Cabinet Secretary for Health and Sport
Jeane Freeman MSP

Scottish Government
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Lewis McDonald
Convener
Health and Sport Committee

11 September 2020

Dear Convener,

I want to, once again, thank you for inviting me to attend the Health and Sport Committee's inquiry into the Supply and Demand for Medicines at the beginning of March. I would also like to offer my apologies for not responding to your letter of 23 March seeking further clarification following my appearance.

While the Committee's report highlights a number of important issues for Government, the NHS and manufacturers of medicines, the executive summary fails to be truly representative of the positive evidence provided to the Committee that is captured within the body of the report. It is particularly disappointing that the Committee has used the report to unfairly and unjustifiably criticise the leadership of those who gave evidence.

It is worth noting that the Committee's inquiry concluded taking evidence as we entered the current public health emergency. 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 service, including access to medicines. It is the systems and leadership, which the committee has criticised within the report, which provided the remarkable resilience that has ensured that medicines have continued to be provided to patients, effectively 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. It is, therefore, disappointing that the Committee's report risks damaging the people of Scotland's trust in the NHS and the care that it provides.

As I outlined in my letter to the Committee dated 28 July 2020, the report goes far beyond the published remit and as such contains misunderstandings, inaccuracies and inconsistencies. A number of areas highlighted, both during the evidence hearings and within the report, are not within the control of the Scottish Government and remain reserved to the UK Government.

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Whilst the Scottish Government will continue to represent the people of Scotland and ensure that decisions taken by the UK Government, such as exiting from the European Union Transition Period, have minimal impact on the NHS in Scotland and the people it cares for, issues represented in the report are misleading and do not capture the nuances of reserved and devolved responsibilities.

What follows is an overarching response to the main themes highlighted in the Committee's report.

Research and development

Personalised medicine and other advanced medicinal therapies offer opportunities to customise medicines for individual patients and have the potential to be transformative, often offering the possibility of long term remission. 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. As the report identifies, there are wide ranging implications for the managed introduction of advanced medicinal therapies encompassing clinical trials, aseptic services, quality assurance, health technology assessment, procurement, reimbursement, pharmacovigilance and the education of both healthcare professionals and patients. Good progress in addressing these types of issues has already been made by the NHS in Scotland and, across the course of the last year, we have seen the Scottish Medicines Consortium (SMC) accept two CAR-T preparations for routine use in Scotland. I very much welcome the therapeutic advancements in this area. 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.

Licensing and acceptance of new medicines

As the Committee will know, 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.

Manufacturers currently can apply to either the European Medicines Agency (EMA) or the MHRA for a marketing authorisation. A marketing authorisation from the EMA means the medicine can be marketed throughout Europe whereas a marketing authorisation from the MHRA means the medicine can only be marketed in the UK.
A marketing authorisation is granted to the manufacturer to market the medicine for a specific indication and not to the medicine itself. The Committee may wish to note that, on 1 September, the UK Government issued initial guidance on how this will operate after the EU Transition Period ends on 31 December.

In Scotland, we have a clear and consistent route for licensed medicines to be appraised through the SMC 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.

Once the SMC has recommended a medicine, it is expected that Health Boards will make it, or an equivalent SMC accepted medicine, available on their local formulary for routine prescribing. If a medicine is not included in a Health Board's formulary, and there are no suitable alternatives on the formulary, a clinician can request to prescribe another medicine if they think it will benefit the patient. Health boards have specific procedures in place to consider these 'non-formulary' requests.

Due to Scottish Government reforms and investment in recent years, we've 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. In addition, we have introduced improved processes for the consideration of individual medicines that have not been approved for populations use by the SMC such as the Peer Approved Clinical System (PACS). We are just in the process of considering any further enhancements to the PACS process in response to a six and twelve month review and I will be writing to the Committee on this matter in due course.

In its report, the Committee raised specific points about the repurposing of medicines, including incentivising and streamlining processes for their licensing and appraisal – processes which are reserved to the UK Government. Due to the reserved nature of medicine licensing processes, the Scottish Government continues to collaborate with the UK Government and other stakeholders in order to encourage and incentivise company licensing in this area. However, while it is a policy priority to increase access to appropriate medicines, we also must ensure that the safety, quality and efficacy of a medicine is not compromised in order to fast-track the licensing process. The recently published Cumberlege Review 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 Cumberlege Review. In addition, the Review is the subject of a debate in the Scottish Parliament.

In addition to incentivising companies to submit applications for licensing, there are other opportunities to use licensed medicines out with their original indication where there is a clinical need, such as off-label use. As the report notes, 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 medicines 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-June, the group had reviewed seventeen proposals and issued advice to NHS Boards.

As part of our response to the COVID-19 outbreak, interim governance arrangements for cancer medicines were 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 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.

Purchasing and procurement

As the committee will appreciate, 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.

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.

Dr Brian Montgomery's Review of Access to New Medicines (2016) noted that the "general approach of NHS Scotland to the negotiation of prices has tended to be reactive". One of his recommendations was to make greater use of National Procurement to lead negotiations on behalf of NHS Scotland on the cost of new medicines. My policy officials have been considering how to implement the recommendations from Dr Montgomery's Review in a way that accords with the Scottish Government's undertakings under the joint UK VPAS. Work is ongoing with key stakeholders on possible new steps to make the fullest use of devolved powers to achieve the best prices for new medicines in the NHS in Scotland.

There is clearly a growing interest from the pharmaceutical industry to explore outcome-based reimbursement and commercial payment agreements.

Scottish Government officials are actively considering new opportunities in relation to innovative and flexible approaches to pricing, including 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 the 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 Exit and, more recently, COVID-19 priorities. 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 Patient Access Schemes (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. 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.

Prescribing, Dispensing and Consumption

A significant reduction in waste and costs can be generated by better medicines use. At a patient level, caring for patients with multi-morbidities and polypharmacy is an increasing global challenge. A number of prescribing strategies have been published which lead to structured reviews of appropriateness, efficacy and tolerability of treatment. Through consideration of more appropriate treatment or non-pharmaceutical management of a condition, there is the potential to reduce medication burden on patients.

A substantial component of waste is 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. Medicines management continues to develop as an expert field in NHS Scotland, consistently delivering improvements to patient safety, effective care and efficient spending.

NHS Discovery provides comparative healthcare information for quality improvement, benchmarking and performance management across NHS Scotland. This information is used to produce quality prescribing information. Since 2012, the Scottish Government has published National Therapeutic Indicators, providing data on the variation in prescribing

across Scotland, allowing outlier prescribing to be identified. Some initiatives that boards have been working on include:

- increasing the use of generic medicines in secondary care
- reducing the amount of drugs dispensed in primary care by more regularly reviewing the medicines that are being prescribed
- switching from high-cost drugs to cheaper alternatives (biosimilars) to achieve the same results.

In recent years the community pharmacy financial settlement has been agreed as a one year financial package. In some respects that has not favoured the development of pharmaceutical care services. The Scottish Government has agreed a three year financial settlement that provides predictability and stability for both community pharmacy owners and NHS Boards up to the end of 2022/23.

The Scottish Government has introduced the new NHS Pharmacy First Scotland service in July 2020. NHS Pharmacy First Scotland ensures that community pharmacies are the first port of call for minor illnesses and common clinical conditions. NHS Pharmacy First provides all users with a consultation, providing advice which includes self-care; referral to another healthcare professional such as an optometrist; and/or treatment from an nationally approved list of medicines, ensuring consistency for patients and cost effectiveness for Boards

The Medicines: Care and Review service, similar to NHS Pharmacy First, provides greater opportunities to support people with long-term conditions by identifying and prioritising risk from medicines with a view to minimising adverse drug reactions, address existing and preventing potential problems with medicines and providing structured follow-up and interventions where necessary. My officials are also considering options to enhance the Pharmacotherapy Service by using community pharmacists, alongside pharmacists and pharmacy technicians already working in GP practices. With recent access to the Emergency Care Summary, community pharmacists are able to provide more effective advice and support to patients, in particular during out-of-hours periods.

The Scottish Government is taking forward a scoping exercise to develop an e-Prescribing system across primary care, as a first step towards an electronic health record that could span primary, secondary and social care. This shall consider an end to end digital solution that will support paper free (or light) approaches across the prescribing and dispensing pathway.

On the topic of the GP contract, 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. This is supported by measures such as contractual provision for protected time.

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 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).

Data and information technology

As the committee's report acknowledges, there is minimal provision to collect information about the purposes for which medicines are prescribed and the outcomes achieved by particular medicines or among particular groups. 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 recognised Scotland's reputation for high quality data. It also identified some of the gaps in existing IT capabilities. In particular, it highlighted the need to develop a more sophisticated approach to the measurement of outcomes achieved by medicines. It set out an aspiration for a suite of measures that includes real world data, patient reported outcomes, and an assessment of wider societal benefit. It also recognised the need to ensure that measures were consistent and allowed meaningful comparisons in order to inform decision making.

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." A Data Scoping Taskforce was established in 2017 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, as part of the Scottish Government's implementation of the Montgomery Review recommendations.

The Taskforce submitted its Report to the Scottish Government in early 2018. The Report provides good insight into the current health data informatics in Scotland and gaps in existing national data capabilities. It proposed five actions to address the Montgomery Review data-oriented recommendations.

These actions are being considered as part of a range of ongoing policy initiatives including our Digital Health and Care Strategy, the Chief Medical Officer's Realistic Medicine approach and the ongoing development and implementation of a Hospital Electronic Prescribing and Medicines Administration (HEPMA) system.

Changes will take time to develop and implement so this work is being progressed in phases and we are prioritising the development of data and datasets with the initial focus on cancer and ultra-orphan medicines. As I stated previously we are evolving our approach to medicines data with a view to enhancing Scotland's international reputation in health data research.

As acknowledged in the evidence session and in your follow up letter, HEPMA systems link the medicines prescribed, dispensed and administered in hospital to an individual patient. This makes HEPMA an important enabler for a single electronic patient record, which can link between primary and secondary care. We are aiming to secure the initial onboarding of HEPMA systems so that all Health Boards have HEPMA implementation processes underway, but not necessarily completed, during 2021. 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 we will be including a shared learning aspect as 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.

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 with nine Health Boards having commenced HEPMA implementation. Boards that have implemented HEPMA 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.

My officials continue to work with Health Boards to ensure a local and regional approach to delivery across all the remaining Boards and to support this we have established a national HEPMA Implementation Oversight Board. 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, digital developments, the digital health and care strategy and the National Digital Platform.

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 Board to continue to provide oversight until the convergence work is completed.

The Committee had asked a number of questions about the procurement process and achieving a uniform standard. A national multi-supplier framework for HEPMA was developed alongside a national Full Business Case in 2016. HEPMA suppliers were required to meet a set of national standards that described NHS Scotland's operational requirements for HEPMA. There was a rigorous assessment process and a robust clinically-led decision making process underpinning the framework, driven by ensuring any HEPMA system under consideration met the required standards and provided appropriate interoperability with existing systems.

When the multi-supplier framework was in place, Health Boards were then able to undertake a local mini-competition to determine which HEPMA system on the national framework offered best value and was the best fit to meet their local requirements. In undertaking the mini-competition Health Boards were driving down costs as well as increasing the functionality being offered. In advance of the national multi-supplier framework a number of Health Boards had progressed with local business cases and implementations based on the patient safety benefits of HEPMA.

Health Boards were also asked to look towards regional convergence which was not an insignificant task. A workshop was held in 2016 which aimed to ensure a greater understanding of the national HEPMA work, and the opportunity to explore the collaborative development of regional HEPMA roadmaps. Due to the complexities involved, the regions (with the exception of the North) have moved towards a board by board roll-out with regional convergence as the longer term view. The work from the North Region will be drawn upon to assist with the overall regional convergence plans. In addition, the framework approach taken, has resulted in all the Health Boards to date opting for the same HEPMA system, which will make the regional convergence easier to deliver in the longer term. Therefore there is not a patchwork of systems, although Health Boards may be operating different instances (versions).

Scottish Government officials have taken a stronger focus on supporting the implementation and the wider benefits of HEPMA and are working to re-energise the roll-out as part of developing the digital strategy. I have already advised that 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 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.

Healthcare Improvement Scotland have been commissioned to implement a shared learning system and will be dependent on the full participation from all Health Boards. To date, Health Boards have been enthusiastic to contribute. These shared learning outputs feed into the HEPMA Implementation Oversight Board.

Medicine outcomes

Returning to the subject of medicine outcomes, I warmly welcome the committee's acknowledgement of the success of the Cancer Medicines Outcome Programme (CMOP). Cancer medicines account for the highest proportion of new medicines introduced within NHS Scotland each year. Currently most of the information about the efficacy and side effects of cancer medicines is obtained through the results of clinical trials. However the outcome of these medicines in the local populations may be different to those reported in trials.

The CMOP is a collaborative programme between NHS Greater Glasgow and Clyde and the University of Strathclyde, funded by the Scottish Government. The aim of CMOP is to explore how to maximise the use of existing and new evolving electronic datasets to gather information on clinical outcomes such as survival rates, duration of therapy and treatment side effects. A recommendation in Dr Montgomery's Review was to develop, agree and implement a national cancer dataset – this programme is a vital first step towards achieving that.

The vision of CMOP is to create a national clinical effectiveness oncology resource to measure the clinical and patient reported outcomes of cancer medicines use in the real world and provide rapid feedback of finding to inform clinical practice.

Year one the programme focussed on patients receiving medicines for prostate cancer and malignant melanoma; year two looked at gynaecological cancers and colorectal cancer; and year three focused on multiple myeloma, renal and head and neck cancers and non-small cell lung cancer. Building on the foundations of the initial 3-year programme of CMOP, Scottish Government has committed additional funding to grow 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. As the committee had suggested, we would wish to extend this approach to other clinical areas in due course.

As highlighted earlier, the NES National Digital Platform will be an important policy enabler. It aims to provide a person-centred electronic health record containing all the information professionals and citizens need at the point of care. It will ensure that data, including clinician and patient reported outcomes, are accessible to health and social care teams, where and when needed.

Kind regards

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