NCPE
National Centre for
Pharmacoeconomics, Ireland

TIPS FOR COMPLETING A PATIENT ORGANISATION SUBMISSION OF EVIDENCE TEMPLATE

FOR EACH ASPECT OF THE SUBMISSION:

Describe the number of patients from whom input was obtained

Include patient demographics (age, sex, ethnicity, disease severity)

Exclude information on statistics and scientific published references

Describe experiences of patients/caregivers that REFLECTS THE POPULATION WHO WILL USE THE PROPOSED DRUG

Including specific and detailed experiences can be very helpful in providing context

SECTION 1

INFORMATION GATHERING – Q1 and Q5

- Describe the methods used to collect data
- How many patients are there from each method of data collection?
- Please include data/insights beyond what is already published in the literature.

Q1 - If possible, include input from patients who received the drug in question and patients who received no treatments/other therapies in a similar clinical context. Input from carers is also valuable.

IMPACT OF CONDITION ON PATIENTS/CARERS/FAMILIES – Q2

- How are daily functions and quality of life affected?
- Describe the range of experiences – what is going well and what isn't?
- Is there a financial impact?
- Have relationships been affected?
- How do current treatments impact on carers/families?

Q2 - Information should be obtained directly from patients/carers/families.

Direct quotes can be very helpful.

If possible report on the experiences of many individuals rather than exceptional cases.

PATIENTS EXPERIENCE WITH *CURRENT* STANDARD TREATMENT – Q3

- How do patients/carers describe some of their experiences with current therapy?
- How effective is it in reducing/controlling side effects?
- What are the most important benefits?
- What are the side effects which are difficult to tolerate?
- Concerns about long-term use of current therapy.
- Be specific about what is going well and what is not, and if experiences might vary by different subgroups of patients.
- Are there challenges in taking it as prescribed?
- Is the dosing modified compared to what is prescribed?

Q3 - If no comparative treatment exists discuss best supportive care.

WHAT ASPECTS OF LIVING WITH THEIR CONDITION DO PATIENTS NEED MOST HELP? – Q4

- What concerns are unaddressed by current treatment?
- Identify major areas of change you would like addressed

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SECTION 2

EXPECTATIONS FOR *NEW* TREATMENT – Q6

- What is the **anticipated** impact and the desired outcomes of using this medicine compared to current therapy
- Include any expected disadvantages or negatives with the new treatment compared to current treatment
- How will the new treatment address unmet needs described in Q4
- Include information on quality of life, daily functioning, side effects, etc.

Q6 - **Information should be obtained from patients who have NO experience with the drug**

EXPERIENCES WITH *NEW* TREATMENT TO DATE – Q7

- How many patients have direct experience with the drug being assessed?
- How has it affected QoL and ability to perform daily activities?
- What specific symptoms have improved?
- What are the key side effects? Include side effects that are most debilitating to quality of life, AND side effects that are tolerable.
- What concerns are unaddressed by new treatment?
- Are there any accessibility and financial implications?
- Include information about how patients with experience are accessing the drug under review.

Q7- **This section is only to be completed by patients who have used the drug being assessed (in the past or are currently on the medicine)**

HOW WILL THE *NEW* TREATMENT ADDRESS UNMET NEEDS? – Q8

- 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?

Q8- **Relates to unmet needs or gaps in current treatment choices that are available to patients or people affected by the condition, identified in Q4**

SECTION 3

SUMMARY – Q9

- This section requires special consideration to ensure that you are getting across your key messages
- Provide a 5 point summary of the KEY points
- Include QoL data, limitations of current treatments, benefits of new treatment

ADDITIONAL INFORMATION – Q10

- Are there any additional data which you believe may be helpful to the decision maker
- Include ethical or social issues
- Data on societal costs of the condition, costs of not treating the condition etc.

SECTION 4

FUNDING FROM PHARMACEUTICAL COMPANIES – Q11

- Full details of all funding received for EACH project within the last TWO years should be highlighted.

DECLARATIONS FROM INDIVIDUALS INVOLVED IN THIS SUBMISSION – Q12

- Relates to individuals that are a shareholder, director or employee of the applicant company, or are in receipt of payments direct or indirect from the applicant company.
- Mention cash/kind received by person or organisation from the applicant company, including expenses.
- Whether the interest relates to the specific medicine under consideration
- Whether it relates to clinical trial work for the medicine under consideration

Don't forget to send your submission as a **Word document** & highlight any **confidential information** in yellow