

26 February 2020

Mr Lewis Macdonald
Convener
Health and Sport Committee
The Scottish Parliament
Edinburgh EH99 1SP

Dear Mr Macdonald

Thank you for your letter of 5 February 2020 following up on several issues that arose during the Health and Sport Committee's evidence session on 21 January 2020. Some of your questions relate to Healthcare Improvement Scotland (HIS) activities out with the Scottish Medicines Consortium (SMC) and the issue of outcomes and value based pricing touches on medicines policy. I am therefore replying to your letter with input from my colleague Laura McIver, Chief Pharmacist at HIS.

In the evidence session the Committee questioned the number of appeals to the [National Review Panel](#) hosted by HIS. Since the panel was set up in June 2018 there has been one appeal which was in September 2018. Health Boards are responsible for the Peer Approved Clinical System (PACS) tier two and the Scottish Government Medicines Policy Team collate data on PACS tier two activity.

In relation to [horizon scanning activities](#), SMC provides Health Boards with early intelligence on new medicines in development to support their financial and service planning. SMC is involved in the use and development of [UK PharmaScan](#), a UK-wide horizon scanning database that provides information on new medicines, indications and formulations in the pharmaceutical pipeline. Forward Look, the SMC's annual horizon scanning report, is published in October each year, it provides concise information on new medicines/indications that are expected to impact Boards over the following financial year. The report is accompanied by a financial planning tool describing estimated uptake and potential budget impact. SMC provides biannual updates to allow Boards to adjust their financial plans within year. We know that Forward Look reports are highly valued by Boards.

In terms of preparing for the next generation of medicines, SMC has recently issued Boards with briefing documents on two important developments that may have significant impact on patients and services: advanced therapy medicinal products (ATMPs) and medicines with histology-independent indications. These contain commercial in confidence information from pharmaceutical companies so are not published. Over the next few years we expect to see more personalised/precision medicines for patients with specific genetic biomarkers, regenerative cell therapies (such as chimeric antigen receptor (CAR) T cell therapy), and complex combination regimens for cancer medicines. SMC is working with the Molecular Pathology Service on the companion diagnostic testing requirements for cancer medicines in the pipeline. In addition, SMC networks with other health technology assessment (HTA) agencies internationally to build knowledge on initiatives and good practice elsewhere.

You asked about whether SMC has considered its role in relation to the use of unlicensed and off-label medicines. SMC has no such role as its remit is confined to the assessment of medicines that have a

marketing authorisation from the European Medicines Agency (EMA) or the Medicines and Healthcare products Regulatory Agency (MHRA).

In certain circumstances HIS can advise on the off-label/unlicensed use of cancer medicines. HIS hosts an Off-label Cancer Medicines Programme recently commissioned by Scottish Government's Cancer Division in response to its *Beating Cancer: Ambition and Action* strategy. This programme aims to provide advice to NHS Board Area Drug and Therapeutics Committees on the managed entry of off-label uses of cancer medicines. Through this advice the programme will facilitate equity of access to off-label uses of cancer medicines and reduce unwarranted variation for patients across NHSScotland. This programme is expected to deliver the first piece of advice to NHSScotland in summer 2020.

In relation to outcomes and value based pricing, as SMC was set up to ensure that the prescribing of new medicines across NHS Scotland is clinically and cost-effective, we are committed to the principle of value based pricing. As discussed in the evidence session on January 21st, the outcomes element is more challenging, largely due to data capabilities at national level, particularly in secondary care. HIS is supportive of the recommendations of the Data Scoping Taskforce report on [Medicines Use and Digital Capabilities](#), and is pleased to note the progress that has been made to date on these.

Meantime, recognising that the clinical evidence base for new medicines is often uncertain, and while the data capabilities are being improved, SMC has begun to develop its assessment process by introducing an option of conditional (interim) acceptance for some medicines. This new approach will support earlier patient access with the reassurance that the medicine's clinical effectiveness will be revisited in around 2-3 years. If a medicine that has been accepted on an interim basis is subsequently not recommended by the SMC, then that medicine will no longer be routinely available in NHS Scotland. Patients taking the medicine who are deriving clinical benefit will, however, be able to remain on the treatment until the patient and clinician consider it appropriate to stop. SMC is currently working on extending this conditional (interim) acceptance approach to capture more of the new medicines where there is clinical uncertainty about their benefits that may be addressed through ongoing clinical studies. It is hoped that this life-cycle approach to health technology assessment will allow patients in Scotland to access future innovative, and potentially cost-effective, medicines while evidence of effectiveness matures. This is an example of how SMC continues to review and revise its processes to respond to emerging technologies and evolving service requirements.

I hope this is helpful and addressing your questions and we are happy to be of any further assistance if required.

Best wishes

Alan MacDonald
Chair, Scottish Medicines Consortium and on behalf of Healthcare Improvement Scotland

Laura McIver
Chief Pharmacist, Healthcare Improvement Scotland