



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

INDIVIDUAL FUNDING REQUEST DRAFT POLICY DOCUMENT

Consultation Response Questionnaire

January 2017

CONSULTATION RESPONSE QUESTIONNAIRE

You can respond to the consultation document by e-mail or letter.

Before you submit your response, please read Appendix 1 about the effect of the Freedom of Information Act 2000 on the confidentiality of responses to public consultation exercises.

Responses should be sent to:

E-mail: IFRPC@health-ni.gov.uk

Written: IFR Policy Consultation
DoH
Room 1
Annex 1
Castle Buildings
Stormont Estate
Belfast, BT4 3SQ

Tel: (028) 9052 2301

Responses must be received no later than 07 April 2017

I am responding: as an individual
on behalf of an organisation
(please tick a box)

Name: Prof Mark Strachan
Job Title: Secretary
Organisation: Royal College of Physicians of Edinburgh
Address: 9 Queen Street, Edinburgh, EH2 1JQ
Tel: 01312473658
e-mail: s.collier@rcpe.ac.uk

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Background

Following concerns raised by patients, charities, the pharmaceutical industry and political representatives about the inconsistencies in the Individual Funding Request (IFR) process and the perceived inequity in access to high cost new specialist drugs in the north of Ireland compared to other UK jurisdictions, the Minister for Health commissioned an evaluation of this process, which was launched in September 2014.

The evaluation and subsequent consultation on proposals to change the IFR process has identified areas with the potential to improve patient access at a time when it is acknowledged that the growth in the number of new and innovative treatments is gaining pace.

The Minister decided established a clinically led task and finish group (T&FG) to take forward reform of the IFR process. The terms of reference for the T&FG were:

- To develop new clinically based exceptionality criteria, taking account of the findings of the evaluation which identified a 95% criterion as being too restrictive;
- Establish regional, clinically led scrutiny committee/s to underpin the current process which will ensure all IFR applications are subject to regionally consistent clinical input and peer review;
- Revise existing IFR guidance to include greater transparency, accountability and governance, and enhance patient involvement;

IFR policy document

The draft policy sets out the criteria and the key features under which IFRs should be considered, including a new definition of clinical exceptionality. The evaluation report had identified that the current definition of clinical exceptionality, which requires a clinician to demonstrate that their patient is different to 95% of patients with the same condition at the same stage, is regarded as too restrictive by clinicians, patients, the voluntary sector and industry.

In addition to setting out the draft policy the document provides clarity and guidance on a number of areas relating to an IFR application, for example it provides advice as to when IFR applications should be more appropriately considered as potential service developments and how to deal with urgent treatment decisions. The new policy also introduces criteria for IFRs on the grounds of rarity for the first time. The policy document provides detailed guidance notes in the appendix.

The policy document does not provide detailed operational procedures such as application forms, communication methods or membership of the regional scrutiny group (RSC) – these will be developed by the RSC in liaison with Department of Health and other stakeholders.

The draft policy document and draft patient and user guidance can be accessed at www.health-ni.gov.uk/consultations.

Purpose

This questionnaire seeks your views on the draft policy document and the patient and user guide and should be read in conjunction with these documents.

The consultation questionnaire

The questionnaire can be completed by an individual health professional, stakeholder or member of the public or it can be completed on behalf of a group or organisation.

Part A: provides an opportunity to answer questions and/or to provide general comments relating to the policy document.

Part B: provides an opportunity for respondents to give additional feedback relating to any equality or human rights implications of the recommendations.

Part A
Feedback on Recommendations

ESSENTIAL CRITERION:

The request does not apply to a cohort of patients

Individual funding requests should apply only to individual patients and not a group of patients, i.e. a cohort of patients. A cohort of patients *“is defined as a group of clinically similar patients. If the numbers of clinically patients for whom treatment is requested per year reached 3 or more, the HSCB will treat this as a service development requiring a commissioning policy and the Specialist Services Commissioning Team will be notified.”*

Q1. Do you agree that access to the IFR process should be for individual patients and not for cohorts of patients?

Strongly agree Agree Neither Disagree Strongly disagree

Comments:

As discussed in the Draft policy document, the Regional Scrutiny Committee (RSC) cannot make Health and Social Care Board (HSCB) service provision decisions which would be required if cohorts of patients were allowed to access the IFR process.

Q2. Do you agree that it is right to develop a commissioning policy for cohorts of patients reaching 3 or more per year?

Strongly agree Agree Neither Disagree Strongly disagree

Comments:

At 3 or more per year the cost implications would usually warrant a more detailed assessment of the needs and cost-benefits of the proposed intervention.

ADDITIONAL CRITERION:

The patient is suffering from a medical condition for which the patient's particular clinical circumstances fall outside the criteria set out in existing commissioning policy for funding the requested treatment.

It is recognised that on occasion an existing policy on the management of a disease may not cover the treatment which the patient's hospital consultant considers would benefit the patient significantly more than other patients with the same condition at the same stage. In cases such as this the requestor would be required to make reference to the existing commissioning position and provide evidence as to the exceptional clinical circumstances which would apply.

Q3. Do you agree with this criterion?

Strongly agree ✓ Agree Neither Disagree Strongly disagree

Comments:

The RSC will need the basic information of the existing commissioning position and why the clinician believes their patient meets the exceptional clinical circumstance to make a reasonable judgement. We agree that the relaxing of the 95% criterion evidence for exceptionality is correct.

Q4. If you do not agree, can you suggest another method of ensuring regional consistency?

Comments:

N/A

ADDITIONAL CRITERION:

The request is for a new intervention or for an intervention for a new indication outwith its licensed indication where no commissioning arrangements exist.

This criterion provides increased access to novel treatments both within and outwith licensed indications where the patient's hospital consultant considers the treatment would benefit the patient significantly more than other patients with the same condition at the same stage. In cases such as this the requestor would be required to provide evidence as to the benefits of the treatment.

Q5. Do you agree with this criterion?

Strongly agree Agree ✓ Neither Disagree Strongly disagree

Comments:

Agree, but in this circumstance the level of evidence in this area is likely to be sparse and potentially weak, through no fault of the submission. This should be kept in mind when discussing levels of evidence for extrapolated benefit in an individual request.

Q6. If you do not agree, can you suggest another method of accessing treatments outside licensed indications?

Strongly agree

Agree

Neither

Disagree

Strongly disagree

Comments:

N/A

ADDITIONAL CRITERION:

The patient has a rare clinical circumstance for whom the hospital consultant wishes to use an existing treatment outwith its licensed clinical indication, with the explicit consent of the patient.

This group of patients represents a distinct group of exceptions and so are assessed in line with expert views as to the patient's clinical suitability. In considering this criterion the panel will assess whether or not it is possible for the patient to access treatment through a clinical trial and if so the IFR will be rejected. Other panel considerations related to this criterion are detailed in the IFR policy document sections 1.10 to 1.13. Guidance notes section 3 refers to rarity.

Q7. Do you consider this criterion should be included in the policy?

Strongly agree

Agree ✓

Neither

Disagree

Strongly disagree

Comments:

Agree, although it is likely that the RSC may need to seek independent views in the rare area on whether or not entry into a clinical trial is likely to be equally beneficial to the patient as receiving the funded treatment in an open label format.

The intended audience and users of the IFR policy document are hospital consultants who are likely to apply for IFRs on behalf of their patients. The policy document provides information and detail about several distinct areas, both in the narrative around the policy and in the guidance notes in the appendix. A patient and user guide has also been developed in easy read format for users other than hospital consultants.

The following questions ask for comment on the policy document only.

SCREENING FOR SERVICE DEVELOPMENTS AND INCOMPLETE SUBMISSIONS

Q8. Do you agree that the section in the policy document (1.3 to 1.7) provides an overview of what is required to screen out applications for service development?

Strongly agree Agree ✓ Neither Disagree Strongly disagree

Comments:

Q9. Do you consider the guidance note in section 1 of the appendix, about service development and cohorts of similar patients, provides sufficient information to enable hospital consultants to come to a decision as to the nature of the request they wish to make?

Strongly agree Agree ✓ Neither Disagree Strongly disagree

Comments:

URGENT TREATMENT DECISIONS

Q10. Do you consider there is sufficient information to aid hospital consultants to make urgent treatment requests (section 1.14 and Appendix A section 4)?

Strongly agree Agree ✓ Neither Disagree Strongly disagree

Comments:

APPROVAL OF INDIVIDUAL FUNDING REQUESTS

Q11. Do you agree with the conditions set out in the section (section 1.18 to 1.22)?

Strongly agree

Agree ✓

Neither

Disagree

Strongly disagree

Comments:

The level of monetary threshold will need annual review as budgetary constraints change.

APPEALING A DECISION

Q12. The appeals process will test whether the RSC panel has followed procedures, has properly considered the evidence and has come to a reasonable decision based upon the evidence. Do you agree with the conditions set out in the section (section 1.23 to 1.26)?

Strongly agree

Agree ✓

Neither

Disagree

Strongly disagree

Comments:

It may be worth stating a limit to the number of times a decision can be appealed as this is not currently clear.

GENERAL COMMENTS

Please use the box below to insert any general comments you would like to make in relation to the recommendations or wider content of the evaluation report.

Comments:

N/A

Part B **Equality Implications**

Section 75 of the Northern Ireland Act 1998 requires the Department 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 persons with a disability and persons without; and between persons with dependants and persons without. The Department is also required to “have regard” to the desirability of promoting good relations between persons of a different religious belief, political opinion or racial group.

The Department has also embarked on an equality screening exercise to determine if any of these recommendations are likely to have a differential impact on equality of opportunity for any of the Section 75 groups. We invite you to consider the recommendations from a section 75 perspective by considering and answering the questions below. Answering these questions will contribute to the completion of the Department’s Screening template and the screening outcome.

Q1. Are the actions/proposals set out in this consultation document likely to have an adverse impact on any of the nine equality groups identified under Section 75 of the Northern Ireland Act 1998? If yes, please state the group or groups and provide comment on how these adverse impacts could be reduced or alleviated in the proposals.

Yes

No

Comments:

Q2. Are you aware of any indication or evidence – qualitative or quantitative – that the actions/proposals set out in this consultation document may have an adverse impact on equality of opportunity or on good relations? If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.

Yes No

Comments:

Q3. Is there an opportunity to better promote equality of opportunity or good relations? If yes, please give details as to how.

Yes No

Comments:

Q4. Are there any aspects of these recommendations where potential human rights violations may occur?

Yes No

Comments:

**Please return your response questionnaire.
Responses must be received no later than 07 April 2017
Thank you for your comments.**

Appendix 1

FREEDOM OF INFORMATION ACT 2000 – CONFIDENTIALITY OF CONSULTATIONS

The Department 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.

The Freedom of Information Act gives the public a right of access to any information held by a public authority, namely, the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential information supplied to it in response to a consultation. 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.

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 Lord Chancellor's 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

For further information about confidentiality of responses please contact the Information Commissioner's Office (or see web site at:

<http://www.informationcommissioner.gov.uk/>).

Produced by:
Department of Health
Castle Buildings, Belfast BT4 3SQ
Telephone (028) 90522424
www.health-ni.gov.uk
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