



The Scottish Parliament
Pàrlamaid na h-Alba

Cabinet Secretary Health,
Wellbeing and Sport

cc. Dr Montgomery

Health and Sport Committee
T3.60

The Scottish Parliament
Edinburgh
EH99 1SP

Tel: 0131 348 5224

Calls via RNID Typetalk: 18001 0131 348 5224

Email: healthandsport@scottish.parliament.uk

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Dear Shona

Access to new medicines — progress update

Thank you for giving evidence to the Health and Sport Committee on 1 March 2016 on access to new medicines – progress update. The Committee has considered the evidence received from you as well as from a range of stakeholders who gave evidence to the Committee at its meeting on [23 February 2016](#) and the [responses](#) the Committee received to a call for written views on access to new medicines which it issued in December 2015. This letter highlights the work conducted by the Committee and some of the main issues which arose at our meetings.

During your evidence session you referred to the launch later this month of a review led by Dr Brian Montgomery on the changes that have been made to the medicines appraisal system. Ensuring appropriate systems are in place for accessing new medicines is an evolving process and we therefore welcome the announcement of this review. We hope our work will be used to inform Dr Montgomery's review and any subsequent changes the Scottish Government decides to make to the current systems.

The Committee has been pleased to contribute to and influence the debate on access to new medicines over the course of this parliamentary session. The Committee welcomes the progress that has been made to date including the increase in the approval rate of drugs by the SMC and improvements in the opportunity for patients and clinicians to engage in the process.

The investment of £80 million in 2015-16 on the New Medicines Fund (NMF) has shown the Scottish Government's continuing commitment to ensuring that the appropriate care and treatment for people who require specialist and often expensive medicines for rare conditions remains a priority.

We note that the Pharmacy Price Regulation Scheme is due to be reviewed in 2018. Stability in the level of funding for new medicines and assurances on the mechanism which will be used to provide the funding over the long term are important. Consideration should also be given to ensuring adequate funding to boards to implement the decisions of the SMC and Individual Patient Treatment Requests. We hope these issues will be considered when determining the approach to future funding of new medicines.

Ensuring the best and fairest price for medicines is achieved as early in the new medicines approval process is vital. We therefore welcome that Dr Montgomery's review will give consideration to whether external commercial negotiations can drive a fairer price at the start of the process which would then be linked to the SMC's consideration of the drug.

Monitoring and assessing access to new medicines is very important. An increased approval rate for drugs by the SMC should be resulting in increased access to new medicines for patients. The Committee welcomes the collaborative approach across the 14 area drug and therapeutic committees to improve communication and timeframes for implementation of new drugs which have been approved by the SMC. There is a need to assess whether the increased SMC approval rate is being translated by the ADTCs into improved access to these medicines.

In relation to the Individual Patient Treatment Requests it is important that there are consistent decisions made across the NHS boards and that there are clear criteria for when applications will be approved or rejected. The Committee hopes that the Peer Approved Clinical System will ensure that there is consistency in the decisions taken.

We are pleased that the review will give consideration to the further development of a Scottish model of value. We hope that Dr Montgomery will propose steps that can be taken to encourage the development of the model as we are supportive of a broader assessment of value that goes beyond the 'cost per QALY'.

We welcome the changes that have been made so that the SMC decision making process is more accessible. Openness and transparency regarding how SMC decisions are reached is essential to ensuring public confidence and understanding in the decisions taken. We welcome the commitment that the review will consider whether further steps can be taken to improve the clarity around decisions taken by the SMC. We note, for example, that there are challenges to the voting of individual SMC members being made public, however we hope that further consideration will be given to whether these barriers can be overcome.

We are pleased that the SMC believe that the PACE statement should have a powerful influence on decision making. We hope that the review will give consideration to whether there are further steps that could be taken to develop the role for patients and clinicians in SMC processes including whether it is appropriate for them to give evidence at the SMC final meeting. This has the potential to further strengthen SMC decision taking and ensure that the PACE statement can be explored by the SMC with those who directly contributed to it.

The 'drug pipeline' has become more efficient and as a result there has been a significant increase in the number of drugs coming to market. We would welcome consideration of this as part of the review to ensure that the mechanisms are in place so that medicines are assessed and processed appropriately and that the anticipated outcomes are then subsequently evaluated.

The Committee is aware that some patients are paying to access a drug that has not been recommended for use by the SMC. The Committee asks the Scottish Government to give consideration to whether there are steps that can be taken to streamline the process to ensure there are no delays to patients accessing the drugs and what support can be provided to patients to secure the best price for the drug.

The Committee received some evidence from stakeholders which questioned why the same level of rigour and scrutiny applied to medicines is not applied to other health interventions. The Committee asks the Scottish Government to give consideration to whether the approach taken to appraising the value of medicines should be applied more widely across the health service.

The Committee has seen positive improvements in the access to new medicines system and is keen to ensure that any further changes seek to improve the system further. I would therefore welcome your assurance that the issues we have raised will be taken into account as part of the Scottish Government's on-going work in this area.

Yours sincerely

A handwritten signature in black ink, appearing to read 'D. McNeil', written in a cursive style.

Duncan McNeil MSP
Convener of the Health and Sport Committee