

# Patient Organisation Submission of Evidence Template



## Record of Updates

Version	Date	Description of changes
2.0	August 2018	
2.1	November 2018	Page 3: Update on need to highlight confidential information
2.2	October 2019	Page 3: Update to include date of submission

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



## Patient Organisation – Submission of Evidence Template

The National Centre for Pharmacoeconomics (NCPE) welcomes submissions from patient organisations as part of our commitment to ensuring the patient's 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*' 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, 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. Please send your submission to us as a Word document.

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



## Patient Organisation – Submission of Evidence Template

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

<b>Name of Patient Organisation</b>	
<b>Name of Medicine</b>	
<b>Condition treated by Medicine</b>	
<b>Contact details for this submission</b>	<i>Please provide the name(s) of one or more contact persons within your organisation, phone and email address</i>
<b>Consent for further contact from the NCPE</b>	<p><i>The NCPE wish to email the above named contacts in relation to this submission, to acknowledge receipt of the submission, to provide information on the outcome of the HTA process and next steps, and to send a feedback questionnaire on your experience with the process.</i></p> <p><i>Please tick this box if you are happy to be contacted by the NCPE for the above specified reasons. <input type="checkbox"/></i></p>
<b>Consent to share this document with the HSE Drugs Group</b>	<p><i>This submission must be shared with the HSE Corporate Pharmaceutical Unit, Drugs Committee and Leadership Committee in order to be considered as part of the decision making process.</i></p> <p><i>Please tick this box if you are happy for the NCPE to share this submission in its entirety with the HSE Corporate Pharmaceutical Unit, Drugs Committee and Leadership Committee. <input type="checkbox"/></i></p>
<b>Date of submission to the NCPE</b>	<i>Please include the date of submission to the NCPE (month and year is sufficient).</i>

Please ensure that **confidential information** is highlighted in yellow throughout this document



# Patient Organisation – Submission of Evidence Template

## Experience of patients, carers and their families

**Question 1: Please 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), questionnaires, one to one discussions*

**Question 2: 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*
- *financial impact*
- *emotional health*



## Patient Organisation – Submission of Evidence Template

**Question 3: Please describe your experience of currently available treatments**

**Question 4: In what aspects of living with their condition do patients need most help?**

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

**Question 5: Please provide details of how you gathered information about the new medicine**

*e.g. helpline, focus groups, published or unpublished research, user-perspective literature (e.g. personal stories), questionnaires, one to one discussions*



## Patient Organisation – Submission of Evidence Template

### Question 6:

For patients who have **NOT** used the medicine being assessed, what are the expectations of patients, carers and their families on the anticipated advantages or disadvantages of the new medicine might be compared to existing treatments.

*Keep in mind that this section is designed to be answered by patients who have never used the medicine being assessed.*

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 than 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*

**Question 7: If possible, please provide any information you might have from patients who have RECEIVED the medicine?**

- *How has it affected quality of life and ability to perform daily activities?*
- *What specific symptoms have improved?*
- *What side effects have occurred?*



## Patient Organisation – Submission of Evidence Template

**Question 8: To what extent will this new medication help to address the unmet needs you have previously highlighted in Question 4?**

*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?*

### Summary Information

**Question 9: In no more than 5 points please summarise the key aspects of your submission that you feel are most important**

*This section is included in the main body of the NCPE report to the HSE. Summarise key messages you would like the decision maker to consider for 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...*



## Patient Organisation – Submission of Evidence Template

**Question 10: Please provide any additional information which you believe would be helpful to the decision maker**

*For example ethical or social issues, data you have collected on societal costs of the condition, and costs of not treating the condition.*





# Patient Organisation – Submission of Evidence Template

## Declarations

**Question 11: 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 12: 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 applicant company*
- *cash/kind received by person or organisation from the applicant 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**