

# Written Ministerial Statement

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## Health, Social Services and Public Safety

### RESULTS OF CONSULTATION ON THE EVALUATION OF THE INDIVIDUAL FUNDING REQUEST PROCESS — REPORT AND ACTIONS

*Published at noon on Tuesday 8 December 2015*

**Mr Hamilton (Minister of Health, Social Services and Public Safety):** The Individual Funding Request (IFR) is the process governing access to specialist drugs that are not routinely commissioned in Northern Ireland's Health and Social Care system. Following concerns raised by patients and survivors, charities, the pharmaceutical industry and political representatives, an evaluation of this process was launched in September 2014 and was then subjected to a 12 week consultation process. The responses to the consultation have now been analysed and I would like to take this opportunity to inform the Assembly of my decisions and the proposed next steps before publishing the report.

#### **Report on the Outcome of the Public Consultation on the Evaluation**

I am pleased to say that there was an excellent response to the consultation from a range of key stakeholders as well as individual members of the public. Feedback was also gathered through a series of public and private meetings with patient representative groups, clinicians, academia and the pharmaceutical industry and their representatives.

The recommendations of the evaluation report were:

#### **Rec 1: That the existing exceptionality criteria should be amended to remove the reference to 95%;**

The evaluation report identified that the current definition of clinical exceptionality used in NI is almost universally regarded as too restrictive. Currently this criterion means a clinician must demonstrate that their patient is different to 95% of patients with the same condition at the same stage.

There was widespread public support for this recommendation. Comments reflected the difficulty in identifying patients who fit the criterion in small patient populations, for example rare conditions which are defined by the size of the number of patients with a certain condition. However other views highlighted the risk that removing exceptionality entirely could undermine the appraisal processes of organisations such as the National Institute for Health and Care Excellence (NICE), which we rely on to provide guidance and reduce variation in the availability and quality of our health treatments and care.

#### **Rec 2: That the establishment of regional scrutiny committee/s should be considered to ensure all IFR applications are subject to regionally consistent clinical input and peer review;**

The evaluation highlighted the fact that there is no regional approach to IFRs at Trust level and there is a lack of evidence on how decisions are made within different areas. This has raised the perception that the approach to IFRs may at times be inconsistently applied in different Trusts.

The creation of a regional group would ensure fair and consistent treatment of all IFRs across all Trusts and would also provide an element of clinical peer review/challenge to IFR decisions which

would lend depth and clinical authority to the IFR process. This recommendation also attracted almost universal support.

**Rec 3: That the existing IFR guidance should be revised to include greater transparency;**

Throughout the consultation and the evaluation process, the team heard repeated criticism that the current system is poorly understood by patients and that the decision making process is not sufficiently transparent. A number of respondents stressed that it would be helpful to understand the reasons why a request had been approved or rejected and that they would welcome greater transparency and feedback in the decision making process. From a clinical perspective, this would also be beneficial in terms of data and evidence collection, and clinicians who responded to the consultation also supported this proposal.

**Rec 4: That the Department should establish a Specialist Medicines Fund to meet the costs of administering and maintaining increased access to specialist drugs;**

The response to this recommendation was mixed, while many respondents welcomed the suggestion of a separate fund, others, particularly clinicians and those within the Health and Social Care system, expressed concern that such a funding mechanism would be inflexible and unsustainable in the long term. Concerns were expressed that creating a specialist medicines fund could create inequity of access by potentially diverting funding from other health activities which may have a better evidence base.

**Rec 5: In order to resource the new fund, the HSC should re-introduce charging for prescriptions.**

The consultation on the evaluation of the IFR process sought views on the re-introduction of prescription charges to support the establishment of a new specialist medicines fund. This recommendation elicited the largest number of responses within the consultation, with the majority respondents being opposed to the re-introduction of prescription charges. Where there was some support for the principle of charging, this was predicated on there being a comprehensive range of exemptions.

**Next steps**

Officials in the Trusts and the Health and Social Care Board have worked hard and have shown great commitment in making difficult decisions about access to new specialist drugs within the constraints of the existing IFR system. I would like to thank them for this work and to emphasise that the changes I propose are no reflection on their performance; rather they are about improving the system within which they operate.

Having considered the responses to the consultation, I have decided to accept and progress options 1 to 3. The consultation has certainly shown that there is widespread support among patients, clinicians and other stakeholders for these measures and I have no doubt they will help to modernise and improve access to specialist drugs for patients in Northern Ireland.

There is however still a great deal of work to do to implement these changes. I therefore propose to establish a short life task and finish group to commence the work to redefine exceptionality, create a regional scrutiny committee to establish peer review and consistency across the province, and revise the IFR guidance to provide more transparency. My officials are currently working to establish this group and it will meet as soon as possible. I understand the importance and urgency attached to this work and I will make sure that the group's terms of reference are tightly focused and that the work is carried out at pace.

With respect to recommendations 4 and 5, I have already made clear that I do not support the re-introduction of prescription charges at this time and this remains my position. On the issue of a specialist drugs fund, I have taken heed of the consultation responses and also the experience in England, where the Cancer Drugs Fund has encountered significant challenges around operation and sustainability. In fact, NHS England is currently conducting a public consultation on proposals to fundamentally change the operating model of the Cancer Drugs Fund which if adopted will provide for

a focus on clinical assessment. I will ensure that the task and finish will take full account this development in considering the best way forward for Northern Ireland.

Patients should have access to the drugs they need and I share some respondents concerns that the creation of a specialist drugs fund is not necessarily the best means to achieve this. I have therefore decided that these changes will be funded from within the Health and Social Care budget. However, we must also be aware that reforming the IFR process to increase access to these drugs will carry significant costs at a time when the Health and Social Care budget is facing real pressures.

There has been a tremendous amount of interest in this evaluation and I thank everyone for their contribution to the debate. A full copy of the consultation analysis is available on the Department's website.

Thank you