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The Scottish Parliament

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04 December 2023

Dear Claire,

I am conscious that several MSPs have written recently about access to medicines to treat cystic fibrosis (CF) and so I thought it may be helpful to set out the current position.

The Scottish Government remains committed to supporting people with CF to benefit from new medicines which help them to live fuller lives, for longer. That is why we introduced a memorandum of understanding (MoU) with the manufacturer, Vertex Pharmaceuticals, in 2018. As part of the MoU, there was an expectation that Vertex would resubmit each of their CF medicines to the Scottish Medicines Consortium (SMC) for a health technology appraisal (HTA). In order to progress this, the SMC is collaborating with the National Institute for Health and Care Excellence (NICE) on a multiple technology appraisal (MTA) of Vertex's CF medicines, including Kaftrio®.

An MTA is designed to assess multiple medicines used to treat one condition. It is useful for an appraisal that is particularly complex, or not suited for a single technology appraisal (STA) process or for reviewing published appraisals. An STA considers the clinical and cost-effectiveness of a single medicine. The SMC does not undertake MTAs, hence why it is working with NICE.

Making decisions about whether to recommend new medicines for routine use is a complex task and HTA agencies, such as the SMC and NICE, base their decisions on the best available evidence provided to them. It is worth noting that any SMC appraisal is undertaken independently of Scottish Ministers and is based on the clinical and cost-effectiveness of a medicine at a population level.

NICE published, on 3 November 2023, draft initial guidance for the CF MTA, not recommending these treatments as they were not considered to be cost-effective at their current price.
Notably, not recommending treatments due to cost-effectiveness is not unusual at this stage in the HTA process and the NICE recommendation could change following the consultation period on the draft guidance.

The NICE MTA committee is due to meet again in December and the NICE final guidance is expected to be published on 21 February 2024. As the SMC is partnering with NICE in the assessment of these medicines, the SMC will publish recommendations aligned with the final NICE guidance thereafter for Health Boards in Scotland to consider.

While the NICE MTA is ongoing, I can confirm that all existing and new patients in Scotland who are on, or who are started on, a CF medicine, including Kaftrio®, will continue to have access to that CF medicine after NICE and the SMC issue their final recommendations. This will be irrespective of the outcome of the appraisal and will cover any need to subsequently switch to a different CF medicine.

In addition, on 15 November, the Medicines and Healthcare products Regulatory Agency (MHRA) announced an extension to the licence for Kaftrio® and Kalydeco® (the two medicines are used in combination as a treatment course) to include children aged two to five years. This UK-wide extension is welcomed and will help address the unmet needs of younger children with CF.

The Chief Pharmaceutical Officer (CPO) is engaging with representatives of Quest for a Cure, the patient group who represent Scottish CF families, and has outlined how the NICE and SMC process will work and is continuing to discuss any of their concerns. The CPO also met with Vertex recently and impressed upon them the importance of offering a revised price to address the NICE advice on the price exceeding what the NHS would consider reasonable.

If any CF medicine is not recommended in the final MTA guidance, clinicians in Scotland will be able to request the use of that medicine on a case-by-case basis for any new patients using the Peer Approved Clinical System (PACS) Tier Two process. National guidance explicitly states that Health Boards should not take account of the cost of medicines when considering applications using the PACS Tier Two system.

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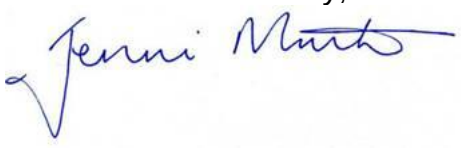
I hope that the Committee considers this a helpful update.

Yours sincerely,



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