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:

IPPOSI – the Irish Platform for Patient Organisations, Science and Industry

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

IPPOSI believes that the patient organisation submissions should be reviewed and considered as part of the NCPE assessment process. As such, it is not practical for the NCPE to accept patient organisation submissions throughout the entire 90-day period allocated for completing a HTA. If a patient organisation submits on day 89, how does this evidence inform the NCPE assessment which needs to be completed by day 90? We would not like to see a practice emerge whereby the NCPE simply append patient organisation submissions to the advice they provide to the HSE. We want the NCPE to critically consider patient organisation submissions and to comment on their validity (or not) in their report to the HSE. To ensure that NCPE assessors have sufficient time to "*include extracts of the [patient organisation submission] template within the main body of the report [to the HSE]*", we propose that the NCPE (with the help of the HSE) adopt a structured approach along the line of the model adopted by the Scottish Medicines Consortium which clearly lays out the 'Product Assessment Timeline' and accompanying deadlines for different stakeholders to feed into the assessment and decision-making process. IPPOSI welcomes the decision by the NCPE to share its final reports with patient organisations who have made a submission, 48 hours in advance of their publication on the NCPE website. We

continue to call on the NCPE to go one step further and allow patient organisations to have sight of and comment on draft recommendations – a practice adopted by CADTH in Canada.

IPPOSI believes that patient involvement or input into HTA in Ireland should not be limited to patient organisation submissions. The *Patient Involvement in HTA in NCPE – Overview* document which details the principles of patient involvement in HTA appears to put forward the patient organisation submission template as the beginning and the end of patient involvement across the assessment process. We believe that a written patient organisation submission template is just the first step in a range of patient involvement steps which could be taken. We believe that patients should also have the opportunity to observe assessments, as well as to provide in-person evidence or expertise to assessors. In the future, patients may also sit on an Assessment Advisory Panel (like the Public Involvement Network Advisory Group at the Scottish Medicines Consortium) or sit as assessors themselves (like the public members of CADTH's Drug Expert Committee).

IPPOSI suggests that guidelines should be provided as to how patient groups can use the patient submission form to provide data/experiences that capture societal impact, which can be formally incorporated into the HTA process. A corresponding re-weighting of the HTA process, to include this patient-submitted societal impact in the NCPE's final report, would be necessary in this regard.

IPPOSI recommends that the NCPE be more transparent as to how patient group submissions are used by permitting the submitting patient group to see the condensed submission that is passed on to the HSE Drugs Group from the NCPE.

IPPOSI believes that the patient organisation submission form should not be the only method by which assessments are informed of the patient experience. Although patients have a unique understanding of their condition and their treatment preferences, IPPOSI believes that the burden of collecting evidence illustrating the patient experience does not rest solely or predominantly with the patient. Patient input is a part of patient involvement in HTA, but the requirement for patient-based evidence is also an important part of involvement. The NCPE needs to think strategically about how and who can gather this evidence and how it can inform the assessment process. It is especially important that these issues are addressed in the context of rare disease communities, which may lack access to the required resources and/or patient populations. Later in the year, IPPOSI will be publishing a document which will expand upon this foundation.

Patient Organisation Database Registration Form

IPPOSI believes that the purpose of the patient organisation database (page 2) should be expanded to include a fourth purpose, namely "notifying relevant patient organisations of the final NCPE advice/recommendation 48 hours in advance of publication on the NCPE website".

In order to provide clarity to submitting patient organisations, IPPOSI believes that clear guidance should be provided to the patient groups using the form as to what weight each section has when the NCPE assesses submitted forms.

Patient Organisation Submission of Evidence Template

IPPOSI suggests:

- introducing two sections: Section 1 – organisations details, consent and existing question 3 & 7 and Section 2 – evidence and information and existing questions 1, 2, 4, 5, 6, 8 & 9
- page 3, including a box to explicitly request consent to share a copy of the submission publicly as part of the NCPE report
- page 3, including a box for the 'Date of submission'
- simplifying the language throughout and engaging NALA to assist with a review, for example on page 3, 'Product to which submission relates' could simply be 'name of medicine'
- moving question 3 & 7 to question 1 & 2. It seems more logical to ask people how they collected information at the start, rather than invite them to share the information, and in the middle of sharing, asking them how they did it.
- taking a second look at questions 2, 4, & 6 which all ask about unmet need and the advantages and disadvantages of one medicine over another. While we understand the nuances, the questions appear somewhat repetitive and the linkages unclear (even more so when read hand-in-hand with the guidance). We suggest reworking and we propose using more direct questions. Here the questions included in the HTAi template and the SMC template appear more suitable.

Guidance Document for completing the Patient Organisation Submission of Evidence Template

IPPOSI notes:

- page 8, guidance on completing question 2 invites patients to share experiences of current medicines, yet the phrasing of question 2 in the template does not help patients easily arrive at this interpretation
- page 9 & 10, guidance on completing question 2, 4 & 6 all invite patients to comment on unmet needs (as mentioned above, these questions might be rephrased in the template)
- page 10, guidance on completing question 3 & 7 might be minded to remind patient to identify any gaps in the information which they have provided, for example, are there sections of their patient community which they could not reach, are there sections of their patient community which have a specific set of needs which become less visible when the entire community is surveyed etc?

We welcome the worked examples which illustrate to patient organisations how they might report the findings of their quantitative and qualitative research.

General feedback

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

Nothing further to add

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