Draft Process for Patient Organisation Submission of Evidence

Public Consultation

The National Centre for Pharmacoeconomics (NCPE) performs detailed reviews of the clinical effectiveness and cost-effectiveness of new and existing drugs at the request of the Health Service Executive (HSE).

In 2016, the NCPE launched the Patient Organisation Submission of Evidence process. The purpose of this process is to supplement our health technology assessment reports with information collected directly by patients, from patients, detailing the real-life experience of living with the disease in question and how the new treatment may address the challenges arising from the disease.

To date, we have received 16 patient organisation submissions which we have included in full with our report to the HSE. Towards the end of 2017, we undertook a review of the process with input from HSE decision makers, submitting patient organisations and participants in the IPPOSI Pilot Patient Education Program. Based on the feedback provided, we have developed new guidelines, processes and updated our Patient Organisation Submission of Evidence template.

Now we would like to hear the views of potential users of the updated documents, to ensure they are relevant, patient focused and user-friendly. Your comments will be considered and will inform the development of the Patient Organisation Submission Process.

Your comments can be submitted by downloading and completing the consultation feedback form and emailing your completed form to us at info@ncpe.ie . Alternatively you can post the completed form to us at The National Centre for Pharmacoeconomics, Old Stone Building, Trinity Centre for Health Sciences, St James Hospital, Dublin 8.

Draft Process for Patient Organisation Submission of Evidence

Public consultation feedback form

29th March 2018

In 2016, the NCPE launched the Patient Organisation Submission of Evidence process. The purpose of this process is to supplement our health technology assessment reports with information collected directly by patients, from patients, detailing the real-life experience of living with the disease in question and how the new treatment may address the challenges arising from the disease.

The NCPE have undertaken a review of the Patient Organisation Submission of Evidence process. We have developed new guidance documents, information sheets and templates to aid patient organisations through the submission process.

We are holding a public consultation to give interested parties an opportunity to provide their feedback on these draft documents. Your input is essential, and we will assess all feedback received and use it to develop the finalised process and documentation. We welcome responses to all questions as well as any additional general comments you would like to make.

How to complete this form

The draft documents are available for review on our website, www.ncpe.ie. There are 4 documents available for review as part of this consultation:

a) The Patient Organisation Submission Process
b) The Patient Organisation Database Registration Form
c) The Patient Organisation Submission of Evidence Template
d) Guidance document on completing the Patient Organisation Submission of Evidence Template

The closing date for the consultation is 5pm on 30th April 2018

Instructions for submitting feedback

- If you are commenting in a personal capacity, there is no need to provide your name or any other personal information
- If you are commenting on behalf of an organisation, please combine all feedback from your organisation into **one** submission form
- Your comments can be submitted by downloading and completing the consultation feedback form and emailing your completed form to us at info@ncpe.ie . Alternatively you can post the completed form to us at The National Centre for Pharmacoeconomics, Old Stone Building, Trinity Centre for Health Sciences, St James Hospital, Dublin 8

Data protection

The NCPE will not collect any personal information during this consultation. All information received will be treated as confidential. Responses may be collated and presented anonymously as part of research and education programmes.

About You

Please tick as appropriate-are you providing feedback as:

An individual ☐

On behalf of an organisation ☒

Please provide the name of the organisation:

Medical Research Charities Group

Feedback on the draft process

In this section, we would like to find out what you think of the content of each of the draft documents. You do not have to comment on all documents

Please consider the following as part of your review:

- Do you think all important areas have been covered?
- Is the language used appropriate and easily understood?
- Is the layout of the document clear and easy to follow?

Patient Organisation Submission Process

Principals/overview document • Congratulations on a clearly explained process and a well laid-out document • We welcome the acknowledgement that patients should have the same rights to contribute to the process as other stakeholders. • Figure 1 implies a circular chain of events, which could be misleading • We recommend a brief explanatory note beside each of the pieces of information listed in Figure 1 • A flow chart might be better suited to Figure 2 • In relation to the notification process, we recommend changing this to a commitment to inform the patient organisation at least two working days in advance of publication (to avoid any late Friday afternoon notifications). We also recommend informing the patient organisation at all key steps of the process e.g. once a full HTA has been initiated or when there are significant delays. • The deadline for making a submission to the process should be made clear to the patient organisation. • We recommend including an overview of timeframes for the process in this document. • We recommend providing more detail on how patient organisation submissions are considered in the process

Patient Organisation Database Registration Form

- The outlined purposes for maintaining the database are very welcome.
- Q4. There should be an option to include more than one named contact
- Q5. The relevance of asking about the type of organisation (A, B, C) is not clear. In any case, these divisions are deemed by some to be outdated. A better question is perhaps at what stage they are at in the process of implementing the governance code. However, there is an implication that, by asking any questions in this regard, you will deem the evidence from certain types of organisations less worthy. A better approach would be simply to assess the quality of the evidence provided.
- Q5. The form makes the presumption that every patient organisation is a registered charity which might not always be the case. We would encourage you to also accept information from less structured groups of patients.
- Q8. You should be aware that organisations use the term 'members' in different ways. For some it can refer to the number of patients they support. For others it might refer to all their supporters. It might be better to ask about the number of patients the organisation has contact with. Even then, this question might be of limited value if the organisation supports people with different forms of the condition in question.
- Q9. We are not aware of any patient organisations with corporate members. You might instead consider asking them if they use a code of conduct for engaging with the healthcare industry (MRCG template here: http://www.mrcg.ie/go/our_work/working_with_industry)

Patient Organisation Submission of Evidence Template

Q1. We suggest adding prompts to include details on financial cost (including the cost of not treating) and psychosocial issues. You should consider allowing the inclusion of supplementary material e.g. peer reviewed papers, survey reports, patient testimonials.
Q2. Be aware that this question might draw out answers not relevant to the product the submission relates to e.g. challenges relating to physical appearance, that the new medicine will not solve.
Q3. You might have challenges relating the answers provided here with the answers provided in Q 1 and 2, particularly in the case of complex conditions that have many effects on the body and on daily life. Perhaps it could be incorporated into questions 1 and 2. A table, where each piece of information can be associated with details of how that information was sourced, might be better.
Q4. A good list of examples. However, it's not clear what 'please list each medicine separately means'? Does this refer to existing medicines (of which there may not be any)? It should specify here, as per the guidelines, that this section is for information sourced from patients who have not previously used the medicine being assessed.
Q5. You might need to be clearer about what sort of information you are looking for here. Is it their personal experiences of effectiveness and side-effects?
Q7. As per Q3
Q8. This gives good scope for the applicant to deliver the messages they would most like you to hear. Consider publishing this piece in the NCPE summary report, so that those represented by the patient organisation can see what has been included.
Q10. What is more relevant here than amount, is the percentage of overall annual income that the contribution from any one company made. As mentioned above, it is also important to ask if the patient organisation has any policies or codes for involvement with the healthcare industry. Also, to note that not all relevant industries can be classified as pharmaceutical companies.

Guidance Document for completing the Patient Organisation Submission of Evidence Template

- We welcome the provision of an example of a past helpful submission but recommend that you include more than one, as the relevant information will vary vastly between disease types (fictional submissions could also be considered).
- You distinguish between quality of life and clinical effectiveness but, in reality, there can be an overlap between the two. There are some aspects of clinical effectiveness that might not be deemed important by healthcare professionals but very important to a patient e.g. improved sleeping patterns might not be measured but it could be argued that they are a marker of clinical effectiveness.
- You state that you are not looking for references to printed sources but how can a patient organisation be sure you will be aware of a relevant source of information e.g. a study on quality of life, unless they can point you to it? A thorough literature review on all aspects of a condition and subsequent appraisal of papers identified by the search can take many months and so it is difficult to imagine that relevant papers are never missed.

General feedback

Please let us know if you have any other general comments to make about the Patient Organisation Submission Process.

- While we have made some suggestions for improvements above, we applaud your efforts to improve the processes by which patient organisations can engage in the HTA process and for the strong documentation you have produced.
- It is a very difficult thing to capture information that is pertinent and clearly laid out, through a form. Patient organisations will provide different data, in different ways and there might also be some challenges as to what constitutes a patient organisation. We recommend a 2-way information session between the NCPE and patient organisations one to two years after implementation and the refinement of the process thereafter.
- There would also be a lot of value in an NCPE-led workshop on how to generate the different type of evidence that can be usefully included in a HTA process. Section 5 & 6 and Appendix 2 of the guidance document offer a good basis for such a workshop.
- In parallel with the current reforms, it is essential that other aspects of the reimbursement process are improved e.g. all stages post-HTA made more transparent and the establishment of the proposed Technology Review Committee.

Thank you for taking the time to give us your views, we appreciate your feedback