EUnetHTA 21 – Stakeholder Meeting

Start: 12 May 2023
Friday 10:00-12:00 CET

1. **Welcome from the Chair of the Consortium Executive Board (CEB) and objective of the meeting**

Niklas Hedberg, TLV

Housekeeping of today's meeting

Juste Jurgutaviciute, ZIN

Information for attendees

Entering the meeting:

- Please ensure you have logged in with your **name, surname, organisation and country** *i.e. Juste Jurgutavičiūtė (ZIN, The Netherlands)*.
- Please note: you cannot switch on your camera or use your microphones.

Information for attendees

Questions:

- To ask questions, you may post them in the Q&A box.
- Responses to all questions will be coordinated by the Chair and will be taken at the **end of relevant presentations or during the Q&A item.**
- Please note: for internal purposes this meeting will be recorded.

Information for attendees

Technical issues:

- If you experience problems with Zoom during the meeting, please:

  1. Go to www.zoom.com and search for help.
  2. Contact eunethta@zinl.nl or call Merle Tenberg on

     +31 6 51 06 80 53 for support (You may wish to take a picture of these contact details).

Today’s agenda

Niklas Hedberg, TLV

Agenda

ID		Description	Presenter/s
#1	10:00-10:10	Welcome from the Chair of the Consortium Executive Board (CEB) and objective of the meeting	Niklas Hedberg, TLV
#2	10:10-10:25	Status update on EUnetHTA 21 deliverable production & upcoming public consultations	Antje Behring, G-BA Roisin Adams, NCPE
#3	10:25-11:30	Preparations for the HTAR	Various
#3a	10:25-11:00	*European preparations for the HTAR* - *EUnetHTA 21 practical experiences* - *Update from the European Commission*	Roisin Adams, NCPE Valentina Barbuto, DG SANTE
#3b	11:00-11:30	*National preparations for the HTAR* - *HAS (France) national preparation process* - *INFARMED (Portugal) process for PICO*	Judith Fernandez, HAS Sara Couto, INFARMED
#4	11:30-11:55	Q&A	Niklas Hedberg, TLV
#5	11:55-12:00	Closing remarks	Niklas Hedberg, TLV

2. **Status update on EUnetHTA 21 deliverable production & upcoming public consultations**

Antje Behring, G-BA
Roisin Adams, NCPE

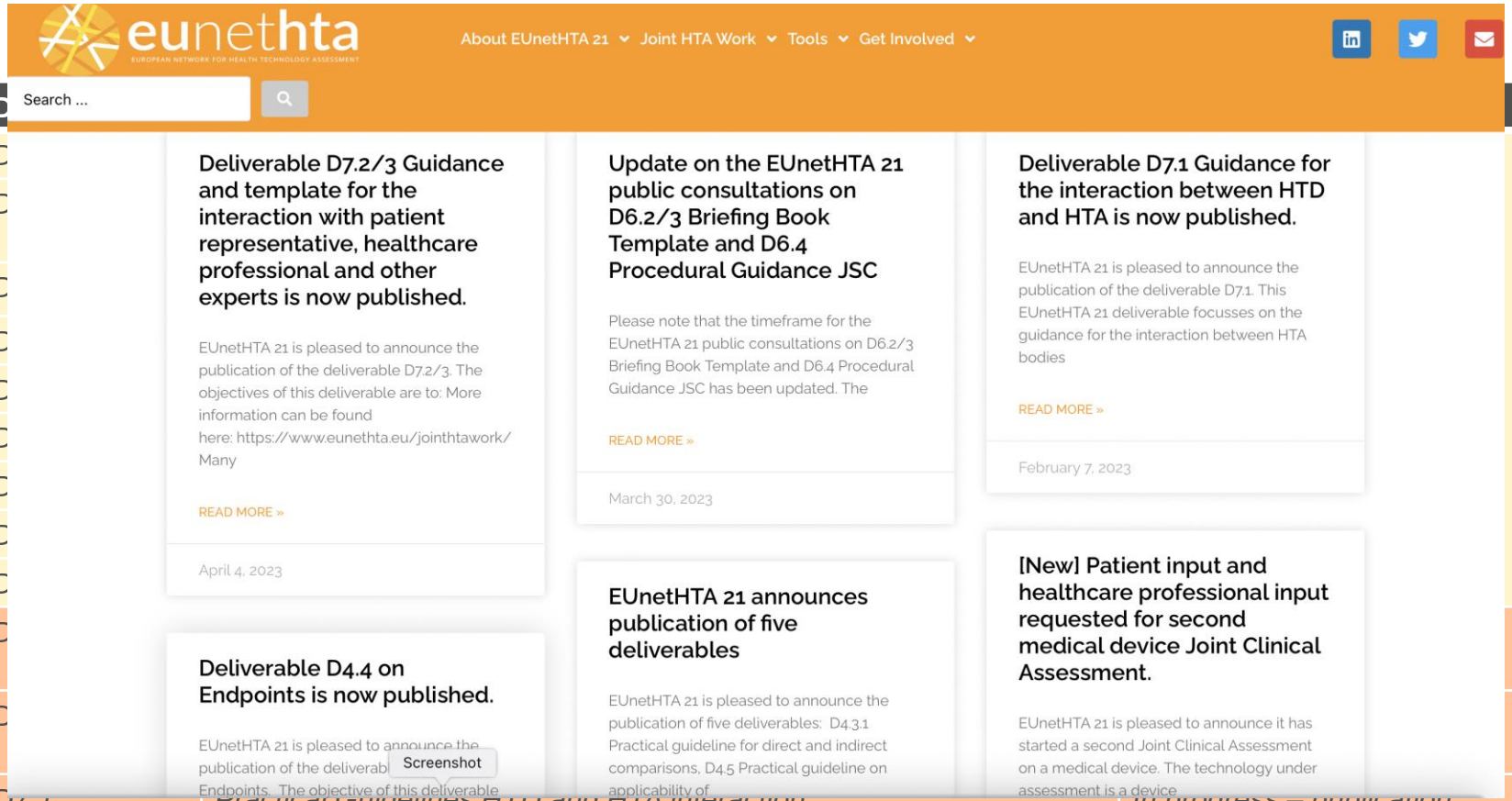
Progress of EUnetHTA 21 deliverables

https://www.eunethta.eu/jointhtawork/

Deliverable	Title	Status
D4.2	*Practical Guideline – Scoping Process*	*Published*
D4.3.1	*Practical Guideline – Direct & Indirect Comparators and Comparisons*	
D4.3.2	*Methodological Guideline – Direct & Indirect Comparators and Comparisons*	
D4.4	*Practical Guideline Endpoints*	
D4.5	*Practical Guideline Applicability of Evidence*	
D4.6	*Practical Guideline Validity of Clinical Studies*	
D4.7.1, 4.7.2	*Framework for JCA of high risk MD*	
D5.1	*Submission Dossier Guidance*	
D5.2	*JCA report template & JCA report guidance*	
D5.3.1	*Selection criteria (co-)assessor JCA*	
D5.3.2	*HTA body technical expert working groups*	
D7.1	*Practical Guidelines HTD and HTA interaction*	
D7.2/7.3	*Patient and HCP guidance & templates for interaction*	
D7.5	*Conflict of Interest forms and procedure*	
D4.7.3, 4.7.4	EUDAMED data reporting template/Guidance for EUDAMED-based TISP process	Ongoing
D5.1	Submission Dossier Template	
D5.4	Timeline for JCA medicinal products	
D6.2/6.3&6.4	JSC briefing book template & procedural guidance public consultation in July 2023	

Progress of EUnetHTA 21 deliverables

https://www.eunethta.eu/jointhtawork/



D7.1	*Practical Guidelines HTD and HTA interaction*	*In progress – publication expected in February 2023*
D7.2/7.3	*Patient and HCP guidance & templates for interaction*	
D6.2/6.3&6.4	JSC briefing book template & procedural guidance	Ongoing – public consultation in August 2023

EUnetHTA 21
Joint Scientific Consultations (JSC)

EUnetHTA 21 service contract: 6-8 JSCs foreseen

- **7 JSC will be conducted during EUnetHTA 21** (all JSC will be completed by mid July 2023)
- Selection criteria of the HTA Regulation applied

Open Call	# of JSCs selected	Characterization of JSCs selected
1st Open Call (2021)	3	2 oncological and 1 non-oncological product: ▪ 3x First in class (FC) ▪ 2x Orphan designation (OD) ▪ 1x PRIME
2nd Open Call (2022)	4	3 oncological and 1 non-oncological product: ▪ 4x First in class (FC) ▪ 1x Orphan designation (OD) ▪ 2x ATMP ▪ 1x PRIME ▪ 1x SME

EUnetHTA 21 JSC

- Overall all **11 partners of the EUnetHTA 21 Committee for Scientific Consistency and Quality (CSCQ) JSC** have been involved in the JSCs
- The roles of **Assessors and Co-Assessors** were taken on by a total of **6 different HTAbs**
- In total, **6 patient experts and 4 clinical experts have been involved at European level**. Additionally, partners involve national experts on national level according to their national procedure
- **Guidelines and templates** were revised and updated at the beginning of EUnetHTA 21, have been revised internally in the mid-term of the project and will now undergo a final round of revision including a **public consultation in July 2023** (01.07.2023 – 31.07.2023)
- The current versions of all JSC documents can be found on the EUnetHTA 21 website: Services - EUnetHTA

EUnetHTA 21 JSC expert involvement

Change throughout EUnetHTA 21 (*D7.2/3 Guidance and template for the interaction with patient representative, healthcare professional and other experts*):

- European level expert recruitment facilitated centrally (via JSC Secretariat)
- National involvement facilitated by participating HTAbs at national level in addition to European level expert involvement

Involvement European level patients: 6/7 JSCs

Involvement European level clinical experts: 4/7 JSCs

EUnetHTA 21 JSC	Expert involvement	
	Patients	Clinical experts
JSC 001	**European level patient** National level in addition	Solely national level
JSC 002	**European level patient** National level in addition	Solely national level
JSC 003	Solely national level	**European level clinical expert** National level in addition
JSC 004	**European level patient**	Solely national input
JSC 005	**European level patient** National level in addition	**European level clinical expert** National level in addition
JSC 006	**European level patient** National level in addition	**European level clinical expert** National level in addition
JSC 007	Application withdrawn by Applicant	
JSC 008	**European level patient**	**European level patient**

EUnetHTA 21 JSC key learnings

JSC open call and selection:

- Shorter intervals between calls for applications / increased number of calls for applications and increased flexibility between the acceptance and the start of the consultation
- Further explanations of the prioritisation criteria and further communication of the selection process needed to encourage applications. Explanations of the Applicant needed in terms of the HTA Regulation selection criteria at the timepoint of application

JSC procedure:

- Procedural adaptation to streamline the process
- Involvement of the entire CSCQ JSC throughout the process
- Optimisation of the exchange with EMA via an additional meeting to exchange prior to the discussion meeting with the Applicant

Expert involvement:

- Raise awareness and reduce barriers for patients and clinical experts to increase participation

Parallel EMA-HTAb Scientific Advice during interim period

Future parallel consultations

Planned by HTAb and EMA for **interim period** (October 2023 – December 2024):
"Parallel EMA-HTAb Scientific Advice"

- Modelled after the EUnetHTA JA3 individual parallel consultation route (Parallel Consultation Individual, PCI)

Framework:

Not under EUnetHTA, but voluntary initiative: EUnetHTA 21 CSCQ JSC, HAG and HTA subgroup on JSC consulted for expression of interest

Key elements:

- Rolling approach upon Applicant's initiative: dependant on available HTAb resources
- HTAR selection criteria apply
- Participation of HTAbs: active or as observers
- Minimum of 2 active HTAb per procedure (Applicant cannot choose)
- Coordination of HTAb involvement by G-BA (HTAb coordination contact)
- Output: EMA Advice Letter + Individual Recommendation Letters of the participating HTAbs (non-consolidated recommendations but joint e-meetings will still enable for a common understanding and exchange)

Future parallel consultations

- **Official announcement planned for June 2023** on both webpages including the info package (External guidance, Application form and Briefing document template)
- Applicants are invited to flag their interest for a parallel scientific advice to EMA (when applying for EMA Scientific Advice) or to G-BA (HTA coordination contact).

JSC under the HTA Regulation

- Start in January 2025

3. **Preparations for the HTAR**

Various

3a. *European preparations for the HTAR*
- EUnetHTA 21 practical experiences

Roisin Adams, NCPE

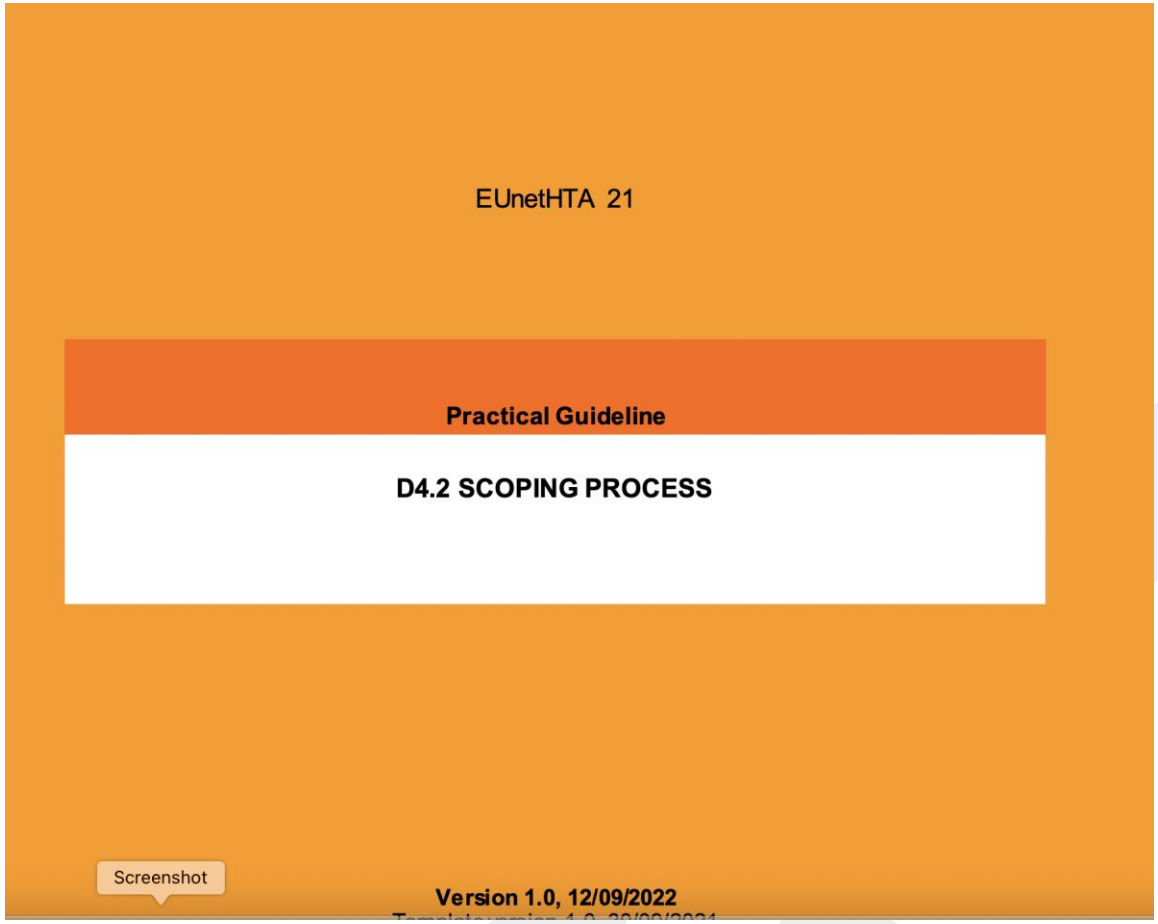
Status of JCA production in EUnetHTA 21

- 2 JCA for Medical Devices
  - JCAMD001: The Optilume® Urethral DCB Catheter for men ≥18 years of age with bothersome urinary symptoms associated with recurrent anterior urethral stricture.
  - JCAMD002: Saluda Medical Evoke® Spinal Cord Stimulation System as an aid in the management of chronic intractable pain of the trunk and/ or limbs
  - Both MD JCAs:
    - Followed the PICO process and consolidation
    - Based on submission dossier by the HTD
    - Followed the EUnetHTA 21 recommended process for external expert and stakeholder involvement
    - Publication expected in summer months

- Pharmaceutical JCA
  - PICO exercises to be conducted, to test the developed procedures and guidelines

Practical Pilot Work

PICO Preparation



Pilot PICO work for medicinal products

- To conduct several PICO exercises
  - On compounds with positive CHMP opinion
- To include some products that will be subject to the HTAR in 2025 i.e. cancer and ATMPs
- Associated HTAb invited to respond to survey
- Consolidated PICO(s) to be published

- Review of the process following this work and improvements to be incorporated.

Learnings

- Support the national HTAbs by providing some additional background information on the disease area.
- Clarification around common understanding.
- Consolidation process working really well.
- Testing a process where authors to propose PICOs for HTAbs
- Notification period of the upcoming PICO survey is important
- Online format to capture national PICOs is working well

3a. *European preparations for the HTAR*
- Update from the European Commission

Valentina Barbuto, DG SANTE

Update on the implementation of the Regulation (EU) 2021/2282 on Health Technology Assessment

Valentina BARBUTO, Policy Officer

DG SANTE C2, Health Technology Assessment

Since the last EUnetHTA 21 Stakeholder meeting…

GOVERNANCE

- HTA Coordination Group (HTACG) 2nd meeting -> 28 November 2022;
- HTA Coordination Group (HTACG): 3rd meeting -> 20 March 2023;
- HTACG Subgroups: designations and 1st meetings -> 24-25 April 2023;
- Stakeholder Network: list of members published -> 5 May 2023. hta_htar_list-org.pdf (europa.eu)

IT PLATFORM

- Third meeting of the IT users working group -> 18 January 2023
- First pilot of the IT Platform -> March 2023
- Fourth meeting of the IT users working group -> 29 March 2023

Since the last EUnetHTA 21 Stakeholder meeting…

IMPLEMENTING ACTS

- Work at full speed on the first implementing act on Joint Clinical Assessments (**JCAs**) **medicines**. Adoption planned for Q4 2023.
- Preparatory work on the second implementing act on **Conflict of Interest** to start soon. Adoption planned for Q1 2024.

PROJECTS

- Training of patients experts (**EU4Health**) – EUPATI & EUCAPA kick off -> March 2023
- Call on HTA methodology research & training (**Horizon Europe**) closed and evaluation phase started -> April/May 2023
- First HTA Infoday (**EU4Health**) -> Stockholm, 11 May 2023

European Commission

The timeline

- Training, capacity building, awareness raising (EC)

Adoption
December 2021

- Developing the IT platform (EC)
- Setting up the comitology committee (EC)

Entry into force

Application

January 2022 | ***Preparatory phase*** | January 2023 | ***Preparatory phase*** | January 2024 | ***Preparatory phase*** | January 2025

- Setting up the Coordination Group (EC)
- Drafting implementing acts (EC)
- Setting up the Stakeholder Network (EC)
- Setting up the subgroups (EC)
- Drafting guidance and procedures (CG)
- Workplan activities with HTA bodies

eunethta

Service contract EUnetHTA 21

EUROPEAN MEDICINES AGENCY

European Commission

Next steps

- First meeting of the Stakeholder Network in June 2023
- Engagement with local stakeholders through the HTA Information days

European Commission

Thank you

Contact of HTA team:

SANTE-HTA@ec.europa.eu

European Commission

3b. *National preparations for the HTAR* - **HAS (France) national preparation process**

Judith Fernandez, HAS

National implementation of the European HTA regulation

French National Authority for health

Judith Fernandez
Deputy director – HTA department

HAS
HAUTE AUTORITÉ DE SANTÉ

HAS - Three core missions

Assess and appraise
pharmaceuticals, devices and procedures for pricing and reimbursement purposes

Recommend
best practices for health care professionals and elaborate public health guidelines

Measure and improve
the quality of care delivered in health and social care organizations

Advance quality in health and social care to serve both individual and collective interests

HAS - Three core missions

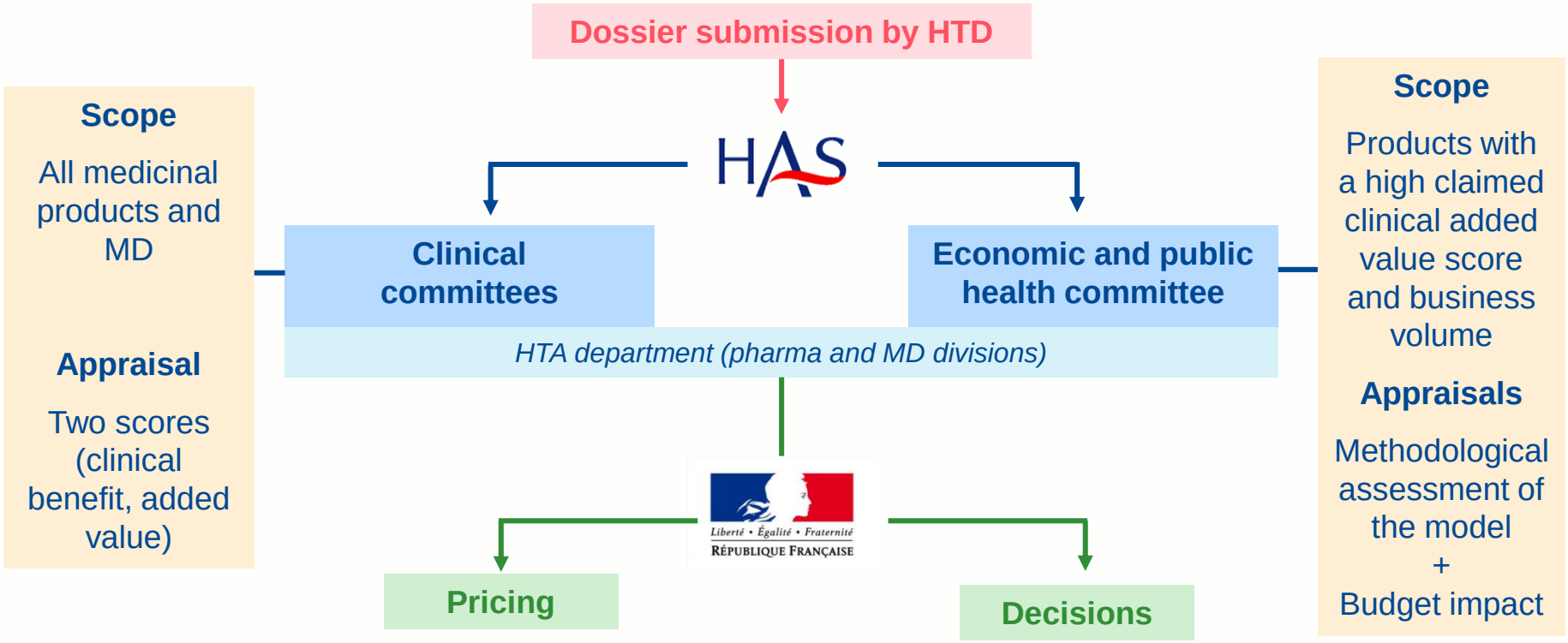
Assess and appraise
pharmaceuticals, devices and procedures for pricing and reimbursement purposes

Recommend
best practices for health care professionals and elaborate public health guidelines

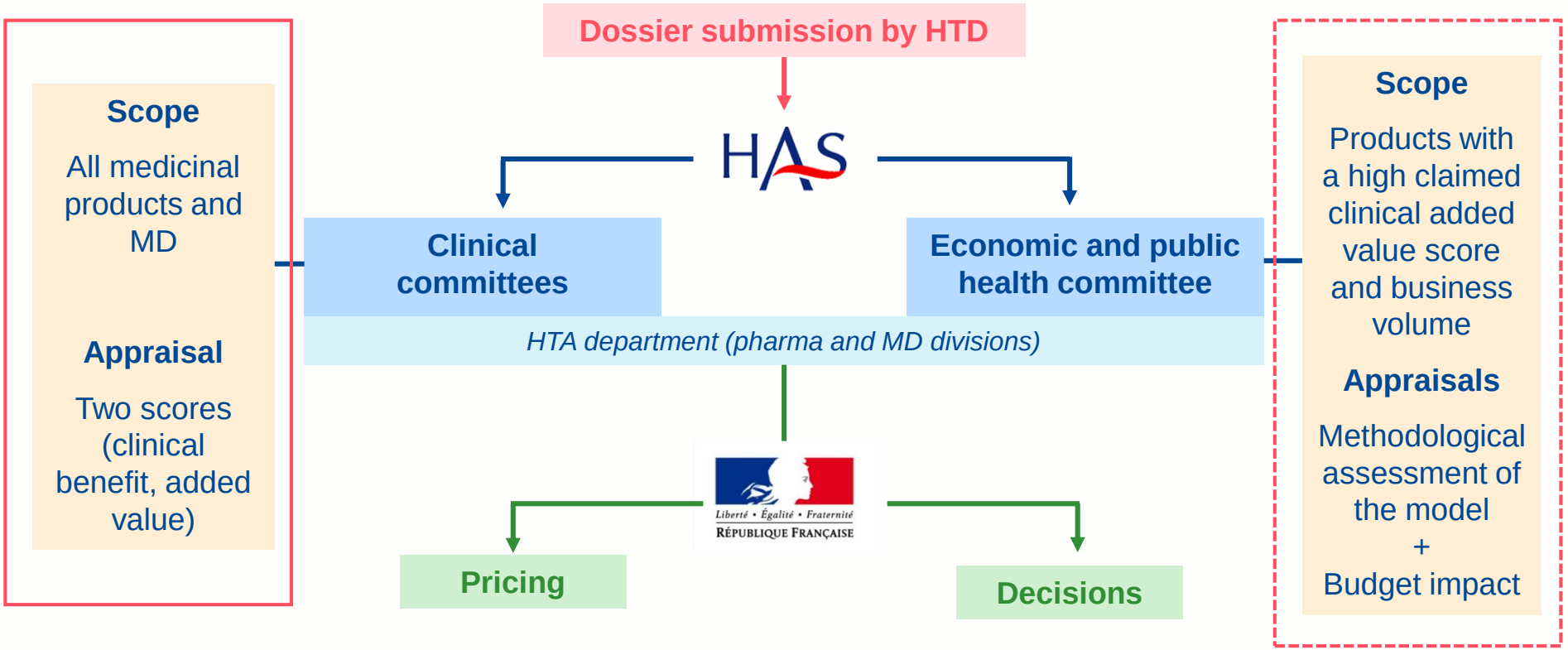
Measure and improve
the quality of care delivered in health and social care organizations

Advance quality in health and social care to serve both individual and collective interests

HTA in France



HTA in France



Strengths and challenges

- **Strong willingness to collaborate** among the HTA community
  - voluntary cooperation since 2005
  - high level of commitment in working together
- **Key milestones reached** with the EUnetHTA21 consortium

- **Scalability:** integrating HTAR activities in the routine of the department
- **Resources and capacity**
- **Connexion with other national activities** (e.g. early access)

Next steps

- **HTA department adopted a workplan** to meet the requirements by 2025
  - Prepare the department to work at the EU level
  - Adapt our national procedures to take into account JCA

- Willingness to **maintain interactions with other HTA bodies** between the end of the EUnetHTA21 consortium and 2025

Next steps

- **Technical support instrument granted by DG REFORM** for the implementation of the regulation in France
  - Internal **capacity building and trainings** including on EUnetHTA21 productions
  - **Disseminate the principles of European cooperation** in the entire HTA department
  - **Optimisation** and review of internal procedures (timing of national assessment/appraisals, connexion with early access authorisations…)
  - Planned **interactions with key stakeholders at national level**
  - …
- **More information here**

Find all our work on

www.has-sante.fr

HAS

HAUTE AUTORITÉ DE SANTÉ

Advancing quality in health and social care services

3b. *National preparations for the HTAR* - **INFARMED (Portugal) process for PICO**

Sara Couto, INFARMED

PICO within a national process

INFARMED, I.P - PORTUGAL

PICO process in Portugal

- In place since 2016
- PICO is used to **structure and answer a clinical or medical care question**
- PICO structure is also used to develop search strategies in the literature, for example, in **systematic literature reviews** (HTD only)
- PICO will define the terms in which the assessment will be carried out
- Discussed with:
  - Clinical experts
  - Patients' associations (empowered to give input)
  - Health Technology Developer (HTD)

PICO process in Portugal

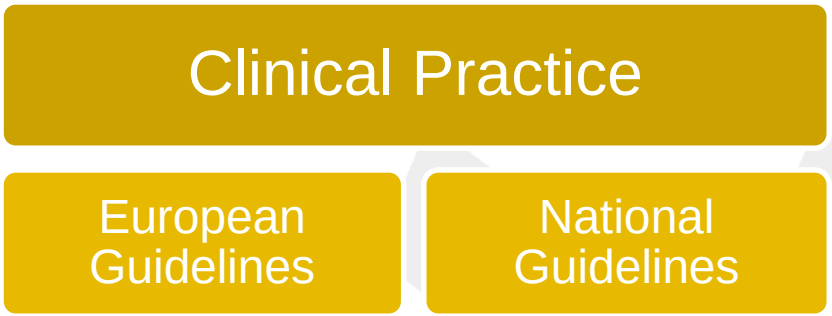
At the time of MA or CHMP positive opinion for new substances and new indications

Company can request clarifications and make comments /suggestions

HTAC: HTA Committee

PICO process in Portugal

- First, the assessment team describe the **epidemiology** (prevalence and incidence data in Portugal, if exists) and social importance of the disease
- Impact on patients' quality of life, mortality, clinical and demographic characteristics of the population(s) under assessment
- Description of the new medicine/ indication (mechanism of action, therapeutic line, sequencing of treatments)
- Description of alternatives: **clinical practice in Portugal** (therapeutic line, sequencing of treatments)



PICO process in Portugal

Population

- Requested by HTD: could be equal to licensed indication or a part of it (subpopulation)
- If HTD requests a subpopulation, it needs to be clinically relevant
- In case the indication under assessment includes different populations distinguished by the **presence of effect modifiers** or usually receiving **different treatments** INFARMED will divide the population to assess the treatment effect separately for each one

PICO process in Portugal

Intervention

- should include only the intervention under assessment and should not include other products that are not part of the indication of interest.
- however, if the technology is to be used in combination with other technologies, these should be part of the definition of the intervention.

PICO process in Portugal

Comparators

- are options against which the new medicinal product is compared with the objective of assessing whether it has additional benefit and is cost-effective
- are all therapeutic alternatives **commonly used in clinical practice in Portugal** to treat the population /subpopulation
- The selection of a comparator does not translate into a judgement on its efficacy → main criterion its usual use in clinical practice in Portugal
- Selected comparators **should not be constrained** by the comparators used for the control group in clinical trials.

PICO process in Portugal

Comparators may include:

- medicines with MA for the indication;
- inactive therapeutic options (e.g. best supportive care, monitoring), if commonly used in Portuguese clinical practice for the indication;
- non-pharmacotherapeutic active options (e.g. surgery), if used in Portuguese clinical practice for the indication;
- therapeutic sequences in which the medicinal product under assessment is used in a second line or another subsequent line, if applicable to the indication and if permitted in its MA and, if relevant, permitted in the comparators' MA.
- In exceptional cases, medicines without MA if their use is well established in Portuguese clinical practice for the population/ subpopulation

PICO process in Portugal

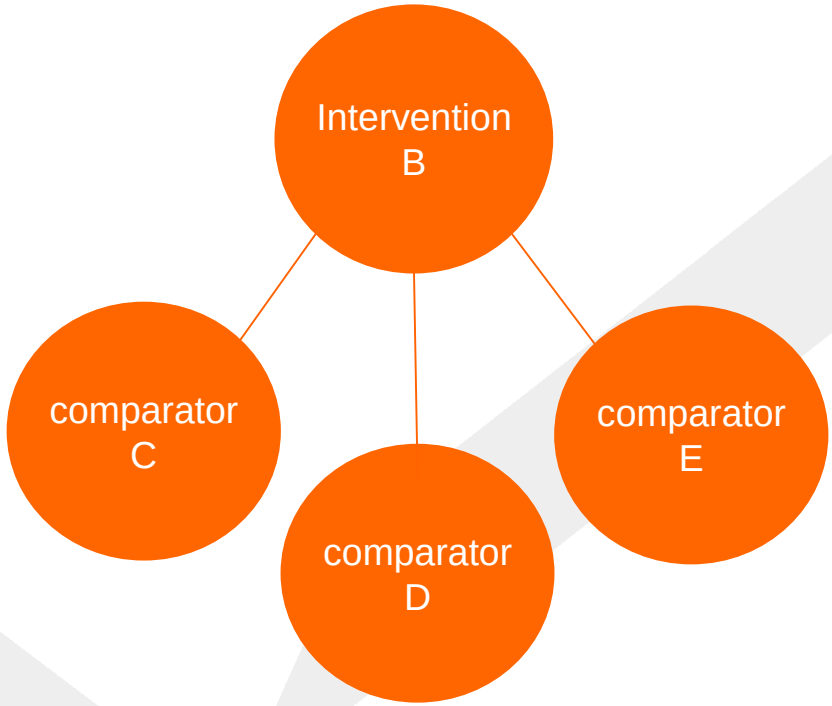
What does this mean in terms of comparative data?

Population A

Intervention B

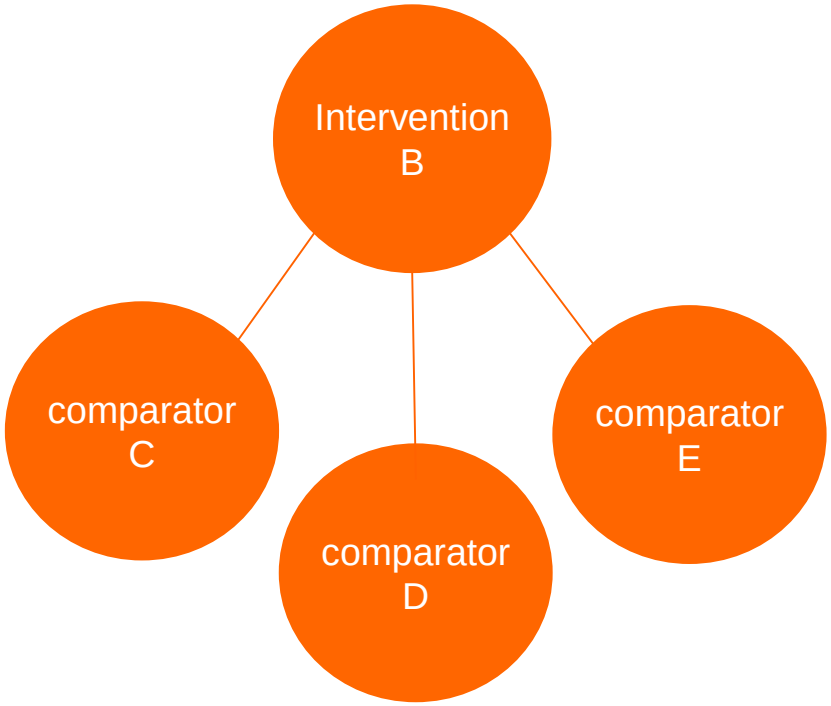
Comparators: medicines C, D, E

Outcomes



PICO process in Portugal

What does this mean in terms of comparative data?



HTD shall conduct a SLR searching for comparative data between intervention B with medicine C **and** medicine D **and** medicine E through direct and/ or indirect comparisons.

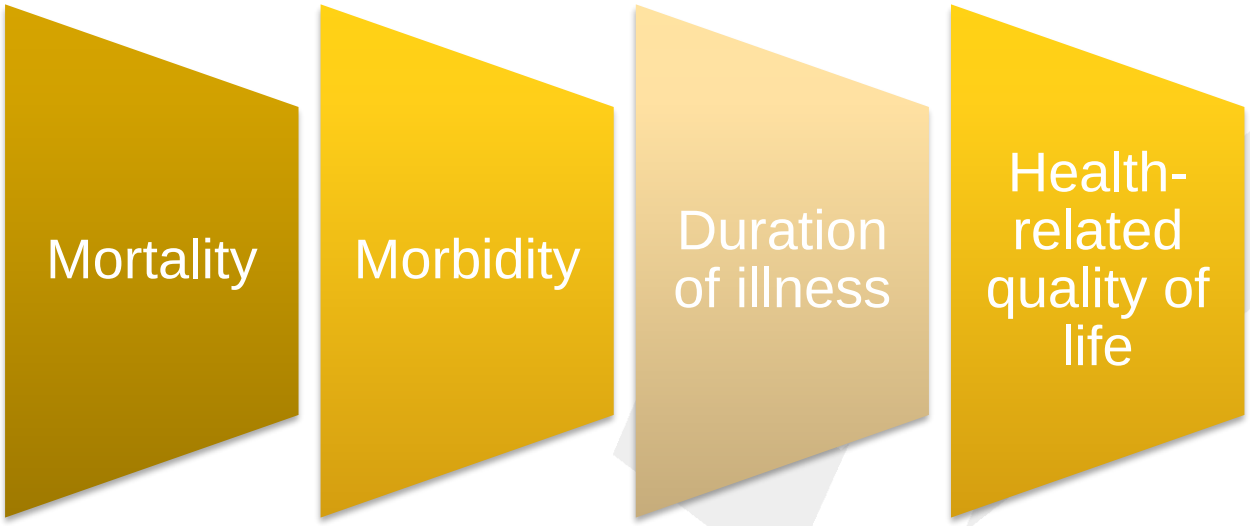
HTD should justify where comparative data are not presented for each of the comparators identified / why it is considered not appropriate an indirect method and provide justification therefor

HTAC to decide on the justification given

PICO process in Portugal

Outcomes

- A set of outcome measures should be proposed, related to the efficacy and safety of the intervention.
- To this end, measures that assess the patient's symptoms, functional capacity or life expectancy are considered relevant to the patient



PICO process in Portugal

Outcomes – classification of their importance – GRADE guideline[1]

Critical — **Score 7 to 9**

they may influence the direction of the assessment;

measures that assess symptoms, functional capacity or patient life expectancy

Important but not critical — **Score 4 to 6**

All the others that are not critical

[1] Guyatt GH, Oxman AD, Kunz R, Atkins D, Brozek J, Vist G, et al. GRADE guidelines: 2. Framing the question and deciding on important outcomes. Journal of Clinical Epidemiology. 2011;64(4):395–400.

PICO process in Portugal

Methodology of Pharmacotherapeutic Assessment version 3.0 –

English version

https://www.infarmed.pt/documents/15786/1963929/METOD_AFT_v3.0_ENvf_fev2023/b0cb1c54-adca-721a-6466-75ba04cdd542

METHODOLOGY

FOR PHARMACOTHERAPEUTIC ASSESSMENT OF HEALTH TECHNOLOGIES

4. **Q&A**

Niklas Hedberg, TLV

5. **Closing remarks**

Niklas Hedberg, TLV

Upcoming stakeholder meetings & public consultations

Meeting date	Objective
13 July 2023	HTD specific meeting to capture input on the submission dossier template and JCA timelines (medicinal products only!)
8 September 2023	6th & final General EUnetHTA 21 Stakeholder Meeting
Fall 2023	EMA/EUnetHTA 21 bilateral in accordance to work plan

- Public Consultations, 1-31 July 2023
  - JSC Briefing Book template & JSC procedural guidance
  - Evaluation of the Public Consultation process

EUnetHTA 21 – Stakeholder Meeting

End: 12 May 2023
Friday 10:00-12:00 CET