



## **Consultation Response**

# **Individual Funding Request**

May 2015

Individual Funding Request

Response from Cancer Focus Northern Ireland

#### Contact Details

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Cancer Focus is willing to have comments attributed to the organisation.

## Cancer Focus Northern Ireland

### Response to the DHSSPS Consultation on the Evaluation of the Individual Funding Request Process

May 2015

#### Context

Cancer Focus Northern Ireland is a local charity dedicated to reducing the impact that cancer has on Northern Ireland's society - the impact of the disease on individuals and their families, and the impact on the wider community in terms of incidence and mortality. We have been serving the community in Northern Ireland for over 40 years with the needs of people living with a cancer diagnosis central to all of our work.

We welcome the decision by Minister Wells to instruct the Department to carry out an evaluation of the Individual Funding Request (IFR) process and the subsequent consultation on proposals emanating from this evaluation.

#### The *Equal Access Campaign*

The Equal Access campaign arose from concerns raised by cancer patients contacting our Helpline or other services, and through research that we carried out in 2011 which indicated long delays in patients accessing NICE approved drugs together with very limited access to non-NICE approved drugs.

In June 2014, Cancer Focus Northern Ireland launched the *Equal Access Campaign* in partnership with 15 other local cancer charities. The campaign called for improved access to new cancer drugs and in particular for the ending of the unfair and inhumane 'exceptionality' clause at the heart of the IFR process.

We acknowledge the significant progress that has been made in accessing NICE approved drugs, but remain deeply concerned that a patient in Northern Ireland is 75-80% less likely to be able to access new drugs than patients with a similar stage/type of cancer in England. We believe this is due to the exceptionality clause in the current IFR process, as a result of which, an estimated 800 patients a year are being denied treatment that could ease their symptoms and extend their life expectancy. The exceptionality clause is, we believe, inhumane and causes great distress to patients in their last few months or years of life. This view is shared by over **26,000** patients and members of the public who pledged their support online or via our post card campaign.

Cancer Focus Northern Ireland welcomes the public consultation on this issue, although we would reiterate that public meetings have perhaps limited efficacy in trying to reach the people most affected by the exceptionality clause - namely those who are terminally ill. We have also expressed concern about the poor geographical spread of consultation events and how poorly they were communicated to the public

## **Cancer Focus Northern Ireland's Response**

Before addressing the specific consultation questions, we would like to very ardently express our grave concerns at the significant delays in making progress in enabling access to new drugs for cancer patients. We have been campaigning on this issue since 2011. While we do appreciate the need for consultation, at every stage in the process there have been significant delays which are having life-limiting effects on patients who do not have time on their side. Northern Ireland is now considerably behind every other part of the United Kingdom in opening access to new cancer treatments. Our consultation with the people most affected by the current policy indicates that patients who are terminally ill are being caused additional stress by the knowledge that they are being denied treatment that could extend their life and/or ease symptoms and which in many cases would be available if they lived elsewhere in the UK. Their final months and years are spent fighting an inhumane system with a loss of confidence that decisions about treatment are being made in their best interests. This view is equally shared by their families who have also made representation to Cancer Focus Northern Ireland.

We believe that the Department ought to have applied the humane, patient centred approach of the CMO in Scotland, by using the PPRS rebate as an interim measure to allow for due consideration and the development of suitable procedures in Northern Ireland. Information on how the PPRS rebate in Northern Ireland is being used has been difficult to obtain. Our concern is that this rebate, intended to fund new medicines may be being used to meet deficits elsewhere in the DHSSPS to the detriment of cancer patients.

The consultation events indicated quite clearly that there is no sense of urgency to resolve this matter other than going through the process of consultation to come up with a further set of proposals, which in turn will go to consultation. In the meantime, patients continue to be denied access, to die without exhausting all possibilities for treatment or in some cases to continue to self-fund treatment which would be freely available if they lived elsewhere in the United Kingdom.

Cancer Focus Northern Ireland would also like to draw attention to the impact of the failure to open access to new drugs on the cancer research and clinical trials landscape in Northern Ireland. We noted in the consultation meetings that reference was made to the 'possibility' that Northern Ireland 'might' be disadvantaged in being included in clinical trials. Further investigation by the Department during the review process would have verified very readily that there is no doubt whatsoever that access to new clinical trials is being curtailed by the current policy.

While the DHSSPS has stated in the Assembly (06/5/14) that '1,200 patients in Northern Ireland are involved in clinical trials', this - rather like the statement that 98% of IFRs are granted - is far from the whole picture. The vast majority of these 1,200 patients are involved in observational studies with fewer than 18% involved in new clinical trials. The current IFR process results in Lead Researchers being unable to make applications for inclusion in major new trials as Northern Ireland cannot meet the treatment protocols due to the lack of access to new medicines available in other parts of the United Kingdom. As drug trials include full infrastructure costs, this has an incalculable cost to the NHS in Northern Ireland.

The current policy is, we believe, not only inhumane to patients but is also economically short-sighted sense, impacting on academic research and development with the potential

to drive excellent researchers to other centres where they have the potential to work at the cutting edge of their specialty.

Cancer Focus Northern Ireland, as the Ulster Cancer Foundation, was instrumental in funding the first cancer research laboratory in Northern Ireland at Queen’s University. With the excellent research leadership and innovation delivered at Queen’s, this facility has grown to have global significance in cancer research and development. In recent years, since the introduction of the current IRF exceptionality criteria, we have seen our capacity to engage in clinical trials compromised and our lead position in UK cancer survivorship eroded. The Department must be mindful of the far-reaching although perhaps unintended consequences of the current IFR policy.

### Responses to Consultations Questions

<b>Please tick which recommendations you are providing feedback on</b>	
Recommendation 1 – Revising the existing exceptionality criteria	<b>X</b>
Recommendation 2 – Establishing regional scrutiny committee(s)	<b>X</b>
Recommendation 3 – Increased transparency	<b>X</b>
Recommendation 4 – Establishment of a Special Medicines Fund	<b>X</b>
Recommendation 5 – Re-introduce prescription charges to resource the Fund	<b>X</b>
General Comments	<b>X</b>

#### 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?**

**Strongly agree**

Comments:

As Cancer Focus Northern Ireland has consistently stated, we believe that the current 95% exceptionality clause is inhumane. The concept is poorly understood by patients and there is evidence that it is not consistently applied across the Northern Ireland. The DHSSPS has provided misleading information by consistently reporting that 98% of Individual Funding Requests are approved. This ignores the critical fact that the exceptionality clause has severely reduced the number of requests that have been coming forward. This in turn results in cancer patients being over 80% less likely to access new cancer drugs than patients with similar disease in other areas of the United Kingdom.

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

Strongly disagree

Comments:

The Cancer Patients Bill of Rights calls for the optimum treatment for all cancer patients at the optimum time. Within this context, Cancer Focus Northern Ireland believes that a 'percentage approach' to exceptionality is a somewhat blunt instrument which is destined to be poorly understood by patients and to ensure that not all patients receive optimum treatment.

Terminally ill cancer patients need to know that decisions regarding treatment are made with their best interests at heart. Clinical need should determine access to treatment.

Cancer Focus Northern Ireland strongly advocates close examination of the peer approved clinical model in Scotland (the New Medicines Fund). This model has been developed with the engagement of clinicians, patients and is closely linked to the decisions of Scottish Medicines Council. It allows decisions to be made by Lead Clinicians, and includes a crucial element of peer review.

**Q3. What would be an appropriate definition of exceptionality?**

Please complete the box below

Comments:

As above we do not feel that terminally ill cancer patients should be treated 'by exception' but rather on the basis of clinical need.

## 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?

Strongly agree

Comments:

A Northern Ireland wide system that is transparent and accountable would be most welcome. We would want to see this Committee placing emphasis on clinical need and peer review and should not serve as a further layer of bureaucracy injecting further delays into the process. The process should include standard response times for patients - rather than target timescales - to avoid patients enduring a lengthy wait for a decision regarding their treatment. Cancer patients frequently report that their lives appear to be spent waiting - to see their specialist, for the outcome of tests, for the next appointment. Cancer Focus Northern Ireland would like to stress that the procedures for access to new medicines should not only be transparent and consistent, but they should also be clearly time-bound to avoid additional stress on patients.

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

Comments:

N/A

### 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?**

Strongly agree

##### Comments:

We fully agree with this proposal and believe that clarity and transparency are essential to meeting patient expectation. Terminally ill patients have a very clear right to understand the basis on which decisions to treat or withhold treatment are made. As stated we would stress that the process should also have clear standards for response times. We would welcome the Patient and Client Council becoming engaged in this debate particularly in the context of engaging with people who are terminally ill and believe their earlier engagement in the review process would have been advantageous.

We are, however, greatly concerned that this 'further work' should not significantly add to the time taken to effect improvements. As stated we are very concerned that change should be implemented as soon as possible to improve patient access. A clear implementation plan with target dates should be drawn up at the end of this consultation period.

#### **Q2. Do you agree that increased transparency would have a positive impact on patients' and clinicians' confidence in the process?**

Strongly agree

##### Comments:

Our engagement with patients indicates that there is a lack of confidence and trust in the present system. Patients report great distress feeling that, in their time of greatest need, the Health Service in Northern Ireland is not acting in their best interests.

Increased consistency, transparency, clarity and timeliness of communication would assist with this, recognising that patients are already coping with a terminal cancer diagnosis. They certainly do not need the added stress of worrying about access to treatment and the inequality of the fact that if they lived elsewhere in the United Kingdom they may have free access to treatment that their clinician believes would benefit them.



#### 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 Specialist Medicines Fund to put funding for medicines on a secure financial footing?**

Agree

Comments:

There is a need for a clearly defined, long-term funding mechanism for new medicines and the associated infrastructure provision including medical, nursing and pharmacy staff. We recommend a review of the current chemotherapy delivery facilities. We further point to the benefits of using innovative molecular testing, where it is available, to ensure that new treatments are directed towards those patients who are most likely to benefit.

Patients need to know that decisions regarding their treatment are being made on the basis of clinical need and that their access to medicines that may benefit them is not limited by where they live.

Cancer Focus Northern Ireland accepts that it will take some time for a process to be developed which is suitable for Northern Ireland. We strongly recommend that the Health Minister looks to Scotland and Wales to see how they have used the PPRS rebate to allow time for a well thought through process to be developed.

Cancer patients should not continue to be the victims of ongoing delays within the Department when there is an interim solution available which has been seen to work in other parts of the UK.

## 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?**

Neither

Comments:

Cancer Focus Northern Ireland believes that the funding of access to cancer drugs should not be linked to the re-introduction of prescription targets. We cannot condone using the emotive issue of terminally ill cancer patients to introduce a potentially divisive policy.

Linking access to cancer drugs to the reintroduction of prescription charges - especially in its very poorly thought through form - has the potential to pit one group of ill or disabled people against another.

Cancer Focus Northern Ireland strongly advocates the use of the PPRS rebate to fund access to new drugs over the next three years to allow for the development of a well thought through process - as we have seen in Scotland and more recently, Wales. We would also recommend that the current list of medicines and other items that may be prescribed should be subject to close scrutiny.

Should the Department wish to reintroduce charges this should be a matter of separate consultation which would need to be much clearer as to:

- Who would pay
- How much they would pay
- How they would pay and the administration process and costs
- Who, if anyone, would be exempt
- The costs of the scheme
- The potential income from the scheme
- How any uplift in charges would be negotiated

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

Comments:

Please see above

## Conclusion

Cancer Focus Northern Ireland, welcomes the opportunity to comment on this consultation but we stress that this should not be used as a mechanism to inject still more delays in opening access to new drugs for cancer patients. The proposals to improve the process to achieve consistency, transparency and clarity are very much welcomed: we believe the issue of timeliness is also crucial.

While we welcome the acknowledgement, albeit belated, that the current IFR process - and the associated exceptionality criteria - is overly restrictive, we are concerned at the lack of clarity around the extent to which access to drugs will increase. Will the proposed specialist medicines fund and IFR changes merely improve the availability of drugs, or will it give equal access compared with the situation in the rest of the United Kingdom? **We are particularly concerned that clinical need and the well-being of patients should be central to any decision regarding treatment.** In respect of this, we strongly recommend consideration of the model in Scotland which enables the expert clinician make decisions with their patients, in discussion with their clinical peers. To date this has led to transparent and speedy decisions where patients can have confidence that decisions have been made fairly and with their best interests at heart.

We feel strongly that the review of the Individual Funding Request process should **not** be linked to the proposal to reintroduce prescription charges. We are disappointed that the DHSSPS has linked the two, thereby potentially using the plight of terminally ill patients to introduce a measure which has been an intention for some time, but is so poorly formed that it is impossible to judge its potential impact. Any proposal to reintroduce prescription charges should be consulted on separately, not least of all because of its potential impact far beyond those directly affected by access to new drugs for cancer and other serious conditions.

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May 2015