Summary of Responses to Consultation on the REPORT OF THE EVALUATION OF THE INDIVIDUAL FUNDING REQUEST PROCESS

01 December 2015
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<thead>
<tr>
<th>ACRONYM</th>
<th>DEFINITION</th>
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<tbody>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
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<tr>
<td>BHF</td>
<td>British Heart Foundation</td>
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<tr>
<td>BSO</td>
<td>Business Services Organisation</td>
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<td>CDF</td>
<td>Cancer Drugs Fund</td>
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<td>SRUK</td>
<td>Cancer Research United Kingdom</td>
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<tr>
<td>DHSSPS</td>
<td>Department of Health, Social Services and Public Safety</td>
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<tr>
<td>EAMS</td>
<td>Early Access to Medicines Scheme</td>
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<tr>
<td>ECR</td>
<td>Extra Contractual Referral</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>HSC</td>
<td>Health and Social Care</td>
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<td>Health and Social Care Board</td>
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<td>HTA</td>
<td>Health Technology Assessment</td>
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<td>IFR</td>
<td>Individual Funding Requests</td>
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<td>MDTs</td>
<td>Multi-Disciplinary Teams</td>
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<tr>
<td>MLA</td>
<td>Member of the Legislative Assembly</td>
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<tr>
<td>NHS</td>
<td>National Health Service</td>
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<td>NI</td>
<td>Northern Ireland</td>
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<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<td>NIECR</td>
<td>Northern Ireland Electronic Care Record</td>
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<tr>
<td>NIMDTA</td>
<td>Northern Ireland Medical and Dental Training Agency</td>
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<tr>
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<td>Northern Ireland Rare Disease Partnership</td>
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<td>NPA</td>
<td>National Pharmacy Association</td>
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<td>PCC</td>
<td>Patient Client Council</td>
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<td>PHA</td>
<td>Public Health Agency</td>
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<tr>
<td>PPRS</td>
<td>Pharmaceutical Price Regulation Scheme</td>
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<tr>
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<td>Quality Assurance</td>
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<td>R&amp;D</td>
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<tr>
<td>SDLP</td>
<td>Social Democratic and Labour Party</td>
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<tr>
<td>SMC</td>
<td>Scottish Medicines Consortium</td>
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<td>SMF</td>
<td>Specialist Medicines Fund</td>
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<td>TA’s</td>
<td>Technical Appraisals</td>
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<td>TYC</td>
<td>Transforming Your Care</td>
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1. **INTRODUCTION**

*Consultation enables an assessment to be made of the views of those who are affected by policy decisions or changes to services. It can help policy makers to become aware of issues and problems which policies may pose for various groups that the organisation might not otherwise discover.*

The Department of Health, Social Services and Public Safety, referred to in this document as “the Department” or “DHSSPS”, ran a consultation from 18 February to 8 May 2015 to engage with patients, clinicians, stakeholders and the general public about the findings of an evaluation of the Individual Funding Request (IFR) process.

This report explains the approach to the consultation and provides a summary of the issues raised through written consultation responses, a series of public meetings held around Northern Ireland and a professional and clinician workshop held in Belfast.

This report concludes with the Department’s response to those issues.

2. **BACKGROUND**

In a Statement to the Northern Ireland Assembly on 17 February 2014 the then Minister for Health, Social Services and Public Safety, Edwin Poots MLA, announced that he had requested an evaluation of the Individual Funding Request (IFR) process in response to concerns that it was not meeting its objective of providing access to specialist drugs that are not routinely available in circumstances where there is an agreed clinical need. This evaluation intended to provide a rapid assessment of the IFR process and make recommendations as to whether it should continue in its current form or whether a new process should be considered.

Although the Minister set the clear aim for the evaluation to investigate whether the IFR process was meeting its objectives, the remit was later widened to include additional factors such as arrangements for access to specialist drugs across the UK, the Early Access to Medicines Scheme (EAMS), the Pharmaceutical Price Regulation Scheme (PPRS) and the potential for the reintroduction of prescription charges to finance a specialist drugs fund.

On 18 February 2015 the Minister released the findings of the evaluation as a report for public consultation to run for 12 weeks. These findings were:

- That the existing exceptionality criteria should be amended to remove the reference to 95%;
- That the establishment of regional scrutiny committees should be considered to ensure all IFR applications are subject to regionally consistent clinical input and peer review;

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• That the existing IFR guidance should be revised to include greater transparency and to enhance patient involvement;
• That the Department should establish a specialist medicines fund to meet the costs of administering and maintaining increased access to specialist drugs;
• In order to resource the new fund, the HSC should re-introduce charging for prescriptions.

Consultation

The Department invited clinicians, patients, key stakeholders and the general public to provide their views on the findings with the aim of informing advice to the Minister which would help the decision making process.

The full Report and Questionnaire documents can be viewed on the Department’s website at:

https://www.dhsspsni.gov.uk/consultations/evaluation-individual-funding-request-process

An overview of the consultation responses can be viewed in Section 3.

Responses were invited using either the questionnaire form provided, by letter or email. A summary of the issues raised through written responses is contained in Section 4.

The Department held a series of public meetings at various locations throughout Northern Ireland. A summary of the issues raised through these public meetings is contained in Section 5.

The Department also ran a special workshop for clinicians and other professional stakeholders who are directly involved in the IFR process. A summary of that event is contained in Section 6.

The Department’s response to the issues raised can be viewed in Section 7.
3. OVERVIEW OF CONSULTATION RESPONSES

In total 91 written responses from a wide range of organisations and individuals were received by the DHSSPS.

Responses were welcomed in any written format:

- 68 responses used the consultation questionnaire;
- 5 responses were received by letter;
- 18 responses were received by email.

Not all respondents who used the questionnaire answered all of the questions and this is also true of those respondents who opted not to use the questionnaire at all. This needs to be taken into account when considering any quantitative analysis.

The 91 written responses have been categorised as per the following table comprising organisational responses including Health and Social Care bodies, business groups, voluntary groups, local political parties and elected representatives.

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of responses</th>
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<tbody>
<tr>
<td>1 Business groups</td>
<td>12</td>
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<tr>
<td>2 Voluntary groups</td>
<td>30</td>
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<tr>
<td>3 Public sector</td>
<td>7</td>
</tr>
<tr>
<td>4 Health professionals &amp; practitioner representative bodies</td>
<td>10</td>
</tr>
<tr>
<td>5 Patients, patient representatives &amp; Trade Unions</td>
<td>17</td>
</tr>
<tr>
<td>6 Members of the public</td>
<td>13</td>
</tr>
<tr>
<td>7 Political parties</td>
<td>2</td>
</tr>
</tbody>
</table>

A list of respondents can be viewed at Annex B.

Both written responses and feedback gathered through the public meetings reflect a range of views that are broadly supportive of positive change in the IFR process and the establishment of a specialist medicines fund as noted by the Report, tempered by a degree of concern over how this will be funded, implemented and managed.

The recommendation that prescription charges should be re-introduced elicited the largest number of responses and opinion was divided and varied, although 25% of written responses were undecided or chose not to comment. The categories with the highest number of written opposition to prescription charges were category 2 (voluntary groups) and category 5 (patients, patient representatives and Trade Unions).
4. SUMMARY OF WRITTEN CONSULTATION RESPONSES

This section provides a summary of the written responses received for each recommendation, as well as additional comments and issues shared with the Department through this process.

Recommendation 1: That the existing exceptionality criteria should be amended to remove the reference to 95%.

It is recommended that a new definition of clinical exceptionality should be developed that is clearly understood by patients and their clinicians, families, carers and representatives and is fully explained as to how it should be applied both at Trust level and at Commissioner level and the interdependency between the two.

Q1. Do you agree that the current exceptionality criteria are too high?

There were 54 responses to this question distributed as:

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<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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<tbody>
<tr>
<td>Responses</td>
<td>33</td>
<td>14</td>
<td>6</td>
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</table>

Of the 54 responses received to this question there was overwhelming agreement (47, 87%) that reference to 95% exceptionality should be amended.

Comments generally related to difficulties in identifying those who fit the criteria in small disease populations and that the criterion is discriminatory. There were a number of comments which suggested lowering the threshold rather than removing it.

Comments included:
- “The concept of exceptionality is poorly understood by patients”
- “…actively discourages clinicians and patients from applying”
- “…difficult for clinicians to clearly demonstrate that the patient is 95% different to other patients with the same condition.”
- “…especially in situations where there are very low patient numbers…”
- “The setting of any such criterion would need to be founded by objectivity, transparency, justice and equity.”
- “95% formula is incomprehensible and unenforceable.”
- One organisation noted the rare disease community is adversely affected by the current IFR process and that exceptionality should be lowered and applied flexibly.
- Another noted the close links and comparable life sciences potential of Scotland and Northern Ireland, recommending the Scottish model for NI to
follow, with the added benefit of minimising duplication by examining the process followed by Scotland and their learning.

- One pharmaceutical organisation suggested that engaging with industry to provide accurate cost modelling could alleviate the concern that removing ‘exceptionality’ would ‘open the floodgates to spending’.

Q2. Do you agree that it is right to retain the concept of exceptionality within the IFR process?

There were 53 responses to this question distributed as:

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<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
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<td>3</td>
<td>19</td>
<td>8</td>
<td>7</td>
<td>16</td>
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</tbody>
</table>

Of the 53 responses received to this question there was an even split between those who agreed (22, 42%) and those who disagreed (23, 43%). Only one category 1 (business groups) ‘agreed’ with the concept of exceptionality being included in the IFR process, with eight of the remaining nine category 1 respondents selecting ‘Strongly disagree’.

Comments included:

For
- “Without the concept of exceptionality the risk is that the rigorous assessment by NICE would be undermined.”
- “…remove the terminology exceptionality.”
- “All cases must be evidence based.”
- “…retained with a lower threshold.”
- “…NICE may recommend not to use a drug for a group of patients but within the literature review, they make reference to a small cohort of patients for whom the drug had significant benefits.”
- “…exceptionality has to remain as otherwise these high tariff drugs would...be added to the normal tariff which is not sustainable in cost terms.”
- “Whatever the criteria are should be clear and on the world wide web so patients can readily access the information.”
- “Some level of exceptionality...ensure that costs did not spiral out of control.”

Against
- “…a patient with a rare condition should not need to demonstrate that they will benefit more from the treatment than any other patient, if the treatment is for a rare condition.”

Q3. What would be an appropriate definition of exceptionality?

Respondents were asked to comment via an open text box. Comments included:
• Suggestions to use similar clinical exceptionality criteria as the Cancer Drugs Fund in England;
• One comment noted that “the concept of exceptionality is discriminatory”
• “How does the patient’s condition differ from the majority of patients?”
• Others felt the Welsh definition was “practical and easier to provide evidence against and evaluate.”
• “...criteria... should be clear, measureable and have consistent applicability.”
• “A patient who does not, or cannot meet the standard conditions for treatment because they have other co-morbidities or unusual reactions to treatments that prevent them from being treated in the normal way.”
• “…vital that the expertise of clinicians with extra insight into particular patients groups, such as MS, are fully utilised.”
• One pharmaceutical organisation queried how the process would work with genomic medicines and rare genetic disease patients.
• One respondent stated that “…clinical need is the best approach for access to drugs, rather than exceptionality.”
Recommendation 2: That the establishment of regional scrutiny committees should be considered to ensure all IFR applications are subject to regionally consistent clinical input and peer review.

It is recommended that a regional group (or groups to cover the clinical specialities which use specialist drugs) be established to meet weekly which will allow for the consideration and clinical endorsement of IFR applications from all Trusts.

Q1. Do you agree with this recommendation?

There were 55 responses to this question distributed as:

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<thead>
<tr>
<th>Responses</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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<tr>
<td>Reponses</td>
<td>16</td>
<td>26</td>
<td>9</td>
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Of the 55 responses received to this question 4 (7%) disagreed on the establishment of a regional scrutiny group. The main concerns were around introducing bureaucracy to a process that is dependent on rapid decision making response times and the composition of the committee. There was also recognition that establishing a regional scrutiny committee may be challenging for the key stakeholders and that it may take time to develop an appropriate process.

Comments included:
- One organisation suggested the committee could have “core membership with specialties co-opted when required.”
- “pharmacy should be represented within this scrutiny committee.”
- With regard to access to drugs for rare conditions, or for treatment not commissioned in NI suggestions included patients having automatic access if they are available elsewhere in the UK.
- One member of the public asked if it would be important to have a quorum.
- One charity pointed to the example of the All-Wales Medicines Strategy Group as a model for a “national committee to provide advice on decisions”.
- One charity questioned whether peer review is possible given the small population in NI.
- One charitable organisation suggested the addition of palliative and/or geriatric expertise on a regional scrutiny committee.

Q2. If you do not agree, can you suggest another method of ensuring regional consistency?

Not all of those who commented on this question disagreed with the concept of a regional scrutiny committee. One business organisation noted that “By removing ambiguous terms (such as exceptionality) many of the issues that give rise to variation will be removed.”
Recommendation 3: That the existing IFR guidance should be revised to include greater transparency.

It is recommended that the Department working in partnership with the HSCB, HSC Trust and the Patient Client Council (PCC) should conduct further work with clinicians and patient representatives to ensure that there is absolute clarity regarding the process itself and professional roles. This work should also consider the collection and recording of data relating to specialist treatments.

Q1. Do you agree that the process would benefit from a greater level of transparency?

There were 56 responses to this question distributed as:

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<thead>
<tr>
<th>Responses</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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<tbody>
<tr>
<td>36</td>
<td>19</td>
<td>1</td>
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Of the 56 responses received to this question there was overwhelming agreement (55, 98%) to revise the current IFR guidance.

Most comments related to including an appeals procedure and clarity of the overall process to promote better understanding.

Comments included:
- “...patients need to be informed of progress and if any delays occur.”
- “Transparency is vitally important for patients.”
- “Patient representatives (including MLAs, councillors, patient lobby groups etc) must ensure their patients are represented but also ensure they take a lead in explaining to the public why difficult decisions are made.”
- “…quarterly feedback...to clinicians to assist in making their decisions. Ideally this should track from decision to the actual outcome...”
- “…advocate the need to include other stakeholder organisations from the third sector, the medical and pharmaceutical profession and representation from civic groups.”
- “Each Trust should have a named accountable individual trained in the process and act as the patient’s advocate alongside the patient in such processes.”
- “…NHS England...full report on each decision made by the review panel...also publishes...number of applications and approvals for each medicine.”
- One charity noted that “In our experience, the current process is too complex and time consuming.”
- One charity suggested the development of an IFR handbook for healthcare providers.
- A number of charities called for data on IFRs, including conditions, treatments and indicators, to be published regularly, with one organisation noting that this would present an “opportunity to gain ‘real-world’ data on the benefits and resource implications of making a treatment or
Q2. Do you agree that increased transparency would have a positive impact on patients’ and clinicians’ confidence in the process?

There were 56 responses to this question distributed as:

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<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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<tbody>
<tr>
<td>Responses</td>
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<td>22</td>
<td>3</td>
<td>0</td>
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Similar to the previous question 95% (53) of respondents concurred that increased transparency would improve patient and clinician confidence in the process.

Comments included:

- “Increased transparency is an absolute requirement. There is a lack of confidence from both patients and healthcare professionals in the current process.”
- “Neither my patients nor my professional colleagues have any confidence or faith in the current IFR system. Increased consistency, transparency, clarity and timeliness of decision making and subsequent communication are absolutely imperative.”
- “Expectations must be managed in light of a health economy that is bleak.”
- “…robust data gathering is completed of all applications and decisions….patient outcomes should also be monitored.”
**Recommendation 4:** That the Department should establish a specialist medicines fund to meet the costs of administering and maintaining increased access to specialist drugs.

It is recommended that the Department should establish a new specialist medicines fund to support the changes proposed here and to ensure that funding for these medicines and the infrastructure necessary to support them is put on a secure financial footing.

Q1. Do you agree that the Department should establish a Fund to put funding for medicines on a secure financial footing?

There were 58 responses to this question distributed as:

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<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither</th>
<th>Disagree</th>
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<tr>
<td>Responses</td>
<td>16</td>
<td>22</td>
<td>7</td>
<td>10</td>
<td>3</td>
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</table>

This question drew a wider spread of opinion however of the 58 responses two thirds agreed (38, 66%) with less than a quarter disagreeing (17, 22%) that a Fund should be established.

There were comments about:

For

- “Recurrent funding is needed to support the IFR process” and other concerns about mechanisms to prevent over spend.
- “...reviewed regularly with respect to demand bearing in mind the demise of the CDF in England.”
- There were comments about Scotland utilising PPRS, e.g. “the PPRS rebate contributes to the specialist medicines fund”.
- “…it is extremely important that this scheme not only provides value for money but that it is sustainable.”
- “…access certain long extending and quality of life improvement treatments that enable them to live longer, work longer and be less of a financial burden to the economy. They are thus contributing to the economic and healthy wellbeing of society.”
- “Do not spend any ‘drugs fund’ on drugs which prolong life of terminal conditions only by a few months. The drugs fund should only be spent where the benefit is long lasting in clinical trials (promote recovery or extend life by a minimum of 2 years.”
- “It is very difficult to see a member of the family being turned down for a treatment which would improve the quality and length of life because no funding could be secured.”
- “…recognises that the rapid establishment of a Specialist Medicines Fund has the potential to enable patients...to gain greater and quicker access to beneficial medicines...whilst evolution and reform of NICE is being considered.”
• One group referred to evidence from a study conducted in 2014 suggests that the establishment of a specialist medicines fund would be supported by people from across Northern Ireland.
• One charity acknowledged that “it will take some time for a process to be developed which is suitable for Northern Ireland.”

Against

• “…it is not necessary to establish a Specialist Medicines Fund to put funding for medicines on a secure financial footing. There is already in place a robust mechanism to support the commissioning of medicines including specialist medicines. The establishment of a Specialist Medicines Fund would potentially create inequity of access to medicines and reduce funding available elsewhere in the HSC to fund cost-effective medicines/interventions.”
• “…notes that the cancer drugs fund in England is now perceived to be unsustainable,”
• “…could be open to abuse, with it being used to fund a wider and wider range of treatments.”
• “…spending on specialist drugs should be subject to the same level of prioritisation as access to other treatments.”
• One group were “…deeply concerned...’scope creep’...access to all specialist or innovative medicines, including those approved by NICE or SMC become subject to release or ring-fenced funds rather than being routinely commissioned.”
• One cancer charity noted that “Since the launch of the Cancer Drugs Fund in England, NICE’s rejection of cancer drugs has risen. This has resulted in a large number of drugs being automatically paid for at their full price through CDF prescribing…”
• Another charity organisation said they would not support a SMF without a mechanism to address the gap between the commissioning and the IFR processes, and the evaluation of specialist medicines, notwithstanding the Regional Group on Specialist Medicines which manages the Red/Amber list who do not evaluate efficacy or value for money, as not all drugs on the list have been assessed by NICE.
Recommendation 5: In order to resource the new fund, the Department should re-introduce charging for prescriptions.

In view of the current financial position, and the need to invest in services such as the provision of new specialist drugs, this is an appropriate time to reconsider the provision of free prescriptions in Northern Ireland. The additional funding provided through this would be used to put funding for specialist medicines on a secure financial footing.

Q1. Do you agree that it is reasonable for patients to make a contribution towards the costs of their prescriptions, particularly in light of the challenges of funding high cost specialist medicines?

There were 83 responses to this question distributed as:

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reponses</td>
<td>9</td>
<td>16</td>
<td>13</td>
<td>23</td>
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It is notable that this question elicited the largest number of response within the consultation. Like the previous question, it also drew a wide spread of opinion. Of the 83 responses 45 (54%) were against the re-introduction of prescription charges as opposed to 25 (30%) for the proposal and 13 (16%) selecting ‘neither’.

The respondents who did not comment or selected “neither” were not necessarily against the re-introduction of prescription charges. They were, however, concerned that there were alternative ways of funding a specialist medicines fund e.g., PPRS payments; that the proposals for charges were not clear; that the two issues should not be linked; and, that prescription charges was a separate issue which required separate consultation.

Similar to the previous question about the SMF there were comments, in particular from category 1 respondents, about the need for recurrent funding to support a SMF and the utilisation of PPRS to do so. There were also recurring comments about waste and prescribing ‘over the counter’ products which could be reduced if prescription charges were re-introduced. There were also emotional responses from patients who described their journeys through illnesses which highlighted additional costs that are not measureable in the same way for everyone, for example those who need extra heating costs because their treatment reduces their temperature threshold, or increased travel expenses to attend regional health centres regularly, or those who have expensive dental outcomes due to their treatment.

Of the 30 charity responses received only five agreed or strongly agreed with the introduction of prescription charges, with a further nine either not commenting or selecting neither. Sixteen (53%) voluntary groups were opposed to the principle.

Nine responses were received from cancer charities and none of these organisations supported the principle of introducing charges for prescriptions to
fund the cost of specialist medicines. Several queried the morality of charging people to pay for medicines for others and that it would be nonsense to help people with cancer through a specialist medicines fund but charge them for prescription medicines.

Q2. What do you consider to be the most appropriate way to apply such a charge?

As indicated above most respondents did not agree with the principle proposed in the consultation that a prescription charge should be introduced to fund the costs of a specialist medicines fund. Most of these respondents did not, therefore, address this question. Some, however, indicated that if charges were to be brought back that a comprehensive range of exemptions would need to be put in place.

Of the 25 responses which indicated some measure of support for the principle of a charge, 17 indicated that any charge should be accompanied by: annual limits; annual limits with exemptions; exemptions for the elderly; exemptions for certain medical conditions; and the re-introduction of the system of exemptions which had previously been in place.

Comments included:

For

- “I agree with this approach – both to fund specialist medicines but also to resolve other medicines related issues ongoing at the moment, e.g. excessive ordering of medicines by patients, GP appointments for items that can be bought over the counter etc.”
- “While I understand that a universally free system might not be available, then a smaller annual fee of say £10 might be better.”
- “Either a low flat rate payable by all (less admin (sic)) or an English style system with exemption certificates/cards. An annual cap would also be fair.”
- “Lifelong conditions have many hidden costs for patients.”
- “I think this is a great idea...raising monies to provide vital drugs...deterrent for those who continually obtain prescriptions they do not need...”
- “It was a nonsense that charges were withdrawn (sic). The money that has been lost since the withdrawal could have saved lives.”
- One organisation reported that most people would be willing to make a contribution towards the cost of their prescriptions, although there were mixed views on how charges should be implemented.

Against

- “The availability of adequate funding to meet the needs of patients who require treatment with specialist medicines should not be dependent on the revenue that could be raised from re-introducing prescription charges.”
- “…wider harm to health and increased health inequality due to large
numbers of patients not taking important prescribed medications for common conditions... due to cost.”

- “I do agree that people out there are abusing the system...take into account the people that need medication to keep them alive.”
- “Tax on the sick and vulnerable.”
- “My wife needs 18 items per month, I need 5...only 50p per item it amounts to quite a lot out of my £102 per week benefits as we can’t work due to ill health.”
- “…born with this condition...I feel disadvantaged already...pay more for the medicines I require...additional tax…”
- “All healthcare, treatment and drugs should be paid for out of the same general pots of money, obtained from tax and National Insurance contributions and used to provide care for all according to need.”
- “…we urge healthcare policy stakeholders to decouple the issue of prescription charges from the issue of access to specialist medicines…”
- “…PPRS option could be made to work and it is worth exploring further.”
- “…free prescriptions should only be available for essential health related treatments and should not be available for over the counter items which do not require a prescription.”
- “…false economy...likely to lead to far greater costs for the health service and the public purse in the long run.”
- Re-introducing prescription charges “runs contrary to the current consensus on the direction of travel for health policy...that encourages people to self-manage their condition to prevent them reaching crisis point.”
- One organisation suggested working with patients so they “understand the contract they enter into with the NHS in order to obtain treatment access” would improve access to treatments and services most valued by patients.

Other

- “…agree that charging for prescriptions should be re-introduced...do not support that this levy should be used to fund specialist meds (sic).”
- “Mandate the use of generic brands...Patients who advise the pharmacist that they have a personal preference for a brand product could be offered the opportunity to pay the difference between the costs of the two products as an alternative to accepting the generic brand...enables...continuity of free prescriptions for all.”
- “A health lottery could be used and anyone who wanted to could subscribe to this.”
- “…hospitals, health centres and doctors’ surgeries could have donation boxes in their receptions...museums and art galleries can have donation boxes so why not health centres and hospitals?”
- “…deliberation on...prescriptions charges should not delay changes made to the IFR Policy Process (sic)...”
- “At the moment patients don’t ‘value’ their medicines because they are free...”
- “All means to raise additional funds for the NHS must be considered including charging for GP appointments.”
- “Standard £2 per item with option of season ticket...”
General comments
At the end of the consultation response document an open text section invited respondents to insert general comments in relation to the recommendations or wider content of the evaluation report. Comments included:

- If re-introducing prescription charges streamline the process by using technology;
- “Establishment of a more streamlined process will enable treatment to be made available to patients sooner, while they are still suitable for therapy”;
- “…some of the funding in a new Specialist Medicines Fund towards a ‘subvention fund’ that would pay for drugs in clinical trials that are not currently funded/available in NI but are available in one or more of the other UK devolved nations.”
- “It should be recognised that by prescribing experimental drugs that not only does it extend or improve life, it helps to refine drugs and treatments to ultimately make them more effective and more affordable.”
- “…on every prescription it showed the dispensing cost...The Department should adopt this as policy so patients see what their drugs are costing.”
5. SUMMARY OF PUBLIC CONSULTATION MEETINGS

List of Public Consultation Meetings

1. Public Meeting – Altnagelvin Area Hospital, Londonderry, 24 March 2015
2. Public Meeting – Craigavon Civil Centre, Craigavon, 31 March 2015
3. Public Meeting – Lagan Valley Island Civic Centre, Lisburn, 13 April 2015
4. Public Meeting – Killyhelvin Hotel, Enniskillen, 16 April 2015
5. Public Meeting – Antrim Civic Centre, Antrim, 21 April 2015
6. Public Meeting – Belfast City Hospital, Belfast, 28 April 2015
7. Clinician and Professional workshop, Belfast, 24 April 2015

Preparation for Consultation Meetings

In light of the need for rapid turnaround, project leads of two successful major consultations recently completed by Secondary Care Directorate were consulted to gather advice and direction in addition to discussion with Cancer Focus NI, Clinical Consultants and Department officials from Pharmacy and the Press Office. The six venues and timings noted above were selected to offer the best practical choices and opportunities for patients, families and representatives across the Province to attend and participate in these public meetings. The format adopted was informal, with cabaret style round tables where possible to encourage discussion and interactive conversation to share views and offer feedback from the panel on each of the five IFR Evaluation findings.

Attendance at Public Meetings

Each meeting was chaired/facilitated by Patricia Donnelly on behalf of the Department of Health Social Services and Public Safety.

The Department was represented at each meeting by Dr Mark Timoney (Chief Pharmaceutical Officer) and/or David Lennox (Head of Pharmacy and Prescribing), Alastair Campbell (Head of Policy and Legislation, Secondary Care Directorate) and/or Jackie Johnston (Director of Secondary Care) and/or Joe Magee (Policy Manager, Secondary Care), who responded to points relating to the Evaluation Report and Departmental policy. Each meeting was also attended by Helena Brown as rapporteur.

At each meeting a Consultant clinician offered their advice and shared their experiences of the current IFR process. Attending Consultants were Dr Martin Eatock (oncology), Dr Paula Scullin (oncology) and Dr Dermot Hughes (pathology).

In addition to coverage on the Department’s website and NI Direct, details of the public meetings were shared with GP surgeries via the Business Services Organisation (BSO), MLA’s personal boxes at the Assembly and relevant voluntary groups and other organisations who in turn publicised events through email/social media. The Department also issued press announcements with event details to local newspapers ahead of each meeting.
The six public meetings were attended by a broad mix of people including patients and/or their carers, patients’ relatives, charity representatives, councillors and MLAs, media, industry academics and Trust employees as follows:

<table>
<thead>
<tr>
<th>Meeting place</th>
<th>Attendees</th>
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<tbody>
<tr>
<td>Londonderry</td>
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<tr>
<td>Craigavon</td>
<td>4</td>
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<td>Lisburn</td>
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<tr>
<td>Antrim</td>
<td>18</td>
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<tr>
<td>Belfast</td>
<td>16</td>
</tr>
</tbody>
</table>

**Format of Meetings**

The findings from the IFR Evaluation Report were introduced via power-point presentation and included an explanation of the models used in the other UK jurisdictions, followed by a group discussion around a series of questions covering each recommendation. Attendees then provided group and individual feedback to the floor on each question.

The interactive process used an improvement model whereby feedback at the end of each meeting allowed changes to be made to improve engagement at future meetings. For example:

- Name badges
- Venue and contact numbers
- Questions were amended after the first meeting to remove closed questions as attendees expressed a preference for open questions
- Amendments of typographical or factual errors.

Feedback was captured in two formats during the meetings: individual feedback forms and notes taken of comments. Attendees were also offered the opportunity to comment on any other issues around the report, process and consultation not covered by the main themes in order to ensure all aspects of concern were identified.

The following notes provide a summary of the key comments and concerns raised at the consultation meetings under each of the five recommendations. They are not intended to be a verbatim minute but are reported as amalgamated comments.
Public meetings – summary of discussions by recommendation

Recommendation 1: That the existing exceptionality criteria should be amended to remove the reference to 95%.

Discussion and comments reflected the general consensus of the written responses in that the reference to 95% should either be removed or the threshold lowered, but that some form of criteria should be used to control access due to the amount of funding required, not just for the drug but also for the infrastructure and support costs.

In common with the written responses there was agreement that in small disease populations it is often difficult to demonstrate how patients meet the 95% criterion.

There was general consensus that different language for ‘exceptionality’ should be used with ‘clinical need’ being one suggestion. One person commented that ‘exceptionality is inhumane and misunderstood by patients.’ There was also some concern about who should be the decision maker for any new criteria.

Similar to the written responses there was broad consensus that the definition should mirror that of the Scotland or Wales models.

There was also broad agreement that implementation of this recommendation may help to remove perceived inconsistencies across Trusts and diseases.

Comment was noted on funding choices and providing effective treatments such as disease modifying therapies for progressive conditions in comparison to providing expensive drugs for little or less benefit.

There was also a discussion about patients in emergency life threatening positions which led to a conclusion that any new process should consider including a mechanism for emergency treatment requiring IFR medicines within a very short period of time - examples of septic shock or septicaemia were given.

There was general discussion about how the current process reports a 98% IFR approval rate and that an unknown ‘unmet need’ currently exists. This led to further discussion about how to estimate the funding envelope required for IFRs and the expected increase in IFR applications if the 95% criterion was removed or lowered.

One person noted that “If the IFR barriers were lowered and the best, newest drugs were available, would we not have a healthier population and a healthier quality of life?”

Finally, there was broad discussion about the availability of drugs to NI patients through clinical trials, both during and after the trial, and the benefits that clinical trials bring to patients and research organisations as well as pharmaceutical organisations.

Points to note included:
• Patients who have not had access to the requisite drugs prior to the trial, some of which are/may be the subject of IFRs, would be ineligible for certain trials;
• Some clinical trials are not run in NI because of the small patient population for a particular disease;
• In some cases patients who had access to a particular drug when participating in a clinical trial could not access that same drug when the trial was completed.
Recommendation 2: That the establishment of regional scrutiny committees should be considered to ensure all IFR applications are subject to regionally consistent clinical input and peer review.

Again, in keeping with written responses there was general agreement that this is a good recommendation and that it would lend depth to the IFR process. Some had concerns about governance issues around committee members also representing their own patients and whether the committee would be making joint decisions, i.e. clinical decisions as well as funding decisions.

Membership of the committee was regarded as very important and included the following suggestions:

- Should be clinically led;
- Patient involvement or representation;
- Further specialist clinicians as required;
- Pharmacy.

Broad discussion included having two regional committees: one for cancer and one for other conditions, however there was general concern about the time required for busy clinicians to attend to committee business. Methods for effective communication were discussed.

Some individuals asked about the timescale for establishing such a committee and the level of finance required to run it.

There were a number of individuals who asked if the format of the committee would be similar to that of the peer review panel in Scotland.
Recommendation 3: That the existing IFR guidance should be revised to include greater transparency and to enhance patient involvement.

This recommendation was welcomed at all meetings. Comments around the subject included increasing patient confidence in the process and improved patient experience; clinicians must be the decision makers; and, equal access across the province.

Timeliness of IFR decision making was considered very important by most people, especially for those patients whose life expectancy is short. There was some concern about potential barriers resulting from declined applications and the impact on patient/clinician relationships where the clinician served on the committee or appeals panel.

There was general discussion about how the process could be improved using modern technology and it was generally agreed that using clear and concise language for IFR documentation and procedures would encourage consistent interpretation and introduce a standardised approach across Trusts.

There was a general consensus that communication with patients on the decision making process would engender better understanding and increase confidence in the process.

There was discussion around IFR data collection and auditing patient outcomes having the potential to measure unmet need where accurate data is not currently available, which could have the added value of assessing drugs so that treatments can be approved more rapidly.
Recommendation 4: That the Department should establish a specialist medicines fund to meet the costs of administering and maintaining increased access to specialist drugs.

Similar to the written responses, there were mixed opinions about this recommendation depending on location and audience. Some meetings compared and contrasted the methods used in the other UK regions without expressing an overall opinion, whereas other meetings held definite views for or against a (SMF).

All attendees were interested in how much a SMF would cost and if it could be sustainably funded. It was agreed that the scope and purpose of such a scheme would need to be transparent and include all specialist drugs. Particular comments included concern about ‘opening the doors’ for more funding requirements with examples given of further expensive lifelong secondary conditions, such as diabetes, which are precipitated by successful treatment of the primary condition. Others were concerned whether the SMF would fund NICE approved treatments and there were comments that a SMF would be a short term solution.

Some spoke of the dilemma within healthcare - whether to fund expensive medicines that tackle the defects or fund palliative care which treats the symptoms. There was debate about which medical conditions other than cancer should be part of the SMF which included, for example, patients who have recently completed clinical trials and those with long term conditions. One individual commented on long term outcomes where a patient has an adverse reaction to first line treatment and is admitted to hospital, that the costs associated with this type of situation should be balanced against prescribing an expensive drug in the first instance and avoiding the costs of hospitalisation.

Discussion around the additional costs involved in the introduction of new drugs prevailed, including clinical infrastructure costs such as clinic rooms, heating, lighting and other expenses plus the cost of equipment, diagnostics, monitoring, nursing, doctors and pharmacy as well as the cost of the medication. Some people talked about primary and community care costs that should be taken into consideration. One group gave a working example of anti-TNF drugs which increase patients’ quality of life. These drugs cost around £7,000 per year per patient, however an additional £3,000 should be added and recognised as the realistic cost of providing the treatment.

There was much detailed discussion about Pharmacy Price Regulation Scheme (PPRS) payments.

The size of the existing drugs budget was discussed at all meetings, including estimates of unmet need and the use of generic drugs to reduce waste.

There were some patients who discussed their own particular experiences with IFRs. One patient noted that a drug was declined as a second line treatment, which then became a first line treatment through England’s CDF. The patient was unable to access the drug in either case.
Recommendation 5: In order to resource the new fund, the HSC should re-introduce charging for prescriptions.

Akin to the written responses most people felt it was difficult to make a decision on this recommendation without having more detail, with mixed reactions overall. There was lively and open debate at all meetings, including negativity about linking prescription charges to a specialist medicines fund and the view that funding raised through prescription charges could be used for other deficits in the health economy. These concerns led others to express a view that alternative means for funding the SMF should be examined in addition to, or instead of, prescription charges.

There was a view that if prescription charges were to be re-introduced consideration should be given to patients with long term conditions and those who would not be able to afford a charge. Some individuals felt prescription charges are a ‘tax on the sick’ but agreed that those who can afford to pay should do so.

General debate about how to support an efficient medicines budget included negotiating with the supplier to reduce the cost of a drug where a patent has/is about to expire; the cost impact of targeted medicine; discontinue supplying over the counter medicines on prescription; the challenge to ensure that patients with long term conditions are monitored effectively on outcome and efficacy of their treatment.

There was concern at some meetings, especially from patients and their carers/relatives, whether the introduction of prescription charges would delay the reform of the IFR process and the introduction of a SMF.
6. SUMMARY OF PROFESSIONAL AND CLINICAL WORKSHOP

Workshop for professional and clinical stakeholders: 9am to 1pm on 24 April 2015 at the Wellington Park Hotel, Belfast.

Preparation for Workshop

It was considered important that the professional and clinical workshop should be scheduled after a number of public meetings had taken place so that the issues and concerns raised at the public meetings could be incorporated into the workshop discussion. A letter seeking nominations was issued from the Chief Medical Officer to relevant HSC Chief Executives.

The event was scheduled to aid attendance and a venue selected to minimise disruption to clinical staff where possible. The format adopted was informal, with cabaret style round tables to encourage discussion and interactive conversation. An agenda and questions for discussion were emailed to clinical panel members for comment and advice.

The event was facilitated by Patricia Donnelly and DHSSPS panel members engaged with attendees (Mark Timoney, Chief Pharmacy Officer, Alastair Campbell, Secondary Care and Joe Magee, Secondary Care). The event was attended by 30 clinicians and stakeholders from HSC Trusts, the Health and Social Care Board, the Public Health Agency and the National Institute for Health and Care Excellence. The workshop was also attended by Helena Brown as rapporteur.

Meeting format and feedback

Guests were invited to sit in groups and encouraged to interact and engage across professions and Trust regions to enable broad discussion. The findings from the IFR Evaluation Report were introduced via power-point presentation, followed by an introduction and explanation of two main themes which would form the basis of the workshop:

1. Exceptionality criteria;
2. Regional scrutiny body.

Group discussion on each theme, with a series of topical questions to help focus dialogue, was followed by feedback from each group to the audience.

An overview of the debate on the two tasks follows.
**TASK 1 – EXCEPTIONALITY CRITERIA**

**Discussion questions and responses**

Much of the discussion during the workshop mirrored opinion both at the public meetings and the formal responses received by the Department.

**Should the IFR process for NI retain some sort of exceptionality criteria?**

There was general consensus that selection criteria and appropriateness should be used to maintain control, however ‘exceptionality’ should not be used as an exclusive criterion on its own. There was a view expressed that the criteria should include clear guidance regarding stopping a treatment where there is evidence it is not benefitting the patient.

Limitations included: patients falling ‘just’ on the wrong side of the criteria limit if a numerical value is used; increased clinical time and resource pressures; cancer versus non-cancer drivers and evidence based treatments; currently there is no measure of the ‘unmet need’ which may initially prove expensive in terms of service delivery and the cost of the treatment; survival and improvement may initially increase resource pressures.

Benefits included: addressing genuine exceptionality; clinical engagement and input; supports transparency and is defendable; improved audit and control of budgets once ‘unmet need’ is factored in.

**Are there any lessons we should learn from other UK models?**

There was general consensus that England’s Cancer Drugs Fund (CDF) has merits with regard to transparency and publication of drug lists, but that it also has issues that cannot be ignored such as the narrow focus to cancer which is often construed as inequitable with respect to other life-limiting or long-term conditions requiring expensive treatments not routinely commissioned. In addition, because there is no audit of CDF patient outcomes there is no hard data on the actual cost of delivering CDF drugs. However it was noted that the CDF exceeded its budget in 2014/15 by 48% resulting in the de-listing of a number of drugs and affecting cancer patient expectations.

Many felt the Scottish model with its rapid peer review is very positive but that it is too early to comment without further information on this new process.

**What would reasonable exceptionality criteria look like – how can we set a reasonable threshold?**

There was a view that the Wales definition was a good basis from which to start because it excludes the use of numbers and would rely on the specialist expert clinical advice of the ‘regional scrutiny body’. Some felt there should be reference to ‘within budgetary constraints’ in the definition, others that ‘off-label use where there is an evidence base’ should be included. One group suggested thresholds should be
built into criteria produced by specialty groups and if a patient falls short that this could lead to ‘exceptionality’.

**Should there be a list of tumour sites/specialties with individual criteria for each?**

Opinion was split on this question with some agreeing on the basis that it would aid management of the IFR process by applying ‘group applications based on evidence’ and option pathways for monitoring and consistency of approach, while others expressed concern that different specialties would need different definitions and therefore perceptions of inequality might emerge. All agreed, however, that this presented an opportunity to build a database which would aid regional review of patient groups, their needs and resources, and that broad principles should be applied to all specialty groups if this were to go ahead.

**How could the system be controlled so as to reduce the risk of exhausting resources/funds?**

This question followed on from the previous question and feedback continued as before. The main points recorded are: a) group/cohort IFRs would help to predict costs; prepare a list of prompt questions such as decision support; b) capping the funding may present problems with budgets; c) audit all IFRs; build baseline data to help estimate the impact on service. There was discussion about repeat approved applications being moved from IFRs to the commissioning cycle. Also discussed was the importance of realistic funding requirements that included infrastructure and delivery of treatments. All agreed that regular monitoring and review of the structure and outcomes of the process would be important to provide oversight, control and accountability.

**How to provide assurance that approved IFRs will follow a line of evidential proven benefit?**

Responses to this question included: auditing and monitoring; this would be one of the responsibilities of the scrutiny panel and would include peer review of panel decisions; use evidence from clinical trial phase III treatments; utilise the advice and awareness of specialty groups; include start and stop criteria.

**Should a task and finish group be established to define criteria for IFRs?**

Generally everyone agreed this would be the most effective way to take forward the task and that it should be concluded as quickly as possible. All agreed that a broad representation of stakeholders should be involved and that an external expert should have input, probably an academic with health and legal expertise. Issues likely to be included in the terms of reference would be: members and role of the group; ethics and public rights, and responsibilities.
TASK 2 – REGIONAL SCRUTINY BODY

Discussion questions and responses

To encourage province wide consistency should we establish HSC level regional scrutiny body/s?

Everyone agreed this should be established.

How will the body converse?

It was recognised that there would be operational challenges during the early development stage, when meetings would likely benefit from personal attendance - depending on demand, however everyone agreed that in the longer term, sufficient technology exists within HSC to accomplish the task effectively. There was discussion around how e-short-listing and/or filtering applications might benefit the panel so that only correctly submitted IFRs would be forwarded.

How often should the body meet?

There was widespread support for weekly meetings, with a mechanism for urgent requests. Volume would dictate time required, which would include preparation time and whether there were single or specialty panels.

Who/which specialties should be included on the body?

There was wide discussion on this issue however there was a general consensus that a core body should be established with named specialty experts available for advice when required. Suggested specialty groups were: oncology, haematology, gastroenterology, neurology, rheumatology, dermatology, cardiology, respiratory, ophthalmology and mental health. Other representation for the core body may include: pharmacy, Trusts, HSCB, PCC, trainers and administration.

Who would be the intended targets?

Discussion on non- NICE approved drugs, off label drugs, early access to medicines, orphan drugs and treatments not examined by NICE led to agreement that a task and finish group would be best placed to focus on this matter.

How will the process work? The objective is to improve access as quickly as possible.

It was agreed that this would be another matter for a task and finish group however the following suggestions could be investigated by that group: QA checklist for Trusts to filter applications so that the right level of information is provided for effective and efficient turnaround; explore ‘group IFRs’ to reduce panel time; develop pathways to remove ‘common’ IFRs; regularly review decisions, especially where further information is made available; monitor patient outcomes; rapid communication of feedback to patient; appropriate training to underpin panel membership which would
lead to consistency of decisions; effective administration including minutes of meetings.

**What needs to be done to improve transparency?**

Debate around this topic led to agreement that transparency is perception driven depending on the viewers’ position as a patient, clinician, commissioner, supplier etc. However most agreed that notated meetings, patient fact sheets, peer challenge, clear definitions, and clarity about how the panel has arrived at decisions, especially when declining an application, are all factors that should be considered when establishing terms of reference for the IFR body. It was also considered important for suitably trained independent and impartial representation and engagement within the process.

**How will patients/the public be confident that they are represented in the process and their needs are being considered? How will their expectations be managed?**

This followed on from the previous discussion on transparency where patient representation through a body such as the PCC, clear guidance so that patient (and clinician) expectations can be effectively managed and efficient communication have the potential to improve confidence in the process.

**What will happen when patients want to appeal a decision?**

All agreed a mechanism for appeal should be in place however debate about the breadth, basis and management of appeals were considered an important action for a task and finish group.

**Should a task and finish group be established for such a body?**

All agreed this is an important step which has the potential to be incorporated into the task and finish group for examining exceptionality criteria, giving a dual function task and finish group chaired by a clinician from the DHSSPS.

**OTHER COMMENTS OR ISSUES RAISED**

Some felt that social circumstance could become a major issue in relation to the financial decision making stage of IFRs.

There was a view that an outcome of providing more transparency may lead to legal challenge.

It was noted that the issue of clinical trials is an important strand for consideration as access to clinical trials are often predicated on access to drugs which require IFR approval.
7. DEPARTMENTAL RESPONSE

The Department is grateful to all organisations and individuals who participated in this consultation, and values the views of those with professional or personal experience in this field. These will continue to shape the way in which access to drugs and treatment via the IFR process is delivered in the future. The Department’s response to the range of issues raised is set out below, in line with the five recommendations which guided the public consultation.

Given the volume of responses it would be impractical to make all individual responses available on the Department’s website or send copies to all respondents, however the overall response has demonstrated wide interest in, and continuing commitment to, the important issues raised by the evaluation of individual funding requests (IFRs). The following table shows responses by recommendation.

<table>
<thead>
<tr>
<th>Totals by rec for all categories</th>
<th>strongly agree</th>
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</table>

Consultation recommendations 1, 2 and 3

The Department notes and shares the common view that recommendations one, two and three should be progressed further as soon as possible. The common view is that:

- IFR exceptionality criteria should be removed, lowered or re-named with clear definitions;
- A regional scrutiny committee should be established;
- IFR guidance should be revised to include greater transparency and understanding.

Therefore with due consideration to the responses to recommendations one, two and three the Department recommends that an expert task and finish group should be created to determine the scope, membership and terms of reference for the establishment of a regional scrutiny committee. One of the new regional committee’s objectives should examine the merits of removing, renaming or lowering the exceptionality clause in addition to the wider considerations of the mechanism for regional scrutiny and relationships with commissioners (both Trusts...
and the HSCB). It is recommended that the task and finish group should include representatives from all stakeholders including relevant voluntary groups, specialties, professionals and patients and that a high level official from the Department should take the chair.

Consultation recommendation 4

Responses and comments to recommendation four, establishing a specialist drugs fund, were varied ranging from the recognition that this type of fund would increase accessibility to drugs that are available in other UK regions (notably England’s Cancer Drugs Fund) to the potential of funding an increasingly wider range of prioritised treatments to the disadvantage of other cost-effective medicines and interventions. There was also recognition that the highly respected role of NICE, both nationally and internationally, in appraising and determining the cost and clinical effectiveness of drugs, treatments and interventions had the potential to be undermined by introducing funding streams to contradict their directions/guidance. In addition it was highlighted that there is a risk that pharmaceutical organisations could take advantage of such a fund by opting out of collective price regulation and appraisal for their more expensive products.

Other major concerns were about the sustainability of such a funding stream, with some indicating that a specialist medicines fund would only provide short term gain. The Department therefore recommends not to proceed with establishing a specialist drugs fund at this juncture.

Consultation recommendation 5

The purpose of introducing this item to the consultation was to test whether the public were supportive of the re-introduction of a prescription charge to finance a specialist medicines fund and how such a charge might be implemented.

This recommendation elicited the largest number of responses to the consultation but not a clear consensus on how this issue might be progressed.

As indicated earlier in this report there was little support for the principle of funding specialist medicines through the imposition of prescription charges. The consultation also set out three high-level charging options for prescriptions for consideration – the reinstatement of arrangements in place prior to 2010; reviewing the range of exemption categories; or the reintroduction of a universal charge without any provision for exemption.

Any support for the principle of charging largely came with a caveat that a comprehensive range of exemptions should be introduced and that the previous medical exemptions may need to be expanded to cover people with cancer and other long-term and chronic conditions. The latter approach would lead to the need for a much higher level of charge to maintain a revenue stream to support specialist medicines.
Given the degree of contention around both the issue of the reintroduction of prescription charges and the length of time required to secure the Executive agreement and regulatory changes required, it has been decided not to progress with this recommendation.

**Equality implications**

There were 22 responses to Part B, Equality Implications section of the Consultation Response Questionnaire. The vast majority of these had been considered and screened out during the pre-consultation process however it is considered important that an overview is highlighted in this report.

No new equality implications have been identified which would have a significant impact on any of the Section 75 groups in the NI population in relation to recommendations one to four, indeed should the recommendations be implemented there would be benefits for people requiring access to specialist medicines which are not routinely commissioned.

In relation to recommendation five, a separate consultation exercise is required and therefore an impact assessment or screening exercise would necessarily be integral to that process.

For those respondents to the consultation who considered there was an impact to equality two main themes emerged, both of which referred to prescription charges:

1. Disability – the argument being that those with large prescription/treatment requirements would be adversely affected by re-introducing prescription charges;

2. Aging population – that as the population grows older so also do health requirements grow not only with respect to frailty but also in relation to more specialist diseases and conditions, therefore an increasingly larger proportion of the population will have a greater reliance on medication.

In addition to the main themes there was reference to higher incidences of various types of cancer specific to ethnic groups and it is appropriate to note that the PHA has recently launched a cancer awareness campaign which takes account of these factors.
SUMMARY OF RECOMMENDATIONS FROM THE EVALUATION OF THE INDIVIDUAL FUNDING REQUEST PROCESS

1. That the existing exceptionality criteria should be amended to remove the reference to 95%;

2. That the establishment of regional scrutiny committees should be considered to ensure all IFR applications are subject to regionally consistent clinical input and peer review;

3. That the existing IFR guidance should be revised to include greater transparency and to enhance patient involvement;

4. That the Department should establish a specialist medicines fund to meet the costs of administering and maintaining increased access to specialist drugs;

5. In order to resource the new fund, the HSC should re-introduce charging for prescriptions.
## Annex B

### List of Respondents

<table>
<thead>
<tr>
<th>Category 1</th>
<th>Business groups</th>
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<td></td>
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<td>Fiona McConnell</td>
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<td>Gerard Greene - Community Pharmacy NI</td>
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