Briefing Book template for Medical Devices

EUnetHTA multi-HTA Early Dialogues

Last updated: 28-May-2019

This template is to be used by companies to submit an overview of the relevant information necessary to support a EUnetHTA multi-HTA Early Dialogue discussion on a medical device in the framework of EUnetHTA JA3.

Standard headings in the template should be used whenever possible. If it is considered necessary to deviate from the pre-specified headings due to product-specific requirements, alternative or additional headings/domains may be considered.

The bracketing convention stated below indicates whether the information to be included is mandatory or optional:

**Bracketing convention:**

*{text}: Required information;*

<*text*>*: Optional information to be given if applicable;*

*[text]: Explanation and guidance.*

**References convention:**

For citation of literature references, footnotes are preferred, alternatively the format (first author <et al.>, publication year) is recommended.

This document must be submitted in Word format. The recommended length of the briefing book is approximately 50 pages, not including annexes. Any essential, self-standing documents such as study protocols, reports etc. should be placed in the annex (section 4 of this template) or submitted as separate documents in Word or PDF format. Referenced articles should be submitted in full text versions including necessary article Annexes. The entire dossier should be provided in one single ZIP file where possible.



Briefing book template for Medical Devices

EUnetHTA multi-HTA Early Dialogues for Medical Devices

Briefing Book Version: {}

Date: {DD/MM/YYYY}

**Product**

Name: {}

Proprietary Name: {}

Reference Codes:

Class/Global Medical Device Nomenclature (GMDN) code: {}

Intended indication(s): {}

**Applicant / Company**

Company Name: {}

Address: {}

Country: {}

Contact Person Details

Title and Name: {}

Direct Telephone Number: {}

Email: {}

Alternate Contact Person Details

Title and Name: {}

Direct Telephone Number: {}

Email: {}

**Table of Contents**

[1. Summary 4](#_Toc9958201)

[1.1. Background information on the disease to be treated 4](#_Toc9958202)

[1.1.1. Overview of the disease/condition 4](#_Toc9958203)

[1.1.2. Treatment options 4](#_Toc9958204)

[1.2. Background information on the product 4](#_Toc9958205)

[1.2.1. Intended use 4](#_Toc9958206)

[1.2.2. Description of the medical device 4](#_Toc9958207)

[1.2.3 Mode of action 4](#_Toc9958208)

[1.2.4. Procedures required for use of the medical device 5](#_Toc9958209)

[1.2.5. Regulatory status of the medical device 5](#_Toc9958210)

[1.3. Status of clinical development programme 5](#_Toc9958211)

[1.3.1. Clinical development to date 5](#_Toc9958212)

[1.4. Post-launch evidence planned 6](#_Toc9958213)

[1.5. Economic evidence planned 6](#_Toc9958214)

[1.6. Product value proposition 7](#_Toc9958215)

[2. Questions and Applicant’s positions 7](#_Toc9958216)

[2.2.1. Clinical 9](#_Toc9958217)

[2.2.2. Financial 9](#_Toc9958218)

[2.2.3. Logistical 9](#_Toc9958219)

[2.2.4. Workforce 9](#_Toc9958220)

[2.2.5. Other 9](#_Toc9958221)

[3. References 9](#_Toc9958222)

[4. Annexes 9](#_Toc9958223)

# 1. Summary

## 1.1. Background information on the disease to be treated

### 1.1.1. Overview of the disease/condition

{}

[Population, relevant epidemiological data, information on natural history of the disease and evolution on treatment should be discussed. Ideally European data are expected; if not available, National data will be accepted.]

### 1.1.2. Treatment options

{}

[The Applicant should list all technologies (drugs, devices, procedures) that present relevant alternatives for the management of the pathology/intended indication (detailing stage, level of severity, line of treatment if applies) and discuss the current standard therapy with regard to the respective labelling status in Europe and North America. In the case of the existence of new technologies that are in advanced phases of development, this information should be included.]

## 1.2. Background information on the product

### 1.2.1. Intended use

{}

[The Applicant is asked to specify clearly the indication and the intended use of the medical device in development, as well as the aim of use (preventive, diagnostic, curative, palliative, symptomatic, disability/handicap compensation, patient empowerment, adherence…). The position of the medical device in the treatment algorithm should be proposed and described in a wide context (one or several positions could be possible). The target population of the medical device should be described as precisely as possible as well as relevant comparators.]

### 1.2.2. Description of the medical device

{}

[Technical characteristics of the medical device should be provided in a sufficient level of detail. A plan, drawing or photo can be included to provide insight into the characteristics or use of the medical device.

If the use of the device is associated with the use of other accessories, services and companion diagnostic (ex. software) this information should be provided and the description should be given. Technical limits (shelf-life, warranty period, etc.) of the device should be provided and discussed.]

### 1.2.3 Mode of action

{}

[Description of the mode of action in respect to the condition or disability should be given.]

### 1.2.4. Procedures required for use of the medical device

{}

[The frequency and the duration of use of the device should be described as well as the procedure related to its use. All the organisational aspects shall be included in the description. If the use of the device requires medical or paramedical intervention or assistance at any stage this should be indicated as well as a description of the procedure for training for patients and health care professionals (if needed). In case the procedure needs to be repeated in order for the treatment to be complete, the foreseen number of procedure repetitions should be stated as well as the optimal time between them. The same applies in case the procedure has to be split into more phases. Any obligations in terms of training, competence level, or level of activity for personnel should be discussed.]

### 1.2.5. Regulatory status of the medical device

{}

[Information should be given on the CE marking status of the medical device (or FCC Declaration of Conformity for the USA). In case the medical device has already obtained a CE marking, its classification should be stated. For products of class II and III details about the Notified Body should be given and the dossier submitted to the notified body should be provided, including a list of reported adverse events. However, strictly confidential parts of the dossier related to the device production process that are of no relevance for safety could be left out if justified by the company. In case the product is on the market, its reimbursement status should be given. The company should indicate whether a scientific advice has been received from other national or European institutions and provide minutes, or if it is planned at any further stage. Eventually, estimated timelines for market entry may be given if this information is available.]

## 1.3. Status of clinical development programme

{}

[This section should contain a summary of the clinical development plan of the medical device and give a clear idea of the stage of development of the medical device. Evidence obtained in the field of the intended use should be mentioned. Existence of trials supporting the use of the medical device in other indications should be mentioned for completeness.

Non-clinical development programme should be summarised if adequate (i.e. if information important to understand safety issues) on the case by case basis.]

### 1.3.1. Clinical development to date

{}

[Preliminary data on technical performance, efficacy and safety coming from trials that are completed or on-going should be presented if available. Safety data should address issues linked directly to the device as well as those related to the procedure needed for use of the device (if applicable). For each trial the design, comparator, number of subjects and description of studied population, results of the trial (or preliminary results of on-going trials if available) should be given. Study reports may be provided in annexes. Cross-links to annexes are recommended.]

1.3.2. Planned trials

{}

[This section should provide a comprehensive overview of all planned trials with the medical device to support its technical performance, efficacy, safety and consideration on patient-reported outcome and experience. (Please fill study overview tables in Annex 1 and 2 as well). One or more trials may be presented for discussion. For the trial(s) that is/are to be the subject of the early dialogue, at least a rationale and a detailed synopsis of the protocol(s) should be provided. The synopsis should contain key information on the objectives of the trial, trial design, patient population (inclusion and exclusion criteria), intervention, comparators (considering that differences can occur between EU countries), outcomes (primary, secondary etc.), flowchart, follow-up, methods of analysis, references to understand not only the statistical but also the clinical benefit of the product if available, etc. The need for specific training or equipment for the proper use of the device should be stated and the effect of training on short-term and long- term endpoints should be discussed. All relevant information should be given at a sufficient level of detail, together with justification for the choice made and a critical discussion of key issues.] All scales and scores that will be used for outcomes measurement should be presented and their validity should be commented.]

## 1.4. Post-launch evidence planned

[This section should contain the rationale for Post Launch Data collection i.e. to resolve uncertainties related to the safety and clinical effectiveness of the health Technology or uncertainties that may arise when the technology is adopted and implemented in real world practice. A synopsis should be presented detailing study objectives, design, target population, intervention, comparators, outcomes, flowchart, follow-up, method of analysis.]

## 1.5. Economic evidence planned

<>

[If the Applicant desires to discuss economic assessment as a part of the early dialogue, then all relevant information about the planned economic analysis should be provided.

The Applicant should state the scope of the planned economic analysis, clearly defining the research questions.

The Applicant should describe the main aspects of the economic analysis; in particular the Applicant should describe the type of analysis, the perspective, the time horizon, the population and the comparator(s) and a sensitivity analysis considering the evidence available or expected and the differences between the different EU Member States’ situations (use of resources, epidemiology…).

An outline of the structure of the model and key assumptions could be provided if available. Relevant published papers could be provided as annexes to the briefing book. Expected data sources and planned sensitivity analyses should be described. Trial endpoints used to derive the model health outcome should be stated where relevant. Tools used to measure resource utilization should be described.]

## 1.6. Product value proposition

{}

[The Applicant should explicit expected positioning and added benefit (medical and economic) of the medical device in the target population with the standard of care by filling table below.]

|  |  |
| --- | --- |
| Targeted Population | [Indication and Line of treatment] {} |
| Intervention | [Condition of use and concomitant treatment] {} |
| Comparators | [Based on current standard of care in EU] {} |
| Outcomes | Added benefit expected to be observed on following clinical outcomes:   * {} * {}   Clinical benefit to be translated into following economic outcomes:   * {} * {} |

# 2. Questions and Applicant’s positions

{}

[The Applicant should list all questions that will be discussed during the face-to-face meeting. Any subject pertaining to relative effectiveness, economic assessment or other aspects of the development can be addressed. Both clinical (pivotal trial(s) and post launch data collection) and economic areas can be covered or just one of them according to the preferences and needs of the company. It is expected that each ED addressed questions related to the choices made in the development concerning the population included in the trials, the usage of the technology, the comparators, and the outcomes.

The wording of questions should be clear and concise. Open questions are not acceptable. Given the timeframe, a high number of questions (i.e. more than 10) is not feasible to be discussed during the meeting. Questions should be ordered by area of expertise.

Each question should be followed by a separate explanation of the company’s position including a comprehensive justification of the chosen approach. Each position description should not be longer than 3 pages. Cross-references to the relevant parts of the briefing document or to annexes can be included if additional details are needed to support the argument.

* Clinical development and post-launch evidence studies questions:

[Regarding the format of questions, the Applicant is kindly asked to clearly separate questions on clinical trial from questions on post launch evidence studies. All questions should be presented following the PICOTS format:

1. Population

[Please add your Question number together with the question]

1. Investigation and Requirements for Specific Training or equipment
2. Comparator
3. Outcomes
4. Type of study
5. Time Span
6. Other questions related to clinical development and post-launch evidence studies]

* Economic development questions:

[All questions should be presented using the following format.

1. Population
2. Choice of comparator
3. Choice of economic model
4. Data used to populate the model
5. Time horizon and extrapolation hypothesis
6. Perspective (societal, healthcare related etc.)
7. Utility values
8. Resource utilisation data]

**2.3. Adoption**

<>

[Issues identified that may impede your product’s adoption]

### 2.2.1. Clinical

### 2.2.2. Financial

### 2.2.3. Logistical

### 2.2.4. Workforce

### 2.2.5. Other

# 3. References

{}

[This section should contain a list of all documents referenced in the text.]

# 4. Annexes

{}

[Any of the following documents should be attached to the briefing book, if applicable:

• Referenced articles in full text versions in English

• Trial protocols, summaries and reports

* Relevant clinical practice guidelines
* Previous scientific advice received]

**Annex 1: Overview of relevant completed clinical studies**

[Please specify/delete as necessary. Please provide as many tables as completed studies]

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Phase { II/III } study – Overview   |  |  | | --- | --- | | Study name/number | {} | | Short description | {} [Open/(double)blind, randomised, placebo/active control, intervention, study population] | | Study objective | {} [Comparison of effectiveness and safety of intervention vs. comparator in description of study population, quality of previous specific therapy] | | Start/End date  Study duration | [Start and end date of patient inclusion and of study treatment.  Date of analysis of primary outcome  Duration of the study] | | METHODS | | | *Population* | | | Inclusion criteria | {} | | Exclusion criteria | {} | | Centres | {} [Type and number of centres, geographic region] | | *Intervention* | | | Studied intervention | {} [Medical device, medical or surgical procedure, duration, requirements for specific training or equipment] | | *Comparator* | | | Comparator | {} [Characteristics of comparator, medical or surgical procedure, duration] | | Additional comparator | <> [Characteristics of additional comparator, medical or surgical procedure, duration] | | *Outcome measures* | | | Primary outcome | {} [Primary outcome measure (and timing of assessments)] | | Secondary outcomes | {} [Secondary outcome measures (and timing of assessments)] | | Supplementary outcomes | <> [Additional outcome measures (and timing of assessments)] | | *Study design* | | | Study type | {} [Parallel-group/cross over/factorial design, superiority/inferiority study] | | Study periods | {} [Duration of pre-randomisation, study, post-treatment periods] | | Size of study | {} [Estimated No. of randomised patients] | | Randomisation | <> [N:M , group allocation] | | Stratification | <> [Disease severity, prior therapy, geographic region, centres] | | Blinding | <> [Blinding for intervention, outcome assessment] | | Study flowchart | {} | | *Statistical analysis* | | | Statistical analysis plan | [Methods and Procedures used] | | Missing data management | <> | | Stratification | <> [Disease severity, prior therapy, geographic region, centres] | | Planned interim analyses | <> [Methods and Procedures used] | | RESULTS | | | Number of subjects analysed | {} | | Follow-up duration | {} | | Patients’ characteristics and group comparability | {} | | Primary outcome results | {} | | Secondary outcome results | {} | | Supplementary outcome results | <> | | Adverse events | {} | |

**Annex 2: Overview of planned clinical studies including the one requesting early dialogue**

[Please specify/delete as necessary. Please provide as many tables as planned studies]

Phase {II/III/post launch} - Study synopsis

|  |  |
| --- | --- |
| Study name/number | {} |
| Short description | {} [Open/(double)blind, randomised, placebo/active control, intervention, study population] |
| Study objective | {} [Comparison of effectiveness and safety of intervention vs. comparator in description of study population, quality of previous specific therapy] |
| Start/End date  Study duration | {} [Start and end date of patient inclusion and of study treatment.  Date of analysis of primary outcome  Duration of the study] |
| METHODS | |
| *Population* | |
| Inclusion criteria | {} |
| Exclusion criteria | {} |
| Centres | {} [Type and number of centres, geographic region] |
| *Intervention* | |
| Studied intervention | {} [Medical device, medical or surgical procedure, duration, requirements for specific training or equipment] |
| *Comparator* | |
| Comparator | {} [Characteristics of comparator, medical or surgical procedure, duration] |
| Additional comparator | <> [Characteristics of additional comparator, medical or surgical procedure, duration] |
| *Outcome measures* | |
| Primary outcome | {} [Primary outcome measure (and timing of assessments)] |
| Secondary outcomes | {} [Secondary outcome measures (and timing of assessments)] |
| Supplementary outcomes | <> [Additional outcome measures (and timing of assessments)] |
| *Study design* | |
| Study type | {} [Parallel-group/cross over/factorial design, superiority/inferiority study |
| Study periods | {} [Duration of pre-randomisation, study, post-treatment periods] |
| Size of study | {} [Estimated No. of randomised patients] |
| Randomisation | <> [N:M , group allocation] |
| Blinding | <> [Blinding for intervention, outcome assessment] |
| Study flowchart | {} |
| *Statistical Analysis* | |
| Statistical analysis plan | {} [Methods and Procedures used] |
| Stratification | <> [Disease severity, prior therapy, geographic region, centres] |
| Missing data management | {} |
| Planned interim analyses | {} [Methods and Procedures used] |

**Other annexes:**

[Any of the following documents can be attached to the briefing book, if applicable:

• Referenced articles in full text versions in English

• Trial protocols, summaries and reports

* Relevant clinical practice guidelines]