Cabinet Secretary for Health and Sport
Jeane Freeman MSP

T: 0300 244 4000
E: scottish.ministers@gov.scot

Lewis Macdonald
Convener
Health and Sport Committee
T3.60
The Scottish Parliament
Edinburgh
EH99 1SP

By email

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Dear Lewis

Access to Medicines

Thank you for your letter sent on the 13th of December 2019 on behalf of the Health and Sport Committee.

As you noted, the letters of 16 November 2017, 2 February 2018 and 17 May 2018 provided an update to the Committee on the Scottish Government's progress in implementing the recommendations from the independent Review of Access to New Medicines undertaken by Dr Brian Montgomery. I write now to provide the Committee with a further update ahead of the Health and Sport Committee's inquiry into the Supply and Demand for Medicines.

I am pleased to be able to advise that, working closely with our partner organisations, patient representatives and the pharmaceutical industry, we have completed the delivery of the vast majority of the Review's recommendations and continue to make good progress with the remaining few. I would like to take the opportunity to acknowledge everyone who has played a part in helping achieve this and, in particular, the key roles played by the Scottish Medicines Consortium (SMC) and its affiliated committees including the Public Involvement Network Advisory Group and Industry User Group Forum, National Services Scotland and the Association of the British Pharmaceutical Industry (ABPI). A number of cross-party groups, including the Muscular Dystrophy and Rare, Genetic and Undiagnosed Conditions groups, were instrumental in providing informal consultation and feedback.

Review of Access to New Medicines

<u>Data and data sets</u>

Dr Montgomery's Review identified a number of benefits in developing national datasets and collecting data which could take account of the outcomes from medicines. As was

acknowledged in the Review, there are challenges associated with this, not least of all that there is no national system to underpin routine data collection on medicine outcomes. As a result, we have taken a strategic approach to data collection, which includes gaining traction and pace in terms of the implementation of Hospital Electronic Prescribing and Medicines Administration (HEPMA) across Scotland, prioritising the development of data and datasets with the initial focus on end-of-life and ultra-orphan medicines and refining data collection systems to enable monitoring of emergent trends.

Starting with recommendations 1, 2 and 3 of the Review, the new ultra-orphan pathway requires pharmaceutical companies to identify data sets to capture relevant clinical and patient reported outcomes for ultra-orphan medicines, as well as addressing the uncertainties associated with the medicines that have been highlighted as part of the SMC's initial assessment of the medicine.

For cancer and end-of-life medicines, the Innovative Healthcare Delivery Programme (IHDP) and National Services Scotland (NSS) are working jointly to develop national Systemic Anti-Cancer Therapy (SACT) reports using the data in the chemotherapy electronic prescribing system, ChemoCare. In parallel, the ChemoCare system is being upgraded across Scotland's cancer networks to better support this work going forward. It is anticipated that next year national-level data will be routinely available and advanced preparatory work is underway to integrate this with the new Scottish Cancer Registry and Intelligence Service. This will allow identification of variation in practice, meaning clinicians can benchmark with peers and for the first time offer real time data to drive improvement. Early in 2020, we will also progress to a common approach on consent for SACT treatments, ensuring patients across the NHS in Scotland have the same support for fully informed consent in their treatment.

We have also centrally funded a Cancer Medicines Outcomes Programme (CMOP), which is a collaborative programme between NHS Greater Glasgow and Clyde (GGC) and the University of Strathclyde, to determine the impact and clinical outcomes of cancer medicines on patients in the real world. Building on the foundations of the initial three year CMOP programme, we are working towards 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 and be recognised internationally in this field.

In relation to recommendation 4, work is continuing with the implementation of HEPMA. To date, three Health Boards (NHS Ayrshire & Arran, NHS Dumfries & Galloway and NHS Forth Valley) have completed implementation and NHS Lanarkshire is due to complete implementation in 2020. During 2019, NHS Lothian, NHS GGC and the North Region Consortium (NHS Grampian, NHS Highland, NHS Orkney, NHS Shetland, NHS Tayside and NHS Western Isles) all commenced their implementation, with the remaining Health Boards due to start in 2020-21. We will continue to work with Health Boards to ensure a local and regional approach to delivery across all the remaining Boards over the next three to five years and to support this we have established a national HEPMA Implementation Oversight Board.

In response to recommendation 5, as you are aware, we established a multi-agency Data Scoping Taskforce to report on the data requirements to support building capability to assess the real world benefits, risks and values of medicines. The Taskforce's remit was to

determine the digital capabilities required to utilise real world health data to support the assessment and introduction of new medicines, together with ensuring the on-going safe and effective use of established medicines. Their Report was published in 2018, completing this recommendation. It made five main recommendations with proposed actions. These describe an ambition for NHS Scotland's future health data capabilities, which goes beyond Dr Montgomery's Review recommendations, with a view to create world-leading data collection for recording and analysing real world medicines use at the patient level that would further enhance Scotland's international reputation in health data research.

As you have highlighted, some of the actions within the Task Force Report are broader than new medicines policy. As a result we are considering a number of the recommendations as part of the implementation of our Health and Care Digital Strategy. The NHS Education for Scotland (NES) Digital Service was established in 2018 to deliver a National Digital Platform, which is a central part of this strategy, and will provide the infrastructure, products and services which will evolve how health and care technology is delivered, managed and experienced in Scotland. On the medicine specific aspects, we are now working across Government and with key stakeholders to identify a planned, phased programme of work to implement changes that will further improve data collection on medicine use and outcomes, taking into account the actions proposed by the Data Scoping Taskforce through close working with the NES Digital Service.

One key aspect of this work, and in order to further underpin recommendations 1 to 4 of Dr Montgomery's Review, has been the establishment of an internal working group to identify and prioritise a programme of work specifically in relation to improving data collection on medicines' uses and outcomes, that will complement and support the overall objectives of the Health and Care Digital Strategy. This will allow us to develop a population-wide approach to medicine intelligence as opposed to the current localised approach. Public Health Scotland, our new public health body will also have a key role in developing new and innovative ways of using data.

Recommendation 12 of the Review was also linked to data collection with a view to enabling meaningful year-by-year comparisons of data and the monitoring of emergent trends. This has been completed and the SMC has developed an internal content management system which allows annual data to be collated on the types of medicine assessed and enables year by year comparison.

Definition of end-of-life, orphan and ultra-orphan medicines

Recommendations 6, 7 and 11 of the Review refer to end-of-life, orphan and ultra-orphan medicines. I am pleased to report that these three recommendations have all been completed. On recommendations 6 and 7, the SMC undertook extensive work with partners and stakeholders to review the definitions for end-of-life, orphan and ultra-orphan medicines that had been implemented in 2014. It was agreed that the definitions for end-of-life and orphan medicines remained suitable for the assessment of anticipated new treatments such as targeted medicines, increasing use of combination therapies and the impact of genomics. However, the SMC will continue to keep this under review.

In September 2018, in response to stakeholder feedback in Dr Montgomery's Review, that the ultra-orphan assessment process was not meeting the desired objective, the SMC

revised their definition for an ultra-orphan medicine. The new definition aims to identify medicines that treat extremely rare conditions.

To be validated as an ultra-orphan medicine the following criteria should be met:

- the condition has a prevalence of 1 in 50,000 or less in Scotland;
- the medicine has an EMA orphan designation for the condition and this is maintained at time of marketing authorisation;
- the condition is chronic and severely disabling; and
- the condition requires highly specialised management.

To date, the SMC has considered company requests to validate more than twenty medicines as ultra-orphan medicines under the new definition.

Recommendation 11 was to develop and implement a new assessment and approval pathway for ultra-orphan medicines. This commenced in October 2018 and was fully implemented in April 2019, meaning that medicines validated by the SMC as ultra-orphan, according to the new definition, can be made available to patients under the new pathway. The new pathway allows ultra-orphan medicines to be prescribed through the NHS in Scotland for a period of three years prior to a decision on their routine use in NHS Scotland. There are a number of criteria that a pharmaceutical company must fulfil if they wish their medicine to be assessed via the new pathway, and these are that:

- the medicine has been validated as ultra-orphan according to the revised SMC definition above;
- a full submission is made to the SMC for the initial assessment stage that meets SMC requirements for the ultra-orphan process;
- a Patient Access Scheme is offered that complies with the standard terms and conditions considered acceptable by the Patient Access Scheme Assessment Group (PASAG); and
- data collection arrangements are undertaken to meet the evidence generation requirements to support the later stage assessment by the SMC under the ultra-orphan pathway.

You specifically asked in your letter if there is any evidence that the new definitions have been raised as an issue since their adoption and whether there were examples of where this has had an impact on decisions. I am not aware of any such issues, although, as you will appreciate, we are less than a year into the new ultra-orphan pathway. The first medicine became available to clinicians to prescribe in July 2019 and we expect a number of ultra-orphan medicines will become available during 2020. The anecdotal feedback from pharmaceutical companies and patient representative groups has been very positive and they have welcomed the approach we are taking in Scotland. It is worth noting that during the transition to the new ultra-orphan pathway, some companies opted to go down the traditional assessment route, which is still a choice available to them.

In your letter you noted the Review's concerns about the limits of the previous assessment process for ultra-orphan medicines and that the route for patients with these extremely rare conditions seeking access to medicines had become via the Individual Patient Treatment Request (IPTR) and Peer Approved Clinical System (PACS) Tier One process. We believe

that the new pathway will address the limitations of the previous assessment process and will increase the availability of ultra-orphan medicines. However, we are mindful that this relies on pharmaceutical companies making a full submission to the SMC and that, due to the very small patient cohorts in Scotland, sometimes fewer than five patients, a company may choose not to submit for assessment. Therefore, we will continue to allow individual access through the PACS system as we review uptake of the pathway approach and any further improvements required.

Patient and Clinician Engagement Process

Recommendations 8, 9 and 10 all refer to patient and clinician engagement in decision making. Again, I am pleased to be able to advise that these have all been completed. Under recommendation 8, the SMC's refreshed website was launched in March 2018 offering a more user-friendly and easy to understand experience for patients and public visitors to the site. The SMC also now publishes public-friendly summaries of their decisions. In response to recommendation 9, the public partner role has been reviewed. To avoid any perception of conflict on their part, Healthcare Improvement Scotland (HIS) staff, not public partners, now present patient group statements to the Committee.

More specifically, in response to recommendation 10 which sought more active involvement of the key participants at PACE meetings in the relevant parts of SMC meetings, where there has been a PACE meeting the SMC now invites the patient groups to attend and participate in the SMC meeting to enhance the quality of discussion and decision making. In your letter you asked specifically about clinician involvement in the SMC meetings. As highlighted in previous correspondence, the feedback from the clinical community was that, on balance and given that the SMC seeks input (in writing) from specialist clinicians for every submission, it was not the best use of a clinician's time to attend the SMC meeting. There is also the issue of how to manage potential conflicts of interest with the pharmaceutical industry and/or a particular medicine. It is important to ensure impartiality in the decision making process and one way to achieve that is by ensuring that there are not more people around the table with an interest than those without. However, the SMC continues to keep this under review.

As part of a commitment to continual process improvement, beyond the Review's recommendation on PACE, the SMC is evaluating how the PACE process is working and its impact on SMC decision making. This work has initially sought to identify key factors and themes that are particularly important to patients in the assessment of new medicines and also to investigate the importance of different aspects of Quality of Life measures to committee members in their decision-making. The next phase of this work will be to explore how PACE actually shapes decision-making. The PACE process has been positively received by patients, patient groups and the pharmaceutical industry in the UK. As an innovative approach to better understanding what really matters to patients, it has also attracted interest from Health Technology Assessment (HTA) bodies internationally.

Transparency of decision making

Recommendations 13 and 14 were related to the transparency of SMC decisions. Since meetings were first held in public in 2014 the SMC has endeavoured to ensure that all the discussion of an individual submission can be held with the public present, as this is an important aspect of transparency. On recommendation 13, the SMC confirmed the intention

to maintain the existing ballot process as members valued the confidence that the current voting system brings as it means that all members contribute to the decision. The majority view was that the voting system should continue.

The pharmaceutical industry, through the SMC User Group Forum, was asked to take forward recommendation 14, which relates to the inclusion of commercial in confidence information in the company submission. This has been addressed to provide increased clarity to committee members on why different types of information must be confidential. There has been a concern highlighted, however, that the actions taken do not support transparency for the public, as companies often require that information on a medicine's cost effectiveness cannot be published in the SMC advice. This does not support public understanding of decisions. The SMC are planning to do some further work on this.

Non-formulary and formulary approaches

Recommendations 15 and 19 of the Review referred to standardising data collection for requests to access to non-formulary medicines (15) and NHS Scotland's approach to formulary development and use (19). On the latter, you will be aware that we have committed to introducing a Single National Formulary (SNF) as part of the Programme for Government (PfG). A new formulary website platform has been developed to host the SNF and this is about to be utilised and tested in clinical practice in the East Region (NHS Lothian, NHS Fife and NHS Borders), starting in NHS Lothian in the first instance. This will provide an opportunity to make any enhancements to the website platform to further improve its functionality based on user experience. In addition, a collaborative consensus model for formulary development based on local and regional cooperation between existing local Health Board governance and decision making processes will be used to develop and agree an East region formulary. This work will respect the existing processes for the consideration and adoption of SMC advice on new medicines. This approach will also inform the next steps in the delivery of the PfG commitment by 2021. It is also important that progress and learning is shared with the other Health Boards. To that end, the Area Drug and Therapeutics Committee Collaborative (ADTCC) will support this as well as planning for wider roll-out in parallel to the East region work with input from colleagues within HIS and all Health Boards. The delivery of recommendation 15 on data collection for requests to access to non-formulary medicines is being taken forward as part of the SNF work programme.

Funding arrangements for end-of-life, orphan and ultra-orphan medicines including the New Medicines Fund

In your letter you have asked for an update on recommendation 16 which was on the future arrangements for the funding of end-of-life, orphan and ultra-orphan medicines and future funding arrangements. Medicines are the second largest item of expenditure for NHS Scotland; a cost of £1.7 billion in 2017-18. This was a modest decrease of 0.1% in real terms from 2016-17, however, an increase of 17% if measured across the past five years. Price competition in the generic medicines market continues, with some exceptions, to exert a deflationary impact on growth, creating capacity in the medicines budget to pay for newer medicines.

As you will know, I am committed to ensuring that we increase access to new medicines, however it is important that this happens in parallel with ensuring that the NHS in Scotland receives best value. One way in which we are pursuing this is through the new Voluntary

Pricing Access Scheme (VPAS), the replacement for the Pharmaceutical Pricing Regulation Scheme (PPRS), which seeks to control the cost of branded medicines to the NHS, providing predictability and stability to both Government and the pharmaceutical industry, as well as ensuring the cost of branded medicines to the NHS stays within affordable limits. The new agreement places a 2% cap on the growth in sales of branded medicines to the NHS for each year of the Scheme with pharmaceutical companies having to repay the NHS for spending above this cap. This is expected to save the NHS in Scotland around £90 million in 2019.

The Scottish Government is also committed to ensuring that the rebates from the UK VPAS continue to fund the New Medicines Fund, in the same way as the rebates were used from its predecessor, the PPRS. The New Medicines Fund is intended to ensure that availability of funding is not a barrier to implementation of policy to increase access to new medicines, whether approved for routine or on an individual case-by-case basis through the PACS process, both Tier One (for ultra-orphan medicines) and Tier Two (all other medicines). From 2014-15 to 2017-18 over £201.5 million was made available to Health Boards via to New Medicines Fund to contribute to the cost of medicines for patients with end-of-life conditions, rare and very rare diseases.

Process for medicines not routinely accepted for use in NHS Scotland - Peer Approved Clinical System (PACS)

Recommendation 20 of the Review referred to a review and evaluation of the PACS process. At the time of the Review, only the Tier One process for ultra-orphan medicines not recommended by the SMC was available. As advised by my predecessor, we replaced the IPTR process for all other medicine with PACS Tier Two and committed to review both Tiers of PACS.

The new PACS Tier Two arrangements commenced on 1 June 2018. Guidance issued offered Health Boards a framework that aimed to enhance consistency among Boards in the ways that they consider clinicians' requests to prescribe certain medicines that are not recommended by the SMC for routine use in NHS Scotland. The guidance asked Health Boards to establish a PACS Tier Two Panel to consider relevant requests from clinicians, introduced refreshed decision making criteria and established a National Review Panel (NRP) to consider requests for reviews of PACS Tier Two decisions taken by Boards. As part of the PACS Tier Two system, and set out in the accompanying guidance, we indicated the data that needs to be provided to the Scottish Government as part of that new process. This completed recommendation 17 of the Review which called for data relating to IPTRs to be collected by Boards with the aim of achieving consistency and comparability.

When the new system was introduced the Scottish Government undertook to review its implementation approximately six and twelve months after commencement. The six month review was undertaken in January 2019 and, whilst there was a limited response, the feedback received focussed on issues connected to the administration of the new system, the desirability of consolidating the number of Board application processes for access to new medicines on an individual basis and the point in the SMC process after which applications should be regarded as admissible. There were no substantial problems highlighted in the practical implementation of the new system.

The twelve month review took place from June to September 2019. The Scottish Government is currently reviewing responses with a view to publishing conclusions and next steps in early 2020, which will include a recommendation on the continuation of PACS Tier One for ultra-orphan medicines. To date there has been one case referred to the National Review Panel under the new PACS Tier Two system so it is challenging to draw any meaningful conclusions about its effectiveness, although the small number of cases referred does suggest that the Government's core objective of the PACS Tier Two system, to provide greater consistency across the country, is being achieved.

Learning from other health economies about Health Technology Assessment (HTA)

Recommendations 18 and 25 of the Review looked to explore opportunities to learn from and collaborate with other health economies in relation to the assessment and managed introduction of new medicines and other health technologies (18) and to undertake a comparative review of the arrangements in place in the healthcare systems of other countries for the introduction of new medicines and specifically end-of-life, orphan and ultra-orphans, seeking to learn from their experiences (25). Whilst I am hesitant to state that these actions are complete, as learning from others is a continuous activity that enables ongoing improvement and agility, the SMC has, and continues to explore and assess best practice in other countries to ensure it continues to be recognised as world-leading.

In addition, my officials commissioned a comparative review of the arrangements in place in the healthcare systems of other countries for the introduction of new medicines and specifically end-of-life orphan and ultra-orphan medicines. The SMC is an active participant in the European Network for Health Technology Assessment (EUnetHTA) and the International Network of Agencies for Health Technology Assessment (INAHTA) which aim to share learning and promote discussion of common challenges. These types of collaborations will become even more important, as the United Kingdom prepares to exit from the European Union (EU) and the need to ensure co-operation between the EU and the UK on areas such as the medicine regulation, including licensing, securing funding and collaborative programmes for research and maintaining a strong and viable life sciences sector.

Introduction of a pause and negotiations on price

Recommendations 22 and 24 of the Review referred to introducing a pause in the HTA process (22) and making greater use of National Procurement to lead on negotiations on behalf of NHS Scotland on the cost of new medicines (24).

We still have to make a policy decision on the introduction of a pause in the HTA process (recommendation 22). Whilst the pharmaceutical industry are keen on a pause, following publication of Dr Montgomery's review the SMC had questioned the purpose of a pause in the process and indicated that the implementation of a pause would need to be carefully considered in terms of any unintended consequences, such as extending timelines in an already complex process, and interdependencies with the other recommendations in the review. In the meantime, the SMC has made some further improvements to their working processes including a fast-track resubmission process, and is developing the ability for a company to have two opportunities to offer a Patient Access Scheme (PAS) for all medicines which should be available in early 2020. They are also working to introduce a 'return to company' option where a submission is identified as flawed before being considered by the

New Drugs Committee (NDC). These improvements themselves may mitigate the need for the introduction of a pause in the process. We will, however, consult further on the introduction of a pause.

Turning to recommendation 24, as I stated earlier, we are committed to ensuring that the NHS in Scotland is supported to achieve the best possible prices for new medicines. Whilst medicine pricing is reserved and regulated through the UK VPAS, a key objective for the Scottish Government during the VPAS negotiations in 2018 was to establish binding commitments on Governments across the UK and the pharmaceutical industry to greater transparency and parity in medicine pricing. As a result, in January 2019 the new scheme introduced provisions that allow the UK Health Administrations to:

- share the details of previously confidential pricing arrangements; and
- imposes new responsibilities on pharmaceutical companies to achieve comparable arrangements that provide an acceptable value proposition in each part of the UK.

In your letter you noted that National Procurement was in advanced stages of discussions with the ABPI about a voluntary price alignment arrangement which would enable companies to adjust the price of a Patient Access Scheme (PAS) in Scotland to ensure equitable pricing arrangements across the UK as a way of ending the possibility of the NHS in Scotland being charged more than the NHS in England for the same medicine and asked for an update. I can confirm that the PAS guidance has been updated to reflect this. In addition, the VPAS arrangements described in the paragraph above will provide a strengthened approach to achieving price alignment. My officials are currently working with the other UK administrations to ensure that these provisions are fully implemented.

I would like to note here that the Scottish Government agreed with the Review that the SMC's strengths lie in health technology assessment and that it should remain the SMC's primary function, rather than extending its remit to cover commercial functions. As a result, the Scottish Government has undertaken work 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. Progress on this work has been slower than first intended, as it had been necessary for officials and NHS partners to divert substantial time to the preparation of medicine supply contingency plans in the case of a no deal UK exit from the EU. Nevertheless, we are now preparing to publish a “Discussion Document” for consultation in 2020 which will outline initial work in relation to potential policy options, including the need for a pause in the SMC process mentioned above.

Managed Access Schemes (MAS)

Recommendation 21 of the Review sought to explore the introduction of Managed Access Schemes (MAS) with a view to early adoption by the NHS in Scotland, building on the experience of complex PAS and payment-by-results schemes in operation in other health systems. National Procurement (NP) has updated the PAS guidance to support the interim acceptance recommendation through a MAS (see the paragraph below). We will consider, in due course, whether and how managed access approaches might be utilised in the future, either in the same way or by addressing similar risks in a different way, including how such an approach aligns with the role of the SMC in considering the clinical and cost effectiveness of new licensed medicines. This includes taking into account the EU Horizon 2020 research which is due to report next year. Of course, thinking has also moved on since Dr

Montgomery's Review and there is now a greater interest from the pharmaceutical industry to explore outcomes-based pricing and commercial agreements. As a result, we are now considering how the VPAS might provide new opportunities in relation to innovative and flexible approaches to pricing. For example, we are currently testing a proof of concept outcome based pricing approach. Critical to the delivery of novel pricing approaches will be the NHS capability to collect outcome data, which is why our strategic approach to data collection and the interdependency with the Digital Health and Care Strategy is important.

Conditional/interim acceptance

You have asked for an update on recommendation 23 of the Review which looked to give SMC the additional decision option of "recommend for use subject to ongoing evaluation and future reassessment." SMC introduced this new decision option in 2018 for medicines with a conditional marketing authorisation (CMA) from the European Medicines Agency (EMA). This approach had been consulted and supported by key stakeholders. These medicines address an unmet need but there is often considerable uncertainty about their expected benefits for patients. These medicines have a marketing authorisation that is conditional on the company providing EMA with further clinical data. SMC will reassess the medicine at that time point to reach a final decision on its availability to NHS Scotland. The SMC is now exploring extending the use of the conditional acceptance option, specifically in the context of clinical uncertainty whether further data is likely to forthcoming at a relatively early stage as a consequence of ongoing clinical trials.

Advances in new medicines approaches and the Scottish Model of Value

Recommendation 27 of the Review sought to consider through wide stakeholder engagement the best way for the NHS in Scotland to take advantage of the opportunities afforded by anticipated developments in the way that new medicines will be introduced in the future. As the Committee will be aware, last year the SMC accepted two new Chimeric Antigen Receptor T-cell immunotherapy agents, Kymriah® and Yescarta®, as well as a number of other Advanced Therapeutic Medicinal Products (ATMPs). We are actively contributing to the review of the UK Early Access to Medicines Scheme (EAMS) to ensure it remains fit for purpose. The SMC also continues to review its processes to ensure they take account of any future developments in medicines. Furthermore, we are working across the UK to develop and test new models for national purchasing arrangements that separate the price paid for antimicrobials from the volume used in order to ensure companies have a financial incentive to invest in an antibiotic development programme and support good stewardship

Recommendation 28 relates to the development of a Scottish Model of Value. The work we are undertaking on negotiations about price will form the foundation of any thinking on a Scottish Model of Value, alongside work a wider societal view can be taken into account, for example one option might be to expand the role of the Citizen's Jury.

Area Drug and Therapeutic Committees

As you outlined in your letter, the Area Drug and Therapeutics Committee Collaborative (ADTCC), hosted by HIS, was created in September 2014. This was as a result of the recommendations to strengthen the work of Area Drug and Therapeutics Committees (ADTCs) in response to the Health and Sport Committee Inquiry in 2013 into Access to New

Medicines. The ADTCC is made up of representatives from all the Health Boards in Scotland which have an ADTC.

Since its establishment in 2014, the Scottish Government has provided yearly funding to HIS for the ADTCC in recognition of the continued value it brings in ensuring that ADTCs across the NHS in Scotland are sighted, engaged and involved in stakeholders' work within Scotland and across the UK, where there is an impact on ADTCs' business.

In early 2019, revised monitoring arrangements between the Scottish Government and HIS were agreed which focus on the continuous review of ADTCC priorities and resource, including:

- driving improvements in the safer use of medicines;
- supporting the effective use of medicines;
- sharing learning, intelligence and engagement;
- patient and public facing work; and
- providing a 'once for Scotland' approach to the development and implementation of policies.

By way of an example, current priorities for the ADTCC are to:

- ensure the standardised approach to the operation of the Early Access to Medicines Scheme (EAMS) in Scotland;
- promote the collaborative approach to the introduction of biosimilars to optimise their uptake and ensure consistency across the country;
- support the engagement of ADTCs in the development and implementation of national medicine policy; and
- host regular communication for ADTCs across Scotland by way of quarterly network meetings and newsletters.

I hope that this letter provides you with a comprehensive update on the progress we have made in terms of the recommendations in Dr Brian Montgomery's Review of Access to New Medicines. I am pleased to be able to report that our reforms and investment in recent years have significantly increased access to new medicines, particularly for rare, very rare and end of life conditions. We do, however, continue to keep this under review.

I look forward to meeting with the Committee in due course.

JEANE FREEMAN

St Andrew's House, Regent Road, Edinburgh EH1 3DG
www.gov.scot