From the Permanent Secretary and HSC Chief Executive

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Dear Lord Sharkey

Thank you for your letter of 13 November 2018 about the announcement on the 12 September 2018, regarding plans to improve access to innovative new medicines for cancers and other conditions for patients in Northern Ireland.

I can advise that those medicines that have been recommended by NICE for use within NHS England's Cancer Drugs Fund (CDF), are now available to patients in Northern Ireland via the routine endorsement process as per Circular HSC (SQSD) 2/13 (See Annex A). However, 'Transition drugs' and 'tail end de-listed drugs' which were included in the legacy fund (old CDF) prior to NICE assuming oversight in 2016 are not included. Should a medicine under the NICE CDF process become de-listed, the process for any medicine not recommended by NICE following a technology appraisal will apply.

Part of ensuring that access to these medicines meets a reasonable degree of value for money and to ensure that unintentional consequences are minimised where possible, it is important that these medicines are subject to the same commercial agreements as those available via the CDF in England. Therefore, the Department has asked the Regional Pharmaceutical Procurement Service to build on existing arrangements and liaise with pharmaceutical companies to confirm the details of each managed access agreement. Discussions commenced mid-October. Once confirmation of a commercial managed access agreement is in place, the medicine may be available to patients who are considered suitable by their clinical consultant, in line with the indications and conditions outlined by NICE. At this point in time it is not possible to provide a timeline for these confidential commercial discussions, but we would hope that they are made available within the coming days.

Regarding Highly Specialised Technologies (HSTs), in the absence of a Health Minister, the Health and Social Care Board (HSCB) can consider commissioning these drugs based on assessment of need and knowledge of available resources within their overall budget allocation.

If the HSCB decides not to commission a medicine through the process outlined above, there is an option for the Board to consider funding requests for treatment where exceptional clinical circumstances can be established. These are known as individual funding requests (IFRs). Requests are submitted by clinicians and supported by nominated senior clinicians and managers within the HSC Trusts. Similar processes are in place throughout the United Kingdom jurisdictions.

The aforementioned IFR process, has undergone a process of policy evaluation, consultation and review, and the announcement on 12 September included reference to the new policy. One of the factors that led to the IFR evaluation was the existence of the CDF in England. As a result of the reforms, CDF expenditure has dropped significantly as more treatments are fast-tracked into routine commissioning, not endorsed, or pharmaceutical companies change their pricing structure in response to the new processes.

Some elements of the new IFR policy are complex and it will take time to develop new procedures to ensure effective mechanisms are in place. However, the Department is keen for patients to benefit from the new process as soon as possible.

The policy will be operated by a new, clinically led, Regional Scrutiny Committee (RSC) and this Committee is best placed to develop the processes and procedures required to take the policy forward effectively. Although this may take some time to progress, we hope it will be actively considering applications from early 2019. The policy will be published once the RSC has agreed a plan of action and the document has undergone final quality assurance checks.

I hope that you find this helpful. Please accept my best wishes.

Yours sincerely

RICHARD PENGELLY