WRITTEN MINISTERIAL STATEMENT

The content of this ministerial statement is as received at the time from the Minister. It has not been subject to the Official Report (Hansard) process.

Health, Social Services and Public

EVALUATION OF THE INDIVIDUAL FUNDING REQUEST PROCESS

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Mr Poots (The Minister of Health, Social Services and Public Safety): Members will recall that during a debate in the Assembly on 6th May 2014 I announced I had instructed my Department to carry out an evaluation of the Individual Funding Request (IFR) process. The purpose of this statement is to provide an update to the Assembly on the evaluation and to outline the next steps in taking this work forwards.

I originally initiated this evaluation because I want to test whether the IFR process is effectively meeting its objectives of providing access to unapproved specialist drugs where there is an agreed clinical need.

There are a large number of new licensed drugs coming to the market each year. In order to determine which of these new treatments offers the best prospect of improvement over standard therapy it is essential that they are assessed for clinical and cost effectiveness and approved before they are made routinely available.

The NHS and the HSC in Northern Ireland are guided in this process by the National Institute for Health and Care Excellence (NICE). The NICE process of assessment and approval has an international reputation of excellence in terms of its scientific rigor, independence and objectivity. The technical expertise and role of NICE in conducting cost-effectiveness assessments is regarded as world class.

However, a consequence of this necessarily rigorous approach to appraisal is that some more expensive treatments that do not meet the thresholds for value for money or which have not yet been assessed by NICE have not been approved for routine use in the HSC. The IFR process is intended to bridge this gap by providing access to specialist drugs which are not normally commissioned within Northern Ireland in circumstances where there is an agreed clinical need.

I have listened to concerns raised by stakeholders from cancer sufferers and survivors, charities, political representatives and the pharmaceutical industry that the current process could be improved and also to their calls for the establishment of a cancer drugs fund similar to that in place in England. As a result, I have decided to widen the scope of the evaluation.

The evaluation will include consideration of factors influencing access to specialist medicines including:

- The IFR process itself; including consideration of clinical exceptionality;

- Arrangements for access to specialist drugs in other UK jurisdictions;
- The Early Access to Medicines Scheme (EAMS);
- The Pharmaceutical Price Regulation Scheme (PPRS);
- The potential for the reintroduction of prescription charges to finance a specialist drugs fund.

I want to deliver an evaluation of the IFR process which will be definitive in terms of concluding if the process is meeting its objectives. The evaluation will also make recommendations as to whether the IFR should continue in its current form or whether a new process should be considered. It is also worth noting that this is a wider issue than access to cancer drugs and includes access to specialist medicines for patients with other serious conditions. Full terms of reference for the evaluation are attached at **Annex A**.

A project management structure has been established under the leadership of the Chief Medical Officer Dr Michael McBride to take forward this work. The Project Board includes membership from the Belfast Health and Social Care Trust, the Health and Social Care Board, the Public Health Agency, the Northern Ireland Cancer Network and the Department.

The Project Team will engage with a range of stakeholders and will organise workshops to inform the evaluation which will be held during October/November 2014. In addition the project team will conduct a literature search and gather evidence from clinicians and practitioners across the HSC, commissioners, the industry and from patient representative groups. I expect the initial findings of the evaluation to be available from late November 2014 and the evaluation will be completed by the end of the year.

I have met many patients who have undergone trauma and stress related to their treatment. I empathise entirely with them and I want to assure them that my aim is to ensure that that they receive the most effective treatment possible and that our health service will continue to strive to provide the best service it can in terms of access to specialist medicines.

ANNEX A

Terms of Reference for the Evaluation of the Individual Funding Request process

- To assess whether the IFR is meeting its objective as a process to determine if a clinically supported request for specialist drugs should be funded rather than as a clinical decision making process.
- To consider the impact of the concept of Clinical Exceptionality in the IFR process in providing access to specialist drugs.
- To give consideration to policies and processes that England, Scotland and Wales have adopted in their approach towards providing access to specialist drugs.

- To evaluate the IFR process in terms of its impact on access to drugs on the Cancer Drugs Fund list, in England, and the related potential impact of the Pharmaceutical Price Regulation Scheme (PPRS).

- To consider the implications for access to specialist drugs arising from the implementation of the Early Access to Medicines Scheme (EAMS) in Northern Ireland.

- To consider the implications of the NICE-led value based assessment process and its proposals to incorporate two new “value elements” into NICE appraisals.