Patient Organisations

Submission of Evidence Template

Record of Updates

Version	Date	Description of changes
2.0	March 2018	

Please Note: This document may be updated periodically, therefore please refer to the NCPE website to obtain the most recent version

Patient Interest Group – Submission of Evidence Template

Patient Organisation Submissions

The National Centre for Pharmacoeconomics (NCPE) welcomes submissions from patient organisations as part of our commitment to ensuring the patients voice is heard in the Health Technology Assessment (HTA) process. We recognise that patients have unique knowledge about what it's like to live with a specific disease or medical condition. They can describe advantages and disadvantages of therapies, which may not be reported in published literature. They can tell us what they would most value from a new treatment.

Purpose of this template:

This template has been created to help patient organisations provide information for the assessment of a particular medicine. It provides prompts to draw out the unique patient knowledge that has the greatest potential to influence the decisions made by the decision maker, the Health Services Executive.

This submission template should be completed with reference to the *Completing a Patient Organisations Submission of Evidence Template: Guidelines for Patient Organisations* (link) available on the NCPE website. This document contains detailed information and advice on what type of information to include, and how to collect relevant information within your organisation. If your organisation has not previously registered as a Patient Partner, you must also complete and return the Database Registration Form.

The submission must be completed and returned to the NCPE within 90 days of the HTA commencing, as recorded on the NCPE website. This is to allow the NCPE to adhere to the timelines specified in the drug reimbursement process.

If you have any more questions after reading the guidelines (link), the NCPE can support you throughout the submission process.

Patient Interest Group – Submission of Evidence Template

You can email us at: info@ncpe.ie or phone: **01 4103427.** Please do not hesitate to get in touch, as we are here to help you.

Name of Patient Organisation	
Product to which submission relates	
Condition to which submission relates	
Contact details for this submission	*Please provide the name of a contact person, phone and email address*

Experience of patients, carers and their families

Question 1: Please provide information about how this condition affects the day-to-day lives of patients, carers and their families

In describing the impact of the health problem on the lives of patients, carers and their families, you should include information about:

- *symptoms,*
- *problems that patients experience carrying out every day activities or tasks where patients require assistance and support,*
- *the impact on personal /family relationships*
- *ability to work*
- *social life.*

Question 2: Which aspects of living with this condition, <u>NOT MET</u> by current treatments, do patients need most help with?

Question 3: Please can you provide details of how you have gathered information about the experience of patients, carers and their families
e.g. helpline, focus groups, published or unpublished research, user-perspective literature (e.g. personal stories), one to one discussions

Views of the patients, carers and their families on the difference the new medicine may make

Question 4: Please advise us of the expectations of patients, carers and their families on what the advantages or disadvantages of the new medicine might be compared to existing treatments
*We want to know **YOUR views** on the difference the new medication would make. For example-* ▪ *side effects,* ▪ *administration (liquid form easier to swallow, once a week injection better that daily injection, tablet form better than injection etc)* ▪ *better compliance (stick to treatment regimens and take medication as directed)* ▪ *less reliance on health care professionals or carers* ▪ *fewer visits to hospital* ▪ *shorter recovery times and able to return work* *Please list each medicine separately*

Question 5: If possible, please provide any information you might have from patients who have direct experience with the medicine?
This section is only to be completed by patients who <u>have</u> used the medicine being assessed (in the past or are currently on the medicine).

Question 6: To what extent will this new medication help to address the unmet needs you have previously highlighted in Question 2?
Unmet needs or gaps in treatment choices available to patients or people affected by the condition. Does the new medicine; • *Fill any of those gaps?* • *How does it fill those gaps?* • *Will it make a real difference?* • *How strongly do you support this medication?*

Question 7: Please provide details of how you gathered information about the new medicine
Gather your members views through focus group, an online or telephone survey or talking to members who have experiences/participated in a clinical trial of the new medicine

Summary Information

Question 8: In no more than 5 points please summarise the key aspects of your submission that you feel are most important

*Key messages you would like the decision maker to consider f*or example:

- *Quality of life impact: The biggest challenges of living with this condition are…*
- *Limitations of current treatments: Current therapies are inadequate because…*
- *Benefits of new treatment: This new medicine will be important for patients because…*

Question 9: Please provide any additional information which you believe would be helpful to the decision maker

For example ethical or social issues

Question 10: Please provide FULL details of any funding received from pharmaceutical companies within the last TWO years

(***Please note that hyperlinks to other documents or websites will not be acceptable***)

Pharmaceutical Company	Amount of funding provided	Purpose of funding

Question 11: Please provide details of any individuals who have had a significant role in drawing up your submission and have interests to declare

Name	Role in Submission	P	O	Description of Interest

*Please tick either **P,** to indicate a personal interest or **O** to indicate an interest related to the organisation of which they are part. The description should include details of:*

- *whether the individual is a shareholder or director of the pharmaceutical company who manufacture the medicine*
- *cash/kind received by person or organisation from the manufacturing company,*
- *whether the interest relates to the specific medicine under consideration,*
- *whether it relates to clinical trial work for the medicine under consideration.*

Thank you for your submission of evidence – we appreciate your time and effort