EUnetHTA 21

**Project Plan**

# D6.1.1 PRODUCTION JSC

**Version 1.0 03/12/2021**
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# DOCUMENT HISTORY AND CONTRIBUTORS

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| | |
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The work in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group will be actively writing the deliverable, the entire EUnetHTA 21 consortium is involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) will review and discuss several drafts of the deliverable prior to validation. For further information on stakeholder involvement in this deliverable, please see section 3.1.

## Copyright

# TABLE OF CONTENTS



# LIST OF TABLES

# LIST OF ABBREVIATIONS

| | |
|---|---|
| AEMPS | Agencia Española de Medicamentos y Productos Sanitarios, Spain |
| AIFA | Agenzia Italiana del Farmaco, Italy |
| ATMP | Advanced Therapy Medicinal Product |
| CEB | Consortium Executive Board |
| CSCQ | Committee for Scientific Consistency and Quality |
| EMA | European Medicines Agency |
| EUnetHTA | European Network of Health Technology Assessment |
| G-BA | Gemeinsamer Bundesausschuss (federal joint Committee), Germany |
| HAS | Haute Autorité de santé, France |
| HCP | Healthcare Professional |
| HOG | Hands-on-group |
| HTA | Health Technology Assessment |
| HTAb | Health Technology Assessment body |
| HTD | Health technology developer |
| INFARMED | Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (National Authority of Medicines and Health Products, Portugal |
| JCA | Joint Clinical Assessment |
| JSC | Joint Scientific Consultation |
| KCE | Belgian Health Care Knowledge Centre |
| MD | medical devices |
| NCPE | National Centre for Pharmacoeconomics, Irland |
| NIPN | National Institute of Pharmacy and Nutrition, Hungary |
| NOMA | Norwegian Medicines Agency |
| PICO | Population/Intervention/Comparison/Outcome-scheme |
| SAWP | Scientific Advice Working Party |
| TLV | Dental and Pharmaceutical Benefits Agency, Sweden |
| ZIN | Zorginstituut Nederland |

# 1 INTRODUCTION

In the technical offer, submitted on 04/05/2021, deliverables for the production of JSC have been defined.

This Project Plan describes the objectives, approach and timelines for the deliverable D6.1.1 on production of JSC.

# 2 BACKGROUND

A JSC is a non-binding scientific advice for HTD, typically given before the start of pivotal clinical trials. JSC are planned as parallel consultations with the EMA. The main objective of this project is to provide common recommendations from HTA bodies (HTAb) on how a drug or medical device can be developed. By reaching a consensus in criteria such as patient populations, comparator selection, relevant endpoints, study design and the economic evidence generation plan we aim to provide guidance on improving data and evidence generation from clinical trials, and thereby providing HTD with the knowledge they need to meet HTA requirements for joint assessments and across multiple countries.

**Table 2-1. Existing EUnetHTA documents**

| Title | Scope |
|---|---|
| EUnetHTA ED Guidance on Parallel Consultation | This guidance highlights ideal timelines and actions for each party undertaking a Parallel Consultation. |
| Guidance on centralized procedure | Step by step guide on how to conduct a JSC incl. timelines and role description |
| Dates of 2021 SAWP meetings and submission deadlines | Scientific Advice Working Party (SAWP) Meeting dates 2021 |
| EUnetHTA Multi-HTA ED Guidance (20200703) | This guidance highlights ideal timelines and actions for each party undertaking a Multi-HTA ED<br>The aim is to conduct all JSCs as European Medicines Agency (EMA) - HTA consultations. HTA - only consultations are only carried out in exceptional cases. |
| EDMD Guidance | This guidance outlines the ideal timelines and actions for each party participating in a EUnetHTA Multi-HTA ED for a Medical Device (MD) |
| EDMD Timeline Template | This guidance outlines the ideal timelines and actions for each party participating in a EUnetHTA Multi-HTA ED for a Medical Device (MD) |

# 3 OBJECTIVE AND METHODS

For all of the objectives below the future EU HTA regulation will serve as the basis and the past JA3 experiences will be taken into account.

The objective of this deliverable is to:

1. Further develop of criteria for selection of products and resource allocation.

2. Gather and provide common recommendations of HTAbto HTD
3. Further develop the interaction with joint assessment production/ methodological framework
4. Increase HCP involvement
5. Improve the quality of outputs and evaluation

## *3.1 Methods to achieve the objectives*

### 3.1.1 selection of products and resource allocation.

Based on the experience of JA3, there is a higher number of requests from HTD and there have been more eligible requests than the number that could be accepted.

**During the project, the following questions should be answered:**

a. Should the calls for participation for a consultation be limited to specific indications/products?

b. Are there preferences for certain products among the participating HTA authorities or should the focus be on certain indications (as indicated for initial JA in the HTA regulation)?

c. Are the selection criteria sufficiently restrictive?

d. How should the roles of author / co-author be distributed? How can the resources and capacities of the participants be used efficiently?

**The following steps will be taken in order to achieve the objective**

<u>ad a) and b)</u>

- Survey among Joint Scientific Consultation (JSC) – participants for preferences of products (see also selection criteria)
- Preparation and initiation of the first call for participation accordingly
- Depending on applications for the first call, different selection criteria could be developed Survey among JSC – participants for preferences of products
- Preparation and initiation of the second call for participation accordingly

No interdependencies with other hands- on – groups

<u>ad c)</u>

A re-evaluation of the selection criteria has to be done. The criteria up to now were:

1. a new mode of action for the indication; and
2. targeting a life-threatening or chronically debilitating disease; and
3. unmet need of patients (no treatment or only unsatisfactory treatment available).

Are there other criteria that have to be considered? For example, the prevalence of the disease within a therapeutic area?

Based on previous experience, the re-evaluation of selection criteria could focus on:

- A re-evaluation of the selection criteria and the extension with one or more prioritisation criteria about breakthrough technology* and/or innovative methodology and/ or priority medicines (accepted as Priority Medicines (PRIME)) should be considered. Additionally, the selection process has to ensure that the selected products are as diverse as possible and represent a wide array of topics, therapeutic areas, (e.g. orphan, Advanced Therapy Medicinal Products (ATMPs), antibiotics, oncology etc.) and the sequence of products for Joint Clinical Assessment (JCA) as outlined in the EUHTA -regulation will be considered.
- To improve the identification and selection of candidates for the JSC, the early identification in particular breakthrough technologies (e.g. PRIME procedure) as early as possible, the cooperation with EMA will be further developed.

  https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines
- Depending on how restrictive these new criteria are and how many equally eligible products apply for one slot, other criteria such as prevalence of the disease within a therapeutic area (not for orphans) aspects with regard to life cycle approach/continuum, with regard to public health and in terms of access to innovation could apply.
- A survey for selection of the products among the participants ensures impartiality of the selection process, avoiding conflict of interest situations and can ensure diverse selection of larger and smaller companies. After approval of the selection criteria and the methodology of decision, the criteria will be published, to ensure transparency.

The Applicant's request for a JSC should provide sufficient information to substantiate the claimed basis of selection and follow the guidance notes provided with the form.

No interdependencies with other hands- on – groups

*Breakthrough technology: Preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint (could include impact on a surrogate or clinical intermediate endpoint or pharmacodynamic biomarker that strongly suggests the potential for a clinically meaningful effect on the underlying disease; improved safety profile or quality of life) or a substantial improvement in practicality or convenience of use or care pathways (organizational impact).

ad d)

Different modes of appointing the of roles of author/ co-author could be discussed at JSC-CSCQ kick off meeting:

- Define criteria for the roles of author/ co-author (e.g. one of them should be experienced in conducting JSC)
- Rotating system
- Voluntary basis

No interdependencies with other hands- on – groups (except COI)

### 3.1.2 Gather and provide common recommendations of HTAb to HTD

**During the project, the following questions should be answered:**

How the production of JSC should be conducted and when to start?

**The following steps will be taken in order to achieve the objective**

JSC will start after the EUnetHTA21 started, the call for participation in JSC is launched and a training of the JSC-participants on the procedure is terminated. It would be better to wait for the first preliminary methodological discussions, but this would lead to significant a delay of JSC.

After the first selection of products, the conduct of JSC will follow the centralized procedure, as developed under JA 3.

The schedule of the different JSC will be adjusted to the EMA timeline.

interdependencies with other hands- on – groups:

- see 3.1.3, and hands – on – group for interaction with stakeholders, COI

### 3.1.3 Further development of interaction with joint assessment production/ methodological framework

**During the project, the following questions should be answered:**

How the exchange of information regarding the methodological framework/ JCA and the production of JSC will be coordinated?

**The following steps will be taken in order to achieve the objective**

Previous consultations have shown, that the national specificities in HTA have to be considered while forming a consolidated response with regard to future JCAs. The aim is to continue to work on finding commonalities in scientific approaches and methodology to incorporate into the joint recommendations. Close cooperation between the JSC and JCA team on developing methodological guidelines is mandatory for improving the quality and usability of the given recommendations.

It is intended to share the JSC's recommendations with the JCA production team on a regular and legal basis. This will allow the PICOs (Population/Intervention/Comparison/Outcome-scheme) agreed at the point of JSC to be used to inform PICO selection at JCA. As the final recommendations are part of the submission dossier for the JCA, the assessors can take the recommendations into account for their assessments.

In order to grant access to JSC documents in a timely manner, steps will be taken to address confidentiality issues or obtain permission from developers prior to the actual process.

Intensive cooperation with the PICO subgroup, the common phrase subgroup and the JCA team to further implement a framework of methodological standards, PICO-schemes and the data set for submission will be established.

Concrete tasks:

Implementation of the first 4 JSCs according to the procedure including

- Qualitative analyses of production to identify different priorities and positions of the HTAb, establishing a feedback survey for HTD and participating stakeholders

- improve quality control by establishing a quality control check list

Discuss possible improvements to the processes and adapt them according to the lessons learnt for the second round of 4 further JSCs

interdependencies with other hands- on – groups:

- Meetings with JCA teams and teams who work on methodological guidelines etc.

### 3.1.4 Output and evaluation

**During the project, the following questions should be answered**

How the quality of the JSC can be assessed?

**The following steps will be taken in order to achieve the objective**

Develop a checklist defining quality criteria in terms of procedures, guidelines, templates as well as rules and methods to control quality, clarity and compliance with methodological guidelines for the common positions. This will help to:

- consistency between the various recommendations

- cover the needs of various participants

A more experienced member of the CSCQ-JSC (with support of the CSCQ-JSC chair) will be appointed as a quality assessor who will be responsible for quality monitoring. A workflow will be set up on SharePoint to track relevant steps.

The Checklist has to be finalized before the first JSC - final written recommendations will be sent to the applicant.

interdependencies with other hands- on – groups:

- None

### 3.1.5 Involvement of HCP

**During the project, the following questions should be answered**

How the involvement of HCP can be improved?

**The following steps will be taken in order to achieve the objective** Develop a robust mechanism to identify HCP, who can give an expert clinical input. At the same time, issues of conflict of interest and confidentiality need to be identified and addressed in the production of JSC.

A successful example for HCP involvement in a centralized manner was an EDMD pilot. Based on this, a transparent approach to HCP involvement will be elaborated.

A similar approach as with patient involvement can be considered.

There is an interdependency with the transversal tasks 7.2/7.3, consideration will be given to using the tools developed under 7.2/7.3 for JSC.

interdependencies with other hands- on – groups:

- None (except COI, and the transversal tasks 7.2/7.3)

### *3.2 Stakeholder inclusion*

EUnetHTA 21 Stakeholder Pool is composed of HTA bodies (HTAb) outside of EUnetHTA 21 consortium, as well as stakeholder groups on patients, health technology developers (HTD), healthcare professionals (HCP), payers, and regulatory agencies from the EU/EEA countries.

Other members of the EUnetHTA 21 Stakeholder pool will also be involved in this project. Their involvement will be according to the procedure for JSC during the conduction of JSC.

The Hands-on Group (HOG) will consult specifically HTD, HCP, Patients and Regulators to collect their point of view prior to developing the deliverable, during development of the deliverable and for review of the first draft of the deliverable.

## 4 ORGANISATION OF THE WORK

### *4.1 Mode of collaboration and frequency of meetings*

The work will be distributed evenly between the agencies of the HOG. All HOG members will review each other's work prior to review by the CSCQ. The HOG will appoint one agency to interact with the three CSCQ configurations and the CEB.

The HOG will have meetings/email updates when needed, but at least monthly meetings, to update each other on the progress.

For each JSC to be conducted, a new HOG will be formed, whereby changes within the previous group are not mandatory.

### *4.2 Timelines*

**Start of the project**

In due time separate Project Plans will be developed for the specific JSC, but for confidentiality reasons these will not be published, therefore no JSC production timeline will be publicly available.