

# Evaluation of the Individual Funding Request Process

DHSSPS February 2015

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## 1. Executive Summary

- 1.1 The Minister for Health Social Services and Public Safety commissioned this evaluation in response to concerns that the Individual Funding Request (IFR) process was not meeting its objective of providing access to unapproved specialist drugs where there is an agreed clinical need.
- 1.2 This evaluation is intended to provide a rapid assessment of the IFR process and make recommendations as to whether the IFR should continue in its current form or whether a new process should be considered. A full public consultation exercise will be conducted regarding the recommendations of this evaluation.
- 1.3 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.
- 1.4 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.
- 1.5 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 HSC 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 clinical exceptionality can be established and there is an agreed clinical need.

- 1.6 The stimulus for the evaluation was the concerns raised by key stakeholders including cancer patients, charities, political representatives and the pharmaceutical industry that the current process could be improved and also their calls for the establishment of a cancer drugs fund similar to that in place in England.
- 1.7 The evaluation included 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.
- 1.8 Since September 2014, the evaluation team has met with a variety of key stakeholders representing, clinicians and other medical professionals, patients, the pharmaceutical industry and officials from the Health and Social Care Trusts, the Department, the Health and Social Care Board and the Public Health Agency. In the course of these meetings, the team identified a number of key factors which have raised concerns. These are:
- The definition of clinical exceptionality particularly the use of the 95% criterion.
  - Perceived inequity of access to cancer drugs in comparison to other models particularly compared to England and Scotland.
  - The risk of variable decision making within Northern Ireland due to the differing approaches taken by each Trust.
  - That the process itself lacks transparency and does not place sufficient emphasis on the clinical input to decision to submit an IFR.

- 1.9 In response to these concerns, the Department proposes a number of changes to the existing system. These are addressed in the recommendations below.
- 1.10 The recommendations will incur implementation costs and the Department wants to ensure that these costs can be met sustainably in the long term. It is therefore also proposed that prescription charges should be re-introduced to help fund a Specialist Medicines Fund, which will keep funding for specialist medicines on a firm financial footing in the long term.

## 2. Recommendations

- 2.1 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.

- 2.2 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.

- 2.3 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.

- 2.4 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.

**2.5 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.

### 3. Term of Reference

3.1 The evaluation was originally intended to test purely whether the IFR process was meeting its objectives. The IFR process is described in detail at 2.7 to 2.13 in Appendix 2. However, the scope was later widened to include additional factors. The final, agreed terms of reference for the evaluation were:

- a) 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.
- b) To consider the impact of the concept of Clinical Exceptionality in the IFR process in providing access to specialist drugs.
- c) To give consideration to policies and processes that England, Scotland and Wales have adopted in their approach towards providing access to specialist drugs.
- d) 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).
- e) To consider the implications for access to specialist drugs arising from the implementation of the Early Access to Medicines Scheme (EAMS) in Northern Ireland.
- f) To consider the potential for the reintroduction of prescription charges to finance a specialist drugs fund.

## 4. Evaluation Process

- 4.1 The work of the evaluation has involved desk based research, an extensive literature search, information gathering from the Trusts and Commissioners, and a series of meetings with key stakeholders. This work was also informed by the expertise and experience of the project board which comprised clinicians, pharmacists, senior officials and commissioners familiar with the operating of the current IFR system. The project Board met at the start of the evaluation. Due to the tight timescales, it did not prove possible to reconstitute the Board in full, however the evaluation team met and communicated with all of the individuals and organisations represented to discuss progress.
- 4.2 The evaluation team met and received written submissions from:
- The main cancer charities
  - Patients both as members of charities and individually
  - Clinicians
  - Clinical academics
  - HSC Trusts
  - Commissioners
- 4.3 The Health and Social Care Trusts have also been surveyed to determine clinical attitudes to the IFR process and arrangements for the internal scrutiny of IFRs. Due to the short timescale in which the evaluation was carried out, it has had to take a focused approach and it has not been possible to carry out extensive collection of data relating to IFR applications. Indeed, the absence of some of this information is included as an element of the key findings.

## 5. IFR Process

- 5.1 The Individual Funding Request (IFR) process provides a mechanism to consider requests for treatment (including drugs and therapies but not limited to cancer) that fall outside the range of services normally commissioned by the HSCB.
- 5.2 This may mean the request falls into one of the following categories:
- The patient's clinical condition represents an unusual or rare circumstance and one likely to occur very infrequently.
  - The treatment requested is a new or developing treatment not normally commissioned or funded by the HSCB.
  - The treatment is commissioned or funded in N. Ireland in certain circumstances but not applicable to the circumstances that apply to the IFR (for example a drug commissioned or funded for one disease but not for the illness for which it is requested).
  - For a variety of reasons, the treatment may not be commissioned or funded in Northern Ireland, for example because national guidance, such as issued by NICE, indicates that it is not recommended.
- 5.3 The procedure for the consideration of an IFR is not a clinical decision making process. Rather, its purpose is to determine whether a particular request should be funded. Each request sent to the Board is considered on its merits.
- 5.4 It is, however, expected that clinical exceptionality should be demonstrated and agreed at HSC Trust level to support IFR requests.
- 5.5 Every effort is made to provide rapid decisions in respect of individual funding requests. The HSCB's IFR panel meets weekly and normally requests are considered and a response provided to the referring clinician within 7 days of the request being received.

5.6 The evaluation found that the HSCB has been extremely efficient and effective in the administration of the current system. In the last three years almost 98% of patients in Northern Ireland who had an IFR submitted on their behalf had their treatment approved. The requests were processed weekly and communication issued within 7 working days. The full detail of the current IFR process is available at Appendix 2.

### **Perceived Inconsistent Processes within Northern Ireland**

5.7 An important finding of the evaluation has been the absence of a consistent approach from the 5 Trusts and between specialist groups. The Department and the HSCB have stated publicly that around “98% of IFR applications are approved by the IFR panel”. This is accurate, but as the evaluation has proceeded, it has become clear that this is not entirely representative of the whole system.

5.8 While this approval rate supports the view that the IFR panel does provide a sound mechanism for considering clinically supported requests, there is a lack of evidence around clarity and consistency on how decisions are made at Trust level. In particular, it is not clear that different specialties in different Trusts apply the same levels of rigour in their scrutiny of potential IFRs.

5.9 Of the five HSC Trusts, only Belfast has a formal scrutiny process in place which meets regularly to consider IFR applications for cancer drugs. Some clinical specialists have agreed regional criteria for certain patient groups to assist in regional consistency for specific conditions.

5.10 As a consequence, there is therefore a risk that applications in other Trusts may not be subject to the same level of expert scrutiny or benefit from a consistent decision making regime as in Belfast.

5.11 Linked to this issue, charities and clinicians also raised the perceived lack of transparency in the system as a factor that discouraged applications and

undermined confidence in the decision making process. This is dealt with in more detail below.

- 5.12 There were also some concerns about the interpretation of the “off label” and “unlicensed” guidance issued by the HSCB in March 2014 which allows for Trusts to fund those medicines up to a ceiling of £50k per annum. Trusts expressed concerns that this could lead to a further inconsistency as clinicians in different Trusts make different decisions on treatments.

***It is recommended that a regional group (or groups to cover the clinical specialities which use specialist drugs) be established which will allow for the consideration and clinical endorsement of IFR applications from all Trusts before they are formally submitted to the Commissioners.***

- 5.13 This approach would provide significant challenges in terms of providing the capacity for key personnel to be available for weekly meetings and would require the development of detailed terms of reference and appeals processes which are transparent, robust and defensible. However it would address equity of access across the system, ensure fairness and bring expert clinical judgement to the centre of the process in a manner which takes account of peer review and consistency.
- 5.14 If this recommendation is implemented, it would be likely also to have implications for the current IFR panel, which is managed by the HSCB and the PHA. Consideration will therefore be required in order to redefine these organisations’ roles in the revised process.
- 5.15 It is recommended that this body (bodies) would also consider applications for the use of medicines which are unlicensed or intended for use “off label”.

## **Transparency and clinical input**

- 5.16 A common criticism of the current system is a perceived lack of transparency. It is essential in that a system which seeks to provide access to unapproved

treatments is based upon best evidence, is transparent and addresses equity of access.

- 5.17 The HSCB keeps detailed records of the numbers and types of IFR applications that are either successful or unsuccessful once they have been considered by the IFR panel. By contrast, in the course of the evaluation, it proved difficult to access data about the number and types of requests that were not submitted to the IFR panel for consideration.
- 5.18 Increased transparency of process would be helpful in raising patients' confidence in the process and, where the request is not successful, would allow them to understand the reasons for this. An agreed process will be developed that will ensure clinicians receive feedback from the new panel(s) on decisions.

***It is therefore recommended that the Department and the HSCB conduct an exercise which will engage clinicians and patient representatives to ensure that there is absolute clarity regarding the process itself and professional roles.***

## 6. Clinical Exceptionality

- 6.1 In the course of discussion with stakeholders, the most frequently cited difficulty with the current IFR process has centred on the exceptionality criteria. Currently, clinicians who seek to apply for an IFR on behalf of a patient must demonstrate that their patients are more than 95% different from others with the same condition as well as significantly more likely to benefit from treatment. The full definition is as follows:

*“The patient is significantly different to the general population of patients with the condition in question. Consistent with commissioners in other parts of the UK, the HSCB will accept as significantly different ‘an individual whose clinical circumstances are outside the range of clinical circumstances presented by at least 95% of patients with the same medical condition at the same stage of progression as the named patient’.*

*AND*

*‘Is likely to gain significantly more benefit for the intervention than might normally be expected for patients with that condition.’*

- 6.2 In our discussions, there has been more or less unanimous agreement from clinicians, patient groups and the pharmaceutical industry that this bar has been set too high. While each of the UK jurisdictions uses the concept of exceptionality in controlling access to new medicines, the definitions vary considerably. There is no doubt that the definition of exceptionality applied in Northern Ireland is significantly more stringent than that used in England, Wales or Scotland.

- 6.3 The guidance supporting the NHS Wales IPFR policy sets out the following criteria for determining exceptionality.

*Is the clinical presentation of the patient unusual/rare?*

*and*

*Does this unusual/rare clinical presentation mean that the patient will derive a greater clinical benefit from the treatment than other patients with the same disease?*

- 6.4 The Welsh IFR panel is expected to consider the evidence supplied in the application that describes the specific clinical circumstances of the IPFR, specifically:
- *What is the clinical presentation of this patient?*
  - *Is evidence supplied to explain why the clinical presentation of this patient is unusual and different to that expected for this disease and this stage of the disease?*
  - *Is evidence supplied to explain why the clinical presentation means that the patient will gain a greater clinical benefit from the treatment than another patient with the same disease at the same?*

- 6.5 Applications for funding from the English CDF for treatments for individual patients which cannot be accessed through NHS England routine commissioning arrangements and which fall outside the routine CDF list/criteria of the cohort policies can be made by clinicians on behalf of their patient. The clinical exceptionality criteria are as follows:

*that the patient is significantly different to the general population of patients with, and at the same stage of, the condition in question*

***and***

*that the patient is likely to gain significantly more clinical benefit from the intervention than might be normally expected for patients with that condition.*

*The fact that a treatment is likely (or has proven) to be efficacious for a patient is not, in itself, a basis for exceptionality.*

- 6.6 While the Department is willing to reconsider the current definition, there is nevertheless a convincing case that the concept of exceptionality should be retained. It is both rational and reasonable that a drug's clinical and cost

effectiveness should influence its availability and the Health Service in Northern Ireland is guided in this by the National Institute for Clinical Excellence's (NICE) appraisal process.

- 6.7 It is important that the IFR process is not considered to be a means of circumventing the expert opinion expressed in NICE assessments. Its purpose is to provide access to unapproved therapies where a patient is significantly different to other patients with the condition and will gain significantly more clinical benefit. It is the evaluation team's view that clinical exceptionality remains a suitable underlying principle and should be retained. However, the team also accepts that the rigid application of the 95% qualifier is viewed by many key stakeholders as not sustainable.

***It is therefore recommended that more work is carried out to formulate a definition of clinical exceptionality 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.***

## 7. Other UK models governing access to unapproved medicines.

- 7.1 Many stakeholders raised the issue of a perceived lack of equity of access to cancer drugs across the UK, and the inability for Northern Ireland patients to access unapproved<sup>1</sup> drugs compared to their counterparts in England and Scotland.
- 7.2 The evaluation confirms that the IFR process cannot match the access to cancer drugs available in England through the Cancer Drugs Fund (CDF). Figures from October 2014 have shown that of the 42 drugs on the CDF list only 13 are available here. However, perhaps surprisingly, stakeholders including charities and individual patients did not offer unqualified support to the introduction of a CDF identical to that established in England in 2011.

### England - The Cancer Drugs Fund

- 7.3 The English CDF of £200m per year was established in 2011 to cover cancer treatments that are not currently available on the NHS. At a national level, there seems to be a growing consensus, echoed by many respondents to the evaluation, that the CDF was only ever a short-term fix to a complex problem, and that it is neither sustainable nor particularly equitable given its emphasis on cancer drugs to the exclusion of other conditions. The CDF has also cost much more than was originally expected. Indeed, in 2014, it exceeded its original budget by £140 million.
- 7.4 The CDF will run until the end of March 2016. However NHS England who administers the CDF has announced the results of consultation on proposals for the future sustainability of the model. The new proposals, which have been agreed, allow for assessing clinical benefit in relation to drugs costs. This is a significant change and can reasonably be interpreted as implicit acceptance by NHS England that the CDF as currently operated (which will see over £1bn spent on unapproved drugs by March 2016) is not sustainable in the context of the financial challenges facing the NHS.

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<sup>1</sup> In this context, 'unapproved' means either not assessed by NICE, not approved by NICE or unlicensed.

## Scotland – New Medicines Fund

- 7.5 Conversely, participants at all of the meetings praised the new Scottish model (the New Medicines Fund). The fund is being financed by utilising the rebate to the Scottish Government made by the pharmaceutical industry under the Pharmaceutical Price Regulation Scheme (PPRS). This Fund replaces the Scottish Rare Conditions Medicines Fund (£20m) established in 2013 and will support an increase in approvals by the Scottish approvals body the Scottish Medicines Consortium (SMC) following changes they have made to their approach to medicines to treat very rare and end of life conditions .
- 7.6 These changes included the abolition of their IFR process and its replacement with a new process which places a greater emphasis on clinical peer approval. Other than the scale of the amount of money being made available, the Scottish model received praise for the involvement of patients in the process, and the use of a peer review model to ensure clinicians' decisions are scrutinised by other clinicians.
- 7.7 While this model certainly has attributes of interest, it would difficult to emulate here due to the fact that we do not have a local equivalent of SMC or NICE. The current financial constraints also mean that we cannot commit to being in position to use PPRS receipts solely to fund new medicines.

## Wales – Review of IPFR

- 7.8 The Welsh Assembly Government has announced the findings of a review of their IPFR process which is broadly similar to our own IFR process. The outcome of the review is that Wales will not introduce a dedicated cancer or specialist drugs fund. However they have announced changes to their IPFR process to ensure timely and evidence based access to new treatments. The proposed changes focus mainly on increasing transparency, consistency, coherence and authority of decision making.
- 7.9 The Welsh Government provided additional funds for the new service to improve the appraisal of and access to new and innovative medicines,

including orphan and ultra-orphan drugs. These investments will be met by using payments to Wales from the 2014 PPRS settlement

## 8. Early Access to Medicines Scheme (EAMS)

- 8.1 The evaluation also considered the implications for access to specialist drugs arising from the implementation of the Early Access to Medicines Scheme (EAMS) in Northern Ireland.
- 8.2 In the UK medicines must be licensed by the Medicines and Healthcare Products Regulatory Authority (MHRA) and then assessed for clinical and cost effectiveness by NICE before they can be made routinely available in the NHS. These processes are entirely separate and have different objectives the MHRA assess new medicines to ensure that they are safe of high quality and efficacious the NICE assessment gives an appraisal of the degree of their effect set against the cost of the treatment.
- 8.3 The purpose of the EAMS is to support patient access to promising unlicensed or off-label medicines in areas of unmet medical need by allowing drugs to come to market before the MHRA's rigorous and often lengthy licensing process is complete.
- 8.4 The scheme will give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a license and where there are no suitable alternative licensed treatments. It will operate within the current regulatory structure and is voluntary and non-statutory.
- 8.5 The EAMS was developed by a working group in the UK following a scientific meeting in September 2007 commissioned as part of a series of events established by the Ministerial Industry Strategy Group (MISG).
- 8.6 It is not clear what impact this measure will have but MHRA estimate that around 2 drugs per year would be made available under the scheme. However, it could be up to 5 drugs per year.

## 9. Other Findings

### Clinical Trials

- 9.1 Apart from the issue of patient access to drugs, an unforeseen impact of the English CDF appears to have been its negative effect on access to clinical trials in Northern Ireland (NI). Clinicians, charities and industry representatives have all raised the issue that lack of access to drugs on the CDF is resulting in fewer drug trials in NI.
- 9.2 The reason for this seems to be that pharmaceutical companies will commonly want to compare their new drugs to those currently in common use. The CDF is skewing the idea of standard treatments as many cohorts of patients in England are currently receiving a new “standard” treatment via the Fund. Therefore when pharmaceutical companies are seeking control groups against which to test new drugs those groups or cohorts of patients on the latest CDF treatment will not exist in NI.
- 9.3 The disadvantages of this are significant and include:
- i. the cumulative effect - year on year, Northern Ireland becomes less and less attractive for trials;
  - ii. the impact on services – Northern Ireland will no longer be at the cutting edge for research, which means that clinicians and academics suffer from lack of experience and investment;
  - iii. patients don't get access to new drugs through trials – these are commonly funded by companies for the duration of treatment rather than just the duration of the trial;
  - iv. Northern Ireland does not get the benefit of savings related to drug companies meeting costs for drugs, scans and other costs associated with trials.

- 9.4 While we received many anecdotal reports of this effect, there is as yet no detailed evidence of the impact. As a result of this, more work is required to identify the extent of the problem and develop options to mitigate it.

**In addition to the five key findings, it is also recommended that officials from the Department and the Public Health Agency with policy responsibility for research and development should continue to work with clinicians and academics involved in clinical trials to establish the scale of the problem and explore possible solutions.**

### **Review of Cancer Services**

- 9.5 Several respondents raised concerns about the apparent lack of strategic oversight of cancer services in Northern Ireland. While they conceded that significant investment had taken place, representatives from charities, clinicians, academics and the pharmaceutical industry all agreed that developments in cancer services were advancing rapidly and it is important that Northern Ireland maintains investment and development of these services.
- 9.6 Across all of the key stakeholders we have spoken to, there was support for a wider review of cancer services to take place, in order to ensure the effective and sustainable delivery of cancer services in the future.
- 9.7 The Department and the HSCB are currently carrying out a review of the Cancer Services Framework which is due to report in October 2015. Following completion of this review, the Department will consider the need for a comprehensive review of cancer services.

## 10. Financial Context

- 10.1 It is accepted that the cost and clinical effectiveness of a drug therapy should influence its availability.
- 10.2 In the current financial climate, options for increasing investment to improve access to unapproved drugs from within existing resources are extremely limited and it is unlikely that Northern Ireland will be in a position to introduce an equivalent of either the English CDF or the Scottish New Medicines Fund.
- 10.3 Recent changes to the CDF would appear to support the view that permissive access to unapproved drugs carries high costs and is unsustainable in the long term. In addition a cancer drugs fund would not address access to unapproved drugs for other serious and life threatening conditions e.g. CF, MD and a host of rare diseases.
- 10.4 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, these must be assessed for clinical and cost effectiveness before being made routinely available. Like the NHS, the HSC in Northern Ireland is guided in this process by the National Institute for Clinical Excellence which has an international reputation for scientific rigor, independence and objectivity.
- 10.5 The HSCB currently spends around £120m a year on approved specialist drugs £27m of which are cancer drugs. The HSCB has indicated potential NICE approved specialist drug pressures of approx £12m in 2015/16. While it is extremely important that patients should be able to access unapproved drugs where there is a compelling clinical reason, it is of course vital that we continue to fully fund therapies that have been assessed by NICE and found to be clinically and cost effective. It is of primary importance that we continue to meet our commitments with respect to NICE approved drugs.
- 10.6 While it is certain that the recommendations identified by this evaluation will have cost implications, it is difficult to predict what the level of these costs

would be with any degree of certainty. Based on current levels of expenditure and set beside expenditure in England and Scotland, it is assumed that costs could range from a minimum of £4.8 million to a maximum of £9.5 million.

- 10.7 It is acknowledged that any changes to the existing IFR process that may allow improved access to off label, unlicensed and uncommissioned drugs regimes must not impact on Government's ability to fully fund new and existing NICE approved therapies and other priority investments. Any proposed solution to these issues must therefore be sustainable and must operate in the context of the wider specialist drugs budget. A proposed solution to these issues must take account of the infrastructure necessary to deliver these therapies.

## PPRS

- 10.8 A common feature of many of the calls for improved access to unapproved drugs quotes the new arrangements under the Prescription Price Regulation Scheme (PPRS) as a possible source of funding.
- 10.9 The 2014 PPRS scheme was implemented in Northern Ireland on 1st January 2014. The scheme is agreed on a UK wide basis and ensures that any cost growth in branded medicines is constrained to 0% in 2014-15 and 2015-16.
- 10.10 The 0% cost growth will be delivered by individual drug companies making payments back to DH (London) in respect of their individual UK portfolios. This payment will be based on Industry sales data at a UK wide level.
- 10.11 All four countries have adopted different budgeting approaches to PPRS payments. Historically PPRS income has been treated as a receipt. Using PPRS to fund some increased investment in unapproved medicines is an attractive option, however it is not yet clear whether it will be possible to re-invest the receipts from PPRS into unapproved medicines or whether these monies will be required to meet pressures elsewhere.
- 10.12 At this stage it is not possible to be definitive about the scale of the payments Northern Ireland is likely to receive or the scale of the financial pressures

facing the Health Service in Northern Ireland. In light of this, it cannot yet be said with certainty how PPRS receipts for Northern Ireland could be used to finance medicines pressures.

10.13 The pharmaceutical industry should be commended for this agreement, which offers a sizeable rebate on expenditure on branded medicine. However, the current scheme only runs until 2019 and while this is likely to be replaced with a new scheme, it would be irresponsible to place the sustainability of funding for specialist medicines in the gift of a third party. It is important to ensure that specialist medicines are put on a secure financial footing in the long term.

## 11. Prescription Charges

- 11.1 In view of increasing financial constraints, the current and the previous Health Ministers have publicly stated that they do not consider it unreasonable for patients to make a contribution towards the costs of their prescriptions, particularly in light of the challenges of funding high cost specialist medicines. The re-introduction of prescription charges has been proposed as a contributor to a Specialist Medicines Fund and to provide a financial foundation for innovative and specialist medicines for the future.
- 11.2 On this basis, the Department is seeking the public's views on their support for the reintroduction of prescription charges to establish and maintain a Specialist Medicines Fund. Views are also sought on how those charges should be applied. Potential options could include a universal charge for everyone, a system with patient exemption categories similar to what existed prior to the abolition of charges in 2010 and variations of these. The views expressed in response to this report will be used to inform a focused consultation on the re-introduction of prescription charges.

### Reinstatement of arrangements in place prior to April 2010

- 11.3 One option for the reintroduction of prescription charges is to return to the arrangements that were in place prior to the abolition of prescription charges in April 2010, including exemptions and Prescription Prepayment Certificates (PPCs)<sup>2</sup>. Further analysis is required to identify an appropriate charge per item. For example, the charge in place prior to prescription charges being abolished in April 2010 of £3.00 per item would generate in the region of £5 million additional revenue per annum. Increasing that charge would generate more revenue for the Specialist Medicines Fund. Views are welcome on whether or not the reinstatement of arrangements prior to April 2010, with a charge per item and access to PPCs, would be considered equitable and ensure people have access to the medicines they need.

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<sup>2</sup> For patients who were not entitled to free prescriptions under the exemption categories, but who required frequent prescriptions, a PPC offered a more affordable method of payment for medication at discounted rates.

## Review the range of exemption categories

11.4 Exemption categories in place prior to the abolition of prescription charges had not been amended since their introduction in 1968 when prescription charges were reintroduced across the United Kingdom. The full list of exemptions is set out at Appendix A, with the main exemption categories being age or income related and exemptions for pregnant women as well as for people with specific medical conditions.

11.5 Consideration will be given to amending the list of exemption categories in conjunction with a prescription charge per item. The medical exemption categories, for example, could be extended to mirror provisions in England to exempt patients being treated for cancer, including the effects of cancer treatment, from prescription charges. Likewise, the list could be extended to include people with other chronic conditions. That would only be feasible, however, with an appropriate level of charge for prescriptions to secure the necessary additional resources for investment in other treatments. Views are welcome on how the list of exemption categories might be redefined, particularly medical exemption categories.

## Introduction of a universal charge

11.6 Another option for a charging mechanism for prescriptions is to introduce a small universal charge of say £0.30, £0.50 or £1.00 per prescription item, without any provision for exemption. That approach to charging would be unique to Northern Ireland and it would be the only region of the United Kingdom where prescriptions for some demographic groups, such as children or elderly people, would be liable for a charge.

11.7 While a small universal charge per prescription item may appear more affordable than the charges in place prior to April 2010, it might be unaffordable to the most disadvantaged in society – particularly to the elderly and others who need a number of medications to control their condition and maintain health and wellbeing. A Pre Payment Certificate scheme could be developed but the

cost of the certificates would need to be lower than previously. The uptake of PPCs is also likely to be much higher with a consequential reduction in overall income.

11.8 The impact of a universal charge without exemptions could be mitigated with some form of a financial assistance fund to help people in receipt of multiple medications and with limited income to obtain the medicines they need. There would need to be clearly defined criteria for accessing the fund as well as an administrative mechanism for delivery of the fund. Views are welcome on whether a universal charge, with no exemptions, would be a more equitable way of paying for prescription charges and supporting a Specialist Medicines Fund. Views are also welcome on what level of a universal charge might be deemed appropriate.

## 12. HOW TO RESPOND TO THIS CONSULTATION

- 12.1 The consultation will run from **17 February 2015 to 08 May 2015**.
- 12.2 **In order to facilitate analysis it is important that respondents use the Questionnaire provided.** To ensure that your response is fully understood, please adhere to the following specifications;
- write or type your response on this questionnaire
  - you do not have to respond to all the questions
- 12.3 **Completed Questionnaires must be received by the Department by 5.00pm on Friday 08 May 2015.**
- 12.4 **Alternatively response forms/questionnaires can be downloaded and e-mailed to:**
- [IFRPC@dhsspsni.gov.uk](mailto:IFRPC@dhsspsni.gov.uk) or posted to:
- Secondary Care Division**  
**DHSSPS**  
**Castle Buildings**  
**Belfast**  
**BT4 3SQ**
- 12.5 Before you submit your response please read the information about the **Freedom of Information Act 2000 and the confidentiality of responses** to public consultation exercises on page 11.

### **Alternative formats**

- 12.6 If you require the consultation document in an alternative format (such as in large print, in Braille, on audio cassette, easy read or computer disc) and/or in another language, please contact Derrick Morrow at [Derrick.Morrow@dhsspsni.gov.uk](mailto:Derrick.Morrow@dhsspsni.gov.uk) to discuss your requirements.

12.7 A summary of consultation responses will be made available on the DHSSPS website <http://www.dhsspsni.gov.uk/> as soon as possible after completion of the consultation and in any event no later than three months after the consultation closes.

## 13. FREEDOM OF INFORMATION ACT 2000 – CONFIDENTIALITY OF CONSULTATIONS

- 13.1 DHSSPS will publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. The Department can only refuse to disclose information in exceptional circumstances. **Before** you submit your response, please read the paragraphs below on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.
- 13.2 The Freedom of Information Act gives the public a right of access to any information held by a public authority, namely, DHSSPS in this case. This right of access to information includes information provided in response to a consultation. DHSSPS cannot automatically consider as confidential, information supplied to it in response to a consultation.
- 13.3 However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity, should be made public or be treated as confidential. ***If you do not wish information about your identity to be made public, please include an explanation in your response.***
- 13.4 This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances. The Secretary of State for Constitutional Affairs' Code of Practice on the Freedom of Information Act provides that:
- the Department should only accept information from third parties in confidence, if it is necessary to obtain that information in connection with the exercise of any of the Department's functions, and it would not otherwise be provided

- the Department should not agree to hold information received from third parties “in confidence” which is not confidential in nature
- acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

13.5 For further information about confidentiality of responses please contact the Information Commissioner’s Office (or see web site at: <http://www.informationcommissioner.gov.uk/>).

## 14. SCREENING/IMPACT ASSESSMENTS

### 14.1 Human Rights and Equality Implications

Section 75 of the Northern Ireland Act 1998 requires Departments in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity:

- between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- between men and women generally;
- between person with a disability and persons without; and
- between persons with dependants and persons without.

14.2 In addition, without prejudice to the above obligation, Departments should also, in carrying out their functions relating to Northern Ireland, have due regard to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group. Departments also have a statutory duty to ensure that their decisions and actions are compatible with the European Convention on Human Rights and to act in accordance with these rights.

14.3 DHSSPS has carried out a preliminary screening of the proposals and as part of this screening process has concluded that an Equality Impact Assessment is not necessary on the key findings of the evaluation.

14.4 The re-introduction of prescription charging may have an impact on equality. However detailed consideration of the impact on equality would be carried out if it is proposed to progress this policy and carry out a further, more focused consultation on prescription charges.

## **Human Rights**

14.5 The outline proposals contained in this consultation need to be considered under the Human Rights Act 1998. The position will need to be kept under review during the policy development process.

## **Disability Discrimination Act 1995**

14.6 The Disability Discrimination Act 1995 (as amended by the Disability Discrimination (Northern Ireland) Order 2006) requires Public Authorities, when carrying out their functions, to have due regard to the need to:

- promote positive attitudes towards disabled people; and
- encourage the participation of disabled people in public life.

## **Rural Proofing**

14.7 It is considered that there are no negative impacts on rural productivity or the provision of services to the rural community as a result of these proposals.

## **Health Impact**

14.8 The proposed changes to the IFR process would be expected to have a positive impact on patients' health.

14.9 The re-introduction of prescription charges may have a negative impact on those people who do not meet the exemption criteria but cannot afford the cost of the medicines they need. The need for a full Health Impact Assessment (HIA) will need to be kept under review during the policy development process.

## **Sustainable development**

14.10 It is considered that there are no negative impacts on sustainable development opportunities.

## **Regulatory Impact Assessment**

14.11 The need for a full Regulatory Impact Assessment will need to be kept under review during the policy development process.

## Appendix 1

### Review Group Members

Dr Michael McBride, Chief Medical Officer, Senior Responsible Officer

Mark Timoney, Chief Pharmaceutical Officer, DHSSPS

Alastair Campbell, Project Director SCD DHSSPS

Joe Magee, Project Manager SCD DHSSPS

Paula Scullion, Consultant Medical Oncologist BHSC

Eimear McCusker, Head of Pharmacy and Medicines Management BHSC

Martin Eatock, Consultant Medical Oncologist, NICaN Network Director

Dr Janet Little, Assistant Director of Public Health PHA

Joe Brogan, Assistant Director Integrated Care HSCB

Teresa Magirr, Assistant Director, Commissioning HSCB

## Appendix 2

### **HSCB ARRANGEMENTS FOR THE CONSIDERATION OF REQUESTS FOR CARE AND /OR TREATMENT ON BEHALF OF INDIVIDUAL PATIENTS**

#### **1 Introduction**

1.1 This document sets out the principles underpinning how decisions to approve or decline the funding of an individual funding request (IFR) or extra contractual referral (ECR) are taken. It also details the process by which submissions are considered. Specifically the document aims to provide clarity on the following:

- The eligibility criteria for an IFR/ECR
- The process by which IFRs/ECRs are considered
- The mechanism by which a review of the relevant panel's determination can be requested.

1.2 The procedure for the consideration of a submission is not a clinical decision making process. Rather, its purpose is to determine whether a particular request should be funded. To enable the Board to consider any request for funding, a clinical recommendation needs to be made by the relevant hospital consultant and supported by the Trust's internal scrutiny procedures.

1.3 There are three categories of funding submission:

1. Individual Funding Request (IFR)
2. Extra Contractual Referral (Acute ECR) falling within the Acute programme of care
3. Extra Contractual Referral (Non Acute ECR) falling within one of the non acute programmes of care.

In all three instances the same broad procedures will be followed, although the composition of the panels may differ and there will be some differences of emphasis.

## **2 Individual Funding Requests (IFRs)**

- 2.1 An individual funding request is a request for an individual to have access to a specific treatment (the majority of which are for a specialist drug treatment) within the acute programme that is not normally commissioned or funded within Northern Ireland. This may mean the request falls into one of the following categories:
1. The patient's clinical condition represents an unusual or rare circumstance and one likely to occur very infrequently.
  2. The treatment requested is a new or developing treatment not normally commissioned or funded by the HSCB.
  3. The treatment is commissioned or funded in N. Ireland in certain circumstances but not applicable to the circumstances that apply to the IFR (for example a drug commissioned or funded for one disease but not for the illness for which it is requested).
  4. For a variety of reasons, the treatment may not be commissioned or funded in Northern Ireland, for example because national guidance, such as issued by NICE, indicates that it is not recommended.
- 2.2 For drugs on which NICE has issued a technology appraisal, which has not yet been endorsed within Northern Ireland with an agreed commissioning plan, a separate process is in place. The IFR procedures are not expected to apply in these circumstances.
- 2.3 Requests for funding in each of the categories set out in paragraph 2.1 can only be approved by the HSCB if exceptional clinical circumstances can be identified.
- 2.4 Confirmation of clinical exceptionality needs to provide an effective response to the question, "On what grounds can the HSC Board justify funding treatment for this patient when others from the same patient group are not receiving the same treatment".
- 2.5 The Board will apply the following definition in considering whether an individual meets a definition of exceptionality:
- The patient is significantly different to the general population of patients with the condition in question. Consistent with commissioners in other parts of the UK, the HSCB will accept as significantly different 'an individual whose clinical circumstances are outside the range of clinical circumstances presented by at least 95% of patients with the same medical condition at the same stage of progression as the named patient'.

AND

- Is likely to gain significantly more benefit for the intervention than might normally be expected for patients with that condition.
- 2.6 It should be noted in considering exceptionality the HSCB can only take account of the clinical circumstances that apply to the individual case. It is not

in a position to take account of any personal or social circumstances such as age, dependants, occupation etc.

## **2.7 IFR Procedures**

The procedures for submitting an IFR to the HSCB and for the Board to make a decision and communicate the outcome is outlined below.

2.8 The HSCB IFR Panel meets on a weekly basis to consider all IFRs received from all Trusts within the preceding 7 days.

2.9 The Panel comprises:

- Assistant Director, Public Health (or nominee), Chair
- Specialist or Consultant in Public Health
- Assistant Director, Specialist Services Commissioning (or nominee)
- HSCB pharmacist
- Doctor in training public health.

2.10 Administrative support is provided by the Board's commissioning staff, under the direction of the Assistant Director of Specialist Commissioning.

2.11 For confidentiality reasons only those individuals required to participate in the decision making process or record the proceedings should be in attendance.

## **2.12 Submission of IFRs**

- IFRs will be submitted on a standard template, by email to [ifrs@hscni.net](mailto:ifrs@hscni.net)
- All IFRs are to be anonymised.
- For IFR requests for specific drug therapies, the HSC Board will only consider a request if the drug holds a UK license;
- IFR requests for off-label use of a licensed drug therapy will be considered.
- Before an IFR can be initiated, the request for treatment should be subjected to internal scrutiny within the Trust and endorsed.
- IFRs should be endorsed by the relevant clinical director (or equivalent) and senior manager of the relevant service area within the Trust.
- It is the responsibility of the individual requesting an IFR to provide the necessary documentation in support of their request.
- On receipt of the request, a member of the IFR Panel may request additional information before the request is formally considered by the Panel.
- The Panel will be advised of all requests received in the preceding week, including those awaiting additional information before being formally included on the agenda for consideration.
- IFRs which are properly completed and contain the necessary information to facilitate decision-making will be considered by the IFR Panel at their next weekly meeting.
- If a patient requires immediate treatment the responsible clinician, using the agreed Trust process, may make a judgement to commence treatment. In these cases the request will be considered retrospectively. The commencement of

treatment on an emergency basis will be without prejudice to the outcome of the IFR Panel's deliberations.

- When the IFR Panel meets it may request further information from the Trust and reconsider the request when additional material is available.
  - At the IFR Panel a record of decisions and the rationale underpinning those decisions will be documented on a standard template.
  - Decisions of the IFR Panel will be communicated, by email, to the relevant Trust (and clinical director) within one week of the IFR Panel meeting.
- 2.13 Funding requests for treatment expected to cost less than £1,000 should not be submitted to the IFR Panel.

### **3     *Extra-contractual Referrals (ECRs) within the Acute Programme***

- 3.1 Extra-contractual referrals (ECRs) normally arise, and are eligible for approval, in the following circumstances:
- 1 The patient's clinical condition requires specialised care that could only be sustained for a large catchment population and cannot be provided for a small geographic area such as Northern Ireland.
  - 2 The patient's clinician wishes to seek a second opinion from a provider outside Northern Ireland because of complexities of the patient's condition or circumstances.
  - 3 The treatment is available locally but the patient has some exceptional reason which renders their case different from the vast majority of other patients with the same condition and which therefore justifies a referral for care or treatment outside Northern Ireland.
  - 4 The service being requested is not reflected in commissioning arrangements such as a service level agreement (SLA) with a provider outside N Ireland.
  - 5 The service being requested is not commissioned for the population of Northern Ireland, but the patient's clinical circumstances are such that exceptionality can be demonstrated and a case justified for an ECR to access care from a provider outside Northern Ireland.
- 3.2 In respect of 5 above, confirmation of clinical exceptionality needs to provide an effective response to the question, "On what grounds can the HSC Board justify funding treatment for this patient when others for the same patient group are not receiving the same treatment?".
- 3.3 The Board will apply the following definition in considering whether an individual meets a definition of exceptionality:
- The patient is significantly different to the general population of patients with the condition in question. Consistent with commissioners in other parts of the UK, the HSCB will accept as significantly different 'an individual whose clinical circumstances are outside the range of clinical circumstances presented by at least 95% of patients with the same medical condition at the same stage of progression as the named patient'.

AND

- Is likely to gain significantly more benefit for the intervention than might normally be expected for patients with that condition.

3.4 It should be noted in considering exceptionality the HSCB can only take account of the clinical circumstances that apply to the individual case. It is not in a position to take account of any personal or social circumstances such as age, dependants, occupation etc.

3.5 Other than in the exceptional circumstances cited above Trusts should not submit ECRs for the following:

- Care or treatment arising out of a service development proposal which has not been supported by commissioners, is under scrutiny or has been deferred because of a lack of recurrent funding.
- Care or treatment which is potentially capable of being developed locally but which has not yet been the subject of a Trust submission or commissioner determination.
- Care or treatment which is provided or capable of being provided in Northern Ireland but is temporarily unavailable. In such circumstances bespoke arrangements will be put in place.
- Care or treatment which falls within the normal profile of local Trust provision, but which is being highlighted to the Board because of its exceptional cost.

3.6 ECRs will normally be to health service providers in other parts of the UK. Only in circumstances where a particular service cannot be accessed from a health service provider will referral to the independent sector be considered.

3.7 There may be particularly specialised services which cannot be provided or accessed within the UK. In such circumstances referral may be made to another EU country with which a reciprocal arrangement exists and to which E112 (S2) procedures apply.

3.8 There may also be rare circumstances where the necessary care or treatment is not available either within the UK or another EU country with which a reciprocal arrangement exists. It may then be appropriate for care or treatment to be accessed from a provider outside the EU.

### **3.9 Procedures for ECRs falling within the acute programme**

The procedures for submitting an Acute ECR to the HSCB and for the Board to make a decision and communicate the outcome are as set out below.

3.10 The HSCB Acute ECR Panel meets on a weekly basis to consider all ECRs received within the preceding 7 days.

3.11 The Panel comprises:

- Assistant Director, Public Health (or nominee), Chair

- Specialist or Consultant in Public Health
- Assistant Director, Commissioning (or nominee)
- Doctor in training public health.

3.12 Administrative support is provided by the Board's commissioning staff, under the direction of the Assistant Director of Commissioning.

3.13 For confidentiality reasons only those individuals required to participate in the decision making process or record the proceedings should be in attendance.

### **3.14 Submission of ECRs**

- ECRs will be submitted on a standard template, by email to [ecrs@hscni.net](mailto:ecrs@hscni.net)
  - All ECRs are to be anonymised.
  - Before an ECR can be requested it should be endorsed by the Trust.
  - It is the responsibility of the individual requesting an ECR to provide the necessary documentation in support of their request.
  - On receipt of the request, a member of the ECR Panel may request additional information before the request is formally considered by the Panel.
  - The Panel will be advised of all requests in the preceding week, including those awaiting additional information before being formally included on the agenda for consideration.
  - ECRs which are properly completed and contain the required information to facilitate decision making will be considered by the ECR Panel at their next weekly meeting.
  - The ECR Panel may request further information from the Trust and reconsider the request when additional material is available.
  - If a patient requires immediate or urgent treatment the Trust may make appropriate arrangements to initiate and the request will be considered retrospectively. The commencement of treatment on an urgent basis will be without prejudice to the outcome of the ECR Panel's deliberations.
  - All ECRs for elective procedures must await the outcome of the ECR Panel's deliberations.
  - At the ECR Panel a record of decisions and the rationale underpinning those decisions will be documented on a standard template.
  - Decisions of the ECR Panel will be communicated, by email, to the relevant Trust (and clinical director) within one week of the ECR Panel meeting.
- 3.15 Funding requests for treatment expected to cost less than £1,000 should not be submitted to the ECR Panel.

#### **4 Extra-contractual Referral (ECR) within the Non Acute Programmes**

- 4.1 Extra-contractual referrals (ECRs) within non acute programmes normally arise, and are eligible for approval, in the following circumstances:
- 1 The patient's clinical condition requires specialised care that could only be sustained for a large catchment population and cannot be provided for a small geographic area such as Northern Ireland.
  - 2 The patient's clinician wishes to seek a second opinion from a provider outside Northern Ireland because of complexities of the patient's condition or circumstances.
  - 3 The treatment is available locally but the patient has some exceptional reason which renders their case different from the vast majority of other patients with the same condition and which therefore justifies a referral for care or treatment outside Northern Ireland.
  - 4 The service being requested is not commissioned for the population of Northern Ireland, but the patient's clinical circumstances are such that exceptionality can be demonstrated and a case justified for an ECR to access care from a provider outside Northern Ireland.
- 4.2 In respect of 4 above, confirmation of clinical exceptionality needs to provide an effective response to the question, "On what grounds can the HSC Board justify funding treatment for this patient when others for the same patient group are not receiving the same treatment".
- 4.3 The Board will apply the following definition in considering whether an individual meets a definition of exceptionality:
- The patient is significantly different to the general population of patients with the condition in question. Consistent with commissioners in other parts of the UK, the HSCB will accept as significantly different 'an individual whose clinical circumstances are outside the range of clinical circumstances presented by at least 95% of patients with the same medical condition at the same stage of progression as the named patient'.
- AND
- Is likely to gain significantly more benefit for the intervention than might normally be expected for patients with that condition.
- 4.4 It should be noted in considering exceptionality the HSCB can only take account of the clinical circumstances that apply to the individual case. It is not in a position to take account of any personal or social circumstances such as age, dependants, occupation etc.
- 4.5 Other than in the exceptional circumstances cited above Trusts should not submit ECRs for the following:

- Care or treatment arising out of a service development proposal which has not been supported by commissioners, is under scrutiny or has been deferred because of a lack of recurrent funding.
- Care or treatment which is potentially capable of being developed locally but which has not yet been the subject of a Trust submission or commissioner determination.
- Care or treatment which is provided or capable of being provided in Northern Ireland but is temporarily unavailable. In such circumstances bespoke arrangements will be put in place.
- Care or treatment which falls within the normal profile of local Trust provision, but which is being highlighted to the Board because of its exceptional cost.

4.6 ECRs will normally be to health service providers in other parts of the UK. Only in circumstances where a particular service cannot be accessed from a health service provider will referral to the independent sector be considered.

4.7 There may be particularly specialised services which cannot be provided or accessed within the UK. In such circumstances referral may be made outside the UK.

#### **4.8 Procedures for ECRs falling within the non acute programmes**

The procedures for submitting an ECR emanating from one of the non acute programmes to the HSCB and for the Board to make a decision and communicate the outcome are as set out below.

4.9 The HSCB Non Acute ECR Panel meets on a fortnightly basis to consider all relevant ECRs received within the preceding 14 days.

4.10 The Panel comprises:

- Assistant Director, Mental Health and Learning Disability (or nominee) (Chair)
- Assistant Director, Social Care and Children (or nominee)
- Social Care Commissioning Lead, Older People and Adults (or nominee)
- Assistant Director, Nursing (or nominee)
- Specialist or Consultant in Public Health
- Assistant Director, Commissioning (or nominee).

4.11 Administrative support is provided by the Board's commissioning staff, under the direction of the Assistant Director of Commissioning.

4.12 For confidentiality reasons only those individuals required to participate in the decision making process or record the proceedings should be in attendance.

#### **4.13 Submission of Non Acute ECRs**

- ECRs will be submitted on a standard template, by email to [ecrs@hscni.net](mailto:ecrs@hscni.net)
  - All ECRs are to be anonymised.
  - Before an ECR can be requested it should be endorsed by the Trust.
  - It is the responsibility of the individual requesting an ECR to provide the necessary documentation in support of their request.
  - On receipt of the request, a member of the ECR Panel may request additional information before the request is formally considered by the Panel.
  - The Panel will be advised of all requests received since the previous meeting, including those awaiting additional information before being formally included on the agenda for consideration.
  - ECRs which are properly completed and contain the required information to facilitate decision making will be considered by the ECR Panel at the next meeting following receipt of a finalised and completed submission.
  - The ECR Panel may request further information from the Trust and reconsider the request when additional material is available.
  - If a patient requires immediate or urgent treatment the Trust will make appropriate arrangements to initiate and the request will be considered retrospectively. The commencement of treatment on an urgent basis will be without prejudice to the outcome of the ECR Panel's deliberations.
  - At the ECR Panel a record of decisions and the rationale underpinning those decisions will be documented on a standard template.
  - Decisions of the ECR Panel will be communicated, by email, to the relevant Trust (and clinical director) within one week of the ECR Panel meeting.
- 4.14 Funding requests for treatment expected to cost less than £1,000 should not be submitted to the ECR Panel.

## **5 Arrangements for Patient Travel**

- 5.1 When an ECR is approved the referring consultant will be asked to inform the Board of travel requirements. The following information should be provided:
- The most appropriate form of travel in terms of cost and the patient's needs.
  - Whether the patient requires an escort or escorts, setting out the reasons. Escorts should be named.
- 5.2 When a patient contacts the Board to request travel arrangements to be made the patient travel officer will establish if the ECR in respect of the patient has been approved and will check to ensure that the travel arrangements booked are in line with the referring consultant's advice. The patient may submit a travel expense claim in line with the Patient Travel Expenses Policy. Reimbursement will be made in line with that policy.

## **6 EU Directive on Cross Border Healthcare (Article 56)**

- 6.1 This EU Directive was adopted in March 2011 and must be implemented by October 2013. Each UK region has been tasked with putting forward an agreed regional timeline for implementation.
- 6.2 The Department of Health will lead on the implementation process on the basis of guidelines to be released by European Commission and consultation on implementation is currently underway.
- 6.3 The key points of the Directive are:
1. EU residents can seek treatment across national boundaries but can only be compensated for healthcare that they would be entitled to receive under the NHS.
  2. Prior authorisation is needed for healthcare which is subject to planning requirements and involves at least one night stay in hospital OR requires the use of highly specialised and cost intensive medical equipment.
  3. Commissioners will be required to cover the cost of treatments which are available within their own healthcare system.
  4. Patients will be reimbursed for the cost of cross-border healthcare up the level of cost of that treatment under the NHS.
  5. There is no requirement that travel expenses are reimbursed for patients accessing care or treatment under this directive.
  6. Treatment may be within either state or private sectors
  7. Local systems will be required to recognise prescriptions filled out in other member states.
  8. National Contact Points will have to be established to provide patients with information related to cross-border healthcare on request.
- 6.4 The Board will consider requests under Article 56 and in doing so will apply the criteria set out above and any further guidance issued by the DHSSPS. In addition, the Board will expect that the care or treatment being sought under Article 56 referrals is considered clinically necessary by the relevant clinician and that appropriate supporting documentation to this effect is received.

## **7 *Review of Panel Decisions***

- 7.1 If an HSCB IFR/ECR Panel declines a request for funding, the referring clinician may submit new or additional clinical information as part of a new IFR request.
- 7.2 Alternatively, they may request a review of the Panel's decision. A request for review must be submitted to the HSCB within 20 working days of receiving communication of the IFR/ECR decision.
- 7.3 The request can be made by the patient's clinician or clinical director of the relevant service area and must be supported by the Trust.
- 7.4 For requests received under Article 56 of the EU Cross Border Directive on Healthcare the request may be made by the individual or their representative.

## **Scope of a Review**

- 7.5 The grounds on which a clinician may request a review of the IFR/ECR Panel decision are as follows:
- 1 The HSCB has failed to act fairly, in accordance with the policy on IFR/ECR submissions
  - 2 The HSCB has made a decision which is irrational in light of the evidence submitted as part of the IFR/ECR
  - 3 The HSCB has exceeded its powers.
- 7.6 It is the responsibility of the individual requesting a review to provide the necessary documentation in support of their request.
- 7.7 It should be noted that a review of the IFR/ECR Panel determination does not constitute a review of the decision. Rather it limits a review to consideration of the process through which a determination was reached, and assesses whether process and procedures were consistent with policy and with the powers and responsibilities of the HSCB as commissioner.

## **7.8 How to Request a review of the IFR or ECR Panels determination**

A review request must be made to the Commissioning Directorate at the HSCB, within 20 working days of receipt of the IFR or ECR Panels' determination.

The request must detail the

- aspect of the decision being challenged and
- the grounds of the review request

- 7.9 The chair of the Review Panel may request additional information and has the discretion to decline to review an IFR/ECR Panel determination unless relevant information is provided. The Review Panel will consider the review within 20 working days of the request being received.

## **Composition of the Review Panel**

- 7.10 The Review Panel will consist of individuals who have not had involvement in the original IFR/ECR Panel process or determination. Specifically the panel will comprise:
- Head of Corporate Services (chair)
  - Director of Integrated Care (where a GP has requested a decision be reviewed, the Director of Finance rather than the Director of integrated Care will sit on the Panel)
  - Non-executive member of HSC Board or PHA Board
- 7.11 Material for consideration of the Review Panel will be prepared by the Commissioning Directorate.

7.12 In the case of the non-executive member of the panel it is proposed that at least two members are nominated, with the intention that one should always be in attendance.

### **Attendance at Review Panel Hearing**

7.13 No new clinical information or data can be considered by the review panel. If circumstances have changed or new clinical information has become available clinicians may wish to forward to commissioners as part of a new IFR or ECR request.

7.14 The Chair and members of the IFR or ECR Panel may be asked to attend the Review Panel to provide the information on the procedures followed and the rationale of decision-making by the IFR/ECR Panel.

7.15 The review panel's role is to consider the process followed by IFR/ECR panel, not to hear new or different evidence in support of an IFR/ECR. In this context it would not normally be appropriate for patients or their representatives to attend the Review Panel.

7.16 However, the Review Panel has discretion to ask relevant individuals to attend the Panel to present the grounds on which a review request has been made. This may include (but is not restricted to) the referring clinician or relevant clinical director or (in the case of Article 56 requests) the patient or their representative.

7.17 The Review Panel may:

- Uphold the grounds of the review and ask the IFR panel to reconsider its determination

OR

- Allow the determination of the IFR Panel to stand

The Panel may also make a recommendation for action to the HSC Board

7.18 The Review Panel will notify the IFR/ECR Panel referring clinician (and clinical director) and the relevant Trust of its decision within 5 working days of the Review Panel decision.

7.19 Notwithstanding the IFR/ECR procedures and the ability to request a review of the IFR/ECR Panel's decision, patients who are dissatisfied may make a complaint through the Board's normal complaints process.