COMPLETING A PATIENT ORGANISATIONS SUBMISSION OF EVIDENCE TEMPLATE: GUIDELINES FOR PATIENT ORGANISATIONS

FOR HEALTH TECHNOLOGY ASSESSMENT AND APPRAISAL OF MEDICINES

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

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1.0 Introduction

1.1 Purpose of this guideline

This guideline is designed to help patient organisations like yours complete the NCPE *Patient Organisations Submission of Evidence Template* to provide input to an assessment of a new medicine. You will find guidance on what information we are looking for within the template and how to collect and report that input. While this guideline provides guidance on collecting and reporting information from surveys and interviews, patient organisations should not feel that they must undertake a survey or conduct interviews to successfully complete the submission template. Patient organisations may already possess the information required to complete the template, for example through existing helpline or chatroom logs, blogs, focus groups or other interactions with your membership. If not, this guide provides you with an overview and step-by-step approach to collecting and presenting patients' and carers' experiences, needs and expectations.

If you have any more questions after reading this guide, the NCPE can support you throughout the submission process. You can get in touch by emailing info@ncpe.ie or by phoning 01 4103427.

2.0 NCPE

2.1 About the NCPE

The NCPE are a team of clinicians, pharmacists, pharmacologists and statisticians who evaluate the benefit and costs of medical technologies and provide advice to the Health Services Executive (HSE). Our aim is to provide impartial advice to help the HSE provide the most effective, safe and value for money treatments for patients. Our advice is for consideration by anyone who has a responsibility for commissioning or providing healthcare, public health or social care services.

The NCPE uses a decision framework to systematically assess whether a technology is cost-effective. This includes clinical effectiveness and health related quality of life benefits, which the new treatment may provide and whether the cost requested by the pharmaceutical company is justified. This is done through assessment of evidence submitted by manufacturers and independent systematic review. We also obtain valuable support from clinicians with expertise in the specific clinical area under consideration. In addition, information from patient organisations is gathered about how people are affected by the condition and the impact of the new medicine on patients and their carers.

Following the recommendation from the NCPE, the HSE examines all the evidence which may be relevant for the decision; the final decision on reimbursement is made by the HSE. In the case of cancer drugs the NCPE recommendation is also considered by the National Cancer Control Programme (NCCP) Technology Review Group.

2.2 The NCPE assessment process

The NCPE conducts the health technology assessment (HTA) of pharmaceutical products for the HSE in Ireland. Since September 2009, in collaboration with the HSE Corporate Pharmaceutical Unit (HSE-CPU), we now consider the cost effectiveness of all new medicines following receipt of an application for reimbursement. In practice, all medicines will be subjected to a preliminary rapid review. High cost products and those with significant budget impact will be subjected to formal

pharmacoeconomic assessment. Similarly, products where there is a query in relation to value for money will also be selected for formal pharmacoeconomic assessment. The rapid review process takes approximately 4 weeks and the formal pharmacoeconomic assessment takes 90 days. Following formal pharmacoeconomic assessment, a full appraisal report outlining NCPE conclusions and recommendations is sent to the HSE-CPU to support evidence-based decision-making on reimbursement. Information on cost-effectiveness of the technology over a threshold-range up to €45,000/QALY is provided.

3.0 The HTA Process and Patient Organisations Submission of Evidence Template

3.1 What is an HTA?

HTA stands for Health Technology Assessment. This is a systematic process that seeks to determine the value of a health technology (such as a new medicine) compared to health technologies that are currently used. Experts review evidence from clinical trials and may also consider other scientific evidence, economic evidence, information on the way services are currently organised, social and ethical impacts of the health technology on the health care system and the lives of patients, and patient input. Its main purpose is to inform decision making by health care policy makers, for example about whether a medicine is reimbursed or recommended for use for certain patients in the health service.

3.2 What is a Patient Organisations Submission of Evidence Template?

The patient organisations submission of evidence template is a document that enables patient organisations to provide suitable patient and carer input to the assessment of a particular medicine. Strong submissions provide clear facts, information and summaries of experiences to give a concise, accurate and balanced overview of a range of patients' and carers' perspectives. The purpose of the submission is to identify important aspects of the medicine that are:

- not identified or well presented in the published literature, or
- not well captured in quality of life measures or other outcome measures that have been used in clinical trials and other research studies, or
- not well known and/or understood by experts in HTA and decision makers

The submission is also an opportunity to identify the priorities and preferences of patients and what the added value of a particular medicine maybe to them.

3.3 How is your submission used within the HTA review process?

Understanding the experiences and perspectives of patients and their carers is key in making recommendations for medicines under review. Patients can provide unique knowledge about what it is like to live with a condition and can explain advantages and disadvantages of therapies that may not be available in the published literature or captured by quality of life or other known measures.

Your efforts in collecting these experiences will provide valuable information for the HSE Drugs Committee. It is important that the HSE understands what matters most to patients (and their carers) when they make recommendations about the reimbursement of medicines.

3.4 What is involved in contributing to the HTA review process?

3.4.1 Register as a Patient Organisation

To be part of the HTA review process, patient organisations may join our patient organisations database. This is very straightforward to do. You complete a registration form, providing details about your patient organisation. It is your responsibility to ensure registration details are up to date each time you provide a submission. You can either register at the same time as you send your first submission, or in advance. The form can be found on the "Patient Information" [link] page of our website.

We accept submissions from patient organisations which are constituted from small local support groups to large national voluntary organisations. **We are unable to accept submissions from individual patients.**

3.4.2 Provide a Patient Organisation Submission

When a HTA is commissioned by the HSE, the NCPE will email the relevant patient organisation(s) in the database, inviting them to complete the Patient Organisation Submission of Evidence Template that is available to download from our website. If a patient organisation is not registered on our database, we will contact IPPOSI (Irish Platform for Patient Organisations, Science and Industry) who may invite relevant members to make a submission to the NCPE. The NCPE website and social media platforms (e.g. Twitter) will simultaneously invite relevant patient organisations to submit on the topic.

The input you provide is included in the HTA to provide a patient/carer perspective in the assessment process. Your input will provide valuable information for the HSE Drugs Committee in understanding what matters most to patients/carers when they make recommendations about the reimbursement of medicines.

3.5 How to access the Patient Organisations Submission of Evidence Template and timeframe for completion

You can find the *Patient Organisations Submission of Evidence Template* on the "Patient Information" page of our website [link]. If you have any problems accessing the electronic version of the form, you can contact the NCPE to either email or post a copy to you. 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.

The NCPE can support you throughout the submission process, and can be contacted by email (info@ncpe.ie or phone (01 4103427) if you have any further questions.

3.6 Planning and completing your submission

Completing a submission takes some time and effort, but it is an opportunity for you to provide valuable information about patient and carer experiences. Putting in time to plan your submission can help you be more efficient in collecting the information needed and completing the template. During the planning phase, you should decide whether you need to gather new information from patients and carers (e.g. via surveys or interviews), or whether you already have the necessary information to complete the submission form.

3.6.1 What information should you include in your submission?

We want to understand the experiences of those living with or caring for people with the health condition for which the medicine being assessed is used. To help you provide the most useful information, Table 1 offers suggestions on what to include in your submission and things to consider when presenting your information.

It is helpful to look at the *Patient Organisations Submission of Evidence Template* (Appendix 1) which also contains prompts while considering the information in this table.

An example of a helpful submission can be found on our website. [link to past submission]

It is important to report on the experiences of many of the individuals living with this condition, rather than exceptional cases. Focus on quality of life impact to patients and carers, rather than cost or clinical effectiveness, as these issues are both comprehensively covered by other parts of our appraisal process.

Please remember to be clear and concise. It is very important that the submission is balanced and acknowledges any shortcomings with the new medicine, as well as the advantages.

Table 1: What to include in your submission

Section of the input template	Considerations
Experiences patients have with this condition Question 1	• Report on the experiences of **many** of the individuals living with this condition, rather than exceptional cases. • Describe the range of experiences, including what is going well and what is not, and if experiences might vary by different subgroups of patients. • Include information about symptoms, problems experienced with carrying out every day activities or tasks where patients require assistance and support, effects on the ability to work and on social life. • Financial impact such as loss of earnings or costs associated with treatments/travelling to appointments.
Impact of the condition on carers/families Question 1	• Report on how the patients' condition and treatment have affected relationships with carers/families and how it has affected carers/families and their daily activities. • Report on how the way current treatments are given impact on carers/families (e.g. driving patients to hospitals or special facilities to receive treatments or tests, etc.)
Patients' experience with their current therapies Question 2	• Report on the range of experiences with **current** therapies (e.g. medicines, surgery and other procedures, medical devices, radiation, physical therapy, rehabilitation, palliation) to understand whether all aspects of the patients' condition are being managed. • Extent to which current treatments control or reduce the most

	challenging aspects of the condition. • The most important benefits of current treatments. • Side effects from treatments which are difficult to tolerate. • Concerns about long-term use of current therapy. • Identify specific unmet needs with current treatments. • Be specific about what is going well and what is not, and if experiences might vary by different subgroups of patients. • Challenges in taking it as prescribed (e.g. swallowing the pill, self-injecting, use of a device to deliver the medicine, taking after food) • Ways in which the dosing is modified compared to what is prescribed (e.g. dividing the dose to avoid unwanted side effects, missing doses to fit into daily life).
What are the expectations for the new medicine? **Question 4**	• Consider information about the new medicine. This information can be obtained from patient information leaflets (PILs) which are freely accessible via www.medicines.ie or www.hpra.ie. • Keep in mind that this section is designed to be answered by patients who have never used the medicine being assessed. • Comment on the **anticipated** impact of the medicine being assessed and the desired outcomes of using this medicine as compared to their current therapy. Be as specific as possible, e.g. what symptom is anticipated to improve or what aspect of quality of life could be improved. Try to describe what "better than current therapy" might look like. • It is important that the submission is balanced and mentions any expected disadvantages or negatives about the medicine compared to current medicines. Explore whether patients are willing to live with some side and late effects in return for some benefits of the new medicine and, if so, which side effects. Are there disadvantages with regards to how the medicine is administered and by whom etc.? • Comment on patients' unmet needs on current therapies, and what major areas of change they would like addressed.
What experiences have patients had to date with the new medicine? **Question 5**	• This section is only to be completed by patients who have used the medicine being assessed (in the past or are currently on the medicine). • Some patients may currently be on the medicine being assessed. If this is the case, please describe their experiences in this section (not in 'What are the expectations for the new medicine?' of the input template). • The purpose of this section is to get a better understanding of

	the **advantages and disadvantages** of the specific medicine, and to learn how it has affected patients' quality of life/everyday life, patient reported outcomes. Be as specific as possible, e.g. what specific symptoms have improved, what specific side effects have occurred and what aspects of quality of life have been impacted?
How will the new medicine address unmet needs? Question 6	• This question relates to unmet needs or gaps in current treatment choices that are available to patients or people affected by the condition. • Will the new medicine fill any of these gaps? • How does it fill those gaps? • Will it make a real difference to patients' lives? • How strongly do you support this medicine?
Information gathering Question 3 and 7	• Mention how information was obtained (e.g. online surveys, interviews, focus groups, etc.). • Include the number of participants who contributed information to your submission, and if possible some of their characteristics (e.g. disease severity, sex, age). • The NCPE are looking for patient and carer experiences and not references to literature or printed sources (e.g. statistics), since this type of information is already reviewed in other parts of the medicine review process.

3.6.2 What information is not necessary?

We are aware that your time is valuable and there is limited space in the template, therefore, we want to help you focus on what is most useful to the medicine assessment process. Table 2 lists information that you do not need to provide.

Table 2: What you do not need to include in your submission

Not necessary	Reason
Clinical or Scientific evidence	As part of the process for assessing the medicine, the assessment team conducts a thorough and systematic search for the available scientific evidence about the medicine; therefore, you do not need to provide this information. However, if you have views about the interpretation of a paper or a particular clinical trial, we would be happy to hear them.
Summarised or reworded information from sources other than patients or carers (e.g. clinicians or other healthcare providers, manufacturers)	The purpose of the patient group submissions is to collect input from both patients and their carers. Input and feedback from clinicians and pharmaceutical manufacturers is received separately.

The same messages repeated under different template headings	Sometimes it may be difficult to assign information to only one section of the input template. Please ensure that you are answering the specific question under each section and not repeating information to 'fill up the space'. We want to ensure that only the most relevant input is obtained in order to guarantee the best recommendations possible for the medicine being assessed.

4.0 How to collect the required information for the submission template

The type of information you collect will depend on the questions you want to answer. Information can be grouped into two categories: **quantitative** (numerical information) and **qualitative** (descriptive information).

Quantitative information

Quantitative information is input that is either counted or measured, such as:

• How much time do you spend getting to your appointments?

• How long does the treatment work for?

• How many treatments have you been on?

One common way to collect this type of information is by using closed questions within surveys, where answers are selected from a predetermined set of responses, for example using ratings on a numbered scale or multiple choice. You can then report the average response or how many times a particular response is chosen.

Qualitative information

It is also important to collect the thoughts, opinions, stories, and feelings of patients and carers. This input is described as qualitative information (descriptive information) and answers questions, such as:

• What challenges have you encountered while managing the side effects of the person you are caring for? For example, it is difficult to get to a hospital or that special equipment or specialists are required that are only available in particular centres.

• Why is it difficult to access your current treatment?

• Can you describe how the treatment would improve your quality of life?

There are many ways to collect qualitative information. Some are very simple and quick to do, for example posting a question on a social networking website, such as Twitter or Facebook, or online

discussion forums. Electronic questionnaires can also be an easy and convenient way to collect key information. You can also use group discussions, interviews or open-ended questions in surveys. These allow participants to explain their experiences in their own voice. Whichever methods you choose, it is important to track and record how you generate your information for inclusion in the submission.

5.0 How to summarise the information for the submission template

The way you present this information will depend on the types of questions that you asked. Remember that the HSE Drugs Committee is looking for an overview of experiences or themes. The way you present quantitative information (closed-ended questions in surveys) is different from how you should present qualitative information (descriptive, open-ended questions in surveys, and interviews).

5.1 How do you summarise the information that can be presented in numbers (quantitative information)?

The quantitative information you collect will mostly come from closed questions used in your survey. To summarise data, it is helpful to combine responses as averages, frequencies or counts (i.e. number of people) or proportions (i.e. percentages). It is best to keep the statistics simple.

Quantitative information can be presented in sentences or as a table. Depending on how much data you have, it may be easier to use a table which allows you to present a large amount of content in a small amount of space. These examples present both methods.

Example 1: Summarising quantitative information in text

Those who completed the survey ranked 'infections' as the most important, with 71.8% (total number participants = 22) rating it as 10, a 'very important' aspect of controlling xxx cancer. 'Infections' were followed by 'kidney problems', 'pain', 'mobility', 'neuropathy', 'shortness of breath', and 'fatigue'. In all cases, more than 50% of respondents rate these aspects as a 10, 'very important' to control. In all cases the rating average was greater than 8, which meant that all listed symptoms were considered important.

Example 2: Using tables to report quantitative information

Symptom or problem related to xxx cancer	% of respondents who rated a '10'	Number of respondents	Rating average (rounded)
Infections	71.8%	22	9
Kidney problems	68.2%	21	9
Pain	64.3%	22	9
Mobility	59.7%	22	9
Neuropathy	56.7%	22	9

Shortness of breath	51.0%	20	8
Fatigue	50.9%	22	9

5.2 How do you summarise the descriptive (qualitative) information?

Regardless of how you collected input, patient and carer experiences need to be summarised. A great way to present descriptive information is to include quotes from participants to highlight or illustrate key points. Before you choose quotes, it is important to analyse all of your qualitative information as a whole. If you begin by selecting random quotes you may not realise that there are specific themes that a majority of participants collectively discussed.

Qualitative information can come either from:

- Responses collected through interviews; or
- Open-ended questions asked in your surveys.

TIP: Use the voice of the participant

Remember that findings should be in the voice of the participant e.g. what participants expressed, reported, said, described, etc. It should be made apparent that they were taken directly from the participants' experiences and are not the opinion of the interviewer.

Example 3: Using quotes to support themes

For an overall theme called 'accessibility', with labels 'distance to place of treatment' and 'financial burden', a response may look like this:

Patients reported difficulties with respect to access to treatments. The most widely discussed factor that affected access to treatment was financial burden, given that the treatment was not covered by some private health plans. Some patients reported that the particular treatment was difficult to access because it was only available at a centre far from their home, which made distance an important factor that limited accessibility. As described by one patient:

> "*It's frustrating that my therapy isn't easier to access because I find that it is working well. I just get so tired having to drive so far to be able to receive my IV medicines at the hospital. This is costing me a lot of time and money, especially as we have to pay for some of my medications out of pocket.*"

5.3 Summary of the qualitative or quantitative analysis process

1. Do an initial read through of all documents (e.g. notes) to become familiar with the information.
2. During the second reading, highlight sections of text with a label that you think is relevant and representative of what is being said. Try to focus on those aspects of the information that relates to the purpose for collecting patient input (e.g. describes patient and carer experiences with the condition, current therapy or a new medicine).
3. Once you have labelled your documents, look for common themes.

4. Review your themes. If some themes do not seem to fit on a second review, consider either reassigning the response or creating a new theme. Alternatively, it may become clear that several themes can be combined into a single idea (i.e. if they are ultimately getting to the same topic or point).

6.0 Reporting your findings in the submission template

To increase the amount of space you have to report responses, remove any instructions and examples provided in the *Patient Organisations Submission of Evidence Template.*

You are now ready to present the patient and carer experiences in the template. Remember there is no right or wrong way to report your responses. Just remember to highlight important experiences from a group of participants, rather than exceptional cases. A good way to do this is to describe general trends and then present a quote to support the finding. This section provides examples of helpful responses on:

- Experiences patients have with this type of health condition
- Impact on carers
- Patients' experience with current therapies
- Information gathering
- What are the expectations for the new medicine?
- What experiences have patients had to date with the new treatment?

TIP: Be concise yet descriptive

It may feel like there is limited space to report responses, but this reporting structure ensures that you are being clear and concise when providing meaningful and descriptive information so that your submission has maximum impact

TIP: Use plain English and avoid technical language whenever possible

Please don't identify patients or carers by their full names. Information about individuals must be kept confidential by you to protect privacy.

6.1 Examples of Helpful Responses

6.1.1 Experiences patients have with this type of health condition (Question 1)

Below is an example of how you can use the information you have gathered from a survey to provide the assessment with an understanding of some specific impacts of the condition on patients' lives.

According to the survey, xx% of patients are negatively impacted by their [condition] in their day-to-day life. Only xx% indicated no major change. The respondents indicated that the biggest impact has

been on their ability to work or volunteer (xx%). In many cases, individuals retired early or went on extended leave due to the increased fatigue and pain experienced living with the disease.

> *"Symptoms and problems at this time impact my day-to-day life and quality of life to a great extent. In the past xxx months I have found that I needed to build up stamina to cook and many times I overexert myself with any day-to-day housekeeping activities. I still need to rest for a minimum of 1-2 hours each afternoon and go to bed between 8 and 9 each evening. The limitations of this disease are frustrating and can bring about fits of depression."*

As a patient organisation, you know how important it is to understand how patients are dealing with their condition on a daily basis. Your goal is to highlight how the diagnosis of the [condition] impacts patients' lives by emphasising general trends and providing quotes, like in the example above. The focus is not to present information you would find in a textbook or scientific article. You are being asked to provide patient and carer experiences on a personal level.

6.1.2 Impact on carers (Question 1)

Carers' experiences are an essential component to understanding the impact of the therapies for the condition on the daily routines, quality of life, relationship with family/friends, and stress and mental health of those dealing with the condition and themselves. Being able to discuss these challenges is the key goal of this section. Usually carers put on a strong face in front of patients, in order to ensure that they are a stable form of support, so patients may not have an accurate description of their true feelings. It is best to ask these questions directly to carers rather than through the patient survey.

Below is an example of how you can use the information you have gathered from carers to describe and provide an understanding of some specific impacts that caring for a patient with the condition has on carers' lives.

Carers were asked to rate the impact of providing assistance and care on various activities, using a scale of 1 to 7 with 7 being most impacted. xx% (N= aa/bb) of responding carers rated impact on the ability to travel as 7 and xx% rated impact on ability to work as 7. Carers rated all activities in the list as 5 or higher on average. Other impacted abilities included the abilities to spend time with family and friends, to fulfil family obligations, to exercise, to volunteer and to do household tasks. In addition, xx% (N=cc/dd) of carer respondents ranked emotional/physical challenges related to fear, anxiety, depression, insomnia, fatigue, personal isolation and negative health effects as the main challenge. They also reported other challenges: helping the patient cope (xx%) and balancing daily routine (xx%).

> *"I was 21 years old at the time and the primary carer for my mother. I was faced with the following challenges: depression, inability to care for myself (healthy eating, etc.), a lack of resources caused me to feel lost and uninformed. The biggest challenge was financial. My mother was no longer able to work and so I had to work to support the household while caring for her."*

The above example reports responses given by carers, including how they rated the impact of providing assistance and care on their various activities and how they ranked various challenges to them. It also includes a quotation from a carer that illustrates the impact of caregiving.

6.1.3 Patients' experience with current therapies (Question 2)

This section should focus on experiences from patients who have never used the medicine under review.

xx% (xxx respondents) of individuals living with [condition] and their carers indicated that they did experience some hardship in accessing treatment for [condition]. Hardships included:

- *the need to pay out-of-pocket for treatments*
- *the need to travel long distances to receive treatment*
- *the need to meet significant criteria to qualify for the treatment*
- *discontinuation of the treatment when the funding ran out*
- *lack of access through the hospital or private health plan to necessary treatment.*

Patients may be on one of many treatments, yet they may describe similar experiences across treatments.

6.1.4 Describing information gathering (Question 3 and Question 7)

Below is an example of a useful way to describe how you collected the information.

[Patient Organisation] conducted a participant [anonymous] online survey, which was sent by e-mail to xxx patients and carers across xxx who were on the [Patient Organisation] database. Respondents of the survey were from across xxx [xxx respondents were from outside of xxx.].

There were a total of xxx respondents; of this total, xxx were individuals living with the condition, and xxx were carers. A total of xxx respondents indicated that either they, or the person they provide care for, used the medicine under review for their condition.

This section can be short and concise. The most important information to get across is:

- The method used to collect patient and carer experiences; and
- The number of participants (divided into patients and carers) who were recruited (e.g. who were sent the survey), who participated, and who are on the treatment under review.

6.1.5 What are the expectations for the new medicine (Question 4)?

If patients have no experience using the new medicine, you should report what their expectations are for it.

- *In considering new treatments, xx% of the respondents (n=xxx) indicated that it is 'extremely important' to see an improvement in their condition (symptoms and signs).*
- *xx% of the respondents (n = xxx) indicated that it was 'extremely important' to realise an improved quality of life when considering a new treatment.*
- *When asked about whether it was important to evaluate the average period of the expected benefit, again, the respondents (xx%) (n = xxx) indicated an extremely high degree of importance to this decision.*

- *In considering a new treatment, xx% of the respondents (n = xxx) indicated that they were willing to tolerate a moderate to high severity of side effects (xxx respondents in the range of 5 to 10, where 10 = significant side effects).*

Bullet points are a quick and easy way to discuss a number of topics in a small amount of space. In the example, the patient group was able to describe the key expectations of the treatment under review, in combination with numerical information (e.g. percentages). It is helpful to include rating scales when reporting numerical information to help the reader understand the response.

6.1.6 What experiences have patients had to date with the new medicine (Question 5)?

It is important to always provide the specified response under the correct section. Many patient organisations tend to combine the *expectations* of the treatment under review with the *experiences* of those currently on the treatment.

A total of xxx respondents had direct experience with the medicine under review in which xx% were accessing it in a late line of treatment. xxx respondents were receiving it in the second line. When asked about the side effects experienced with the treatment, respondents mentioned fatigue, nausea, diarrhoea, and high blood pressure. In rating the side effects of the treatment, xx% of xxx respondents assigned a score of low to moderate (respondents in the range of: 1, no side effects at all, to 4) and xx% indicated that the side effects were debilitating (respondents in the range of 8 to 10, with one of these respondents (xx%) rating the side effects at 10, debilitating side effects that impact daily life). Of the side effects experienced, respondents indicated xx% were willing to accept them, xx% felt some were acceptable and others were not, one person (x%) had an adverse event and discontinued usage; xxx respondents did not answer directly.

The above example incorporates a number of points into a small paragraph. This response highlights:

- The number of respondents who had direct experience with the treatment under review
- The key side effects experienced by patients
- The percentage of respondents who were in each section of the rating scale

Appendix 1: Patient Organisations Submission of Evidence Template

[insert sample template here]

Appendix 2: Key ethical considerations for patient groups collecting and reporting information for HTA submissions

Purpose

To complete submissions for health technology assessments (HTAs), patient groups may gather information about patients' and carers' experiences of living with a condition, preferences and unmet needs for treatment. This may involve (but is not limited to) conducting interviews, focus groups and surveys and collecting input using social media. As a result, patient groups need to think about the ethical and legal issues involved when engaging with people and using their personal information. This document aims to help your patient group identify and respond to those issues. It is not mandatory guidance and can be adapted to meet your needs.

Background

Many patient groups do not have the time, resources or training to undertake the rigorous, systematic investigations required for academic healthcare research. But most patient groups do have a network of patients and caregivers that they can collect information from to inform their HTA submissions.

Collecting information of relevance to HTAs can touch on sensitive issues and has the potential to impact on personal privacy. This means there are ethical issues that patient groups should consider when undertaking these activities.

When gathering information from patients and caregivers, it is important to protect their personal safety, dignity, rights and well-being. A balance is needed between fairness in providing the opportunity to have a voice in the HTA process and overburdening people with requests for information and feedback. This document provides some guidance on:

- The need for the activity
- Inclusivity
- Informed consent
- Ensuring anonymity and confidentiality
- Data protection and privacy

Issue	Consider
1. Need for activity	• Do you already have information that can answer the HTA submission questions? • Have you found a gap in the available information? Does this gap mean you need to collect new information? • Have you planned and tested the way you will collect the information to make sure it meets your needs?
2. Inclusivity	Have you taken steps to reach out to as broad a population (including vulnerable groups) as feasible?
3. Informed consent	Is each person who is asked to take part competent to consent? If yes, have they been told: • how the information being collected will be used and shared? • who is collecting the information? • that they can refuse to take part, stop taking part at any time, or choose not to answer all the questions without this being held against them? • any perceived or potential conflicts of interest of the person(s) or group collecting the information? • what is involved in taking part (how much time, what will be discussed, possible use of their actual words or stories in the submission)? • the realistic potential benefits? • the risks or potential harm of taking part (such as distressing thoughts, sense of stigma)? • that they will not be able to be identified from the submission? Have the people taking part: • knowingly given consent for the collection and use of their information for this submission? • been asked if they consider themselves to belong to a vulnerable population (which will be noted)? • declared their own conflicts of interest? • knowingly given consent for the information collected for the submission to be used again for other submissions? Does your patient group have: • a process in place to destroy information given by people who

	choose to no longer take part (if permitted by law)? • steps in place to reduce any potential risks to the people taking part?

4. Ensuring anonymity and confidentiality	Have you put in place a process that makes sure that people taking part:
	• cannot be identified in the submission, such as:
	  ○ not using the real names of those taking part
	  ○ using initials, letters or numbers
	  ○ not collecting any identifying information?
	• are told the outcome of the HTA in a way that does not reveal to others that they took part?
	
	Do the people taking part understand:
	• the guarantees given about concealing their identity?
	• how their information will be stored and kept safe?

5. Data protection and privacy	Does your patient group have a data protection policy you need to follow?
	• Does your region/country have a data protection or privacy policy you need to follow?
	• Have you informed the people collecting the information that:
	  ○ responses must be stored securely
	  ○ they must not discuss or report responses in a way that would allow someone to be identified?
	• Have you locked the data you collected and reported in a drawer or password protected it?
	• Have you backed up the data you collected and reported?

This information has been taken from Health Technology Assessment international (HTAi). A longer version of this guide is also available, see: *Key Ethical considerations for patient groups collecting and reporting information for HTA submissions: Long Guide* if further details are required www.HTAi.org.

Appendix 3: Useful resources

Health Technology Assessment International (HTAi) provides a variety of educational and learning tools for helping patient organisations capturing patient and carer experiences.

Find out more at: www.htai.org/index.php?id=744