

# Scottish Government Response to the Health and Sport Committee Inquiry into the Supply and Demand for Medicines

November 2020



Scottish Government  
Riaghaltas na h-Alba  
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## **Introduction**

1. On 30 June 2020, the Health and Sport Committee published its report<sup>1</sup> on the inquiry into the “Supply and Demand for Medicines”.

2. The report contained 129 recommendations. Recommendations identified in the report varied and included recommendations for future action, requests for further information and observations on specific policies. Across the recommendations, there are duplications and repetition. The purpose of this paper is to provide a detailed Scottish Government response to each of the 129 recommendations outlined in the report as requested by the Health and Sport Committee Convener. In addition to responding to the recommendations, we have highlighted where future action, if applicable, will be taken (in bold).

3. Whilst the Scottish Government acknowledges that the report highlights numerous important issues related to the supply and demand for medicines, overall we believe that the report goes far beyond the published remit of the inquiry and contains misunderstandings, inaccuracies and inconsistencies. There are numerous areas highlighted within the report (and at the evidence hearings) that are not within the control of the Scottish Government and remain reserved to the UK Government. We will address these concerns within the context of our responses to the recommendations.

## **Scottish Government response**

### **Executive Summary**

**(Page 2) 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.**

### **Scottish Government response**

4. The Scottish Government does not accept that there is a lack of accountability for improvement and that leaders across the NHS do not propose innovative, coherent and comprehensive solutions. We believe that the Committee’s report unfairly and unjustifiably criticises the leadership of those who gave evidence and those groups they represented. In terms of pharmacy more generally, we have an Achieving Excellence in Pharmaceutical Care Advisory group, led by a Director of Pharmacy, which plans and oversees the implementation of the pharmacy strategy. Similarly, there is an ePharmacy Programme Board, chaired by the Chief Pharmaceutical Officer, which provides oversight to the development of digital services in primary care and the implementation of Hospital Electronic Prescribing and Medicines Administration (HEPMA). Throughout the COVID-19 pandemic the NHS in Scotland has undertaken considerable change to minimise the loss of life, while maintaining access to critical NHS services, including access to medicines. It is the very systems

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<sup>1</sup> <https://sp-bpr-en-prod-cdnep.azureedge.net/published/HS/2020/6/30/Supply-and-demand-for-medicines/HSS052020R6.pdf>

and leadership, which the committee has criticised within the report, which provided the resilience that has ensured that medicines have continued to be provided to patients, effectively, efficiently and safely. Despite the challenges of an increasing global demand for medicines as a result of the COVID-19 pandemic, the NHS in Scotland did not run out of medicines, instead managing supply and demand in immensely challenging circumstances. Health Board leaders sought innovative solutions which not only delivered services in a way that reduced any unnecessary contact with the health service, but also introduced new technology solutions such as video consultations in both secondary and primary care. Our healthcare professionals have been involved in ground breaking research which has resulted in new supportive treatments for COVID-19, and more recently potential vaccines. The team in Healthcare Improvement Scotland involved in the Scottish Medicines Consortium (SMC) have been working with the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE) to rapidly review the evidence on emerging COVID-19 treatments, ensuring rapid adoption. The pharmacy team in National Procurement have worked tirelessly to manage the demands medicines, build a stockpile of intensive care medicines and plan the logistics associated with the distributions of COVID-19 vaccine and associated consumables. It is also worth noting that healthcare is an ecosystem, meaning that some solutions need to be managed in a way that does not destabilise another part of the system – in other words some change requires careful consideration in order to avoid unintended consequences. We will continue to encourage leaders to bring forward innovative ideas and solutions and wherever possible introduce them at pace.

## Research and development

**(Page 11) 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.**

## Scottish Government response

5. We are well placed to support the expansion of personalised medicine. These complex medicines, that target restricted numbers of patients within current disease populations, can be transformative, offering the potential for long term remission or a 'one-off' curative treatment often in areas of unmet need. There are wide-ranging implications as well as some challenges for their managed introduction, which will require a co-ordinated approach across the NHS. Some of these therapies are given as a single treatment, whilst others are highly complex products with regards to their production, administration, adverse event monitoring and handling. Scotland has invested significantly in the development of these advanced therapies (cellular therapies, gene therapies and tissue engineered therapies) over the past 10-15 years through academic research, manufacturing, clinical trials and infrastructure, including the Scottish Centre for Regenerative Medicine. We are participating in Innovate UK's Northern Alliance Advanced Therapy Treatment Centre (ATTC) which includes public

sector and commercial companies in Scotland (University of Edinburgh, NHS Lothian, NHS Greater Glasgow and Clyde, Scottish National Blood Transfusion Service (SNTBS), National Services Scotland and RoslinCT. The Northern Alliance ATTC will work with the other two ATTCs and the Cell and Gene Therapy Catapult to co-ordinate new activity and facilitate large scale pivotal clinical trials leading to Marketing Authorisation, health economics analysis, commissioning and supporting adoption within the healthcare environment. NHS Scotland's National Services Division (NSD) has an important role in commissioning very specialist services where local or even regional commissioning is not appropriate. The services are generally concerned with the diagnosis and/or treatment of rare conditions in order to help patients who need access to treatment or investigation of a very specialised nature. They also manage a number of national financial risk share schemes on behalf of health boards. This results in a funding pool across the country, so that health boards can share the financial impact of any unpredictable expenditure, in respect of the treatment, for very rare conditions that may require a high cost intervention. NSD will have an important role in supporting the implementation of personalised medicines. Taking a national approach will allow improved efficiency and offers a reliable consistent service, whilst also ensuring that available funding is used equitably. It will also reduce unnecessary variation and duplication across Scotland, furthermore, the national approach helps drive a consistent quality of care. The SMC are aware of the developments in personalised medicines and continue to ensure that its assessment takes account of the best available evidence to support its decisions on the clinical and cost effectiveness of such medicines. Across the course of the last year, we have seen the SMC accept two CAR-T preparations for routine use in Scotland. Our work on the refresh of the Digital Health & Care Strategy will help inform the creation of a dedicated Data Strategy for Health & Social Care in Scotland which will help align programmes and projects together, including the national digital platform, to ensure appropriate data capture and linkage.

### **Provision of personalised medicine, including data collection**

<p><b>(Page 11) We recommend the Scottish Government make provision for the use of personalised medicine in the future, including data collection.</b></p>
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### **Scottish Government Response**

6. The Scottish Government is actively supporting the use of personalised medicine. For example, we have funded some work specifically in precision medicine approaches to multiple sclerosis (MS). As part of the £4 million investment in the Precision Medicine Ecosystem, we committed to the Future MS study based in the University of Edinburgh. Scotland has one of the highest rates of MS in the world; an estimated 10,000 people here are living with the condition. When people are newly diagnosed with MS, they do not know what the future will hold. Most people experience occasional bouts of symptoms called 'relapses', but doctors cannot predict how often, and how severe, these relapses will be. There is therefore a pressing clinical need for a tool to enable patients and doctors to predict how a person's MS is likely to progress, and over what timescales. Future MS involves the collection of clinical data and biological samples from recently diagnosed, treatment naïve, relapsing-onset multiple sclerosis patients in order to develop a more personalised approach to clinical management. The project has exceeded its patient recruitment

targets, having enrolled 440 patients from across all the territorial health boards in Scotland. The eventual aim of Future MS is to support the development of a clinical dashboard for MS that will facilitate management of the condition by offering patients and clinicians greater insight into current status and probable progression.

## Licensing

**(Page 16) 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.**

### Scottish Government Response

7. The regulation for the licensing of medicines is currently reserved to the UK Government and is the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA). Before a medicine can be marketed, the manufacturer must be able to demonstrate its safety, quality and efficacy. Applications for a marketing authorisation must include data demonstrating these factors. After detailed assessment and providing the data is satisfactory, a marketing authorisation - sometimes called a licence - may be granted. It is for the MHRA to consider options to encourage and incentivise companies to apply for new marketing authorisations for repurposed medicines.

**(Page 17) 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.**

### Scottish Government Response

8. Despite the reserved nature of medicine licensing processes, the Scottish Government continues to collaborate with the UK Government and other stakeholders in order to encourage this work. It is also important to ensure that the safety, quality and efficacy of a medicine is not compromised in order to fast-track the licensing process. The recently published Independent Medicines and Medical Devices Safety (IMMDS) Review<sup>2</sup> is an essential reminder of the importance of balancing the desire for innovative and fast regulatory processes against the need to maintain a focus on patient safety. We are working closely with the Department of Health and Social Care (DHSC) and the MHRA, as well as the Association of British Pharmaceutical Industry (ABPI) and other key stakeholders across Scotland, to consider the implications of the IMMDS Review, including establishing our own delivery plan on the non-reserved elements. **We will keep the Committee updated on our planned work to address the non-reserved elements of the IMMDS Review.**

The MHRA is developing new regulatory pathways and an overarching licensing framework in response to the end of the EU transition period. Scottish Government

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<sup>2</sup> <https://www.immndsreview.org.uk/>

officials have strengthened their working relationships at official level with the MHRA and continue to work together to ensure appropriate licensing arrangements will be in place. Establishing a strong strategic partnership with the MHRA is critical to ensuring that we understand and influence work undertaken by the agency including but not limited to their remit in the development of new regulatory pathways for medicines. The MHRA is currently leading work that will focus on the linkage between licensing and health technology assessment (HTA) functions. The SMC are actively supporting this work (which is in the developmental stages) and are a member of the core strategic group taking this forward. Within this core strategic group the SMC are considered equal partners alongside the National Institute for Care and Excellence (NICE), enabling the Scottish policy perspective to be included early in developmental changes. Having the SMC represented as an equal partner in the core strategic group alongside MHRA and NICE signals the way in which we want to work with the MHRA across the regulatory portfolio. **We will keep the Committee updated on this work.**

**(Page 16) 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.**

### **Scottish Government Response**

9. As previously stated, the regulation of licensing of medicines is reserved to the UK Government. However, there are other opportunities to use licensed medicines out with their original indication where there is a clinical need, such as off-label use. In response to the Scottish Government strategy *Beating Cancer: Ambition and Action*, an Off-label Cancer Medicines Programme, funded by the Scottish Government and supported by Healthcare Improvement Scotland (HIS), was established to provide advice to Health Board Area Drug and Therapeutics Committees (ADTCs) on the managed entry of off-label uses of cancer medicines. The two year programme is testing and evaluating the principles and methodology to support the production of advice that will maximise both use of off-label cancer medicines (where a medicine is within its patent life) and off-patent cancer medicines, where 'repurposing' a medicine presents opportunities for improving patient outcomes. From initiation until March 2020 the programme team and group has developed and agreed guiding principles to deliver national advice for off-label and off-patent use of cancer medicines that is consistent and meets specific criteria and standards. They have also developed an operational framework and started to test the framework with the assessment of a cancer medicine. By mid-November, the group have reviewed twenty-six proposals and issued twenty-five pieces of advice to NHS Boards, with one proposal having been withdrawn. As part of our response to the COVID-19 outbreak, interim governance arrangements for cancer medicines was issued by the Scottish Government, including oversight of proposed changes to adult Systemic Anti-Cancer Therapy (SACT) practice in the context of COVID-19. The three regional cancer networks worked together to facilitate rapid decision-making and support to ensure consistency in these changes. This was led by the National Cancer Medicines Advisory Group (NCMAG) on a 'Once for Scotland' approach, where possible, to implement these interim changes to practice. The off-label cancer medicines programme team was redirected to support the work of the NCMAG. The agility and collective clinical leadership skills

demonstrated by multi-professionals; participation from all three cancer networks and; access to additional critical appraisal and clinical capacity to meet demand during COVID-19 has been critical to the overwhelming success of this initiative. The valuable and relevant learning from this will be incorporated into the off-label cancer medicines programme. There is scope for using the learning from this programme and applying it to other medicines where there is demand for off-label use.

**(Page 16) 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.**

### **Scottish Government Response**

10. The Scottish Government, through the Chief Scientist Office (CSO), funds research within NHS Scotland. The CSO provides support funding to non-commercial research projects to enable health boards and clinicians to engage, as well as resourcing research infrastructure, for example to enable studies to recruit patients. The CSO also funds proposals from the clinical community in Scotland for new research. This provides patients with the opportunity to access the latest medicines as well as trials involving re-purposed medicines.

**(Page 17) 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.**

### **Scottish Government Response**

11. As noted previously, Scottish Government officials have strengthened their working relationships at official level with the DHSC and the MHRA and continue to work together to ensure appropriate licensing arrangements will be in place. Establishing a strong strategic partnership with the MHRA is critical to ensuring that we understand and influence work undertaken by the agency including, but not limited to, their remit in the development of new regulatory pathways for medicines, and any subsequent impact on the devolved HTA process undertaken by the SMC. The MHRA is currently leading work that will focus on how the new licensing framework and regulatory pathways will interface with HTA functions. The SMC are actively supporting this work and is a member of the core strategic group taking this forward. Within this core strategic group the SMC are considered equal partners alongside NICE, enabling the Scottish policy perspective to be included early in developmental changes. Having the SMC represented as an equal partner in the core strategic group alongside MHRA and NICE signals the way in which we want to work with the MHRA across the regulatory portfolio. It is also important in that it ensures that Scotland doesn't fall behind other parts of the UK from an HTA perspective.

## Access to new medicines

**(Page 22) 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.**

### Scottish Government Response

12. We do not believe that there is a problem with the speed of the SMC's HTA process. It provides a clear and consistent route for licensed medicines to be appraised to determine whether a medicine should be accepted for routine use in the NHS in Scotland. Following receipt of a submission by the manufacturer, the SMC appraises medicines independently of Ministers and the Scottish Parliament, which is important because it means decisions on whether to accept newly licensed medicines are based on clinical and cost-effectiveness at a national population level for all Scotland. This is done within an eighteen to twenty four week window depending on whether there is the requirement to hold a Patient and Clinician Engagement (PACE) meeting. The SMC has an international reputation as one of the fastest HTA processes globally and is certainly faster than any UK equivalents. In addition, the SMC's Patient and Clinician Engagement (PACE) process has attracted interest from Health Technology Assessment (HTA) bodies internationally as an innovative approach to better understanding what really matters to patients.

**(Page 22) 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.**

### Scottish Government Response

13. It is worth noting that it is for individual companies to determine whether they submit a medicine for consideration by the SMC. We believe that Scottish Government reforms and investment over recent years have significantly increased access to new medicines. The SMC has made a series of changes to the way that new medicines are considered for routine population use in Scotland that mean more medicines are made available, particularly for rare, very rare and end of life conditions. This includes the introduction of a new ultra-orphan pathway and an interim acceptance option. In addition, we have introduced improved processes for the consideration of individual medicines that have not been approved for population use by the SMC such as the Peer Approved Clinical System (PACS). These are all incentives for companies to submit to the SMC.

**(Page 26) We recommend the Scottish Government provide details of how it will reduce inconsistency in the application of PACS Tier 2.**

### **Scottish Government Response**

14. The Scottish Government does not believe that there is evidence of inconsistency in the application of the Peer Approved Clinical System (PACS) Tier Two process. However, we committed to and, have undertaken, a six and twelve month review, which allows us to further refine the process based on experience of applying it in the real world. As the committee will be aware, the PACS Tier Two process provides an opportunity for doctors to, on a 'case by case' basis for individual patients, request the use of a licensed medicine under particular sets of circumstances. The national guidance sets out the process and aims to provide greater consistency across the country in the application of the process by ensuring that health boards apply the same principles. The process includes refreshed decision making criteria and the introduction of a National Review Panel. The PACS Tier Two process will never guarantee the same decision, and it was never designed with the intention to achieve that. Each decision is individual to each patient and their particular circumstances. Applying a consistent approach to different individuals will result in individual decisions.

**(Page 26) 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.**

### **Scottish Government Response**

15. We have undertaken a six and twelve month review of the PACS Tier Two process and we are currently considering the findings and any potential improvements to the current guidance. This work has been delayed as a result of COVID-19 but **the Committee will be updated on the review findings and planned next steps in spring 2021.** As part of the review of the PACS Tier Two process, we received feedback about the budget impact and opportunity cost of greater access to new medicines, in the context of PACS Tier Two and in general. We are considering these issues as part of any further enhancements to the PACS process. However, we are not in a position to be able to identify the costs of PACS Tier Two medicines at this point in time or to undertake comparisons with spend under the previous Individual Patient Treatment Requests (IPTR) systems. The collection of this data is complex; for example, sometimes a medicine prescribed through PACS for one indication may already be available for routine use in a different patient cohort. **We will be discussing with Public Health Scotland what might be possible in terms of the data we currently collect on PACS Tier two medicines,** but there may be some limitations to what can be published in order to ensure a patient cannot be identified from the data. This is, however, something that may be possible in the future as we implement HEPMA and other digital solutions. **We will update the committee on any future reporting arrangements for this data.**

**(Page 27) 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.**

### **Scottish Government Response**

16. The PACS guidance clearly outlines the role of key stakeholders in the PACS Tier One and Tier Two process. As set out in the guidance, the Area Drug and Therapeutics Committee Collaborative (ADTCC) is responsible for ensuring that an ongoing review and development of the PACS Tier Two paperwork is carried out and provides relevant best practice statements as appropriate. The ADTCC ensure that there is a consistent process applied across all NHS Health Boards to consider medicines which are non-submissions or have not yet been submitted to the SMC. The PACS Tier Two guidance does not specifically describe the role of Directors of Pharmacy or other senior leaders it does advise that in establishing a PACS Tier Two Panel, health boards should ensure that the panel is clinically composed and include appropriate senior medical and pharmacist perspectives. It also states that the individuals involved in the PACS Tier Two Panel should be fully conversant with the NHS Board policies on PACS Tier Two. In addition, HIS will notify the Chief Executive, Medical Director and Director of Pharmacy in the relevant NHS Health Board when an application for a PACS Tier Two review has been made.

**(Page 29) We recognise it is still early days for the new definitions and pathways and request the Scottish Government publish reports on evaluations**

### **Scottish Government Response**

17. As noted previously, **we have committed to publishing the findings of the six and twelve month reviews of the PACS Tier 2 process** which replaced IPTR. This is equally applicable to the new ultra-orphan pathway. We are mindful that the regulatory framework for medicines will undergo significant changes in the coming months following our departure from the EU and as such we will be considering all pathways and process in due course. Additionally, we remain fully committed to improving the efficiencies and effectiveness of our current working practices (regardless of formal reviews).

**(Page 32) We request detail of how and the planned timescale in which the Scottish Medicines Consortium processes [in relation to horizon scanning] will be reviewed and updated to accommodate innovations in medicines.**

### **Scottish Government Response**

18. The SMC produce an annual horizon scanning report, *Forward Look*, each October. *Forward Look* reports feature medicines expected to have actual / anticipated UK launch date between July of the year the report was published and June of the following year with the potential to have a high net impact on the drug budget and/or significant implications for service delivery. The report is accompanied by a set of financial spreadsheets that can be adapted locally as required and are used in conjunction with the *Forward Look* report. The spreadsheets include an estimate of

uptake of the new medicine in the target population and the corresponding potential budget impact in year 1 and at steady state. The budget impact estimates take account of the anticipated costs and savings associated with the new medicine; for example, this might involve offsetting the costs of a displaced medicine. Information on medicines in development can change rapidly. Two updates are therefore produced to highlight any change in information on significant developments included in the report. This could include information on a change to an estimated UK launch date, development discontinuation of a medicine or notification of additional new products anticipated to come to the UK market in the *Forward Look* report timeframe. Due to the commercial in confidence nature of the content, access to *Forward Look* reports, financial spreadsheets and updates is restricted. The SMC is also fully engaged with the UK wide horizon scanning database, UK PharmaScan which is a prime source of information on new medicines, indications and formulations in the pharmaceutical pipeline for all horizon scanning organisations across the UK, including the SMC. The SMC continually review their processes, including horizon scanning. Work continues both at policy level and across the NHS to ensure an overarching approach to considering advanced medicinal therapies is in place in order to facilitate a 'once for Scotland' approach where possible. This includes horizon scanning, payment models and budgetary planning considerations. It is worth noting that the SMC's horizon scanning work is considered exemplar.

**(Page 32) 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.**

### **Scottish Government Response**

19. The Scottish Government has committed significant funding to providing Access to New Medicines and will continue to do so. Decisions regarding funding allocations for 2021-2022 are under consideration and to be finalised.

**(Page 33) 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.**

### **Scottish Government Response**

20. The Scottish Government and the SMC continually keep their HTA methods under review. We are also following the NICE Methods review with interest. It is worth acknowledging in terms of responsiveness, the SMC was stood down earlier this year to enable clinical experts who participate in the SMC HTA functions to support the immediate response to the COVID-19 pandemic. Since re-starting business as usual activities in September 2020, the SMC has cleared the backlog of outstanding submissions received during the COVID-19 pandemic and adapted practices to incorporate new definitions and include "interim acceptance" decisions in their acceptance options for medicines undergoing an HTA. As we have noted previously,

the SMC has an international reputation as one of the fastest HTA processes globally and is certainly faster than any UK equivalents.

### **Patient Access Schemes**

**(Page 34) 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".**

### **Scottish Government Response**

21. The SMC operates independently of the Scottish Government. As such it is for the SMC to consider the level of information released whilst considering the commercial confidentiality of PAS submissions. Some information that is not considered commercially sensitive may be available on the SMC Detailed Advice Document. The Detailed Advice Document is publicly available, however the pharmaceutical company determine which elements of the PAS should be treated in confidence, for example the level of discount, purchase price and/or scheme mechanism and therefore what can be published. Health Boards are informed confidentially of the PAS details to inform their budgeting and planning processes.

**(Page 34) 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.**

### **Scottish Government Response**

22. The regulation for the pricing of medicines is a matter reserved to the UK Government. However, it is a Scottish Government policy objective to achieve, within devolved competence, the best possible prices for medicines. Whilst medicine pricing is reserved and regulated through the UK Voluntary Pricing and Access Scheme (VPAS), a key objective that was achieved during the VPAS negotiations was to establish binding commitments on Governments across the UK and the pharmaceutical industry to greater transparency and parity in medicine pricing, including Patient Access Schemes (PAS). VPAS was introduced in January 2019 and includes provisions that allow the UK Health Administrations to share the details of previously confidential pricing arrangements as well as imposing new responsibilities on pharmaceutical companies to achieve comparable arrangements that provide an acceptable value proposition in each part of the UK. Scottish Government officials are currently working with the other UK administrations to ensure that these provisions are fully implemented.

**(Page 35) 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."**

## **Scottish Government Response**

23. As noted previously, the SMC operates independently of the Scottish Government. As such it is for the SMC to consider the level of information released whilst considering the commercial confidentiality of PAS submissions. Some information that is not considered commercially sensitive may be made available on the SMC Detailed Advice Document. The Detailed Advice Document is publicly available, however the pharmaceutical company determines which elements of the scheme should be treated in confidence, for example the level of discount, purchase price and/or scheme mechanism.

## **Interaction with the pharmaceutical industry**

**(Page 35) 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.**

## **Scottish Government Response**

24. The Scottish Government has regular dialogue with representatives from across the pharmaceutical industry including the representative trade body, the Association of the British Pharmaceutical Industry (ABPI). We recognise the importance of maintaining our established relationship with industry partners and have previously sought their views on the assessment process for new medicines. The SMC has an established pharmaceutical industry user group forum which provides an opportunity for representatives from the pharmaceutical industry with hands-on experience of health technology issues to work collaboratively with SMC. The group meets quarterly to address technical and process issues and facilitates pharmaceutical industry representation on NDC and SMC committees. The pharmaceutical industry is also an active participant in the SMC. Similarly, the SMC engages with pharmaceutical companies as identified in the horizon scanning activities and openly encourage companies to engage with the SMC secretariat at the earliest opportunity when developing new medicines.

## **Scrutiny of non-medicine interventions**

**(Page 37) 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).**

## **Scottish Government Response**

25. The methodology for the health technology of medicines is well established and the tools and processes used are internationally validated and robust. This can lead to a perceptions that the scrutiny of medicines varies to that of other health technologies. However, the Scottish Health Technologies Group's (SHTG) assessment of non-medicine interventions assesses both the cost and clinical

effectiveness of new products. The SMC and the SHTG work closely as part of the HIS Evidence Directorate allowing comparisons to be made. The SMC and the SHTG both take into account a range of factors when deciding whether an intervention is good value for money, comparing new treatments with the current treatment used in clinical practice in Scotland. The SMC guidance to pharmaceutical companies states that the comparator can be a medicine or another healthcare intervention. For the vast majority of SMC submissions, however, a new medicine will generally be compared with an existing medicine, and there is very limited direct comparison between a medicine and other health technologies. It can be challenging to compare the benefits of medicines with non-medicine intervention as, although all medicines undergo assessments, only a few non-medicine interventions go through the HTA process. **The Scottish Government is working to address this through the formation of a health technology unit to bring clarity and vision to this policy area** and support the work of SHTG to enable more health technologies undergo assessments.

**(Page 37) 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.**

### **Scottish Government Response**

26. The Medical Devices and Legislation Unit was established in Scottish Government in March 2020 with responsibility for medical devices policy and legislation. The initial focus of the Unit has been on responding to the COVID-19 pandemic and the planned expansion of NHS Scotland ICU capacity to ensure access to the medical devices and clinical consumables (MDCC) to support the pandemic; EU transition planning to ensure NHS Scotland preparedness and the continuity of MDCC supplies from 1 Jan 2021; and developing the national policy on transvaginal mesh. As a result of leaving the EU, the regulation of medical devices will undergo unprecedented reform during 2021, led by the UK Government for which medical devices are reserved to. The Unit is working with the UK Government, MHRA and Devolved Administrations on the future medical devices regulatory landscape and has an integral role in ensuring that developments in this area are consulted appropriately with key stakeholders to ensure they are optimal to Scotland.

### **Purchase and Procurement**

**(Page 42) 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.**

### **Scottish Government Response**

27. The supply of medicines including medicines shortages is a reserved matter and therefore the responsibility of the Department of Health and Social Care (DHSC). The DHSC work closely with a range of other organisations to support reducing the risk and impact of shortages. Medicines shortages can occur at a local, national, European

or global level. The Scottish Government and NHSScotland National Procurement have regular engagement with the DHSC and other stakeholders including Community Pharmacy Scotland on issues relating to the supply and provision of drugs for patients in the community. We are not aware of significant medicines shortages across NHS Scotland. As noted earlier, over the course of the COVID-19 pandemic medicines have continued to be provided to patients, effectively, efficiently and safely. Despite the challenges of an increasing global demand for medicines as a result of the COVID-19 pandemic, the NHS in Scotland did not run out of medicines, instead managing supply and demand in immensely challenging circumstances.

**(Page 45) 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.**

### **Scottish Government Response**

28. NHS England colleagues provide regular updates to NHS Scotland National Procurement with details of Patent Access Schemes agreed and other pricing agreements for England on a regular basis and work is also underway between officials to establish a formalised process for sharing commercial arrangements routinely amongst the UK nations as part of the 2019 VPAS agreement.

**(Page 45) 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.**

### **Scottish Government Response**

29. As noted previously, price transparency across the UK was one of the main priorities for the VPAS negotiations, and the Scottish Government is pleased to see an explicit undertaking in the new agreement, that the details of national commercial arrangements agreed in one country will be made available on a confidential basis to the other purchasing authorities in the UK. The agreement also supports the principle of price parity by stipulating that companies will work with purchasing authorities to achieve comparable arrangements that provide an acceptable value proposition in each part of the UK. NHS England colleagues provide regular updates to National Procurement with details of a PAS agreed for England shared on a regular basis and work is also underway between officials to establish a formalised process for sharing commercial arrangements routinely amongst the UK nations.

**(Page 45). We recommend the Scottish Government ensure the NHS is gathering data on purchasing and stock holding by individual boards to improve procurement processes.**

## Scottish Government Response

30. Historically, the only way to gather real-time information on the stockholding of medicines in hospitals across NHS Scotland was by requesting a manual stock check to be undertaken on each occasion the information was required. This made stock analysis and accurate modelling work, in terms of supply and demand for medicines, very difficult, and as a result this activity was only undertaken by exception. In October 2020, the Scottish Government confirmed funding for the roll out of two IT reporting tools across NHS Scotland. The RX-info Define and Extend programmes enable the gathering of real-time data on both stockholding and stock usage in hospitals and will better support NHS Scotland to respond quickly to any medicine supply issues. This will be particularly beneficial for our response to any future waves of COVID-19 and any potential disruption after the EU transition period ends. This reporting tool is being used across all health boards and **we will update the Committee on the benefits in due course.**

**(Page 46) 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.**

## Scottish Government Response

31. In 2018, the First Minister made a public commitment to continue to fund the cost of medicines for patients with rare diseases via the New Medicines Fund. As a result, the rebate from the new VPAS continues to flow into the New Medicines Fund. The Scottish Government is not aware of any discrepancy between rebates received and funding provided to NHS Health Boards through the New Medicines Fund. The level of rebate itself is subject to fluctuations depending on usage of medicines.

**(Page 46) 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.**

## Scottish Government Response

32. The Scottish Government is committed to investing the rebate from the VPAS agreement into the New Medicines Fund which is intended to ensure that the availability of funding is not a barrier to implementation of policy to increase access to new medicines. Since 2014, there has been more than £200 million made available to Boards via the New Medicines Fund for medicines. **Scottish Government officials are working with Public Health Scotland to review the available data on medicines spend and how that might best be structured to be most meaningful. We will update the Committee on progress in due course.**

## Pricing based on other considerations

**(Page 46) 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.**

### Scottish Government Response

33. Scottish Government officials are actively considering new opportunities in relation to innovative and flexible approaches to pricing, including exploring outcome based reimbursement and commercial payment agreements across the range of healthcare settings, as well as dealing with some of the associated uncertainty about a medicine's clinical and/or cost effectiveness. Progress since the end of 2018 has been slower than first intended, as it has been necessary for officials and NHS partners to devote substantial time to the preparation of medicine supply contingency plans for the eventuality of a no deal EU End of Transition Period and, more recently, COVID-19 priorities. The Scottish Government funded Cancer Medicines Outcomes Programme (CMOP) is an example of using real world outcome data to consider the impact of cancer medicines in patients. The CMOP programme is growing a scalable and sustainable capability of expertise in cancer medicines intelligence to drive continued improvement in the safe and effective use of these medicines across Scotland. **The lessons learnt in cancer can then be applied across other clinical priority areas.** Critical to the delivery of any novel pricing approaches is the NHS capability to collect outcome data, which is why a strategic approach to data collection and the interdependency with the Digital Health and Care Strategy is important. **This year's Programme for Government, outlines our commitment to refresh the digital health & care strategy and create a dedicated data strategy for health & social care for the first time.** This is a key enabler in delivering the necessary functionality to support data collection in a way that does not place a burden on clinicians. In the meantime, there is already an established route for pharmaceutical companies to propose outcome-based pricing schemes via a PAS and there are a number of such schemes already in operation across the NHS in Scotland. One of the main challenges is the lack of a national system to underpin routine data collection on medicine outcomes, meaning they are resource intensive and rely on individuals, usually pharmacists, manually collating and analysing the data.

**(Page 50) 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.**

### Scottish Government Response

34. As noted previously, developing a strategic approach to data collection and ensuring the interdependency with the Digital Health and Care Strategy is crucial for the future of medicines policy. Alongside the CMOP work referred to earlier, the new ultra-orphan pathway also requires an element of data collection as does the interim

acceptance option. All of these offer opportunities to learn and extend our approach. **This year's Programme for Government outlines our commitment to refresh the digital health & care strategy and create a dedicated data strategy for health & social care for the first time.** This is a key enabler in delivering the necessary functionality to support data collection in a way that does not place a burden on clinicians. In line with the Programme for Government commitment, **we will undertake a phased and joined up approach to developing processes for collecting outcome data for medicines.** It is essential that any developments in the collection and utilisation of medicines outcome data are underpinned by the appropriate infrastructure that enables accessible, robust and reliable data systems and does not place an unnecessary burden on healthcare professionals.

**(Page 51) 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.**

### **Scottish Government Response**

35. The price of a medicine is set by the manufacturer. In the event that the MHRA suspends or revokes a license clinicians would not normally continue to prescribe the medicine and therefore the medicine would no longer be purchased and no reimbursement received by the manufacturer.

**(Page 52) 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.**

### **Scottish Government Response**

36. Scottish Government officials are actively considering new opportunities in relation to innovative and flexible approaches to pricing, including exploring outcome based reimbursement and commercial payment agreements. This work also consider some of the associated uncertainty about a medicine's clinical and/or cost effectiveness. As the work progresses, **Scottish Government will engage with a range of stakeholders who can provide expertise in this area.**

### *Purchasing in primary care*

**(Page 62) 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.**

## Scottish Government Response

37. As part of Achieving Excellence in Pharmaceutical Care (AEiPC), our strategy for pharmaceutical care in Scotland, we made a commitment to work in collaboration with NHS National Education Scotland (NES) and other key stakeholders to address the education and training needs of the pharmacy technician profession. Much of the work has started on pharmacy technician training. A qualification meeting new GPhC initial education and training standards is now being delivered, and a flexible Foundation programme – with pilots and evaluation still underway – is now available to community pharmacy technicians. As part of AEiPC recommendation, we have had a Scottish Pharmacy Technician Clinical Leadership Fellow in each of the first two years working on development of pharmacy technician education and training to ensure that the training received is fit for purpose. **We will work with NES to develop appropriate training in consultation with other key stakeholders to consider the inclusion of procurement of medicines in formalised training for pharmacy technicians.**

**(Page 62) 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.**

## Scottish Government Response

38. Our AEiPC strategy priorities were developed to open up new and rewarding career pathways for pharmacists and pharmacy technicians in increasingly clinical roles. We recognise an increasing interest across the profession to develop a more flexible approach to their career pathways including portfolio career opportunities. In response, NES established an advisory group to provide expert advice on the future options for a framework focusing on early careers, advanced practice level careers, and consultant level careers. It also examined the strengths and weaknesses of existing postgraduate career pathways. NES recently published their review of the pharmacy postgraduate programmes. **We are currently considering the recommendations and will liaise with key stakeholders on the best approach to taking these forward to develop a Postgraduate Career Framework for pharmacists in Scotland. We will do this, in parallel, with the pharmacy technician educational developments.** Our intention would be for a career framework to be applicable at all levels of development, to all specialities, and will allow for recognition and transferability across the other UK nations. The General Pharmaceutical Council (GPhC) recently proposed reforms to the current initial education and training of pharmacists which help underpin future career pathways for pharmacists in increasingly clinical roles. As part of the 2020/21 specific funding is being directed to a community pharmacy career framework and independent prescribing pathway.

**(Page 64) We recommend the NHS pay community pharmacy on the same payment terms as have been requested by wholesalers.**

## Scottish Government Response

39. Each NHS Health Board has in place arrangements with pharmacy contractors that facilitates advance payment for high cost medicines. **Work is being taken forward to drive efficiencies in the payment process for both community pharmacy contractors and Health Boards.**

Conclusion

**(Page 66) 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.**

## Scottish Government Response

40. Regular monthly and annual reporting on the costs of medicines procured across both primary and secondary care are published by Public Health Scotland (PHS). All medicines are prescribed on a clinical need basis, with 84% of medicines prescribed being generic, therefore comparing with equivalent products may be perceived as questioning the clinical choice of the prescriber. The Scottish Government believes that the existing procurement routes, through NHS National Procurement for secondary care and community pharmacy for primary care, achieve value for the NHS in Scotland and is dynamic to respond to changes in market conditions and existing prescribing strategies provide greater prescribing efficiencies.

**(Page 66) 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.**

## Scottish Government Response

41. The Scottish Government will continue to **provide regular updates to the parliament on the end of EU Transition period and any subsequent impact on the cost of drugs.**

Prescribing

**(Page 70) 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.**

## Scottish Government Response

42. As we have noted previously the Scottish Government is fully committed to exploiting future developments across the digital and innovation landscape for the

supply and demand of medicines. However, as we have also acknowledged earlier, data collection is a complex issue that requires the appropriate infrastructure to ensure robust, accessible data systems are in place that do not increase burden on clinicians and improve patient outcomes. Extant guidance sets out the responsibilities of Health Boards with regard to ensuring transparency in local consideration of SMC accepted medicines, including a standard timescale for making and publishing formulary decisions and clarifying that Health Board decisions about SMC accepted medicines should be published in a standardised way. Monitoring the uptake of new medicines by Health Boards can be difficult however, some data on the uptake and outcomes are already collected, for example if the medicine has a PAS in place. The collection of data may increase in the future with the introduction of digital solutions such as HEPMA although there may still be difficulties in making some information available in order to prevent any patient being identified. The Scottish Government will **work with key stakeholders, including Public Health Scotland, to better understand the extent to which data opportunities for measuring new medicine uptake can be realised within current data systems.**

**(Page 70) We would welcome the view of the Scottish Government on whether a "tighter" formulary, with a narrower range of choices, is preferable.**

#### **Scottish Government Response**

43. There are a great number of considerations around how many choices should be presented within each section of a formulary. For example, too many choices may create difficulties in ensuring the most clinically and cost-effective prescribing, while necessitating the need for pharmacies to stock a wide range of items leading to potential waste. Too few choices may create difficulties when there are supply issues of a particular product, leading to additional work for clinical staff and patient dissatisfaction around changes of medication. As formularies provide recommended medicines for a wide range of therapeutic indications, it would not be desirable to state that only a specific number of medicines should be listed in all areas. Instead, we believe that the move towards condition-based formulary recommendations will help to provide the ability for formulary teams to ensure that the appropriate number of formulations of medicine are listed to meet each specific therapeutic need.

**(Page 73) 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.**

#### **Scottish Government Response**

44. We are currently engaged in a programme of work to develop a single national formulary (further details are provided under a separate recommendation below). As part of the development work for this programme a comprehensive review of formularies will be undertaken which will support equity of access. HIS has produced a biosimilar prescribing framework. It contains prescribing principles to promote the safe use of biosimilar medicines in a consistent way across Health Boards. It complements the existing NHS boards' governance processes for the managed introduction of new medicines. The experience of applying this framework

demonstrates that it is possible to maintain the highest level of care for the patient and make financial efficiencies by adopting a shared decision-making approach between clinician and patient. NHS National Procurement (NP) produce routine monthly biosimilar uptake data reports for NHS Boards on a regular basis to encourage and promote the uptake of biosimilar medicines. These reports are designed to encourage Boards to change to using biosimilars in recognition of lost financial opportunities. This work will also be considered as part of the work programme for the single national formulary.

**(Page 75) 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.**

### **Scottish Government Response**

45. Discussions with national stakeholders around formulary development highlighted at an early stage the strong desire to see the role of a formulary develop from the traditional 'list of medicines' towards a condition-based structure that focuses on the appropriate use of medicine in the treatment of patients. This has been central to the ongoing work and has seen a new digital platform developed that enhances the traditional methods of navigating formulary content, with a new condition-based structure that provides formulary recommendations via condition specific pathways.

**(Page 75) 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.**

### **Scottish Government Response**

46. During the course of this programme of work we have listened carefully to feedback from across the NHS and wider stakeholder groups. This has informed a revised approach to developing a national formulary which seeks to transition from the 11 local formularies in a measured way that ensures local clinical ownership and decision making. Our revised approach involves existing local formulary teams working collaboratively to initially develop regional formularies that will be made available to prescribers via a new national platform. This approach ensures that the function of developing a formulary continues to be delivered by Health Boards underpinned by local clinical ownership and existing governance arrangements. By utilising existing local formulary teams to evolve formulary recommendations regionally, we believe that the end-product will continue to reflect local needs and retain the buy-in of local prescribers. The new national platform has been developed and is ready to host the formulary recommendations. The first region to utilise the new platform will be the East of Scotland, where NHS Lothian are currently completing the transition of their formulary to the new platform. This will be completed this year, with discussions between local formulary teams in the East region then continuing with a view to reaching a consensus on the preferred regional medicine choices. Once consensus

is reached the formulary platform will be updated and made available for the other Health Boards in the region to adopt. Progress and learnings will continue to be shared throughout with the other Health Boards, with a view to informing an approach to begin replicating this model in the West and North regions during 2021. As described above, the approach being taken is driven by local formulary teams with regional recommendations built from the existing formularies. The regional formularies will therefore be created using existing local processes and governance arrangements. The approach being taken actively encourages the sharing of best practice between Health Boards within each region. In addition, we will work closely with the ADTCC to ensure the development of appropriate forums to support national discussions on best practice between each region.

**(Page 75) 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.**

### **Scottish Government Response**

47. The new national formulary platform uses the NHS Business Services Authority 'Dictionary of Medicines and Devices' (dm+d) as its underlying data source, providing a robust recognised NHS standard for uniquely identifying medicines. All medicines contained within the dm+d have unique identifiers that are compliant with SNOMED clinical terminology standards. In practice this means that the medicines recommended on the formulary, including the specific formulations of each medicine, can be extracted from the formulary platform in a format that can be recognised by clinical systems such as HEPMA which will support integration with HEPMA and other systems.

**(Page 76) 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.**

### **Scottish Government Response**

48. The current work programme on the Single National Formulary is focused on medicines. There is an opportunity to include, as part of a future iteration of the Single National Formulary, to include non-medicines in line with those listed on existing local formularies and where a sufficient evidence base exists to allow reasonable comparison of products. **We will discuss with the appropriate policy officials and HIS if and when there may be an opportunity to include non-medicine in the Single National Formulary.**

### **Prescribing in primary care**

**(Page 82) 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.**

### **Scottish Government Response**

49. We are currently analysing the latest returns from Health and Social Care Partnerships as to the current number of Pharmacists and Technicians recruited to GP practices and **we will be able to provide an update on this figure later this year.** However, figures to November 2019 showed that Boards were mostly on track to meet the 2021 deadline. Two thirds of practices across Scotland were receiving pharmacy support. A recent GAP analysis by the Scottish Practice Pharmacist and Prescribing Advisers Association indicated that 88% practices now had at least a level 1 service in place. Pharmacists and pharmacy technicians in GP practices are employed mostly by Health Boards, funded through the Primary Care Transformation Fund, although there are some practices who have employed pharmacists directly. These arrangements are most likely to precede the Primary Care Fund. Health Board Directors of Pharmacy have accountability for the pharmacists' performance and overall oversight of the pharmacotherapy service. Responsibility for meeting the targets lie with Health Boards and Health and Social Care Partnerships (HSCPs). If the target cannot be met in particular areas we will work with Board Directors of Pharmacy to identify solutions that can be implemented to ensure pharmacy support can be accessed. Areas initially identified as being most at risk of not meeting the target are remote and rural Boards. This is due to practices being geographically distant from centres of population (some even requiring ferry transport to access). Regular cover for these types of practices is difficult to achieve. Significant improvements in GP IT is also required for some practices to allow a pharmacotherapy service to be delivered remotely. Other reasons for the target not being met are lack of financial resource, and recruiting from a limited pool when other Health Boards are also recruiting at the same time.

**(Page 84) 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.**

### **Scottish Government Response**

50. Medication and polypharmacy reviews from part of the Level 3 of the pharmacotherapy service and therefore are part of the General Medical Service (GMS) contract. The NHS in Scotland has led the way on addressing the burden of polypharmacy. Polypharmacy reviews focus on patients with multiple morbidities and a holistic polypharmacy review should result in a medication regime that is tailored to the patient. The 2018 NHS Scotland Polypharmacy Guidance states that 11% of unplanned hospital admissions are attributable to harm from medicines, and

polypharmacy reviews aim to reduce this while also providing financial benefit. Until 2012/13 there was an annual volume increase in medication of 3%; since the introduction of the first Polypharmacy Guidance in 2012 the rate of volume increase has fallen each year. For the first time there has been a fall in the volume (items) of medicines prescribed in primary care in 2018/19. In addition, and to complement this, we are refreshing the Chronic Medication Service component of the community pharmacy contract. The Medicines: Care and Review service will include an annual review of their medicines for patients who have registered for the service. **We will continue to strengthen the medication review elements of both the GMS and community pharmacy contracts.**

**(Page 84) 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.**

### **Scottish Government Response**

**51.** In terms of progress on development of the evaluation and reporting mechanism for the GMS, our approach to monitoring and evaluating the reform of Primary Care, including the GMS contract, is set out in our 10 year monitoring and evaluation strategy for Primary Care Reform<sup>3</sup>.

A work plan containing our early priorities for the strategy is available online<sup>4</sup>. As part of the GMS arrangements, GP practice participation in GP clusters is a mandatory feature of practice contracts. GP clusters are professional groupings of general practices that meet regularly, with each practice represented by their Practice Quality Lead (PQL). GP practices must appoint a PQL and provide agreed local and national data extractions to enable intelligence led quality planning, quality improvement and quality assurance, as well as adoption of Realistic Medicine initiatives. This is supported by measures such as contractual provision for protected time. This has replaced how GP performance was measured through the Quality and Outcomes Framework element. GP practices and clusters are supplied with information on prescribing, outpatient referrals and admissions to hospital to support quality activity in these areas. Practices are also supplied with risk predictive information based on the High Health Gain Potential predictive tool to support them to identify individuals with more complex needs and to consistently deliver anticipatory care planning. GP practices engage in quality improvement activities as agreed through GP cluster

<sup>3</sup> <https://www.gov.scot/publications/national-monitoring-evaluation-strategy-primary-care-scotland/pages/1/>.

<sup>4</sup> <https://www.gov.scot/publications/primary-care-monitoring-and-evaluation-strategy-work-plan-2019-2020/>

quality improvement planning. Practices supply information to HSCPs and NHS Boards on their workforce and demand for their services to improve sustainability and facilitate service redesign. GP clusters work with the wider system, in particular HSCPs, to achieve whole system quality improvement. Quality Improvement is a continuous process. Individual doctors have a professional responsibility to maintain their skills and knowledge, and contribute and comply with systems to protect patients. GPs continue to be registered with the GMC, undergo annual appraisal, learn from Significant Adverse Events, contribute to confidential enquiries and comply with NHS Complaints procedures and Duty of Candour legislation. GP practices participate in a cluster quality peer review process, whereby their quality improvement activity and quality data are reviewed by their cluster. Healthcare Improvement Scotland's Quality of Care Approach involves an increased emphasis on local systems of assurance. Service providers evaluate the quality of care they provide and identify areas for local improvement work. As GP clusters mature, Scottish Government will expect practices and clusters to take part in the peer-led values driven assurance process. The methodology for this will be negotiated by the Scottish Government and the Scottish General Practitioners Committee of the BMA (SGPC).

Implementation of the 2018 GP Contract is underpinned by a memorandum of understanding ("MOU") signed on behalf of the Scottish Government, BMA, Health and Social Care Partnerships and Health Boards. The MOU<sup>5</sup> sets out the principles by which primary care redesign will be delivered. Crucial to this agreement is that services will only be transferred where it is sustainable for the local healthcare system and, most importantly, where it is safe, appropriate, and improves patient care. The MOU is currently in the process of being reviewed and updated.

We can confirm that for each of the last three years, GMS has made up approximately half of the total Community Health Services Budget.

GPs are required by their contracts to have regard to all relevant guidance issued by the Health Board and the Scottish Ministers. GPs who do not do so are potentially in breach of their contracts.

**(Page 88) 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.**

### **Scottish Government Response**

52. Our 2018 Programme for Government committed to refreshing the Chronic Medication Service (CMS). The refreshed service, Medicines: Care and Review is a core service of the community pharmacy national framework. The service has three key elements, and patients who have long term stable conditions are entitled to any depending on their individual need(s). This includes an initial review of a person's medication review to help identify any potential care issues but also aid suitability and

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<sup>5</sup> <https://www.gov.scot/publications/delivering-the-new-gms-contract-in-scotland-memorandum-of-understanding/>

selection for a serial prescription; the development of a pharmaceutical care plan which documents any pharmaceutical care issues, actions to address those issues and responses to the actions, recorded on the secure web based application, the Pharmacy Care Record (PCR); and the option for serial prescribing and dispensing where a patients who are stabilised on their medication can have their items prescribed on a prescription that will be valid for 24, 48 or 56 weeks without having to return to their GP practice for repeats. **We plan to further develop the Medicines: Care and Review service to include an ongoing annual review of medication.** The use of serial prescribing is key in the NHS response to the current pandemic. A programme of work on rapid mobilisation and creating better links between community pharmacists and clinical pharmacists working in GP practice is also underway.

### Prescribing in secondary care

**(Page 89) 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.**

### Scottish Government Response

53. We do not hold this information centrally and there are so many variables it would be impossible to capture this data. There are well-documented challenges with regards delays at discharge. A number of solutions have been tested including: not providing discharge medication if people have sufficient medicine supplies at home; the use of NHS hospital prescriptions for those for whom discharge is simple and who are able to access a community pharmacy for their medication; the use of 'take home' pre-labelled packs of medication in the case of simple analgesics and antibiotics; and the use of people's own medicines on the ward. However, there are often other factors that can impact such as discharge sign-off being tied to a consultant ward round. It is also important to acknowledge the workload challenges and multiplicity of priorities for Foundation Year Doctors who have a critical role in the discharge process. There is a need to work with them to identify and deliver solutions. HEPMA brings advantages in that it allows all of a person's medication to be pre-populated into the electronic discharge letter thereby improving the discharge process. A further improvement to explore is whether providing people with an electronic copy of the discharge letter could improve the discharge process and timelines. Achieving Excellence in Pharmaceutical Care, the pharmacy strategy, has an action to commission work to explore ways to improve all pharmacy-related aspects of the hospital discharge process utilising integrated models of pharmaceutical care. **We will take this work forward as a priority.**

**(Page 89) 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.**

### Scottish Government Response

54. **HIS has been commissioned to implement a shared learning system, which will be dependent on the full participation from all Health Boards, including Dumfries and Galloway.** To date, Health Boards have been enthusiastic to

contribute. The shared learning outputs feed into the Hospital Electronic Prescribing and Medicine Administration (HEPMA) Implementation Oversight Board. **Two clinical pharmacy fellows, one from NHS Dumfries and Galloway, are working with Healthcare Improvement Scotland to help deliver this work.**

**(Page 95) We recommend the Scottish Government clarify who is responsible and who is accountable for the delivery and implementation of HEPMA.**

### **Scottish Government Response**

55. The Scottish Government has taken a stronger focus on supporting the implementation and the wider benefits of Hospital Electronic Prescribing and Medicine Administration (HEPMA) and we are working to re-energise the roll-out as part of developing the digital strategy. To support this we have established a HEPMA Implementation Oversight Board, that is clinically led, and which reports into the ePharmacy Programme Board, chaired by the Interim Chief Pharmaceutical Officer, who is overall programme sponsor, responsible for ensuring the delivery of HEPMA, in partnership with Health Boards themselves. The ePharmacy Programme Board reports into the Health & Social Care Management Board and Digital Digital Health and Care Strategic Portfolio Board which ensures that it aligns with the overall digital programme. Health Boards are responsible and accountable for local delivery of HEPMA and are represented at the HEPMA Implementation Oversight Board.

**(Page 95) 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.**

### **Scottish Government Response**

56. The role of the HEPMA Implementation Oversight Board is to provide national leadership to and effective oversight of the implementation of HEPMA systems by advising, monitoring and challenging implementations and convergence across the three regions. The Oversight Board will also inform and direct the alignment of implementations with wider national policy and digital developments. In order to further support the implementation phase at a local level Health Boards are being asked to develop a high level road map with milestones to support the implementation of HEPMA, including the opportunities for regional convergence and alignment of clinical processes. At a national level the Oversight Board will work with Health Boards who have HEPMA implementation experience to drive forward the roll-out of HEPMA. The local and national approaches will assist with monitoring and information sharing as well as supporting regional working and convergence. The plan is for the Oversight Board to continue to provide oversight until the convergence work is completed.

**(Page 95) 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**

### **Scottish Government Response**

57. The HIS shared learning system, described earlier, will be key in communicating the benefits of the use of HEPMA to all NHS staff as well as best practice. Training of staff is a core part of the local implementations of HEPMA.

**(Page 96) 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.**

### **Scottish Government Response**

58. We have made significant progress over the last year in addressing concerns about the sharing of information and associated governance implications. However clearly, more may still require to be done. **We will review this as part of the work programme of the ePharmacy Programme and align with the refresh of the digital health and care strategy.**

**(page 98) 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.**

### **Scottish Government Response**

59. There are a number of initiatives that are being piloted in Health Boards, including the Forth Valley example referenced in the Committee’s report. We are aware that some Health Boards are using the clinical portal, others using a Shared Care Pharmacy Care Record and some bespoke models. **We will consider these tests of change as part of the ePharmacy Programme Board work programme and align with the refresh of the digital health and care strategy.**

**(Page 98) 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.**

### **Scottish Government Response**

60. Both the HEPMA Implementation Oversight Boards and the electronic transfer of prescriptions in primary care are under the governance of the ePharmacy Programme, chaired by the Chief Pharmaceutical Officer. In 2019, the Pharmacy

and Medicines and Primary Care Division commissioned NHS National Services Scotland (NSS) to bring together a broad range of users, including patient representatives, to explore the potential transformation of prescribing and dispensing pathways across Primary Care in the context of extended multi-disciplinary team (MDT) working. Three multi-disciplinary workshops were held between September and November 2019. The workshops brought together clinical staff from across primary care as well as representatives of national organisations, territorial health boards and independent contractors, including GP practices and community pharmacy. The work identified a number of key focus areas and critical dependencies required to deliver an end to end digital solution that will support paper-light and eventually paper-free approaches across the prescribing and dispensing pathway. In order to build upon this, the Pharmacy and Medicines Division, the Primary Care Division and the Digital and Digital Health & Care Directorate (all within Scottish Government) are now co-sponsoring a work programme to be delivered by NSS and the NHS Education for Scotland (NES) National Digital Service (NDS). It is anticipated that the programme will continue for at least a two-year period during which prioritised and funded outputs will be developed and delivered with a view to digitalising the prescribing and dispensing pathway to support full electronic prescribing and dispensing across primary care and also between primary and secondary care.

**(Page 99) 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.**

### **Scottish Government Response**

61. In terms of confirming that HEPMA will be in place across all Health Boards by March 2021, we would like to clarify that this date refers to the initial onboarding of HEPMA systems so that all Health Boards will have HEPMA implementation processes underway, but not necessarily completed. As you will appreciate, implementation is less about the technology itself and more about the clinical teams using HEPMA and the associated change management. Hence why the shared learning aspect is an important cornerstone of our approach. By March 2021, there will be a mix of Health Boards having completed their roll-out and supporting benefits realisation developments, others will be working towards full HEPMA implementation and considering regional convergence. Whilst COVID-19 has undoubtedly set timescales back a little, there is evidence of the added benefits of HEPMA in this unprecedented time, and existing examples of how the service can scale up to deliver technology solutions as we have seen, for example, with the roll out of digital consultations. In addition there are opportunities to learn from and use resources from Boards where HEPMA has already been implemented to increase the pace of roll out.

**(Page 99) 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.**

## Scottish Government Response

62. In terms of progress to date, four Health Boards (NHS Ayrshire & Arran, NHS Dumfries & Galloway, NHS Forth Valley and NHS Lanarkshire) have either implemented or are close to completing implementation of HEPMA. These Boards are now focusing on benefits realisation by developing local reporting tools to maximise the use of available data to support service improvement, audit and monitoring. One Health Board (NHS Fife) is in the process of finalising their preferred HEPMA system and two others (NHS Borders and the NHS Golden Jubilee) are finalising business cases. All other Health Boards have commenced HEPMA implementation, with six Boards working together as a North of Scotland regional collaboration (NHS Grampian, NHS Highland, NHS Tayside, NHS Shetland, NHS Orkney and NHS Western Isles). Scottish Government officials continue to work with Health Boards to ensure a local and regional approach to delivery across all the remaining Boards.

**(Page 99) If it is no longer on track, we would welcome an indication of the likely timescales for implementation in each health board in Scotland.**

## Scottish Government Response

63. As noted previously, in terms of confirming that HEPMA will be in place across all Health Boards by March 2021, we would like to clarify that this date refers to the initial onboarding of HEPMA systems so that all Health Boards will have HEPMA implementation processes underway, but not necessarily completed. The implementation of HEPMA remains on track.

**(Page 99) 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 ring-fenced for the purpose.**

## Scottish Government Response

64. In terms of funding, this is shared between Scottish Government and Health Boards. The Scottish Government has invested over £21m since 2016 in supporting HEPMA implementations. In, in 2019 and 2020 £16m was provided to support the implementations of NHS Greater Glasgow and Clyde (£5.093m), NHS Lothian (£3.261m), The State Hospital (£335K) and the six Health Boards that form the North of Scotland regional collaboration (£7.6m).

### *Non-pharmaceutical interventions*

**(Page 101) 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.**

## Scottish Government Response

65. The Scottish Intercollegiate Guideline Network (SIGN) is part of the Evidence Directorate of HIS. However, SIGN remains editorially independent from HIS and the Scottish Government. SIGN aims to improve the health care for patients in Scotland through the development and dissemination of clinical guidelines that contain recommendations for effective practice based on best current evidence available. The Scottish Government recognises the importance of SIGN remaining independent. Whilst we are committed to working collaboratively with stakeholders it would be inappropriate for the Scottish Government to interfere with the development of guidelines and potentially devalue the contributions of unpaid clinical experts and advisors to provide advice to SIGN in the development of their guidance.

**(page 103) 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.**

## Scottish Government Response

66. We support the principle of the same level of governance that is undertaken for medicines, being applied to other interventions. However, this is not without its challenges. We have an established national body for the assessment of non-medicine health technologies, the Scottish Health Technologies Group, and accept assessments for high profile technologies and have strong links with national planning. We have recently put in place a new policy team in the Scottish Government's Planning and Quality Directorate to manage this work with joint interests in the Chief Scientist Office and the Economy Directorate. Supportive developments have been discussed with the Health and Social Care Management Board and are being actively followed up.

*Social prescribing*

**(Page 105) 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.**

## Scottish Government Response

67. We committed to establishing a short life working group to take this forward and this commitment was reiterated in the Programme for Government. Unfortunately, the establishment of the Working Group has been delayed by the COVID-19 pandemic but will recommence shortly. We continue to work with partners who are delivering social prescribing initiatives.

**(Page 107) 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.**

### **Scottish Government Response**

68. The use of social prescribing is an emerging practice to compliment healthcare provision so people can make informed choices about their care in line with their preferences. Community Link Workers are a form of social prescribing and enable person-centred support. Resources to build this capacity and expertise are provided via the Primary Care Improvement fund. We remain committed to our target of recruiting 250 Community Link Workers across Scotland by the end of the Parliament. Shared Decision Making and Realistic Medicine has the partnership between physicians and patients at its core, focusing on what matters to the patient. This is also at the centre of the 7 Step process that we promote for polypharmacy<sup>6</sup>. As the Cabinet Secretary for Health and Sport advised the Committee in her February response to the report on social prescribing, there is a growing interest in the contribution which social prescribing by healthcare practitioners can make to helping people into physical activity and sport, as well as to experience the physical and mental health benefits of a wide range of other activities available within their local communities. The Scottish Government recognises that whilst we are making progress in this area there is always more that can be done to build on this, including increasing the pace and scale. **The Scottish Government has committed to establishing a short life working group to examine social prescribing of physical activity** that will identify and communicate examples of best practice and co-produce resources for practitioners in the many roles which make up the overall system. This commitment was reiterated in this year's Programme for Government. Notably, the establishment of the Working Group has been delayed by the COVID-19 pandemic but will recommence shortly. **We continue to work with partners who are delivering social prescribing initiatives.**

**(Page 108) 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.**

### **Scottish Government Response**

69. The 2018 GMS Contract included an agreement that every GP practice will receive pharmacy and prescribing support. The pharmacotherapy service allows GPs to focus on their role as expert medical generalists, improve clinical outcomes, more appropriately distribute workload, address practice sustainability and support prescribing improvement work. In general pharmacists and pharmacy technicians will take on responsibility for core elements of the service, including acute and repeat prescribing, medicines reconciliation, monitoring high risk medicines and additional elements of the service, including: medication and polypharmacy reviews and specialist clinics (e.g. chronic pain). At the time the 2018 GMS contract was agreed promotion of social prescribing was not included as part of the pharmacotherapy service that was envisioned. However **we will consider any recommendations**

<sup>6</sup> <https://managingmeds.scot.nhs.uk/for-healthcare-professionals/7-steps/> .

**emerging from the short life working group to examine the social prescribing of physical activity in this context.** Progress towards the implementation of the priority areas of the GMS contract (of which the pharmacotherapy service is one) is monitored through the completion of biannual trackers by Health and Social Care Partnerships. These trackers are analysed and findings shared with the National GMS oversight group. The GMS contract forms one crucial part of wider ongoing reforms to primary care in Scotland. Our approach to monitoring and evaluating this wider programme of reform is set out in our 10 year monitoring and evaluation strategy for Primary Care Reform<sup>7</sup>.

**(Page 108) 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.**

### **Scottish Government Response**

70. We remain committed to recruiting 250 Community Link Workers across Scotland by the end of the Parliament. This programme was on course prior to the COVID-19 pandemic, and as of September 2019 there were 112 Community Link Workers in post. **We are currently analysing the latest returns from HSCPs as to the current number of Community Links Workers recruited and we will be able to provide an update on this figure later this year.**

**(Page 109) We would welcome an outline of how this supply and demand [of community link workers in general practices] is determined. It would be helpful to see detail of any guidance on this for Integration Authorities.**

### **Scottish Government Response**

71. Implementation of the 2018 GMS Contract is underpinned by a memorandum of understanding (“MOU”)<sup>8</sup> signed on behalf of the Scottish Government, BMA, Health and Social Care Partnerships and Health Boards. Community Links Workers (“CLWs”) are allocated in accordance with the MOU which states that CLW’s and recruitment to these roles is based on local need and priorities, but that areas of high deprivation are prioritised where possible. It is important to note that HSCPs are ensuring that the right model for the specific local circumstances is deployed which should involve GPs and other stakeholders in planning and implementation of CLWs services. There is no one size fits all model.

**(Page 110) 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.**

<sup>7</sup> <https://www.gov.scot/publications/national-monitoring-evaluation-strategy-primary-care-scotland/pages/1/>

<sup>8</sup> <https://www.gov.scot/publications/delivering-the-new-gms-contract-in-scotland-memorandum-of-understanding/>

## Scottish Government Response

72. The 2018 GMS contract proposed a refocused role for GPs from 2018. This will incorporate the core existing aspects of general practice and introduce a renewed focus on quality and the sharing of system wide clinical knowledge. This acknowledges the GP's expertise as the senior clinical leader in the community, who will focus on undifferentiated presentations, complex care in the community and whole system quality improvement and clinical leadership. A key change in the contract offer is the proposal that GPs become more involved in complex care and system wide activities, necessitating a refocusing of GP activity. As we refocus the GP role, we expect GPs to be less involved in more routine tasks, with these tasks being delivered by other health professions in the wider primary care multi-disciplinary team. This will enable GP time to be available when really needed by patients, and where necessary GPs can consider reviewing appointment time length to better meet the needs of their patients. Again, there is no one size fits all. Our approach to monitoring and evaluating the reform of Primary Care, including the GMS contract, is set out in our 10 year monitoring and evaluation strategy for Primary Care Reform<sup>9</sup>. A work plan containing our early priorities for the strategy is available online<sup>10</sup>:

**(Page 110) 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.**

## Scottish Government Response

73. As noted previously our approach to monitoring and evaluating the reform of Primary Care, including the GMS contract, is set out in our 10 year monitoring and evaluation strategy for Primary Care Reform. A work plan containing our early priorities for the strategy is available online. Implementation of the 2018 GMS contract is underpinned by a memorandum of understanding ("MOU") signed on behalf of the Scottish Government, BMA, Health and Social Care Partnerships and Health Boards. The MOU sets out the principles by which primary care redesign will be delivered. Crucial to this agreement is that services will only be transferred where it is sustainable for the local healthcare system and, most importantly, where it is safe, appropriate, and improves patient care.

**(Page 112) 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.**

<sup>9</sup> <https://www.gov.scot/publications/national-monitoring-evaluation-strategy-primary-care-scotland/pages/1/>

<sup>10</sup> <https://www.gov.scot/publications/primary-care-monitoring-and-evaluation-strategy-work-plan-2019-2020/>

## Scottish Government Response

74. The World Health Organization (WHO) Global Action Plan for Physical Activity indicates that health professionals should be competent to undertake assessment and provide brief advice and/or counselling on physical activity in routine practice and that physical activity promotion in healthcare should focus on both primary and secondary prevention, given there is strong evidence on the benefits of physical activity for both prevention and disease management. Healthcare professionals come into contact with large proportions of the population, and frequently interact with people and are widely respected and trusted, meaning they have considerable potential to influence public and individual opinion. There is strong evidence for health professionals providing brief advice and signposting or referral of patients to physical activity opportunities within the community. Interventions are most effective when inactive individuals with the greatest readiness to change are identified, simple and realistic advice is given, and behavioural and cognitive approaches are used to facilitate the adoption and maintenance of physical activity. The National Physical Activity Pathway (NPAP) is an evidence based approach to enable the integration of physical activity across the healthcare system via existing clinical pathways and or routine care in both primary and secondary care settings and is strongly based on NICE Guidance.

**(Page 112) 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.**

## Scottish Government Response

75. We believe that we continue to make progress on both social prescribing and changing the culture of the way healthcare is practised in Scotland. Healthcare professionals are embracing the role as stewards of healthcare resources. To support this, many Health Boards now include questions for patients to ask that will help them make an informed choice about the treatment and care that is right for them on the back of appointment letters and we are looking to include similar questions within virtual consultations. This can include non-medicine interventions. Local Health Board Realistic Medicine Leads can support staff to improve their communication and shared decision making skills by signposting to local development opportunities. NES has also produced an online introductory module on shared decision making. As part of the GMS arrangements, GP practice participation in GP clusters is a mandatory feature of practice contracts. The clusters enable intelligence led quality planning, quality improvement and quality assurance, as well as adoption of Realistic Medicine initiatives. This is supported by measures such as contractual provision for protected time.

**(Page 112) 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.**

## Scottish Government Response

76. [NPAP guidance](#) (developed by NHS Health Scotland prior to the formation of Public Health Scotland) suggests that those delivering the pathway should record data via existing NHS data systems. Unpublished guidance drafted by Public Health Scotland recommends the use of existing NHS data systems for recording, reporting and referral and suggests the steps needed to integrate the National Physical Activity Pathway into existing data systems.

**(Page 112) 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, "e-learning opportunities such as Raising the Issue of Physical Activity, and resources such as Moving Medicine".**

## Scottish Government Response

77. Prior to the formation of PHS, NHS Health Scotland led the development of a practitioner support materials to enable delivery of the National Physical Activity Pathway which can be accessed online<sup>11</sup>. The e-learning module "Raising the Issue of Physical Activity" has been superseded by a new module called "Encouraging and Enabling Physical Activity" which will be launched in November 2020. PHS has partnered with Sport Scotland to jointly fund the paediatric section of the Faculty of Sport and Exercise Medicine online health professional resource [Moving Medicine](#)<sup>12</sup> which will enable health professionals to extend delivery of NPAP to children and young people with long term conditions. **This new resource will also be launched in November 2020.** An NHS Physical Activity Special Interest Group including representatives from all territorial NHS Boards acts as a forum through which guidance and learning on NPAP is disseminated to NHS Boards. Guidance has been drafted by Public Health Scotland and members of the Physical Activity Special Interest Group in the form of a NPAP Logic Model and Improvement Cycle to support NHS Boards to implement the NPAP.

**(Page 112) 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.**

## Scottish Government Response

78. As we have noted previously, Community Link Workers are a form of social prescribing and enable person-centred support. Resources to build this capacity and expertise are provided via the Primary Care Improvement fund. The Scottish Government recognises that whilst we are making progress in this area there is always more that can be done to build on this, including increasing the pace and scale. **The Scottish Government has committed to establishing a short life working group**

<sup>11</sup> <http://www.healthscotland.scot/health-topics/physical-activity/national-physical-activity-pathway>.

<sup>12</sup> <https://scotland.movingmedicine.ac.uk/>

to examine social prescribing of physical activity that will identify and communicate examples of best practice and co-produce resources for practitioners in the many roles which make up the overall system.

**(Page 113) We seek confirmation of when the Quality Standards for Physical Activity Referral will be complete and in use by practitioners.**

### **Scottish Government Response**

79. Development of the Quality Standards for Physical Activity Referrals has been delayed due to the COVID-19 pandemic, with many stakeholders from the leisure and fitness sector unable to engage in the co-production process as planned. **It is hoped that the Standards will be ready for publication by spring 2021.**

**(Page 113) 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.**

### **Scottish Government Response**

80. mPower<sup>13</sup> is a five year project managed by the Special EU Programmes Body and aims to create cross-border services for older people, aged 65+, who are living with long-term conditions. NHS National Services Scotland is the lead programme partner, with the University of the Highlands and Islands evaluating the programme. **Scottish Government will consider the findings of the evaluation once available.**

**(Page 113) 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.**

### **Scottish Government Response**

81. Remote Blood Pressure Monitoring (tele-monitoring) remains a priority for the Scottish Government. The Technology Enabled Care programme has supported the remote diagnosis and management of hypertension for well over 13,000 patients to date and 423 GP practices have already signed up for remote hypertension management alone. This is currently available across 13 of 14 Health Boards in Scotland. Scale up BP is by far the biggest remote monitoring intervention we've been trying in Scotland. There is strong evidence that this is effective both in reducing blood pressure and reducing workload on general practitioners and nurses. It has been extremely popular with practices, particularly during the pandemic where it is seen as the means of managing the condition remotely. A blood pressure taskforce is in place,

<sup>13</sup> <https://mpowerhealth.eu/about>

being co-chaired by Professor David Webb and Professor Brian McKinstry. There remains significant scope for this remote management of blood pressure to be utilised even further. A number of evaluation studies<sup>14</sup> have been undertaken to support the development of this work and feedback from partners and the public who have used it remains positive.

**(Page 114) 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.**

### Scottish Government Response

82. As set out in our response to the Committee's report on the social prescribing of physical activity and sport, the Scottish Government greatly values the very significant contributions of voluntary sector and community organisations to improving the health and wellbeing of people in Scotland. Our response detailed a range of programmes in place to support and build capacity among community organisations and establish strong connections with healthcare practitioners, such as the Scottish Health Walk Network, the Active Living Becomes Achievable pilot programme, and the Changing Lives Fund.

**(Page 114) 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.**

### Scottish Government Response

83. A Local Information System for Scotland (ALISS) is a web-based resource which maps community assets and connects people with local sources of support that will enable them to manage their own health conditions more effectively. The Scottish Government funds the Health and Social Care Alliance Scotland (the ALLIANCE) to deliver 'ALISS'. ALISS is already available to be used as a support for social prescribing and primary prevention activities. ALISS is available online across Scotland to both the public and healthcare practitioners. As part of developing and building the system, the ALLIANCE has been working in partnership with NHS 24 and Macmillan Cancer Support to develop Scotland's Service Directory<sup>15</sup>, which forms part of the NHS Inform website. Through this partnership, the information contained in the ALISS database can also now be accessed through Scotland's Service Directory alongside other information provided directly by individual Health and Social Care Partnerships in order to provide a more comprehensive picture of statutory, Third Sector and community resources available across the country.

<sup>14</sup> <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003124>

<sup>15</sup> <https://www.nhsinform.scot/about-scotlands-service-directory#:~:text=Scotland%27s%20Service%20Directory%20%28SSD%29%20provides%20details%20of%20all,growing%20range%20of%20channels%20including%3A%20online%3B%20telephone%3B%20webchat>

**(Page 114) 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.**

### **Scottish Government Response**

84. As noted previously, **The Scottish Government has committed to establishing a short life working group to examine social prescribing of physical activity** that will identify and communicate examples of best practice and co-produce resources for practitioners in the many roles which make up the overall system. Examples of best practice will provide an opportunity for local initiatives and implementation to be shared and reviewed.

**(page 115) We would appreciate further detail on the aims and targets the Scottish Government is hoping to achieve through this work [on inequalities of access], alongside how the Scottish Government is measuring if this work is making a difference to people's lives.**

### **Scottish Government Response**

85. The Scottish Government is committed to making sport and physical activity accessible to all, regardless of background. In order to achieve this aim, as the Committee is aware from previous correspondence on the issue, we are working with partners to tackle inequalities through a wide range of actions, supporting people in overcoming the barriers many encounter in becoming active and staying active throughout their lives. As part of the detailed indicator set developed for our Active Scotland Outcomes, breakdowns are available across a range of different categories to enable our progress on tackling inequalities to be monitored. This data can be viewed at: <https://scotland.shinyapps.io/sq-active-scotland-outcomes-framework-indicators/>

**(Page 115) 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.**

### **Scottish Government Response**

86. Tackling health inequalities is a clear ambition for the Scottish Government alongside improving population health and tackling poverty. These principles are at the heart of our renewal and remobilisation plans. We want to ensure equity of access to all services, so that everyone in Scotland, can get the support they need to live healthy lives. Our healthy living strategies, published in 2018, include targeted actions that will help to prevent ill health and reduce health inequalities. We must now, more than ever, give our communities and local services the support they need to tackle these issues head on. As the committee will be aware, measuring the impact of

interventions targeted to improve health and wellbeing outcomes take time to be realised.

**(Page 115) We would welcome further detail on the timescales for this work [on developing community wellbeing services and supports across Scotland for 5-24 year olds], plans for how it will be achieved and what further action Scottish Government is taking to promote social environments, community assets and local connectedness.**

### **Scottish Government Response**

87. In March 2020, Scottish Government awarded every local authority a share of £2 million to allow them to review existing provision, map need and consult with stakeholders in their area. Due to the pandemic, some areas are further ahead with this than others, but all are now in the process of submitting plans on new and enhanced supports and services that will be introduced from January 2021. These services will be responsive to local need but all adhere to the principles of the Children and Young People's Mental Health and Wellbeing Supports and Services Framework which was developed by the Taskforce and is being overseen by the Programme Board. The Framework is being supported by an annual investment of £15 million via Local Authorities.

**(Page 116) 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.**

### **Scottish Government Response**

88. Scotland's physical activity delivery plan, A More Active Scotland, sets out our headline measure of progress as the proportion of the population meeting the recommended level of physical activity. This is a National Indicator and contributes to the Scottish Government National Outcome "We live longer, healthier lives." We also continue to measure our progress through a range of more detailed indicators which support each of the Active Scotland Outcomes. A substantial revision and expansion of these indicators has been undertaken, and data contributing to each of these outcomes is now available online<sup>16</sup>.

**(Page 116) 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.**

### **Scottish Government Response**

89. As set out in previous correspondence with the Committee, following its audit of community access to school sport facilities conducted in 2013, **sport** Scotland has been working with local authorities to encourage and support them in widening access to school sport facilities. Although this work has for obvious reasons been affected by the COVID-19 pandemic, this has involved working in partnership with local authorities

<sup>16</sup> <https://scotland.shinyapps.io/sg-active-scotland-outcomes-framework-indicators/>

to support various aspects of their planning, including facilitating the development of local sport and sport facilities strategies, and supporting operational planning at individual school level, including developing Community Sport Hubs within schools.

**(Page 116) We would welcome further detail on when the Scottish Government will start allocating three-year contracts [for third sector organisations], and timescales for ensuring this happens for all organisations.**

### **Scottish Government Response**

90. We recognise the importance both of long-term funding stability and of timely payments for the third sector to fulfil its vital role in Scotland's communities. The Scottish Government has committed to seek to extend three-year rolling funding where possible and we are actively progressing this work. To provide early certainty, our practice is wherever possible to confirm future grant offers before the preceding funding period ends. We are of course constrained to a degree by the wider UK budgeting arrangements. For example, in 2019-20 the UK Government provided a budget settlement for 2019-20 only, and for the year 2020-21 the UK budget announcement was delayed until March. Obviously this has serious implications for the Scottish Government's ability to invest over the longer term. We hope that future UK Spending Reviews will offer sufficient multi-year budget information to better enable longer-term funding arrangements.

**(page 117) We are unclear whether the examples given [where Integration Authorities are investing in physical activity programmes and working with local communities] 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.**

### **Scottish Government Response**

91. The Public Bodies (Joint Working)(Scotland) Act 2014 places a duty on Integration Authorities to create a strategic plan for the integrated functions and budgets that they control, and how they will best meet the needs of their local population. Each Partnership's strategic commissioning plan should be based upon a Strategic Needs Assessment of local people's needs. Stakeholders must be fully engaged in the preparation, publication and review of the strategic commissioning plan, in order to establish a meaningful co-productive approach, to enable Integration Authorities to deliver the national outcomes for health and wellbeing, and achieve the core aims of integration. Integration Authorities routinely underpin these plans with a suite of specific plans, which will provide more detail on how they will support and provide care for those in the partnership area. This requires close working with stakeholders, professionals and local communities to deliver sustainable models of care and support that are focused on improving outcomes for people.

**(Page 117) We request further detail on timescales, proposed membership and remit for the Working Group [to identify and communicate examples of best practice, and coproduce resources for practitioners in the many roles which make up the overall system].**

### **Scottish Government Response**

92. As noted previously, **the Scottish Government has committed to establishing a short life working group to examine social prescribing of physical activity** that will identify and communicate examples of best practice and co-produce resources for practitioners in the many roles which make up the overall system. Examples of best practice will provide an opportunity for local initiatives and implementation to be shared and reviewed. Notably, the establishment of the Working Group has been delayed by the COVID-19 pandemic but will recommence shortly. **We continue to work with partners who are delivering social prescribing initiatives** and can provide further details in due to course.

*Realistic Medicine*

**(page 121) We recommend the Scottish Government consider use of the GMS contract as a tool to go beyond mere encouragement of its realistic medicine agenda.**

### **Scottish Government Response**

93. Realistic Medicine is primarily about changing the culture of the way healthcare is practised in Scotland – to persuade professionals that they are the stewards of healthcare resources and they must help to redirect resource from low value to higher value care and reduce the waste and harm. The online Scottish Atlas of Healthcare Variation will be an important tool in supporting clinicians do just that. It is a key component of our work to support healthcare professionals to practise Realistic Medicine, by seeking out and tackling unwarranted variation in health, treatment and outcomes. Atlas maps can help ensure the prevention of harm and waste caused by overuse and overtreatment. By doing so, resources currently used with little or no clinical benefit can be freed up and redirected to address the under-provision of clinically appropriate care elsewhere. The Atlas includes maps on prescribing data, which aim to support clinicians in identifying optimal approaches and outcomes in care. On 30 September, the General Medical Council (GMC) launched updated guidance on *decision making and consent*. The guidance focuses on person centred care and aligns with the Realistic Medicine agenda in Scotland. It promotes shared decision making as the key to ensuring people receive the treatment and care that they need, based on what matters to them, and ensuring they have all the information they need to give informed consent. *Decision making and consent*<sup>17</sup> provides a framework to help doctors practise shared decision making. The focus is on the importance of ongoing and meaningful dialogue and empowering people to take an active role in in their care and treatment. This updated guidance provides an opportunity to bring person centred care to the forefront and allow clinicians to reflect on any areas for improvement when helping patients to make healthcare decisions. It

<sup>17</sup> <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent>

also addresses some of the issues raised by the Paterson inquiry and IMMDS (*First Do No Harm*) review. Practising in line with the guidance can help to mitigate the likelihood of similar circumstances arising in the future. We also know that the COVID-19 pandemic has created new and ongoing challenges for many doctors and that the profession continues to adapt to enable flexible delivery of services. Increased use of remote consultations, more frequent multidisciplinary team working and greater need for delegation are just a few examples of this. The way clinicians have adapted and embraced new ways of contact is testament to the commitment and dedication of our medical workforce. It has transformed models of care whilst maintaining the high quality experience for people accessing healthcare services. Many Health Boards now include questions for patients to ask that will help them make an informed choice about the treatment and care that is right for them on the back of appointment letters and we are looking to include similar questions within virtual consultations. **The Scottish Government has provided NHS 24 with funding to develop and promote a campaign to raise awareness that it is alright for people to ask questions of their professionals. This campaign will be developed and run over the next two years.** In addition, local Health Board Realistic Medicine Leads will be able to support staff to improve their communication and shared decision making skills by signposting to local development opportunities. NHS Education for Scotland has also produced an online introductory module on shared decision making and the Chief Medical Officer has encouraged staff to complete it.

## Dispensing

### Community Pharmacy Contract

**(Page 123) 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.**

### Scottish Government Response

94. Work continues between Scottish Government and NHS Boards on sharing best practice and achieving the best clinical outcome for patients through effective prescribing and also tangible savings for the NHS. Our work on biosimilars has been described earlier in this response.

**(Page 125) 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.**

### Scottish Government Response

95. A company may only market and sell a medicine in the UK if it holds a Marketing Authorisation (MA), for that product. The therapeutic or diagnostic purposes for which the product can be marketed and the dose, route of administration etc. are limited by the terms of the Marketing Authorisation. The arrangements for issuing a Marketing

Authorisation are determined by the Medicines Act 1968 and implemented through the Medicines and Healthcare Products Regulatory Agency (MHRA). The MA for a medicine provides assurance regarding the safety, quality and efficacy of that medicine and places certain liability on the holders of the MA. Relevant legislation does not affect the clinical freedom of prescribers to prescribe what they believe is best for their patient including medicines that do not have a licence (“unlicensed”) or used in ways different from those specified in the Marketing Authorisation (“off-label”). We adapted the Off-label Cancer Medicines Programme, which has been considering the off-label use of cancer medicines, in March in response to COVID-19. The programme team was redirected to support the work of the National Cancer Medicines Advisory Group (NCMAG) convened by the SGHD COVID-19 Cancer Treatment Response Group ([link](#)). This resource along with the guiding principles and operational framework developed by the programme has enabled a rapid response to facilitate assessment and access to alternative cancer treatment during COVID-19. The group has reviewed multiple proposals and issued advice to Health Boards. Critical to the success of this work has been the multi-professional clinical leadership, participation from all three cancer networks and access to additional critical appraisal and clinical capacity to meet demand during COVID-9. There is scope for using the learning from the revised off-label cancer outcome programme and apply it to other medicines where there is demand for off-label use. **We will give this further consideration early in 2021 as part of a wider review of our access to medicines policy which will include the governance and guidance of off-label prescribing.**

**(Page 129) 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.**

### **Scottish Government Response**

96. Recognising the professional and clinical expertise that pharmacists bring to the NHS and in particular community pharmacy services have been key to discussions with the representative body, Community Pharmacy Scotland. The contractual framework has developed over a number years to not only achieve best value for money for the public purse, but ensure that the pharmacists and those in the pharmacy network, as medicine experts, deliver our services based on pharmaceutical care provided to patients. The focus of discussion on the national contractual framework has been on these aspects with services such as NHS Pharmacy First Scotland which will record and evidence the value which the pharmacy network are providing. **The Scottish Government will continue to focus on these discussions with Community Pharmacy Scotland in developing Pharmaceutical Care Services for Scotland.**

**(Page 134) 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.**

### **Scottish Government Response**

97. Pharmacists would need to ensure that they practise in line with the Regulator's, the General Pharmaceutical Council (GPhC), standards when visiting individual private residences. Pharmacists are subject to enhanced disclosure checks. There are no arrangements made in the community pharmacy national framework and therefore such services would most likely be offered as a locally enhanced pharmacy service, negotiated, remunerated and any appropriate Service Level Agreement and governance agreed with the territorial Health Board.

**(Page 134) We also ask the Scottish Government to advise what aspects of data collection are covered in the new pharmacy contract.**

#### **Scottish Government Response**

98. Data collection continues to remain core in the delivery of all pharmaceutical care services provided through the national contractual framework. As services are enhanced or new services developed, Public Health Scotland will report against a range of measures including financial impact including the core services, Medicines: Care and Review, NHS Pharmacy First Scotland, Acute Medicines Service and Public Health Services.

**(Page 134) 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.**

#### **Scottish Government Response**

99. In response to the COVID-19 pandemic, rollout of the Emergency Care Summary was accelerated across the range of Primary Care independent contractors. **We continue to take forward this work forward through the Health and Care Digital Strategy.**

**(Page 134) 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.**

#### **Scottish Government Response**

100. Deliveries are not offered as part of an NHS Pharmaceutical Service. The Scottish Government does not endorse the introduction of delivery charges for patients for the delivery of prescription medicines and have called on such charges to be removed not only for patients in Scotland but across the UK. The introduction of delivery charges can be seen as counterproductive to the removal of prescription charges. While not supportive of such charges, each pharmacy contractor, irrespective of size, is responsible for its own day-to-day operational processes taking into account their business model. The previous Chief Pharmaceutical Officer and her officials have met with a representatives to discuss a number of issues including the impact that the home delivery charge may have on patients in Scotland. While the company concerned understand the concerns of patients, the introduction of these charges was

not taken lightly and is a direct result of the impact on the company's financial accounts in both their UK and Global operations, making the continuation of free home delivery unsustainable. **The Scottish Government will continue to push for pharmacy service providers to ensure such approaches do not impact on patient equity of access to their prescribed medicines.**

**(Page 135) We recommend the next iteration of the Community Pharmacy contract takes account of compensation for pharmacist delivery of prescriptions.**

### **Scottish Government Response**

101. Delivery of prescription medicines are not considered an NHS Service. Offering them as such could lead to an imbalance of service provision across the pharmacy network. The decision to offer such services are wholly for the pharmacy contractor taking into account their business operating models. For those reasons it would not be financially sustainable to offer such services, even if remunerated through the pharmacy funding model, particularly for those more remote and rural pharmacy owners. There has been no call, or concerns raised, by the representative body, Community Pharmacy Scotland, to consider this as part of the funding arrangements.

**(Page 136) 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".**

### **Scottish Government Response**

102. Through Scottish Government investment, NES have provided a number of training places on courses to support pharmacists since the start of the current GMS contract in 2017. The initial area NES focused on was provision of training for senior pharmacists appointed into the General Practices by providing a national Advanced Practice Learning Pathway which included the following aspects:

- Underpinning knowledge e-learning resources (additional e-learning resources in development to support clinical decision making and online tutorials for basic clinical examination skills)
- Advanced Practice Framework with Educational (ES) and Clinical Supervision (CS) with biannual assessments
- Residential training course (Bootcamp) with multidisciplinary teaching
- IP and Clinical Assessment Skills qualification

To date, 394 pharmacists have commenced on the NES Advanced Practice Learning Pathway, with a further 35 expected to commence in January 2021 (this will be Cohort 9). From October 2017 to November 2019, 194 pharmacists working in GP Practice have undertaken or are currently undertaking their independent prescribing qualification. In addition, 190 senior pharmacists have been trained as Educational Supervisors, with a further 11 due to undertake training in December 2020. On review of the skill mix to deliver the three levels of Pharmacotherapy services it became apparent that more junior pharmacists, pharmacy technicians and pharmacist assistants could be trained to deliver Level 1 and 2 services, allowing the more senior pharmacists trained to deliver parts of Level 2 but mainly Level 3 services. Foundation training for newly qualified pharmacists was also set up to accommodate the more junior pharmacists appointed into GP practices – this involves a 2 year programme with training days and educational/clinical supervision. To date, 53 Foundation pharmacists have commenced the training practice programme to deliver pharmacotherapy services, with a further 24 having completed the programme. To date, 38 Pharmacy Technicians have commenced the Foundation training practice programme for pharmacy technicians to deliver pharmacotherapy services and a further 30 are due to commence this in January 2021. In terms of pharmacy support staff are being trained to mainly deliver parts of the Pharmacotherapy level 1 service. They are receiving ad hoc training within each of the HSCPs with access to some of the NES e-learning resources developed for pharmacy technicians who have commenced the Foundation training practice programme to deliver pharmacotherapy services. In addition, a training needs analysis of Primary Care pharmacy staff across Scotland has been completed. **We are progressing data analysis to inform the future training requirements to meet the needs at all levels of pharmacotherapy across Scotland.**

**(Page 139) 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.**

### **Scottish Government Response**

103. The project team at Strathclyde University submitted a draft final report in January 2019 on the adoption of automation in community pharmacy. The aim of the evaluation was to provide evidence to assess the potential role of technology and automation in supporting the delivery of safe and effective pharmaceutical care in the community setting, and to highlight the key issues faced by pharmacies installing new technologies in order to facilitate greater information sharing and learning of potential benefits, costs, challenges and enablers. The evaluation comprised 9 ‘early adopters’, 5 standalone (single site) pilot pharmacies, and two spoke and hub operations. The early adopters were UK-wide and comprised 5 pharmacies with standalone robots, 2 pharmacies with hub technology, and two spokes associated with each hub. All data on the standalone pharmacies has been received and analysed, and the report has been updated to include this along with case profiles. Both the Scottish Government and the evaluation team agreed that the evaluation should be extended into 2019 to evaluate the spokes and hub data (which had been delayed due to technical issues around software compatibility), and to provide an update on the data from the standalone pilots. A revised timeframe was agreed and the project was due to

complete in April 2020. This revised date was then subject to more delay as a result of the pandemic. **Scottish Government officials are due to meet with the project team at the end of this month to discuss a project completion date and dissemination of the final report.**

## Care homes

**(Page 142) We ask the Scottish Government how much wastage is produced from care homes returning medicine and at what cost to the NHS?**

### Scottish Government Response

104. It is not possible to quantify the volume of wastage in returned medicines from care homes. It is worth noting that not all medicines wastage is avoidable, or is the result of poor practice. Previous studies have indicated that less than 50 per cent of medicines waste is likely to be cost effectively preventable.

**(Page 143) 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.**

### Scottish Government Response

105. Just in Case boxes (JICB) are recommended in the Scottish Palliative Care guidelines to provide timely access to palliative care medicines for symptom control, for end of life care. Care homes use the appropriate prescribing pathway to prescribe JICB for care home residents, on an individual patient basis. However, with the changing patient demographics in care homes, care home residents are older and frailer, and the increased number of care home residents that are palliative, this may result in numerous JICB being prescribed per care home.

There are advantages of care home residents being able to access JIC medicines -

- Palliative care patients may suddenly deteriorate, having timely access to JIC medicines can provide symptom relief for end of life care.
- Decreases the stress of care home staff having to obtain urgent palliative care medicines from a pharmacy, especially out of hours.
- Relief for care home residents, families and staff that JICB medicines are readily available, if required
- Supports patients to remain at the care home for end of life care, if that is their preferred place of death. Allows the care home residents to be supported by care home staff that they know and trust.
- Increases the chance of the care home resident remaining in the care home for end of life care, rather than being transferred to hospital for symptom relief/end of life care.
- Decreases unscheduled care admissions
- Empowers nursing/care home staff to allow better care
- Reduces calls to NHS 24/Out Of Hours team for palliative care medicines.

**(Page 143) 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.**

### **Scottish Government Response**

106. Care homes being granted a controlled drug licence would enable care homes to stock JIC medicines as ward stock but there are associated risks with doing this, namely the potential risk of diversion. The current legislation, which is reserved to the Home Office, does not permit care homes (except in a few exceptional circumstances) to stock controlled drugs as and so Just in Case Box (JICB) medicines for end of life care are provided on an individual basis as part of anticipatory care planning. We made representations to the Home Office, as part of our COVID-19 response, for this to be relaxed but this was not accepted. **The Scottish Pharmacy Clinical Leadership Fellow intends to undertake an audit to determine the wastage of just in case box medicines in care homes, and we will await the Fellows report and recommendations in Spring 2021.**

**(Page 144) 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.**

### **Scottish Government Response**

107. Lessons from the NHS Tayside work will be considered by Scottish Government and NHS Boards to consider factors in scaling such schemes across Scotland.

**(Page 146) We request detail from the Scottish Government on what learning from good practice elsewhere is undertaken in this area and how that is encouraged.**

### **Scottish Government Response**

108. As part of the work of the Scottish Pharmacy Clinical Leadership Fellow, local examples of good practice of pharmaceutical care in care homes that could be further tested or spread are being collated. We await the Fellow's final report in January 2021 to consider how these can be encouraged.

**(Page 146) 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.**

## Scottish Government Response

109. In May, it was announced that multi-disciplinary enhanced clinical and professional oversight arrangements for care homes should be put in place in every Health and Social Care Partnership area. This included a daily meeting of the Chief Officer, Chief Social Work Officer, Director of Nursing, Director of Public Health and Clinical Director (or their representatives) to review the position of all adult care homes in their area. Infection Prevention and Control – updating IPC guidance specifically for adult residential settings, including care homes and community care practice guidance. We are providing an additional £7 million to enable IPC support and training for adult social care staff led by Health Board Nurse Directors. Introducing a daily review of COVID symptoms in care home residents and staff for which we will shortly issue a checklist of the broader COVID symptoms common to the care home cohort. We are also providing £5 million to support greater early escalation and oversight of outbreaks. There are emerging models of care where Advance Nurse Practitioners (ANPs) have replaced the role of GPs in care homes in reviewing residents' health care needs, which will include prescribing. The best models we have are a Multi-Disciplinary Team approach to care which includes the GP, Pharmacist, ANP, District Nurse and/or the care home liaison nurse working together. Pharmacists play a key role in polypharmacy which is a key issue in care homes and working alongside registered nurses or GPs can provide an invaluable interdisciplinary service to improve medicines management and care in care homes.

The work being progressed under Transforming Roles (TR) specifically looked at the role, competencies and education requirements of registered nurses working in care homes and also looked at the peripatetic models of care for care homes. Unfortunately this work was halted due to COVID but is due to be recommenced again soon. Non-medical prescribing is a core requirement for district nurses and the Scottish Government has funded additional education for District Nurses in non-medical prescribing and advance clinical decision making which is not part of the District Nursing Specialist Practitioner Qualification. There is also funding to support an additional 375 nurses within the district nursing service based upon the current skills mix. However, District Nurses must be given the opportunity to have their competencies signed off by a medical practitioner and opportunities to maintain their competencies. It is crucial therefore that as part of the new model of clinical care for care homes all of the above is given full consideration. Another issue in the report of note is the implementation of the electronic MARs system in care homes which is the medicines administration and recording system. As part of the TR work we were also reviewing the roles, competencies and education requirements of the wider care team to enable them to meet the changing needs of residents. The TR group for Nursing in Care Homes included members from NHS Boards, the care home sector, pharmacy, palliative care, SSSC, the Care Inspectorate and Scottish Care. Many care homes in Scotland do not have registered nurses and it is essential that the social care workers have the support and skill to meet the changing needs of residents in care homes many who now require ongoing nursing support and leadership, along with pharmacy and AHP support.

**(Page 146) 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 Response

110. GP practice-based pharmacists can play an important role working closely with care homes to ensure seamless care and reduce potential medication related problems and errors. However, we agree there is a need for high quality pharmaceutical care to meet the medication needs of the whole cohort of care home residents, many of whom have increasing dependency and multi-morbidity. We believe there is an opportunity to build on the role that community pharmacists fulfil in terms of the supply of medicines and related advice and support for people in care homes too. More recently new models of care have been emerging with community pharmacists. GP practice-based pharmacists and pharmacy technicians providing more tailored pharmaceutical care in care homes. Our Achieving Excellence in Pharmaceutical Care (AEiPC) strategy identified that opportunities exist to determine national standards for documentation and recording systems which can support integrated information exchange, including medicines reconciliation at admission, transfer and discharge for residents. Additional benefits include the introduction of national standards for the safe administration of medicines, the development and delivery of quality assured training for care home staff and regular multidisciplinary reviews of medication. AEiPC committed to working with Chief Officers of Integrated Joint Boards to identify national approaches to improve NHS pharmaceutical care for residents in care homes. The work of our Scottish Pharmacy Clinical Leadership Fellow will support this and make recommendations for the next steps in moving forward. The Fellow will focus on representing the pharmacy profession on the new national specialist interest care homes group, setting up the infrastructure within the profession to collaborate, prioritise and deliver priorities and where appropriate influence the support of national organisations to respond with a once for Scotland solution. The Fellow is due to produce a report for the Chief Pharmaceutical Officer in January 2021.

**(Page 147) We note the exploration going on [around the Pharmacy Clinical Leadership Fellow’s work on improving the pharmaceutical care of residents in care homes] 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.**

## Scottish Government Response

111. The Scottish Pharmacy Clinical Leadership Fellow’s work was paused due to the global pandemic, which has resulted in a delay to progress. The pandemic exposed the vulnerability of care home residents and their need for additional support from health and social care professionals. The Clinical Fellow will continue to engage with the key stakeholders as required to understand the scope and quality of pharmaceutical care in care homes and their priorities for improvement until January 2021. The Fellow has set up a Care Homes Special Interest Group, which is due to have their next meeting in December 20. The Fellow will produce a final report, to be submitted to the Chief Pharmaceutical Officer by January 2021, with recommendations for consideration

## Online Pharmacy

**(Page 147) 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.**

### Scottish Government Response

112. While the existing NHS Pharmaceutical Services (Scotland) Regulations 2009 do not support the operations of online pharmacies in a Scottish context, our strategy on Achieving Excellence in Pharmaceutical Care commits to review the existing contractual framework to support the delivery of pharmaceutical care to patients providing them with direct access to a healthcare professional and maximising the expertise of the pharmacists and discouraging an operating model based on transactions.

### Consumption

#### Waste

**(Page 155) 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.**

### Scottish Government Response

113. The prescribing and dispensing of the majority of prescriptions in primary care is underpinned by the electronic transfer of prescriptions. The ePharmacy Programme provides community pharmacists with the opportunity to cancel an electronic claim message for any medicine which have been dispensed but not collected, which means that in the majority of situations there should not be an overpayment. There is a time limit on when an electronic cancellation message can be sent and so there is also a manual process which can be used out with the electronic option. Payment verification processes provide an additional measure of governance. On balance, asking community pharmacists to undertake an audit, which would only give a snapshot at a moment in time, would be a disproportionate measure. **We will continue to keep this under review though.**

**(Page 156) 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.**

### Scottish Government Response

114. The Falsified Medicines Directive has introduced the concept of anti-tamper proof packaging which can provide a degree of reassurance. However, it is almost

impossible to be able to provide an assurance that the medicine has been stored in appropriate conditions, which varies from medicine to medicine. Waste often occurs where medication is not taken as prescribed (often referred to as non-adherence) **and we are working to develop tools to identify patients with medication adherence issues to allow them to be prioritised for clinical review.** This is supported through our approach to Realistic Medicine, our Polypharmacy work, the pharmacotherapy component of the GP contract and the Medicines Care and Review element of the community pharmacy contract.

**(Page 158) 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.**

### **Scottish Government Response**

115. The Scottish Patient Safety Programme (SPSP), launched in January 2008, is a unique national initiative that aims to improve the safety and reliability of health and social care, and reduce harm whenever care is delivered. The SPSP is led and co-ordinated nationally by Healthcare Improvement Scotland. Healthcare Improvement Scotland supports Health Boards through local teams within hospitals, GP practices, mental health inpatient units and community pharmacies using a collaborative approach to bring NHS Boards together to share and learn from each other. This is interspersed with periods where local teams test and implement changes using improvement methodology to bring about improvements in care provision. Improvement areas, such as leadership, communication, safety culture and safer use of medicines, are key elements across the entire SPSP. Since the introduction of the SPSP, the Scottish Government has had a Clinical Lead for Safety and Quality. Part of their role is to ensure the direction of the Patient Safety work is joined up across Government and the NHS, and more recently social care. The SPSP continues to be implemented in every NHS Board across Scotland, and is designed to improve the safety of care. **There is a specific work stream that focuses on medicines.** Our Realistic Medicine policy also aims to add value and limit the harm caused by medicines by reducing: unwarranted variation and waste; over-investigation; over-diagnosis; and over-treatment. It encourages clinicians to lead with the least invasive processes first, to manage risk proportionately and to understand the limits of evidence. A key area of focus includes working in active partnership with people to build a personalised approach to their care. We continue to explore ways to strengthen this approach. **As part of Achieving Excellence in Pharmaceutical Care we will be commissioning Healthcare Improvement Scotland to strengthen the available data on harm and establish measuring and monitoring parameters for medicines safety more broadly to consider past, present and predictable future harm.** Recent developments in the community pharmacy contract have included introducing continuous improvement as an on-going element of the community pharmacy funding arrangements with the aim of applying improvement methodology into day-to-day practice. This has included the national roll-out of the patient safety climate survey across community pharmacy. The work has been supported by Quality Improvement in Pharmacy Practice Collaborative (QIPP) consisting of the Royal Pharmaceutical Society (RPS), Community Pharmacy Scotland (CPS), NHS Education for Scotland (NES), Health Improvement Scotland, The Health

and Social Care Alliance Scotland (The ALLIANCE), Yellow Card Centre Scotland and NHS Boards. **We will continue to build on this.**

**(Page 158) 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.**

### **Scottish Government Response**

116. We continually consider how improvements can be made to our systems for prescribing and dispensing medicines, including how technology and scanning can support this. **This will form part of the work described earlier in terms of the digital prescribing and dispensing pathway we have commissioned. In addition, we will ask the QIPP programme to consider further improvements and enhancements.**

**(Page 158) 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**

### **Scottish Government Response**

117. All consultations between GPs and other prescribers are undertaken with the patient or the patient's representative to ensure the suggested prescribed action is most appropriate for the patient, and achieves the best clinical outcome, taking the patient's medical history into account. In addition to this, a patient information leaflet is a technical document included in every medicine package to offer written information about the medication. Patient information leaflets (PILs) are provided by the manufacturer following a standard template consisting of the same types of information for every medication. In addition, the General Medical Council (GMC) launched updated guidance on *decision making and consent*. The guidance focuses on person centred care and aligns with the Realistic Medicine agenda in Scotland. It promotes shared decision making as the key to ensuring people receive the treatment and care that they need, based on what matters to them, and ensuring they have all the information they need to give informed consent.

**(Page 159) 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.**

### **Scottish Government Response**

118. All healthcare professionals have a professional duty of care to their patients which includes ensuring good communications occur and where necessary are recorded.

**(Page 159) Manufacturers should be encouraged to consider packaging which both aids consumption and enables returned medicines when in date to be reused.**

### **Scottish Government Response**

119. The packaging of medicines is regulated by the MHRA. The safety and efficacy cannot be guaranteed once the product has left the pharmacy premises, particularly for medicines which have specific storage conditions.

**(Page 160) 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**

### **Scottish Government Response**

120. Some care homes are moving to an electronic MAR (eMAR) system which will be able to, in future, provide more prescribing data on just in case box/palliative care prescribing. **We will commission the Care Home Clinical Fellow to review the benefits and report to the Chief Pharmaceutical Officer with a view to alignment with the refreshed digital health and care strategy.**

**(Page 160) 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.**

### **Scottish Government Response**

121. Along with local Health Board and HSCP campaigns, the Scottish Government will consider the use of better public messaging in health and social care settings on the correct way to dispose of medicines.

**(Page 163) 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.**

### **Scottish Government Response**

122. Ensuring all clinicians and healthcare professionals have access to the best available information about their patients at the appropriate time is essential to the delivery of high quality care. The Scottish Government are committed to improving information sharing and our data systems to improve patient outcomes. The National Digital Platform is intended to provide the technical architecture which ensures that key things are only done in one way across Scotland, such as how people are identified and where clinical data is stored, thus avoiding having to have a different

log-in for every system and the duplication of information. It is envisaged that the NSS/NDS work programme described earlier will be a key enabler in supporting a person-centred electronic health record ensuring relevant data are accessible to health and social care teams where and when needed, as will the implementation of HEPMA.

## Data & IT

### *Outcomes*

**(Page 168) 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**

### **Scottish Government Response**

123. As we noted previously, the Scottish Government funded Cancer Medicines Outcomes Programme (CMOP) is an example of using real world outcome data to consider the impact of cancer medicines in patients. The CMOP programme is growing a scalable and sustainable capability of expertise in cancer medicines intelligence to drive continued improvement in the safe and effective use of these medicines across Scotland. **The lessons learnt in cancer can then be applied across other clinical priority areas.** The CMOP team will share findings and engage with key stakeholders over the lifespan of the programme.

**(Page 168) 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.**

### **Scottish Government Response**

124. This was an internal Medicines Data Requirements Working Group which was established to better understand the existing systems that capture medicines use and outcomes data in Scotland and the quality of the data to inform our considerations on how to implement the data requirements highlighted in Dr Montgomery's review on access to medicines.

**(Page 168) 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.**

### **Scottish Government Response**

125. The group mapped the data infrastructure and capabilities in Scotland, and opportunities and gaps in relation to medicines and outcomes. Its findings, along with our CMOP experience and other data initiatives, will be used to inform the data strategy document that will be published in 2021.

## Conclusion

**Page 169) 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.**

### Scottish Government Response

126. COVID-19 has demonstrated that the health care system can respond at pace and scale. Ensuring appropriate levels of access to health information for all health and social care professionals will continue to be taken forward and enhanced as part of the refresh of the Digital Health and Care Strategy.

**(Page 169) 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.**
- **A progress update on delivering the Health and Care Digital Strategy, including timescales for implementation of the "national digital platform" and how the "programme of work" will integrate with this.**

### Scottish Government Response

127. As outlined previously, there is little provision in existing NHS IT systems to collect information about the purposes for which medicines are prescribed and the outcomes achieved by particular medicines. While this gap is a common feature of health systems in the UK and internationally, it is a significant constraint on the development of medicines policy and is a particular focus for the pharmaceutical industry, for whom data about outcomes achieved is of obvious scientific and commercial interest. Dr Brian Montgomery's Review of Access to New Medicines recognised Scotland's reputation for high quality data. It also identified some of the gaps in existing IT capabilities and highlighted the need to develop a more sophisticated approach to the measurement of outcomes achieved by medicines. As the Committee will know, the Review made six recommendations specifically on data, including data capabilities, data requirements, data sets and a recommendation to "establish a multi-agency taskforce or equivalent to report on data requirements to support the assessment and introduction of new medicines going forwards." In response we established a Data Scoping Taskforce to determine the digital capabilities required to utilise real world health data to support the assessment and introduction of new medicines, together with ensuring on-going safe, effective use of established medicines. The Taskforce Report was published on 18th September 2018, and proposed five actions and this work is now informing our current plans. As announced in our Programme for Government, we are working with COSLA to refresh our digital health & care strategy which we hope to publish Spring 2021. **Thereafter we plan to create a dedicated data strategy for health & social care.** Changes will take time to develop and implement so this work is being progressed in phases, with the development of data

and datasets and the initial focus on cancer and ultra-orphan medicines. **More recently the Interim Chief Pharmaceutical Officer has commissioned a specific piece of work to use cancer as an exemplar on how this can be progressed.**

**(Page 170) 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.**

### **Scottish Government Response**

130. The National Digital Platform is intended to provide the technical architecture which ensures that key things are only done in one way across Scotland, such as how people are identified and where clinical data is stored, thus avoiding having to have a different log-in for every system and the duplication of information. This will be taken forward through the refresh of the digital health and care strategy

**(Page 170) 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.**

### **Scottish Government Response**

131. We have previously described the work underway through CMOP which will be instrumental in informing our approach to collecting and utilising both clinician and patient reported outcomes. This work, along with other developments described in this response, will inform the data strategy to be published in 2021.

**(Page 170) We recommend the Scottish Government establish a means of collecting information on medicine use by patients.**

### **Scottish Government Response**

132. We acknowledge that there is lots of data out there but not necessarily being utilised in a coordinated way so that is why we will publish a data strategy for Health & Care for the first time next year. In its development we will have extensive engagement with partners and various working groups to ensure that we can fully align and realise the benefits that the sharing of data will bring. We fully intend to provide the technical architecture which ensures that key things are only done in one way across Scotland and that citizens and our health & care staff work have access to the right information at the right time and that was a key aim within the Digital Health and Care Strategy. It is essential that we become more consistent on where data is stored and shared for not only medicines but the wider system. In 2021, **we will publish a refreshed Digital Health & Care strategy and provide an associated delivery plan that will include timescales for key developments such as the National Digital Platform.** This will help avoid duplication, reduce risks and harm. Covid-19 has meant changes to the way our health and care staff work, and changes to the way in which we deliver health and care services. We have learnt that it is important to have clear guidance and support for people transitioning to working in different ways and that it is critically important to

be open and transparent about how data is being used. We must hang on to the gains that we have made through increased use of digital technologies and further advance our aims to utilise digital first approaches wherever possible and deliver these as business as usual services for our citizens and Health & Social care staff. For ease of reference we have also written to the committee in July on the Digital response to COVID-19<sup>18</sup>.

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[https://www.parliament.scot/S5\\_HealthandSportCommittee/General%20Documents/20200706\\_Ltr\\_IN\\_from\\_CabSecHS\\_re\\_digital\\_response\\_COVID-19\\_WEB.pdf](https://www.parliament.scot/S5_HealthandSportCommittee/General%20Documents/20200706_Ltr_IN_from_CabSecHS_re_digital_response_COVID-19_WEB.pdf)