effect, the most expensive medicine that we could buy.

Professor Angela Timoney, Director of Pharmacy, NHS Lothian

- 713. One of the underlying themes running throughout the inquiry was how to reduce waste associated with the consumption of medicines. It was proposed to us there were several ways in which waste could manifest itself—
 - Adherence to prescriptions patients failing to take medicines as prescribed, not taking them at all and by not taking them in the manner described, failing to obtain the full clinical value of the medicine;
 - Medicines which have not been taken medicines once prescribed and/ dispensed but are not taken cannot be brought back into the stock of medicines in the system;
 - Over-ordering by patients patients ordering more than was required as part of repeat prescriptions;
 - Prescription of drugs which are ineffective even when taken, not all
 medicine will work for everyone and taking ineffective drugs is as wasteful as
 not taking them at all; and
 - Errors and Harm
- 714. A number of respondents suggested there was insufficient information and understanding of how waste might arise and called for work to be commissioned to explore this area further.

Adherence

- 715. A Price Waterhouse Coopers report from December 2016 estimated 50% of patients do not take medicines as directed.
- 716. Several reasons were cited as to the causes and why lack of adherence was problematic—
 - It could result in drug resistant microorganisms emerging dcclv;
 - Patients failing to take medicines as prescribed and denying themselves the clinical benefit;
 - Patients failing to take medicines but continuing to order them on repeat prescriptions^{dcclvi};
 - Symptomatic of insufficient time with patients dcclvii;
 - Suggested poor understanding on behalf of patients regarding their conditions and inadequate health literacy^{dcclviii}; and
 - Side effects of medicines may cause patients to be reluctant to take them^{dcclix}.

Proposals to improve adherence

- 717. The Association of the British Pharmaceutical Industry (ABPI) said^{dcclx} the NHS could learn from the support provided to patients during trials of medicines on how to take them which would improve adherence and Dr Sheuli Porkess, Executive Director of Research, Medical and Innovation^{dcclxi} said adherence should be a public health priority. She further suggested^{dcclxii} the role of the pharmaceutical industry in improving adherence relied on feedback as to why patients were not taking medicines in order to develop products which suited patient needs better (such as one tablet in place of three).
- 718. Use of technology was also cited as a way to support adherence, including dosette boxes, apps and text messages. Dr David Shackles of the Royal College of GPs told us technology can assist—

dccliv Price Waterhouse Coopers (2016) "Clinical Pharmacology and Therapeutics: The Case for Savings in the NHS"

dcclv Royal College of Physicians of Edinburgh. Written Submission.

dcclvi NHS Grampian Area Drug and Therapeutic Committee. Written Submission.

dcclvii British Medical Association. Written Submission.

dcclviii British Medical Association. Written Submission.

dcclix University of Strathclyde. Written Submission.

dcclx Letter from the Association of the British Pharmaceutical Industry on Supply and Demand for Medicines following 21 January 2020 meeting, 26 February 2020

dcclxi Health and Sport Committee, Official Report, 18 February 2020, Col 24

dcclxii Health and Sport Committee, *Official Report, 18 February 2020,* Col 25 dcclxiii Royal College of Physicians of Edinburgh. Written Submission.

- "We can use the repeat prescribing record to look back to see how well patients collect their medications, and to have conversations with our colleagues in community pharmacy, who alert us if medications are not being collected. There is a multidisciplinary team effort in that discussion. For example, community nursing colleagues might report back that there is a stockpile of medications in a patient's home, which would alert us to the fact that they were not taking their medications as effectively as we might think."
- 719. Above all however, respondents overwhelmingly told us the most important aspect of improving adherence was in conversations with patients, both at the point of prescription and dispensing.
- 720. Matt Barclay, Director of Operations, Community Pharmacy Scotland said—
 - "It might be that patients themselves will make a decision, after an informed discussion, not to take a medicine, perhaps for reasons of harm or side effects or perhaps because the medicine is just not doing what the patient wanted it to do. That is at an individual patient or clinician-to-patient level."
- 721. Dr Scott Jamieson of the Royal College of GPs said "If a patient does not know why they are taking a medicine or what its intended benefit is, that is a failure of the system. When we have time to ensure that realistic conversations are being had with patients, and the positives of taking their medicine are being explained to them, they will be more likely to value the medicines and take them." He also said "When patients know why they are taking a medicine and value it, and they know the benefit of taking it, they are more willing to take it."
- 722. Dr David Shackles of the Royal College of GPs^{dcclxviii} spoke of the importance of discussions with patients to ensure they understood the medications and were sufficiently advised. He spoke of trust issues and working to ensure prescribers advice was taken. He noted issues of time for GPs to have such discussions with their patients.

Discussions with patients on adherence

723. Matt Barclay of Community Pharmacy Scotland said "In respect of long-term conditions and multi-morbidity, pharmacists—as the experts on medicines—obviously like to take a view and to have conversations with patients about what is prescribed for them, how they are taking those medicines and whether they are taking them at all", adding "In some instances, we know before the doctor knows when patients' prescribing and pick-up patterns change. There are

dcclxiv Health and Sport Committee, *Official Report, 18 February 2020,* Col 23 dcclxv Further detail on the Medicines Care Review is available here. dcclxvi Health and Sport Committee, *Official Report, 28 January 2020,* Col 18

dcclxvii Health and Sport Committee, *Official Report, 28 January 2020,* Col 18 dcclxviii Health and Sport Committee, *Official Report, 18 February 2020,* Col 25

Health and Sport Committee

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- opportunities to ensure that the realistic medicine conversation...happens more frequently in community pharmacy." dcclxix
- 724. Matt Barclay also declxx said waste could be reduced through conversations with patients on adherence and getting benefit from medicines.
- 725. The Company Chemists Association said "Often the relationship between patient and pharmacist in the community gives a better insight into social issues surrounding medicines supply and adherence."
- 726. The Royal Pharmaceutical Society in Scotland (RPS) said the role of pharmacists in discussing medicines with patients was not suitably embedded within contractual arrangements.
- 727. Jonathan Burton, Chair, Scottish Pharmacy Board, RPS^{dcclxxii}, said patients were sometimes ashamed to admit to prescribers they had not taken a medicine as prescribed but would share that information with a pharmacist.
- 728. Community Pharmacy Scotland told us discussions with patients as to why medicines were being returned were not recorded, but patients were often very willing to explain why they were returning something.

Use of technology and packaging to support adherence

- 729. In August 2017, the Scottish Government published "Achieving excellence in pharmaceutical care: a strategy for Scotland" which included a recognition of the need to transform delivery of services through use of technology. It stated—
 - "We are committed to this transformative programme of work which includes...technology enabled approaches to support people to better manage their medication. dcclxxv"
- 730. The University of Strathclyde said "New sensor and monitoring technologies will enable key stakeholders from health care professionals through to the pharma producers to engage more effectively with patients and to understand compliance and adherence."

dcclxix Health and Sport Committee, Official Report, 28 January 2020, Col 16

dcclxx Health and Sport Committee, Official Report, 28 January 2020, Col 16

dcclxxi Company Chemists Association. Written Submission.

dcclxxii Health and Sport Committee, Official Report, 28 January 2020, Col 40

dcclxxiii Letter from Community Pharmacy Scotland on Supply and Demand for Medicines, 4
March 2020

dcclxxiv Scottish Government (2017). Achieving excellent in pharmaceutical care: a strategy for Scotland

dcclxxv Scottish Government (2017). Achieving excellent in pharmaceutical care: a strategy for Scotland, page 5

dcclxxvi University of Strathclyde. Written Submission.

- 731. AstraZeneca^{dcclxxvii} proposed packaging could be better utilised to support adherence, providing an example of a 'smart inhaler' linked to an app to ensure the regime was adhered to.
- 732. The Association of the British Pharmaceutical Industry (ABPI)^{dcclxxviii} suggested indications could be printed on the packaging of medicines to support better management of conditions, leading us to question why this is not taking place. Dr Sheuli Porkess, Executive Director of Research, Medical and Innovation, ABPI^{dcclxxix} told us of the regulation involved in packaging of medicines and suggested feedback from healthcare professionals would help in the design of better packaging. However, we question whether there is anything stopping manufacturers from seeking this directly. It was acknowledged dcclxxx some companies were seeking this, but a comprehensive approach to sharing of information was called for.
- 733. We were interested in whether inclusion of the cost of medicines on packaging would improve adherence and the value placed on that by patients. Adam Osprey, Policy and Development Pharmacist, Community Pharmacy Scotland suggested this may provoke unintended consequences by encouraging patients not to take expensive medicines to save the NHS money.
- 734. The Company Chemists Association suggested better use of technology could be made in order to support "patients with complex medication regimes, moving complicated medicines from hospital to community locations and addressing key medicine use issues."
- 735. Dr Scott Jamieson of the Royal College of GPs discussed dcclxxxiii software options to support those with long-term conditions to manage those better.
- 736. We were also interested in whether packaging could be designed to replicate the conditions required for the storage of some medicines, to address one of the reasons given that returned medicines cannot be reused. We note this approach was refuted dcclxxxiv by the ABPI.
- 737. Scottish Care lauded the eMar system, a process of barcoding, which it described as—

dcclxxvii AstraZeneca. Written Submission.

dcclxxviii Association of the British Pharmaceutical Industry. Written Submission.

dcclxxix Health and Sport Committee, Official Report, 18 February 2020, Col 27

dcclxxx Letter from the Association of the British Pharmaceutical Industry on the Supply and Demand for Medicines, 4 March 2020

dcclxxxi Health and Sport Committee, Official Report, 18 February 2020, Col 32

dcclxxxii Company Chemists Association. Written Submission.

dcclxxxiii Health and Sport Committee, Official Report, 28 January 2020, Col 19

dcclxxxiv Letter from the Association of the British Pharmaceutical Industry on the Supply and Demand for Medicines, 4 March 2020

"significantly reduce medicines errors and also resulting unplanned hospital admissions. The average care home resident takes 7 medicines per day and this system not only makes it easy to track medicines thus reducing the risk of incorrect or missed doses, but can also create individualise and personalise alerts to medicines approaching their end date, or contraindications and so on. eMAR can also identify trends which may point to need for a medicines review. There should be resource available to roll out this system to all care homes in Scotland as standard practice."

Compliance aids

- Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde said—
 - "Blister packs and compliance aids are sometimes viewed as a panacea, but I do not think that that is so. They are a solution to supporting patients to take their medicines as intended, but they bring risks. Some medicines in a compliance aid are not stable, and they can disempower the patient. Sometimes it would be better if the patient had a polypharmacy review to explore other strategies such as medicines administration records, known as MAR charts, or large-labels technology that could support better compliance. We ought to communicate better about that important area of risk"
- 739. Campbell Shimmins of Community Pharmacy Scotland said compliance aids could play a part but concurred they were not a panacea and could increase, rather than decrease risks. He also advocated the role of reviews to reduce waste, before using compliance aids. The Royal Pharmaceutical Society in Scotland colland us of the time involved in compiling medicine trays, an aid to remind people at what time of day to take medicines, and suggested keeping these in their original packaging could help reduce waste. They also said the process made obsolete the manufacturers guarantee and, as not all medicines could be included, could increase the risk of a patient forgetting to take a medicine.

Environmental concerns

740. Jonathan Burton of the Royal Pharmaceutical Society in Scotland dcclxxxix spoke on the issue of medicines ending up in landfill. He noted it was easy for people to return medicines to pharmacists and there was no need for it to end up in household waste. He suggested this should be part of wider waste disposal messaging, rather than just coming from health professionals. He felt emphasising the environmental messages might help with encouraging people to bring medicines back for disposal by pharmacists.

dcclxxxv Scottish Care. Written Submission.
dcclxxxvi Health and Sport Committee, Official Report, 4 February 2020, Col 21

dcclxxxvii Health and Sport Committee, Official Report, 4 February 2020, Col 21

dcclxxxviii Letter from the Royal Pharmaceutical Society in Scotland on the Supply and Demand for Medicine, 25 March 2020

741. We were interested in how packaging could support proper disposal of items such as contact lenses to avoid these being flushed. Dr Sheuli Porkess of the ABPI^{dccxc} reiterated messages about regulation of packaging and said the industry was attempting to streamline packaging in so far as possible. Adam Osprey^{dccxci} of Community Pharmacy Scotland surprised us with his suggestion this may prevent environmental messaging from being included.

Medicines which have not been taken

- 742. An issue raised in various written submissions was what happens to medicines which have been prescribed and the prescription has been presented to the pharmacy but then—
 - · Not picked up; or
 - Picked up but not taken and returned

Medicines which are prescribed but not picked up

- 743. Respondents highlighted the issue of medicines which have been prescribed and requested from a pharmacy but have not been picked up. The perception of respondents was those medicines cannot then be assumed back into the stock of a pharmacy and are considered waste.
- 744. Campbell Shimmins of Community Pharmacy Scotland suggested less than "2 to 3%" of medicines requested will not be picked up. He said if medicines were still in the pharmacy and had been stored properly, they would be added back into the stock and not claimed for.
- 745. We were also interested in the reimbursement arrangement for this. Jonathan Burton of the Royal Pharmaceutical Society in Scotland said—
 - "...our systems are not technically proficient enough to account for every last tablet in the system that might or might not be collected by a patient. A certain amount of professional judgement and discretion and a sense of fair play are required in the pharmacy in relation to what is submitted for reimbursement and what is not. For example, we might dispense to a patient 95 tablets out of 100 because we do not have the other five in stock. If the patient never collects the other five and they just sit on our shelves, there is currently no way, technically, to ensure that we are paid for only 95 and not 100."
- 746. He said^{dccxciv} pharmacies were expected to maintain a significant stock and were not recompensed for medicines which go out of date or were damaged while held in the pharmacy.

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dccxxix Health and Sport Committee, Official Report, 18 February 2020, Col 29 dccxc Health and Sport Committee, Official Report, 18 February 2020, Col 31
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dccxcii Health and Sport Committee, *Official Report, 18 February 2020,* Col 31 dccxciii Health and Sport Committee, *Official Report, 4 February 2020,* Col 8 dccxciii Health and Sport Committee, *Official Report, 4 February 2020,* Col 8

Health and Sport Committee

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- Jonathan Burton^{dccxcv} said used of technology, and in particular text messaging, allowed pharmacists to remind patients if they had not collected a prescription.
- 748. We recommend the Scottish Government investigate the issue of auditing systems in community pharmacy and whether this is resulting in over payments for pills which are not dispensed or collected.

Prescriptions which have been picked up but subsequently returned to the pharmacy unopened

- 749. It was suggested that medicines which have been picked up from the pharmacy in a prescription, but then returned without having been taken should not be considered waste. These are currently disposed of and cannot be re-dispensed.
- 750. Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde dccxcvi, Jonathan Burton of the Royal Pharmaceutical Society in Scotland and Dr Sheuli Porkess of the ABPI dccxcviii said once a medicine had been dispensed to a care home or to a patient, and it had left the control of the pharmacy, the pharmacist could no longer be assured of its quality and so, even if returned unused and unopened, it could not be re-dispensed to another patient. Gail Caldwell later confirmed^{dccxcix} this is not a blanket rule, but comes from regulation of pharmacists and it is they personally who must satisfy themselves as to the quality of a product. She also suggested the requirements of packaging for anti-counterfeit legislation would also make return difficult. The APBI^{dccc} and the Royal Pharmaceutical Society in Scotland dccci informed us of World Health Organisation (WHO) guidance guidance suggesting returned materials should not be taken back as stock, but should be destroyed." ABPI also suggested for some low value medicines, the cost of ensuring their efficacy and quality would outweigh the cost of provision of a replacement.

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dccxciv Health and Sport Committee, Official Report, 4 February 2020, Col 8 dccxcv Health and Sport Committee, Official Report, 4 February 2020, Col 9 dccxcvi Health and Sport Committee, Official Report, 4 February 2020, Col 7
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dccxcvii Health and Sport Committee, Official Report, 4 February 2020, Col 7

dccxcviii Health and Sport Committee, Official Report, 18 February 2020, Col 27

dccxcix Letter from Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde, on Supply and Demand for Medicines, 28 February 2020

dccc Letter from the Association of the British Pharmaceutical Industry on the Supply and Demand for Medicines, 4 March 2020

dccci Letter from the Royal Pharmaceutical Society in Scotland on the Supply and Demand for Medicine. 25 March 2020

dcccii <u>https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf?ua=1</u>

- 751. Graeme Bryson, Director of Pharmacy, NHS Dumfries and Galloway^{dccciii}, suggested there was less opportunity for waste in secondary care due to the closed nature of the system but acknowledged this did happen.
- 752. The main reason for the reluctance of pharmacists to re-dispense returned medicines related to storage and Gail Caldwell provided decciv us with extensive detail on testing, conditions of licence and packaging. Acknowledging there are legitimate concerns as to quality control, we were disappointed by the lack of innovative thinking presented to us which did not include suggestions as to how packaging and technology might address some of the issues highlighted by pharmacists for some if not all medicines.
- 753. An anomaly emerged on use of patients' own prescriptions in hospitals. Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde^{dcccv},told us that a patient's own medication continued to be used once they were admitted to hospitals, rather than writing a new prescription. She suggested it was safer for patients to use something they were familiar with to prevent something being taken twice.
- 754. This contradicts the principle of quality control cited as a reason not to use medicines which were returned to pharmacies un-used. Gail Caldwell suggested this is because it was not going to another patient and, through an assessment process, the quality and storage conditions of the medicine would be ascertained.
- 755. We consider the blanket opposition to the re-use of medicines to be wasteful. If the issue was quality and storage, it is not clear why it is deemed acceptable to give it to the person upon admission to hospital who could equally have wrongly stored it within their own home. This may undermine all the treatment being provided by the hospital, at a potentially much higher cost than providing new prescriptions.
- The Cabinet Secretary for Health and Sport, Jeane Freeman was of the view "Boards should allow patients to manage their own medication, subject to a risk assessment. We are looking to ensure that that policy is in place across all boards, so that all patients are treated in the same way." We sought the further detail as to how this would be achieved by the Cabinet Secretary for Health and Sport on this issue in correspondence decevii. We also sought detail of analysis of where waste is occurring and why.
- 757. We urge the Scottish Government to work with the pharmaceutical industry to develop means of presenting medication for return unused which provides a guarantee for pharmacists and clinicians at to the maintenance of quality of that product.

dccciii Health and Sport Committee, *Official Report, 18 February 2020,* Col 32 dccciv Letter from Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde, on Supply and Demand for Medicines, 28 February 2020 dcccv Health and Sport Committee, *Official Report, 4 February 2020,* Col 30 dcccvi Health and Sport Committee, *Official Report, 10 March 2020,* Col 6

dcccvii Letter to the Cabinet Secretary for Health and Sport on the Supply and Demand for Medicines, 23 March 2020

Medicines which are dispensed but not taken

758. Dr Sheuli Porkess, Executive Director of Research, Medical and Innovation, ABPI^{dcccviii} was keen to stress the need for feedback to the pharmaceutical industry on reasons for patients not taking medicines, which could be anything from packaging related issues to side effects. She noted pharmaceutical companies' interest in ensuring medicines were taken properly, as she believed doctors would not prescribe medicines which had no effect, and said industry wanted to be part of the solution. She acknowledged^{dcccix} some companies were surveying patients to ascertain reasons for non-adherence in the absence of a comprehensive approach to collection of this information.

Over ordering by patients

- 759. Community Pharmacy Scotland^{dcccx} suggested systems should be in place to identify patients who consistently over ordered medicines. NHS Grampian Area Drug and Therapeutics Committee (ADTC)^{dcccxi} noted over ordering through repeat prescriptions could be done by patients themselves, but also where other parties, such as care homes, were ordering on behalf of the patient.
- 760. The issue of managed repeats was raised with us, but both Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde^{dcccxii}, and Campbell Shimmins, Community Pharmacy Scotland^{dcccxiii}, suggested this had been proven not to be a huge source of waste in of itself.
- 761. Claire Fernie, Public Partner Volunteer, NHS Fife^{dcccxiv} said "There are as many reasons for patients over-ordering as there are patients" but suggested fear of shortages and repeat prescriptions as two potential reasons for stockpiling. Adam Stachura, Head of Policy and Communications, Age Scotland^{dcccxv}, suggested better systems of review would help with people ordering repeat prescriptions they no longer needed. He also noted a danger associated with people retaining and potentially taking medicines which were out of date.
- 762. Dr David Shackles of the Royal College of GPs^{dcccxvi} suggested multidisciplinary teams may keep one another informed of issues such as stockpiling within a patient's home through informal channels.

dcccviii Health and Sport Committee, Official Report, 18 February 2020, Col 27

Demand for Medicines, 4 March 2020

Letter from the Association of the British Pharmaceutical Industry on the Supply and Demand for Medicines, 4 March 2020

Letter from the Association of the British Pharmaceutical Industry on the Supply and Demand for Medicines, 4 March 2020

dcccx Community Pharmacy Scotland. Written Submission.

dcccxi NHS Grampian Area Drug and Therapeutics Committee. Written Submission. dcccxii Health and Sport Committee, *Official Report, 4 February 2020,* Col 1

dcccxiii Health and Sport Committee, *Official Report, 4 February 2020,* Col 3 dcccxiv Health and Sport Committee, *Official Report, 18 February 2020,* Col 12

dcccxv Health and Sport Committee, Official Report, 18 February 2020, Col 13

Prescribing ineffective medicines

- 763. Many of the representations made to us in the course of our inquiry have focused on the need for evidence based prescribing and on the efficacy of drugs taken. Respondents and witnesses have told us taking ineffective drugs is as wasteful as not taking prescriptions at all.
- 764. Linked to this was the need for meaningful reviews of patient prescriptions and in depth discussions on the impact on the patient of taking medicines on the patient. Such discussions are considered in detail in the SOCIAL PRESCRIBING section and the REVIEWS OF PRESCRIPTIONS section of this report.

Errors and harm

- 765. Where an error occurs on a prescription in favour of over provision, it was suggested pharmacists found it easier to dispense the incorrect amount than to seek correction from the prescriber. This results in the patient being provided with an over supply which they cannot use and cannot return. Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland said errors on prescriptions were sometimes raised with clinical colleagues but it seems are not recorded.
- 766. The Cabinet Secretary for Health and Sport, Jeane Freeman, said—
 - "Eleven per cent of all hospital admissions are attributable to medication-related harm, and half of those are preventable, so the work [polypharmacy guidance] reduces harm and waste. Integral to that is a patient discussion on adherence."
- 767. We are very concerned by this, especially in light of comments from pharmacists about it being easier to dispense in error than to correct prescriptions.
- 768. We recommend the Scottish Government review the issue of medicine related harm as a matter of urgency to ensure the safety of patients and prevent their admission to hospital.
- 769. We also recommend the Scottish Government consider acting to prevent prescriptions containing errors from being fulfilled, accompanied by a review of systems to ensure this is a sophisticated system based on more formal processes than hand written notes.

dcccxvi Health and Sport Committee, *Official Report*, *18 February 2020*, Col 23 dcccxvii Christine Jardine. Written Submission.

Research into the causes of waste

- 770. Several respondents suggested there was simply insufficient information and understanding of how waste might arise and called for work to be commissioned to explore this area further.
- 771. There was also an issue of how waste is measured. Campbell Shimmins of Community Pharmacy Scotland and Claire Fernie, Public Partner Volunteer, NHS Fife cccxxi told the Committee wasted medicines were recorded by weight, rather than by the value of the item. He also said there was no formal key performance indicator for waste in community pharmacy as there is in secondary care.

Disposal of medicines

- 772. Claire Fernie, Public Partner Volunteer, NHS Fife spoke of the experience in Fife of promoting the return of unused medicines to pharmacies, suggesting it was improving. She said—
 - "If someone has been prescribed medicine that they do not want or need, it becomes waste as soon as it goes out the pharmacy door. The majority of patients are not aware of that. We are making moves to get that information into the public domain through leaflets and poster campaigns in hospitals and GP surgeries, but we are not there yet."
- 773. This raises the question for us of how a patient is to know they have been given something they do not need? The prescription by this point will have been through two qualified medical professionals and it would be hard for a patient to insist on giving it back to the pharmacy on the basis they do not think they need it.
- 774. We consider GPs and all other prescribers have a duty to explain the risks and benefits of taking medicines when writing prescriptions. We do not consider it is acceptable to cite a lack of time as an excuse for not providing this.
- 775. Similarly, we do not accept the absence of lines of communication between those engaging with patients taking medicines. All involved have, in our opinion, a duty to ensure proper communication occurs and is recorded. If this is required to be written into contracts then it must be done as a matter of urgency.
- 776. Manufacturers should be encouraged to consider packaging which both aids consumption and enables returned medicines when in date to be reused.

dcccxx Health and Sport Committee, Official Report, 4 February 2020, Col 3

dcccxxi Health and Sport Committee, Official Report, 18 February 2020, Col 14

dcccxxii Health and Sport Committee, *Official Report, 4 February 2020,* Col 3 dcccxxiii Health and Sport Committee, *Official Report, 18 February 2020,* Col 14

- 777. Having considered the arguments for putting the cost of medicines on packaging we are not convinced this would be beneficial.
- 778. We recommend the e-Mar system or an equivalent is introduced into all care homes and ask the Scottish Government how this could be mandated.
- 779. We recommend the Scottish Government improve awareness of the best way to dispose of medicines, such as the public awareness raising campaign in NHS Fife.

Waste - conclusions

- 780. The primary issue raised with us on the consumption of medicines was the potential for waste at this point in the process.
- 781. Lack of adherence to prescriptions was a cause of waste, and we heard a variety of proposals for solutions including patient support akin to that offered in clinical trials, use of technology and conversations with patients at the point of prescribing and dispensing. We also heard calls for public campaigns on adherence to medicines and improved health literacy.
- 782. While we understand the concerns of pharmacists over re-dispensing medicines which have left their control but been returned unopened, we consider there must be a solution, be that technological or packaging based. We urge the Scottish Government to work with industry to explore such options. We also look forward to hearing the outcome from of ensuring there is a uniform policy on the use of patients' own medicines in hospitals.
- 783. Feedback from patients and communication between all parties involved was cited as a key factor in reducing waste through people not taking medications once dispensed.
- 784. People cannot be allowed to languish on medication regimes which are ineffective for them and reviews are essential.
- 785. The safe disposal of medicines was also highlighted to us as important, not least from an environmental point of view. Initiatives such as those in NHS Fife to raise awareness on the safe disposal of medicines are to be encouraged.

Data and IT



Digital will be key to the transformation of health & social care. NHS chief executives are committed to the major opportunities for the development and application of digital solutions to empower individuals, facilitate greater self-management and transform how our citizens engage and interact with a 21st-century health service.

Jeff Ace, Chief Executive, NHS Dumfries & Galloway and Chair, NHS Chief Executive's Group

- 786. The most prevalent theme throughout our inquiry was related to the use of data and the technology used to gather it. The University of Strathclyde said "Digital solutions can play a critical role in informing patients about all aspects of their treatments and provide more opportunities for them to engage with the appropriate experts if they have queries or concerns." In every area and stage of the system of supply and demand for medicines in Scotland we considered, we heard significant improvements would be achieved through better collection of data and better technology to support that.
- 787. We have therefore included an additional chapter to our report summarising what we heard and allowing for system wide observations to be made. We are clear there needs to be consistent and uniform IT systems in operation across the NHS in Scotland.
- 788. The main issues arising were—
 - The sharing of medical records;
 - Need for a uniform system for medicines management across Scotland with accessibility by all areas of the health service;
 - The work of the Data Scoping Taskforce and the Digital Health and Care Strategy;
 - · Preparedness for the medicines of the future;
 - · Collection of outcome data; and

· Digitisation of reviews of medicines.

Sharing of medical records

- 789. The case was made repeatedly for other medical professionals, but particularly community pharmacists to have access to patients' medical records in order to optimise their role. This will help ensure a smoother journey for patients through the various stages of the healthcare system and assist professionals while being in possession of all the facts. We heard about all of the following benefits—
 - Help to reduce polypharmacy^{dcccxxv};
 - Monitor repeat prescribing^{dcccxxvi};
 - Assist with a reduction in wastage^{dcccxxvii};
 - Ease transfers between secondary and primary care dcccxxviii;
 - Support those with long-term conditions dcccxxix,
 - Uphold safety and provide a second set of eyes to spot errors dcccxxx;
 - Help identify those at risk of non-adherence to prescriptions^{dcccxxxi};
 - Provide an early alert and resolution to errors^{dcccxxxiii} (which could help reduce unnecessary hospital admissions^{dcccxxxiiii});
 - Expedite patient medicine reconciliation when someone moves from one part
 of the health service to another^{dcccxxxiv} both Community Pharmacy
 Scotland^{dcccxxxv} and the Royal Pharmaceutical Society in Scotland called for
 discharge information to be shared with pharmacy;
 - Prevent valuable information on outcomes being lost^{dcccxxxvi};
 - Progress solutions for patients quickly within community pharmacy settings^{dcccxxxvii};
 - Would allow pharmacists to work across multiple sites^{dcccxxxviii};
 - Give out-of-hours doctors the ability to access records^{dcccxxxix};
 - Meet the expectations of patients, who would assume their doctor both within and outwith hospital, and subsequently their pharmacist could access records^{dcccxl}; and
 - Stop patients having to repeatedly tell their story dcccxli.

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- 790. The NHS Scotland Directors of Pharmacy^{dcccxlii} called for investment in linking up data to be fully accessible to all professionals who needed it and suggested this should be linked to the national digital platform and owned by the patient.
- 791. We heard from both health boards and pharmacy that the absence of a joined up system between community pharmacy and the NHS "constrains clinical and cost effectiveness" and impairs the ability of pharmacists to contribute their knowledge and intelligence gathered into patient records. These remain siloed at present where they exist.
- 792. We heard some health boards had already provided community pharmacists with access to records, in particular NHS Greater Glasgow and Clyde^{dcccxliv} said 63% of pharmacists in the board area had access.
- 793. We welcome the Scottish Government's swift move to optimise use of all parts of the system providing health care in Scotland in response to the COVID-19 pandemic. While welcome, these actions have highlighted the necessity for all parts of the health care system in Scotland to be operating based on joined up information and the need for appropriate parts of medical records to be make available to those who require them at the earliest opportunity.
- 794. It is clear to us a comprehensive system of care should include information sharing across all parts of the system and everybody providing patients with medical care and advice should have the requisite details of the patient in order to make evidence-based judgements. This applies equally to all.

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dcccxxviii Company Chemists Association. Written Submission.
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dcccxxix Company Chemists Association. Written Submission.

dcccxxx Health and Sport Committee, Official Report, 4 February 2020, Col 13

dcccxxxi McKesson UK. Written Submission.

dcccxxxii Royal Pharmaceutical Society in Scotland. Written Submission.

dcccxxxiii McKesson UK. Written Submission.

dcccxxxiv McKesson UK. Written Submission.

dcccxxxv Community Pharmacy Scotland. Written Submission.

dcccxxxvi Health and Sport Committee, Official Report, 28 January 2020, Col 47

dcccxxxvii Health and Sport Committee, Official Report, 4 February 2020, Col 4

dcccxxxviii University of Strathclyde. Written Submission.

dcccxxxix Health and Sport Committee, Official Report, 1 October 2019, Col 50

dcccxi Health and Sport Committee, Official Report, 18 February 2020, Col 15

dcccxli Health and Sport Committee, Official Report, 18 February 2020, Col 15

dcccxlii NHS Scotland Directors of Pharmacy. Written Submission.

dcccxliii NHS Ayrshire and Arran. Written Submission.

dcccxliv Health and Sport Committee, Official Report, 4 February 2020, Col 13

Uniform IT and data systems

- 795. The need for uniform and comprehensive systems to collect and use data across Scotland was present strongly to us.
- 796. It will help—
 - · Eradicate duplication of processes;
 - Reduced waste;
 - Accelerate communication across the health system;
 - Reduce errors and improve safety monitoring;
 - Support efficient use of old and new medicines^{dcccxlv};
 - · Improve pricing and help secure better deals for the NHS;
 - Allow for the transfer of care from a secondary to a primary setting;
 - · Optimise use of personalised medicines;
 - Improve economic outcomes dcccxlvi; and
 - · Provide a basis on which to invest or disinvest in medicines.
- 797. Examples were abundant throughout our inquiry of efficient solutions which should be progressing but are not due to multiple IT systems in operation which cannot communicate easily.
- 798. There were calls for a uniform system across the NHS which enabled medical professionals at all levels to access the same information on the same system. We heard NHS Education for Scotland (NES) was currently working on the shared digital platform to link health and social care information, which we were told "cannot come soon enough".
- 799. We note the ambition in the "Achieving excellence in pharmaceutical care: a strategy for Scotland"—
 - "Our focus is on ensuring safe, effective and person-centred pharmaceutical care, and safer use of medicines is a core component of health and social care services in all settings. These settings include care homes and those requiring more care at home. We need to understand the enablers to deliver this which includes identifying the clinical capability and capacity required within the pharmacy workforce, the resources needed to improve IT system interoperability and leverage digital technologies and data and modernising our planning and delivery systems for securing NHS pharmaceutical care services."

Data Scoping Taskforce and the Digital Health and Care Strategy

- 800. The creation of a Data Scoping Taskforce was a recommendation decertian of the Review of Access to Medicines. Its purpose was to—
 - "...determine the digital capabilities required to utilise real-world health data to support the assessment and introduction of new medicines, together with ensuring the on-going safe, effective use of established medicines".
- 801. It made five key recommendations in its September 2018 report dcccl
 - "Capture medicines use for patients in all clinical settings

Include medicine indication in all prescribing systems

Create a national laboratory data resource

Improve recording of patient outcomes

Create a Scottish Medicines Intelligence Unit"dcccli

- 802. Stakeholders were supportive of the recommendations of the report and called for action in several areas to fulfil them—
 - Build on use of the Chemotherapy Electronic Prescribing and Administration System^{dccclii};
 - Invest further in data infrastructures deceliii;
 - Monitoring of prescribed treatment regimens^{dcccliv};
 - Tracking uptake of new treatments dccclv;
 - Collecting information and examining the variation across boards^{dccclvi} and across conditions^{dccclvii}; and
 - Collecting information on why medicines are prescribed dccclviii.
- dcccxlviii Scottish Government (2017). Achieving excellence in pharmaceutical care: a strategy for Scotland, page 10
- dcccxlix Scottish Government (2016). Review of Access to New Medicines
 - dcccl Scottish Government (2018). Medicines Use and Digital Capabilities: Building Capability to assess real world benefits, risks and value of medicines Towards a Scottish Medicines Intelligence Unit,
 - dcccli Scottish Government (2018). Medicines Use and Digital Capabilities: Building Capability to assess real world benefits, risks and value of medicines Towards a Scottish Medicines Intelligence Unit, Page 3
 - dccclii Cancer Research UK. Written Submission.
- dcccliii Cancer Research UK, Written Submission.
- dcccliv Cancer Research UK. Written Submission.
- dccclv Cancer Research UK. Written Submission.

803. In January 2020, the Cabinet Secretary for Health and Sport, Jeane Freeman, told told us the Scottish Government were considering a number of the recommendations as part of the implementation of the Health and Care Digital Strategy. That strategy was established in 2018 to deliver a National Digital Platform to provide the infrastructure, products and services to allow health and care technology to be delivered, managed and consumed in Scotland.

Scotland's Digital Health and Care Strategy

- 804. The Digital Health and Care Strategy also states the platform will allow for—
 - "Information capture and access at point of contact providing up-to-date high quality and timely role based, secure access to multiple specialist health and care information and knowledge sources, which is essential and fundamental to enabling excellent care, supporting staff, empowering citizens and enabling self-care."
- 805. In May 2019, we received an update on development of the National Digital Platform (NDP) which included—
 - Live testing of the platform was about to begin in NHS Greater Glasgow and Clyde and NHS Forth Valley in May 2019. Although, not all access would be read/write access;
 - Only clinicians would have access in the pilots; and
 - The national digital platform will communicate with "multiple historical systems".
- 806. As discussed in the SHARING OF MEDICAL RECORDS section of this report, we agree with the previous Cabinet Secretary for Health and Sport that interoperability across health and social care, including the community care sector, hospices and prisons, is absolutely essential and fundamental "dccclxii" and that all health professionals, be they working for the NHS or otherwise, who require access to records should have it and this must include involvement at the testing phase. We were disappointed to learn only clinicians were involved in pilots.
- 807. We are in no doubt the piecemeal approach to procurement of IT systems, such as has been the case with HEPMA, on a board by board basis across Scotland, is unhelpful and each board must be required to operate from the same systems.

dccclvi Cancer Research UK. Written Submission.

dccclvii Janice Birrell. Written Submission.

dccclviii Royal College of Psychiatrists. Written Submission.

dccclix Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, on the Review of Access to New Medicines, 13 January 2020

dccclx Scottish Government (2018). Scotland's Digital Health and Care Strategy: enabling, connecting and empowering, Page 16

dccclxi Letter from the Cabinet Secretary for Health and Sport, Jeane Freeman, on technology and innovation in health and social care, 23 May 2019

dccclxii Letter from Cabinet Secretary for Health and Sport, Shona Robison, in response to the Committee's inquiry on Technology and Innovation in Health and Social Care, 8 June 2018

Data Ownership

808. The Committee's view on who owns the patients' data has been clear and consistent through a number of recent inquiries; patient data belongs to the patient.

Technology for the medicines of the future

- 809. Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government, emphasised decelviii the need for "appropriate IT and data" to "cope" with the medicines of the future. Alison Culpan of the Association of the British Pharmaceutical Industry (ABPI) decelviv and the University of Strathclyde decelviv agreed, with the latter noting achieving such systems of data collection was too much for one company or group to achieve alone and that Government support and incentives would be required.
- 810. We are of the view it is important to ensure the IT solutions proposed are fit for the revolutionised healthcare delivery that is coming and coming quickly.

Outcomes

- 811. The importance of collecting data on patient outcomes has been emphasised throughout this report.
- 812. Many have called for outcomes data from medicines to be collected to support evidence based prescribing and to eradicate waste by ensuring only the most effective drugs were used for patients in the first instance. The differences between outcomes achieved in clinical trials and those experienced in 'real-world' scenarios is important beyond being able to achieve innovative and cost effective pricing.
- 813. Cost effectiveness cannot be properly assessed without information on outcomes. This includes an understanding of the impact on patients.
- 814. The pharmaceutical industry rely on outcomes data to improve products and innovation in the Government's pricing arrangements similarly leant on such data.

Outcomes data for research, development, purchasing and procurement - Cancer Medicines Outcome Programme

815. The programme is a collaboration between NHS Greater Glasgow and Clyde and the University of Strathclyde to assess the impact on cancer patients of medicines in real-world settings and was being considered across different populations around

dccclxiii Health and Sport Committee, Official Report, 21 January 2020, Col 14

dccclxiv Health and Sport Committee, Official Report, 21 January 2020, Col 26

dccclxv University of Strathclyde. Written Submission.

- the country^{dccclxvi}. We understand^{dccclxvii} the scalability of the project across other clinical areas was being considered.
- 816. We would welcome further details on the timescales for this.
- 817. The Cabinet Secretary for Health and Sport, Jeane Freeman decolarii, also told us of other programmes to collect data based on patient experiences with cancer medications such as the Systematic Anti-Cancer Therapy (SACT) through ChemoCare system. On SACT she added a common approach for consent would be taken forward in early 2020 and data from the scheme was expected to be nationally available next year and be integrated with the New Scottish Cancer Registry and Intelligence Service.
- 818. We were pleased to learn an internal working group "to identify and prioritise a programme of work specifically in relation to improving data collection on medicines' uses and outcomes, that will complement and support the overall objectives of the Health and Care Digital Strategy" has been established.
- 819. We are pleased to hear of the Cancer Medicines Outcome Programme and suggest this model should be rolled out across the NHS and for other ailments. The pharmaceutical industry should be involved in this work.
- 820. We ask the Scottish Government to provide details of the remit and work programme for the working group, including timescales for delivery and how it intends to bring together all the various projects taking place on data collection.
- 821. We also ask for detail on how the work of the internal working group on medicines will link with work on the National Digital Platform and the Health and Social Care Digital Strategy.

Prescribing

- 822. Throughout this inquiry we were surprised to learn how little evidence gathering of outcomes and effectiveness takes place. Yet the importance of data to support prescription decision making was emphasised to us from many parties.
- 823. The Royal College of GPs, who support annual awards with a focus on research and innovation in primary care, spoke about databases which included information linking interventions and outcomes, but noted the information and research in this area was not systematic or comprehensive. It was generally undertaken when investment was available with a view to publication.

dccclxvi Health and Sport Committee, Official Report, 21 January 2020, Col 6

- dccclxvii Letter from Rose Marie Parr, Chief Medical Officer on Supply and Demand for Medicines, 26 February 2020
- dccclxviii Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 13 January 2020
- dccclxix Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 13 January 2020

The Royal College of Psychiatrists also said decclar there needed to be better monitoring of deviation from standard models of care, and while acknowledging such activity was inevitable, saying a better understanding of those who did not respond to standard models of care or common medicines was required. They emphasised decclar the need for data collection to be at no extra burden to the clinician.

Consumption

- 825. Matt Barclay of Community Pharmacy Scotland told decclexii us some data on medicine use, along with adverse events, are probably haphazardly captured throughout the system, but not in any routine way.
- 826. We believe information on how patients are using medicines once dispensed is essential and this should be collected in a comprehensive and routine fashion.

Data and IT - conclusions

- 827. We are not surprised by the prominence of data and IT over the course of our work on medicines as it has been a recurring theme in most of our inquiries throughout the last four years. In particular, one of the two central pillars of our 2018 inquiry into technology and innovation in health and social care was "use of technology to transform the way medicine is practiced and delivered to patients".
- 828. What we await to hear is how that will be achieved comprehensively and uniformly across the NHS in Scotland.
- 829. We ask the Scottish Government to reflect on why the sharing of medical records through the Emergency Care Summary suddenly became possible when COVID-19 struck and to make arrangements to extend access to health records to all health professionals who require them to ensure health care provision is as clinically and cost effective as possible. We request a date when this will be achieved.
- 830. We ask the Scottish Government in its response to this report to include—
 - full detail, including timescales, of the "programme of work" to improve data collection on medicines use and outcomes in Scotland.

dccclxx Royal College of Psychiatrists. Written Submission.

dccclxxi Royal College of Psychiatrists. Written Submission.

dccclxxii Health and Sport Committee, Official Report, 28 January 2020, Col 8

dccclxxiii Health and Sport Committee. 1st Report, 2018 (Session 5). *Technology and innovation in health and social care*, Page 2

dccclxxiv Letter from the Cabinet Secretary for Health and Sport on the Review of Access to New Medicines, 13 January 2020

- A progress update on delivering the Health and Care Digital Strategy, including timescales for implementation of the "national digital platform"^{dccclxxv} and how the "programme of work"^{dccclxxvi} will integrate with this.
- 831. We recommend all those with a role in delivering health and social care in Scotland have appropriate access to the national digital platform and again seeks timescales for how rapidly such access will be granted.
- 832. We recommend the Scottish Government provide detail of its influence on areas of research which would be beneficial in developing functioning outcomes gathering systems and how it supports/persuades other organisations to do the same.
- 833. We recommend the Scottish Government establish a means of collecting information on medicine use by patients.

Glossary

Definition of terms

Community Health Index number

"The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index" dccclxxviii.

End-of-Life Medicine

"A medicine used to treat a condition at a stage that usually leads to death within 3 years with currently available treatments." dccclxxviii

General Medical Services Contract (GMS)

The General Medical Services Contract is negotiated between the Scottish Government and the British Medical Association and sets out what will be delivered by general practitioners (who are self employed) in Scotland.

National Therapeutic Indicators

"National Therapeutic Indicators (NTIs) and Additional Prescribing Measures (APMs) use prescription data to provide a measure of prescribing activity in specified therapeutic areas and a comparison across the GP practices in Scotland, Health Boards within Scotland and GP practices within these Health Boards. These are then made available to Health Boards, Health and Social Care Partnerships, GP practice clusters and GP practices for use in quality improvement initiatives and medicines management work. The relevant NTIs and APMs are included in the national prescribing strategy documents for Polypharmacy, Diabetes, Respiratory Medicine and Chronic Pain. They complement the national Realistic Medicine agenda and the Scottish Patient Safety Programme for Primary Care."

Orphan Medicine

"A medicine with European Medicines Agency (EMA) designated orphan status (i.e. conditions affecting fewer than 2,500 people in a population of 5 million) or a medicine to treat an equivalent size of populations irrespective of whether it has designated orphan status."

Patient Access Schemes

"Companies can submit Patient Access Schemes (PAS) to improve the cost effectiveness of a medicine. The Patient Access Scheme Assessment Group (PASAG) reviews and

dccclxxvii ISD Scotland - https://www.ndc.scot.nhs.uk/Data-Dictionary/SMR-Datasets/Patient-Identification-and-Demographic-Information/Community-Health-Index-Number/

dccclxxviii Scottish Government (2016). Review of Access to New Medicines

dccclxxix Scottish Government (2017). National Therapeutic Indicators and Additional Prescribing
Measures 2017/18 - Early Release Document

dccclxxx Scottish Government (2016). Review of Access to New Medicines

advises NHSScotland on the feasibility of proposed schemes for implementation. It operates separately from SMC to maintain the integrity of the assessment process."

Patient and Clinician Engagement (PACE) process

"For medicines used to treat end of life and/or rare conditions, the Scottish Medicines Consortium (SMC) offers the submitting company the opportunity to request a Patient and Clinician Engagement (PACE) meeting which gives patient groups and clinicians a stronger voice in SMC decision making."

Peer Approved Clinical System (PACS) Tier Two

"Clinicians (on behalf of their patients) can ask a Peer Approved Clinical System (PACS) Tier Two Panel within their NHS board whether they can access a medicine that has not been recommended by the Scottish Medicines Consortium and is therefore not routinely available in the NHS in Scotland. New Scottish Government guidance has now been issued which means that, in the event where a requesting clinician and patient feel they have grounds for a review of the local decision, the clinicians (on behalf of patients) are now able to ask for the decision to be referred to the National Review Panel. This replaces each NHS board's local appeal process."

Pharmaceutical Pricing Regulation Scheme (PPRS)

"This voluntary scheme has been in place for over 50 years and helps to provide the pharmaceutical industry and the Government with a stable environment to introduce medicines into the NHS, making sure patients can get access to the newest, most effective treatments available, while helping to sustain a thriving UK pharmaceutical industry. A voluntary scheme has been negotiated every five years, with the next scheme due to start in January 2019. The current PPRS – negotiated in 2014 at a time of austerity in the UK – sought to cap the growth of NHS spend on branded medicines at an agreed rate, with any overspend paid back to the NHS. This was to provide stability of spend to the NHS and offer an incentive to use new medicines at no extra cost."

Pharmacotherapy

The new General Medical Services contract includes provision for pharmacists to be located within GP surgeries, known as pharmacotherapy.

Polypharmacy

"...the concurrent use of multiple medications by one individual."

Quality Adjusted Life Year (QALY)

dccclxxxi Scottish Medicines Consortium Patient Access Schemes

dccclxxxii Scottish Medicines Consortium Patient and Clinician Engagement (PACE) Meetings
Overview

dccclxxxiii Healthcare Improvement Scotland. Peer Approved Clinical System (PACS) Tier Two dccclxxxiv Assocation of the British Pharmaceutical Industry. Pharmaceutical Pricing Regulation Scheme.

dccclxxxv The Kings Fund (2013). *Polypharmacy and medicines optimisation: Making it safe and sound*

Health and Sport Committee

Supply and demand for medicines, 6th Report, 2020 (Session 5)

"The health economics tool used to measure the benefit of a medicine is the quality-adjusted life year (QALY). This takes into account how a treatment affects a patient's quantity of life (how long they live for) and the quality of life (the quality of their remaining years of life). These factors are then combined into a single measure that puts a figure on the health benefits for a medicine. The resulting QALY can then be used to benchmark the benefits each medicine is likely to offer. Then, to consider the cost effectiveness of the medicine, the QALY is combined with the cost of the medicine to produce a ratio called the cost per QALY."

Quality and Outcomes Framework (QOF)

Audit Scotland describe this as-

"...a voluntary incentive scheme for GPs which uses financial incentives to encourage high quality care. The QOF has had considerable influence on the way GPs work, including their prescribing. For example, it includes targets for managing particular conditions, such as hypertension, which have an effect on prescribing."

Repurposing

"Repurposing" is a concept used to describe a new use for an existing medicine which is already licensed for another treatment indication(s). The new use will usually be supported by some level of clinical data, and this may or may not, be planned to be submitted to a competent regulatory authority for licensing. In cases where the data is submitted to a regulator and is approved, the medicine will be granted a licence extension for that use as a new treatment indication."

Scottish Drug Tariff

"The Drug Tariff is published on behalf of Scottish Ministers. It sets out the rates payable for the provision of pharmaceutical services, the way in which reimbursement is calculated for drugs (both generic and proprietary products) and appliances supplied and it lists those appliances which are approved for supply."

The Scottish Drug Tariff^{dcccxc} is published by ISD Scotland.

Scottish Intercollegiate Guidelines Network (SIGN)

"The Scottish Intercollegiate Guidelines Network (SIGN) aims to improve the quality of healthcare for patients in Scotland by reducing variation in practice and outcomes through the development of national clinical guidelines. These guidelines provide evidence-based recommendations on the management of common conditions, including the use of medicines."

dccclxxxvi Health and Sport Committee. 8th Report, 2013 (Session 4). Access to New Medicines (SP Paper 378)

decelxxxviii Audit Scotland (2013). Prescribing in general practice in Scotland, page 3

for Medicines following 21 January 2020 meeting, 26 February 2020

dccclxxxix Community Pharmacy Scotland. The Scottish Drug Tariff

dcccxc ISD Scotland. The Scottish Drug Tariff

dcccxci Healthcare Improvement Scotland. Written Submission

cccxci Healthcare Improvement Scotland. Wr

Ultra-Orphan Medicine

"To be considered as an ultra-orphan medicine all criteria listed should be met—

- the condition* has a prevalence of 1 in 50,000 or less in Scotland,
- the medicine has an EMA orphan designation for the condition and this is maintained at time of marketing authorisation,
- · the condition is chronic and severely disabling, and
- the condition requires highly specialised management.
- * SMC uses the description of the condition within the European Medicines Agency's (EMA) Orphan Maintenance Assessment Report (OMAR) as a reference (or the description within the original orphan designation if the OMAR is not available).

Submissions for medicines that are validated as ultra-orphan according to this definition will be assessed by SMC and will then be available to prescribers for a period of up to three years while further clinical effectiveness data are gathered. After this period the company will be asked to provide an updated submission for reassessment and SMC will make a decision on routine use of the medicine in NHSScotland."

Voluntary Patient Access Scheme (VPAS)

"VPAS ensures the annual spend on branded medicines can increase by a maximum of two percent every year. Anything over this increase is repaid by industry to the NHS."

Acronyms

Acronym	Meaning
ABPI	Association of the British Pharmaceutical Industry
СМОР	Cancer Medicines Outcome Programme
GMS contract	General Medical Services contract
HEPMA	Hospital Electronic Prescribing and Administration
HTA	Health Technology Assessment
IPTR	Individual Patient Treatment Request
NICE	National Institute for Health and Care Excellence
MHRA	Medicines and Healthcare products Regulatory Agency
MCR	Medicines Care Review
ОТ	Occupational Therapist
PACS	Peer Approved Clinical System
PACS T2	Peer Approved Clinical System Tier 2
PAS	Patient Access Schemes
PASAG	Patient Access Scheme Assessment Group
PPRS	Pharmaceutical Pricing Regulation Scheme
QALY	Quality Adjusted Lift Year
QOF	Quality and Outcomes Framework
SNF	Single National Formulary
SMC	Scottish Medicines Consortium
STAMP	European Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)
VPAS	Voluntary Patient Access Scheme

Annexe A - Minutes of Meetings

18th Meeting, 2020 (Session 5) Tuesday 23 June 2020

7. Supply and demand for medicines inquiry (in private): The Committee considered and agreed a draft report.

17th Meeting, 2020 (Session 5) Wednesday 17 June 2020

4. Supply and demand for medicines inquiry (in private): The Committee considered a draft report. Various changes were agreed to, and the Committee agreed to consider a draft report, in private, at a future meeting.

16th Meeting, 2020 (Session 5) Tuesday 9 June 2020

3. Supply and demand for medicines (in private): The Committee considered a draft report. Various changes were agreed to, and the Committee agreed to consider a revised draft, in private, at a future meeting.

14th Meeting, 2020 (Session 5) Tuesday 2 June 2020

1. Supply and demand for medicines inquiry (in private): The Committee considered a draft report. Various changes were agreed to, and the Committee agreed to consider a revised draft, in private, at a future meeting.

6th Meeting, 2020 (Session 5) Tuesday 10 March 2020

- **1. The supply and demand for medicines inquiry:** The Committee took evidence from—Jeane Freeman, Cabinet Secretary for Health and Sport, Rose Marie Parr, Chief Pharmaceutical Officer, Alison Strath, Principal Pharmaceutical Officer, Bryan Lamb, Head of Pharmacy Branch, and Alpana Mair, Head of Effective Prescribing and Therapeutics, Scottish Government.
- **3. The supply and demand for medicines inquiry (in private):** The Committee considered the evidence heard earlier in the meeting.

4th Meeting, 2020 (Session 5) Tuesday 18 February 2020

- 1. The supply and demand for medicines inquiry: The Committee took evidence from—
 - · Adam Stachura, Head of Policy and Communications, Age Scotland;
 - Claire Fernie, Public Partner Volunteer, NHS Fife;

and then from—

- Dr David Shackles, Executive Officer for Interface and Out of Hours, Royal College of General Practitioners Scotland;
- Adam Osprey, Policy and Development Pharmacist, Community Pharmacy Scotland;
- Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland, Chair, Royal Pharmaceutical Society, Scottish Pharmacy Board;

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- Dr Sheuli Porkess, Executive Director of Research, Medical and Innovation, The Association of the British Pharmaceutical Industry;
- Graeme Bryson, Director of Pharmacy, NHS Dumfries and Galloway.
- **3. The supply and demand for medicines inquiry (in private):** The Committee considered the evidence heard earlier in the meeting.

3rd Meeting, 2020 (Session 5) Tuesday 4 February 2020

- 1. The supply and demand for medicines inquiry: The Committee took evidence from— Professor Angela Timoney, Director of Pharmacy, NHS Lothian;
- · Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde;
- Campbell Shimmins, Community Pharmacist, Forth Valley, Community Pharmacy Scotland;
- Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland.
- **2.** The supply and demand for medicines inquiry (in private): The Committee considered the evidence heard earlier in the meeting.

2nd Meeting, 2020 (Session 5) Tuesday 28 January 2020

- 1. The supply and demand for medicines inquiry: The Committee took evidence from—
 - Dr Ewan Bell, National Clinical Lead, Area Drug and Therapeutics Committee Collaborative, Healthcare Improvement Scotland;
 - Matt Barclay, Director of Operations, Community Pharmacy Scotland;
 - Dr Scott Jamieson, Royal College of General Practitioners; David Coulson, Assistant Director of Pharmacy, NHS Tayside;
 - Eileen McKenna, Associate Director Professional Practice, Royal College of Nursing Scotland;
 - Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland;
 - Lewis Morrison, Chair of BMA Scotland, British Medical Association.
- **3. The supply and demand for medicines inquiry (in private):** The Committee considered the evidence heard earlier in the meeting.

1st Meeting, 2020 (Session 5) Tuesday 21 January

- 1. The supply and demand for medicines inquiry: The Committee took evidence from—
 - Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government;
 - Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of Health and Social Care, UK Government;

- Jonathan Mogford, Director of Policy, Medicines and Healthcare products Regulatory Agency;
- Alison Culpan, Scotland Director, The Association of the British Pharmaceutical Industry;
- Warwick Smith, Director General, British Generic Manufacturers Association; Martin Sawer, Executive Director, Healthcare Distribution Association;
- Dr Alan MacDonald, Chair, Scottish Medicines Consortium;
- Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland;
- Matt Barclay, Director of Operations, Community Pharmacy Scotland;
- Dr Brian Montgomery, Author of the Review of Access to New Medicines.
- **2.** The supply and demand for medicines inquiry (in private): The Committee considered the evidence heard earlier in the meeting.

21st Meeting, 2019 (Session 5) Tuesday 24 September 2019

5. Medicines Inquiry (in private): The Committee considered and agreed its approach to the inquiry.

17th Meeting, 2019 (Session 5) Tuesday 25 June 2019

7. Medicines Inquiry (in private): The Committee considered its approach to the inquiry.

Annexe B

Written Submissions

The Committee received the following written submissions on the inquiry -

- 001 Barbara Robertson
- 002 Henry Robb
- 003 Nico Grunenberg
- 004 Munro Stewart
- 005 Judith Pinnick
- 006 Janice Birrell
- · 007 Royal College of Physicians of Edinburgh
- 008 Royal College of General Practitioners Scotland
- 009 Community Pharmacy Scotland
- 010 Chiesi Ltd
- 011 British Dental Association
- 012 NHS Scotland Directors of Pharmacy
- 013 NHS Fife ADTC
- 014 NHS Grampian ADTC
- 015 Cancer Research UK
- 016 Royal College of Occupational Therapists
- 017 Dr Jo Huckley, Dr Susan Shenkin and Anne Wilson
- 018 Angus O'Henley
- 019 European Medicines Group
- 020 Janssen
- 021 NHS Ayrshire & Arran
- 022 AstraZeneca
- 023 Healthcare Improvement Scotland
- · 024 NHS Borders
- 025 Prostate Cancer UK

- 026 Merck Sharp & Dohme UK
- 027 Celgene
- 028 Royal College of Nursing
- 029 Company Chemists' Association
- · 030 Royal Pharmaceutical Society
- 031 Kyowa Kirin International
- 032 McKesson UK
- · 033 University of Strathclyde
- 034 BMA Scotland
- 035 Teva UK Limited
- 036 Royal College of Psychiatrists
- 037 National Pharmacy Association Ltd
- 038 Roche Products Ltd
- 039 One Health Breakthrough Partnership
- 040 Dr Karen Helwig
- 041 Pfizer UK
- 042 Association of the British Pharmaceutical Industry Scotland
- 043 Blood Cancer Alliance
- 044 Omnicell
- · 045 MS Society Scotland
- 046 NHS Tayside
- 047 AbbVie
- 048 Bristol-Myers Squibb
- 049 Scottish Care
- 050 Christine Jardine
- 051 NHS Chief Executives Group, NHS Scotland
- 052 NHS Lothian ADTC
- 053 Daiichi-Sankyo UK
- 054 British Generics Manufacturers Association

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- · 055 Royal Society of Edinburgh
- 056 Children's Hospices Across Scotland
- 057 Elaine Smith MSP
- 058 NHS National Services Scotland
- Anonymous submission
- Updated submission Omnicell

Supplementary Evidence

The Committee received supplementary evidence.

- Roche Products Ltd
- Jonathan Burton, Chair, Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland
- Campbell Shimmins Community Pharmacy Scotland
- Healthcare Distribution Association
- Claire Fernie NHS Fife

Correspondence

- Letter to Jeane Freeman MSP, Cabinet Secretary for Health and Sport from Lewis Macdonald MSP, Convener of the Health and Sport Committee - 13 December 2019
- Letter from Jeane Freeman MSP, Cabinet Secretary for Health and Sport to Lewis Macdonald MSP, Convener of the Health and Sport Committee - 13 January 2020
- Letter from Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of Health and Social Care, UK Government to Lewis Macdonald MSP, Convener of the Health and Sport Committee - 24 January 2020

The Convener issued letters seeking further information following the evidence sessions on 21 January 2020:

- Letter to Alison Culpan, Scotland Director, Association of the British Pharmaceutical Industry - 5 February 2020
- Letter to Warwick Smith, Director General, British Generic Manufacturers Association
 5 February 2020
- Letter to Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government 5
 February 2020
- Letter to Matt Barclay, Director of Operations, Community Pharmacy Scotland 5
 February 2020
- Letter to Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of Health and Social Care, UK Government - 5 February 2020

- Letter to Jonathan Mogford, Director of Policy, Medicines and Healthcare products Regulatory Agency (MHRA) - 5 February 2020
- Letter to Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland - 5 February 2020
- Letter to Dr Alan MacDonald, Chair, Scottish Medicines Consortium 5 February 2020
- Letter to The Rt Hon Priti Patel MP, Secretary of State for the Home Department, Home Office - 6 February 2020

The Convener received the following responses to the above letters:

- Letter from Matt Barclay, Director of Operations, Community Pharmacy Scotland 20 February 2020
- Letter from Lindsay McClure, Associate Director, Medicines Pricing and Supply, NHS National Services Scotland - 24 February 2020
- Letter from Elizabeth Woodeson, Director of Medicines and Pharmacy, Department of Health and Social Care, UK Government - 26 February 2020
- Letter from Alison Culpan, Scotland Director, Association of the British Pharmaceutical Industry - 26 February 2020
- Letter from Rose Marie Parr, Chief Pharmaceutical Officer, Scottish Government 26 February 2020
- Letter from Dr Alan MacDonald, Chair, Scottish Medicines Consortium 26 February 2020
- Letter from Warwick Smith, Director General, British Generics Manufacturers Association - 26 February 2020
- Letter from the Minister of State for Crime and Policing 3 March 2020
- Letter from Jonathan Mogford, Director of Policy, Medicines and Healthcare products Regulatory Agency (MHRA) - 4 March 2020

The Convener issued letters seeking further information following the evidence sessions on 28 January and 4 February 2020:

- Letter to Matt Barclay, Director of Operations, Community Pharmacy Scotland 17 February 2020
- Letter to John Burns, Chief Executive, NHS Ayrshire and Arran 17 February 2020
- Letter to Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde 17 February 2020
- Letter to Professor Angela Timoney, Director of Pharmacy, NHS Lothian 17 February 2020
- Letter to David Coulson, Assistant Director of Pharmacy, NHS Tayside 17 February 2020

Supply and demand for medicines, 6th Report, 2020 (Session 5)

- Letter to Dr Scott Jamieson, Royal College of General Practitioners 17 February 2020
- Letter to Jonathan Burton, Chair of the Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland - 17 February 2020

The Convener received the following responses to the above letters:

- Letter from Gail Caldwell, Director of Pharmacy, NHS Greater Glasgow and Clyde 28 February 2020
- Letter from David Coulson, Assistant Director of Pharmacy, NHS Tayside 2 March 2020
- Letter from Professor Angela Timoney, Director of Pharmacy, NHS Lothian 2 March 2020
- Letter from Dr Scott Jamieson, Royal College of General Practitioners 2 March 2020
- Letter from Matt Barclay, Director of Operations, Community Pharmacy Scotland 3 March 2020
- Letter from John Burns, Chief Executive, NHS Ayrshire and Arran 3 March 2020

The Convener issued letters seeking further information following the evidence session on 18 February 2020:

- Letter to Dr Sheuli Porkess, Executive Director of Research, Medical and Innovation, Association of the British Pharmaceutical Industry - 28 February 2020
- Letter to Adam Stachura, Head of Policy and Communications, Age Scotland 28
 February 2020
- Letter to Nicola Cotter, Head of GMC Scotland (General Medical Council) 28
 February 2020
- Letter to Dr David Shackles, Executive Officer for Interface and Out of Hours, Royal College of General Practitioners - 28 February 2020
- Letter to Jonathan Burton, Chair of the Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland - 28 February 2020

The Convener received the following responses to the above letters:

- Letter from Dr Sheuli Porkess, Executive Director of Research, Medical and Innovation, Association of the British Pharmaceutical Industry - 4 March 2020
- Letter from Nicola Cotter, Head of GMC Scotland (General Medical Council) 4 March 2020
- Letter from Dr David Shackles, Executive Officer for Interface and Out of Hours, Royal College of General Practitioners - 9 March 2020
- Letter from Jonathan Burton, Chair of the Scottish Pharmacy Board, Royal Pharmaceutical Society in Scotland - 25 March 2020

Following the Cabinet Secretary for Health and Sport's evidence session on 10 March 2020, the Convener issued a letter seeking further information on a number of points:

 Letter to Jeane Freeman MSP, Cabinet Secretary for Health and Sport from Lewis Macdonald MSP, Convener of the Health and Sport Committee - 23 March 2020

Official reports

- Tuesday 10 March 2020 Evidence from the Cabinet Secretary for Health and Sport
- Tuesday 18 February 2020 Evidence from stakeholders
- Tuesday 04 February 2020 Evidence from stakeholders
- Tuesday 28 January 2020 Evidence from stakeholders
- Tuesday 21 January 2020 Evidence from stakeholders

Annexe C

Core and additional pharmacotherapy services Scottish Government (2017). The 2018 General Medical Services Contract in Scotland, Page 31

	Pharmacists	Pharmacy Technicians
Level one (core)	Authorising/actioning ^{dcccxciv} all acute prescribing requests	Monitoring clinics
	Authorising/actioning all repeat prescribing	 Medication compliance reviews (patient's own home) Medication management advice and reviews (care homes) Formulary adherence
	 Authorising/actioning hospital Immediate Discharge Letters 	
	Medicines reconciliation	Prescribing indicators and audits
	Medicine safety reviews/recalls	3
	Monitoring high risk medicines	
	Non-clinical medication review Acute and repeat prescribing requests includes/ authorising/actioning—	
	hospital outpatient requests	
	non-medicine prescriptions	
	installment requests	
	serial prescriptions	
	Pharmaceutical queries	
	Medicine shortages	
	 Review of use of 'specials' and 'off-licence' requests 	
Level two (additional - advanced)	Medication review (more than 5 medicines)	Non-clinical medication review
advanoca)	Resolving high risk medicine problems	Medicines shortage
		Pharmaceutical queries
Level three (additional - specialist)	 Polypharmacy reviews: pharmacy contribution to complex care 	Medicines reconciliation
. ,	Specialist clinics (e.g. chronic pain, heart failure)	Telephone triage

dcccxciv "Pharmacist Independent Prescribers can action (instigate and sign) prescriptions, non-prescriber pharmacists can action prescriptions but they still require to be signed by a prescriber." Scottish Government (2017). The 2018 General Medical Services Contract in Scotland, Page 31

