EUnetHTA 21 – Stakeholder Meeting

29 April 2022
13:00-15:00 CET

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

Niklas Hedberg, TLV

Upcoming stakeholder meetings

Meeting date	Objective
25 March 2022	HTD & Consultancy (Pharma & MD) - Focus on production process JCA & high level overview Submission Dossier Template
29 April 2022	2n General EUnetHTA 21 Stakeholder Meeting
25 May 2022	Patient and Healthcare Professional (HCP) roundtable - Discuss proposed methods for involvement in JSC and JCA
July 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
13 July 2022 (instead of 15th of July)	3rd General EUnetHTA 21 Stakeholder Meeting
October 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
18 November 2022	4th General EUnetHTA 21 Stakeholder Meeting
February 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
12 May 2023	5th General EUnetHTA 21 Stakeholder Meeting
8 September 2023	6th & final General EUnetHTA 21 Stakeholder Meeting
September/October 2023	EMA/EUnetHTA 21 bilateral in accordance to work plan

Housekeeping of today's meeting

Alzbeta Tuckova, ZIN

Information for attendees

Entering the meeting:

- Please ensure you have logged in with your **name, surname, organisation and country** *i.e. Alzbeta Tuckova(ZIN, The Netherlands)*.
- You can rename yourself after you have logged in.
- Please do not try switching your webcam on. Only presenters are able to do so.

Information for attendees

Questions:

- To ask questions, you may:
  - Use the Q&A box 

- Responses to all questions will be coordinated by the Chair and will be taken at the **end of relevant item**.
- You may also “like” other people’s questions, which will push the question further up the list.
- Please note: The chat function, used in regular Zoom meetings, is disabled for this webinar. Please use the Q&A box for your questions. **You have the option to raise hand, but we will not use this function.**

- 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 **atuckova@zinl.nl** or call Alzbeta Tuckova on **+31 6 48 22 06 37** 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	13:00-13:10	Welcome from the Chair of the Consortium Executive Board (CEB) and objective of the meeting	Niklas Hedberg, TLV
#2	13:10-13:40	Update on status of deliverables 1.Joint Scientific Consultations 2.Joint Clinical Assessments 3.Transversal Activities	Chantal Guilhaume, HAS Antje Behring, G-BA
#3	13:40-14:10	Principles of public consultation	Anne Willemsen, ZIN
#4	14:10-14:40	Update on future HTAR	Ioana Siska, DG SANTE
#5	14:40-14:55	Q&A	Niklas Hedberg, TLV
#6	14:55-15:00	Closing remarks	Niklas Hedberg, TLV

2. **Update on status of deliverables**

Antje Behring, G-BA
Chantal Guilhaume, HAS

An update on the CSCQ tasks and activities

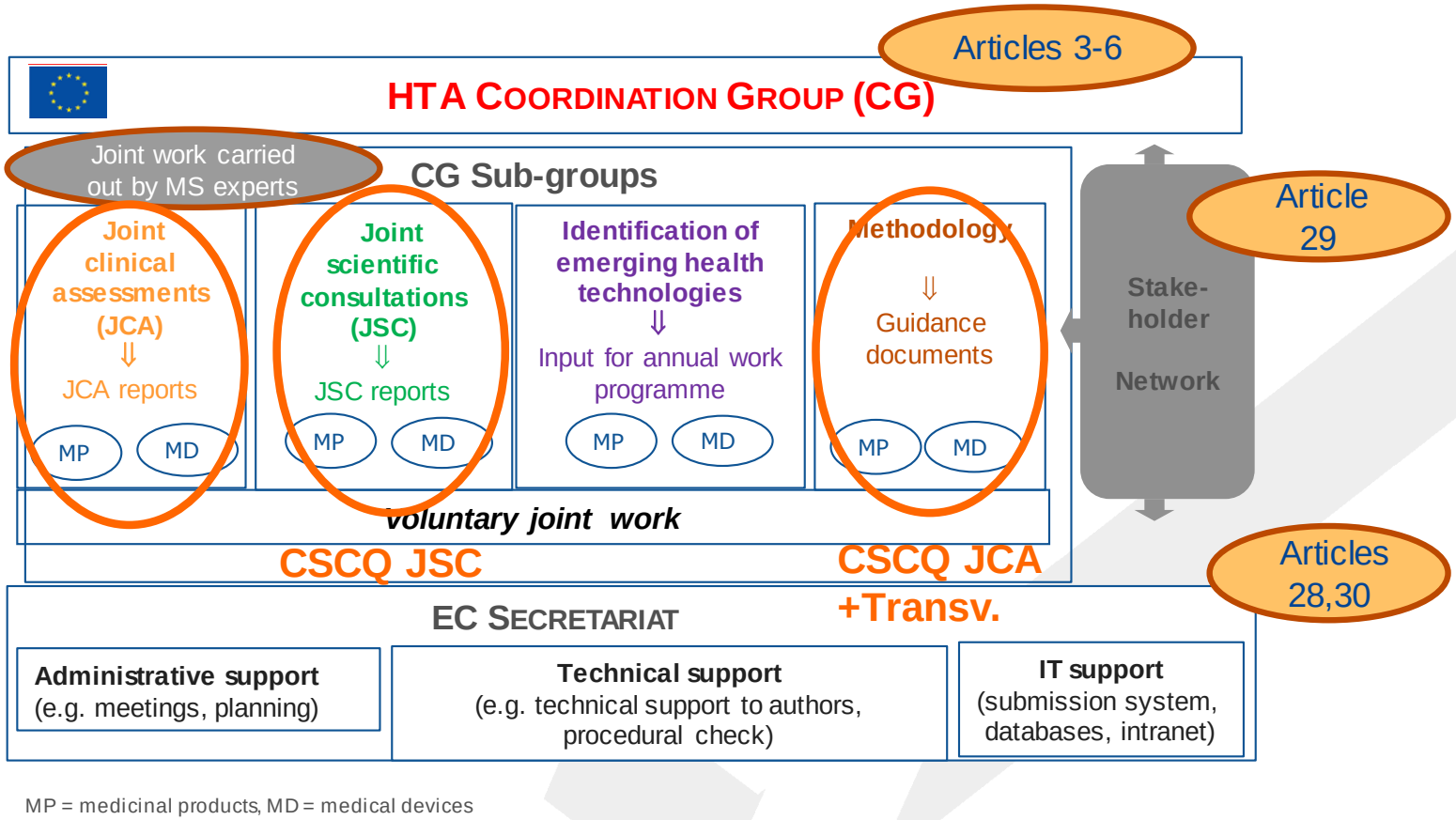
Chantal Guilhaume, HAS

EUnetHTA 21 mimicking the HTAR governance, enhancing inclusiveness

CSCQ JCA

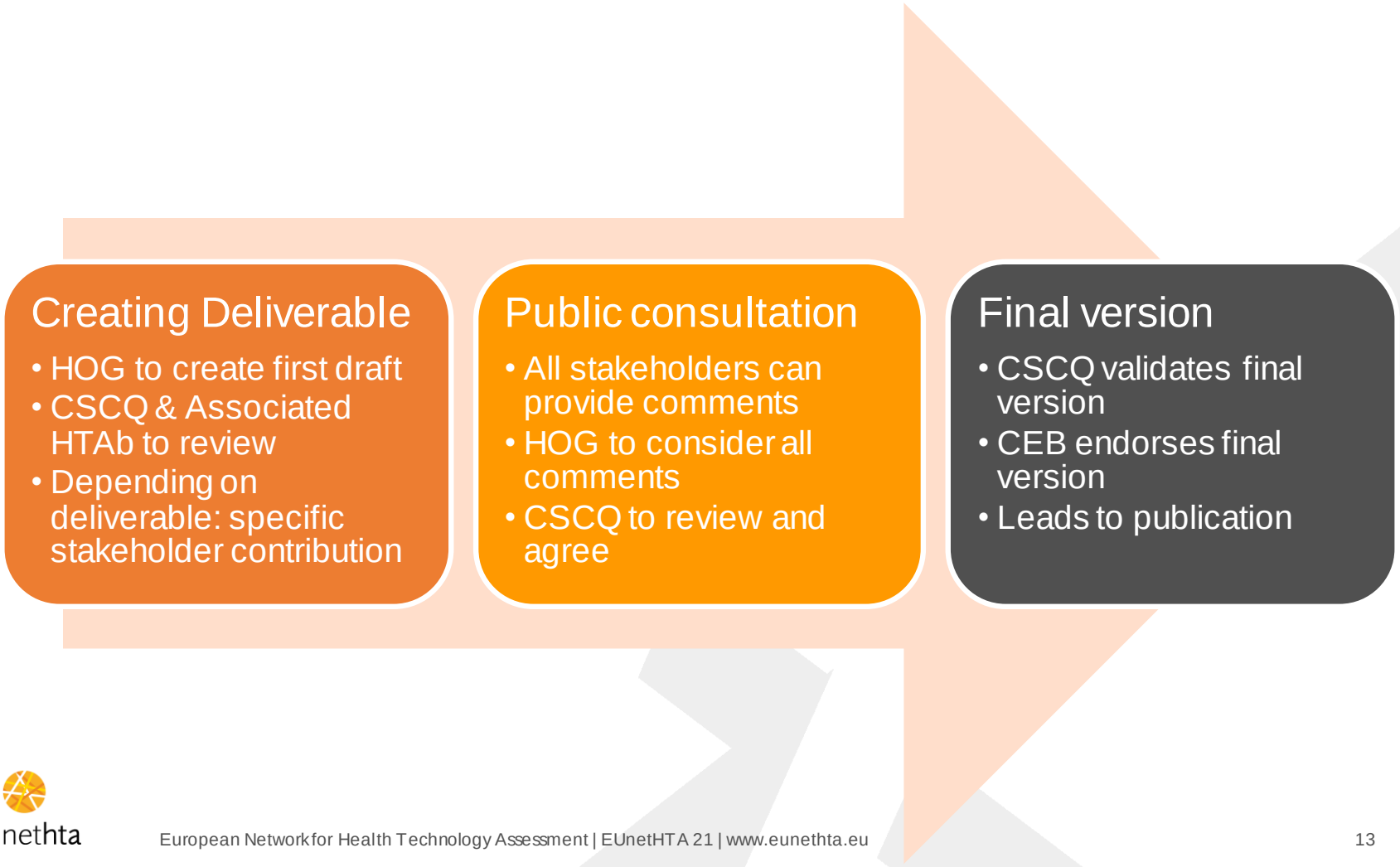
All consortium HTAb

+Associated HTAb



MP = medicinal products, MD = medical devices

Process flow for deliverable production



2a. **Joint Scientific Consultations**

Antje Behring, G-BA

EUnetHTA 21 Joint Scientific Consultations (JSC) update on activities

Deliverables	Start Public Consultation
D6.1.1 JSC PRODUCTIONS	n.a
TEMPLATES	
• D6.2.1 Briefing Book Template	Aug. 2023
• D6.2.2 Letter of intent	n.a.
• D6.3.1 JSC common recommendation template	n.a
PROCEDURAL GUIDANCE	Aug. 2023

Objective of JSC

- A JSC is a non-binding scientific advice for HTDs,
- typically given before the start of pivotal clinical trials.
- JSC are planned as parallel consultations with the EMA.
- main objective: 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
- reaching consensus on main recommendations or, where necessary, information on the specificities of the requirements of the individual countries on certain criteria such as
    - patient populations,
    - comparator selection,
    - relevant endpoints,
    - study design.

Conduction of JSC

Pre JSC

- Open Call
- Application
- Selection and information of HTD

internal

- Setting up hands on group for JSC (min. 6 HTAs)
- Appointing assessor and co - assessor

JSC

- According to procedural guidance
- Involvement of experts (patients and HCP)
- F2F meeting (virtual) with EMA and HTD
- Validation of the final recommendation by the CSCQ JSC (11 HTAs).

JSC Deliverables

- Updated procedure and templates are published in December 2021
- First open call for JSC closed and first of 3 JSC started
- Prenotification for 2nd Open Call EUnetHTA 21 JSC

2nd Open Call open	6.6. - 31.8.2022
Review of applicants by CSCQ-JSC members	1.9. - 12.9.2022
Discussion on selection of product CSCQ-JSC	12.9.2022
Information sent to the applicants	14.9.2022
Start of the 1st JSC (out of 5 JSC foreseen in 2nd batch)	1.11.2022

Lessons learnt from 1st Open Call

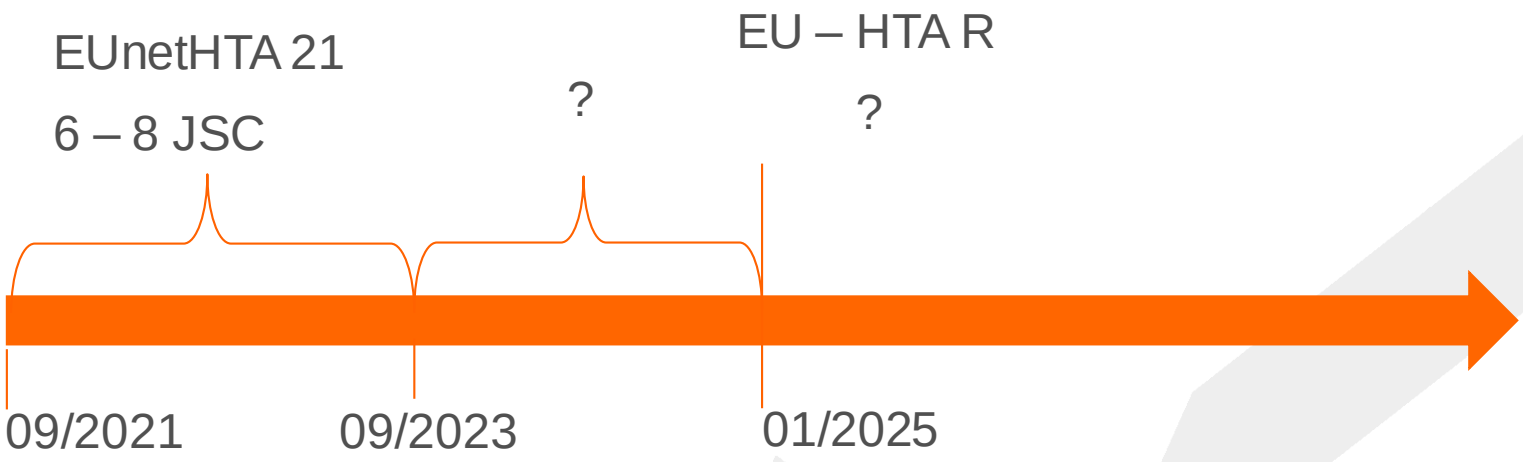
Survey on feedback to EUnetHTA21's first open call was sent to pharmaceutical companies and to pharmaceutical associations, which we previously informed about the open call, and were requested to share the survey with their members.

Feedback from 7 participants:

- Was the **duration** of the first open call appropriate? Y:5; N:2
- Were the **instructions on the website** clear to follow? Y:5; N:2
- Was the **application form** clear? Y:6; N:1
- Were the **selection criteria** clear to you? Y:4, N:1: Other:2

However, in the comments companies gave feedback that internal processes to apply for JSC take longer and the time for the preparation of an application takes longer.

JSC beyond 2023: infrastructure & resources



Selection criteria

- where the clinical studies […] **are still in the planning stage.**
- select the health technologies that are to be subject to JSC, ensuring the equal treatment of requests concerning health technologies with similar intended indications.

The criteria for selecting from eligible requests for medicinal products and medical devices shall be:

- (a) unmet medical needs;
- (b) first in class;
- (c) potential impact on patients, public health, or healthcare systems;
- (d) significant cross-border dimension;
- (e) major Union-wide added value; or
- (f) Union clinical research priorities.

2b. **Joint Clinical Assessments**

Chantal Guilhaume, HAS

JCA Deliverables for Public Consultation

Deliverables	Start Public consultation
JCA PRODUCTIONS	**NA**
METHODOLOGICAL GUIDELINES	
• D4.2.1 Scoping	**May 2nd 2022**
• D4.3.1/D4.3.2 Comparators and Comparisons	**May 2nd /August 1st 2022**
• D4.4.1 Endpoints	**October 3rd 2022**
• D4.5.1 Applicability of evidence	**July 4th 2022**
• D4.6.1 Validity of clinical studies	**July 4th 2022**
• D4.7.2. Assessment of High risk MD and IVD	**May 2nd 2022**
• D4.7.3 + 4.7.4 EUDAMED Reporting template, Guidance for EUDAMED	**June 6th 2022**
TEMPLATES	
• D5.1. Submission Dossier Template	**July 4th 2022**
• D5.2.1.JCA Report Template	**Aug 1st 2022**
PROCEDURAL GUIDELINES	
• D5.3.1 Selection criteria for assessor and co-assessor • D5.3.2 HTAb Technical Expert Working Group	**Closed** **April 20th- May 20th 2022**

2c. **Transversal Activities**

Chantal Guilhaume, HAS

Transversal Deliverables for Public Consultation

Deliverables	Start Public consultation
D7.1 Guidance for the interaction between HTA experts and health technology developers (HTD) during JCA and JSC	**20-07-2022**
D7.2. Guidance for consulting patients, clinical experts and other experts during JCA and JSC	**01-08-2022**
D7.3 Expert input templates	**01-08-2022**
D7.4 Workplan for Interaction with Regulators of medicinal products and of medical devices (section 7.4)	n.a.
D7.5 Guidance for identifying and handling conflict of interest (COI), declaration of interest and confidentiality agreement form	n.a.

3. **Principles of public consultation**

Anne Willemsen, ZIN

Public Consultations

- EUnetHTA 21 draft deliverables will undergo public consultation prior to finalization.
  - The following will not go for public consultation:
    - Internal documents (i.e. SOP); confidential documents & JSC and or JCA/CA reports

- Public Consultation takes place:
  - During drafting stage, before endorsement by the Consortium Executive Board
  - Therefore, changes to the content of the final deliverable may be made

- Comments received
  - When eligible (next slide), will be reviewed but not necessarily reflected
  - Comments received and answers provided will be published
    - When the final deliverable is endorsed and published

First experience & Lessons learnt

First public consultation took place between March 7 – April 5, 2022

- On D5.3.1 – selection criteria for JCA (co-)assessor

Lessons learnt

- Comment forms should only be submitted as a **Word-file**
- Stakeholders are asked to also comment on **national specificities**
- EUnetHTA 21 can **answer** comments in a **consolidated** manner
- EUnetHTA 21 deliverables will **avoid citing internal** documents
  - If documents have to be cited, a brief summary (1-2) sentences will be provided on what the internal document describes

Summary of principles for public consultation

- Eligible comments are from organisations in EU/EEA countries
  - If outside EU/EEA, your comments are welcomed if your organisation is directly impacted by the HTA Regulation (HTAR)
- Refrain from editorial comments, but do:
  - Consider the published project plan & content of HTAR
  - Make concrete rewording suggestions & clear rationale for the suggested change
- Comments must be received in the correct format & prior to deadline
  - No deadline extensions are possible
  - Please submit the comments as a **Word-file**. PDF files will not be accepted
  - The table at the start of the comment form must be completed, otherwise the comment form is not accepted
  - One consolidated comment form per organisation is accepted

https://www.eunethta.eu/public-consultation/

Ongoing & Anticipated Public Consultations

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

Status	Deadline	Deliverable	Title
Closed	*March 7 – April 5, 2022*	*D5.3.1*	*Selection criteria (co-)assessor JCA*
Ongoing	May 20, 2022, EOB	D5.3.2	HTA body technical expert working groups
Announced	May 2 – May 31, 2022	D4.2	Practical Guideline – Scoping Process
		D4.3.2	Methodological Guideline – Direct & Indirect Comparators and Comparisons
		D4.7.1, 4.7.2	Framework for JCA of high risk MD
Planned	June 6 – July 7, 2022	D4.7.3, 4.7.4	EUDAMED data reporting template/Guidance for EUDAMED-based TISP process
	July 4 – Aug 2, 2022	D4.5	Applicability of Evidence
		D4.6	Validity of Clinical Studies
		D5.1	Submission Dossier Template
	July 20 – Aug 19, 2022	D7.1	HTD and HTA interaction
	Aug 1 – Aug 30, 2022	D5.2	JCA report template
		D7.2/7.3	Patient and HCP guidance & templates for interaction
	Oct 3 – Nov 1, 2022	D4.4	Endpoints
	Aug 1 – Aug 31, 2023	D6.2/6.3 & 6.4	JSC briefing book template & procedural guidance

4. **Update on future HTAR**

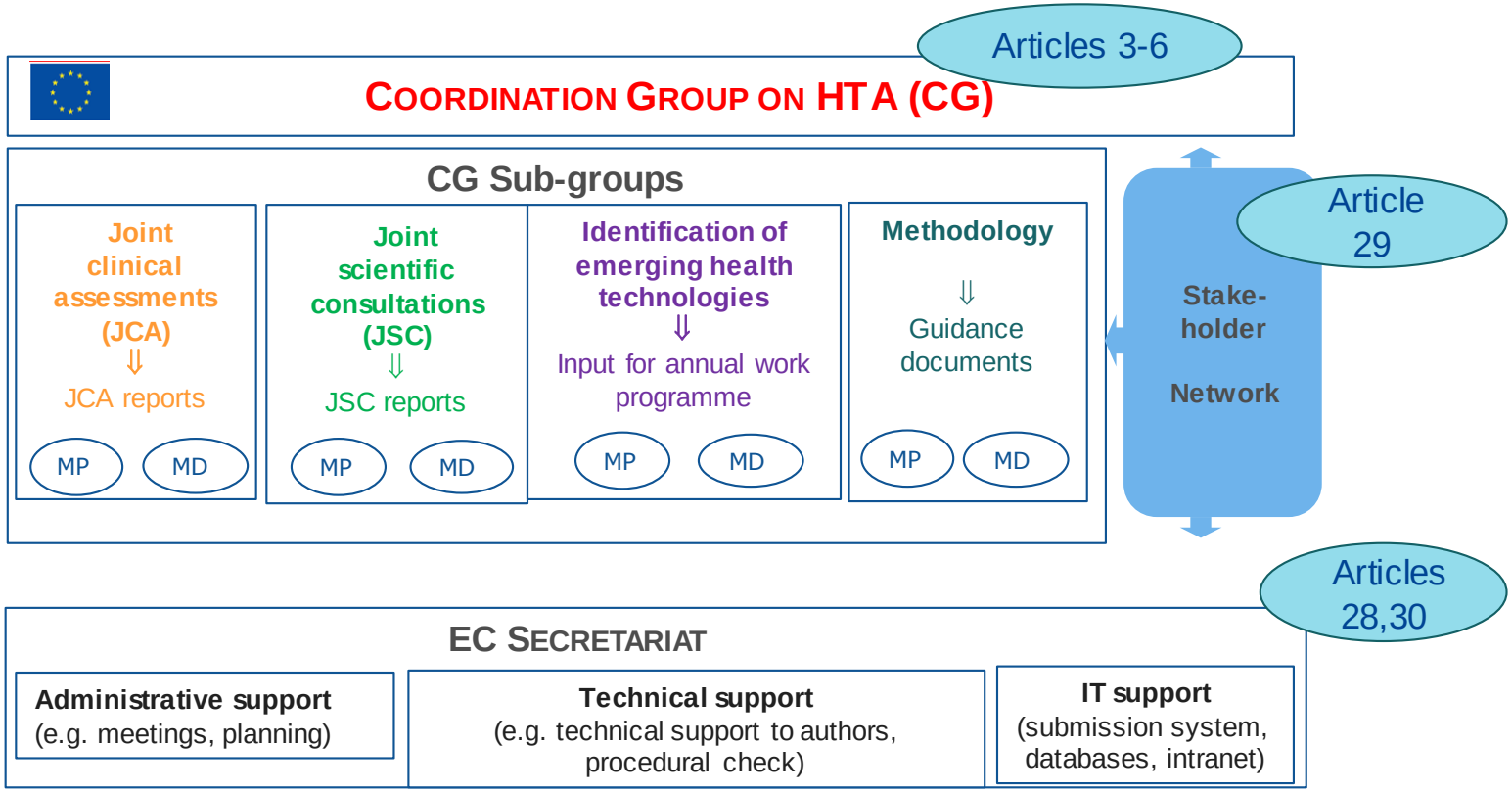
Ioana Siska, DG SANTE

Update on the implementation of the HTA Regulation (EU) 2021/2282

Ioana SISKA, MD, PhD

Policy Officer, HTA

HTA Regulation Governance



MP = medicinal products, MD = medical devices

European Commission

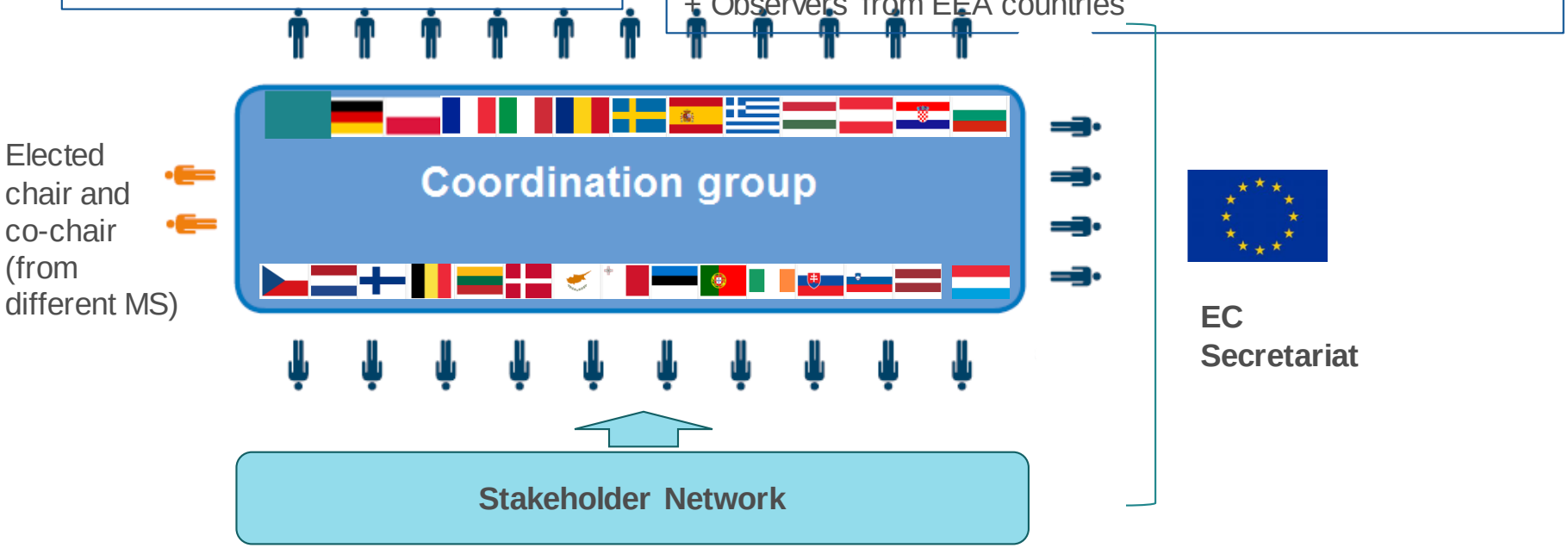
HTA Regulation
MS Coordination Group on HTA (Article 3)

Configurations:
- Medicinal products
- Medical devices (including IVDs)

- More than 1 member organisation/MS/configuration possible

(1 representative +1 alternate/member organisation)
- Decision by consensus; if voting is necessary: 1 vote/ MS

+ Observers from EEA countries



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HTA Regulation
MS Coordination Group on HTA (Article 3.7)

The Coordination Group shall:

(a) adopt its **rules of procedure** and update those rules where necessary;

(b) adopt its **annual work programme and annual report** pursuant to Article 6;

(c) provide **strategic direction for the work of its subgroups**;

(d) adopt **methodological guidance** on joint work following international standards of evidence-based medicine;

Input from EunetHTA21

(e) adopt **detailed procedural steps and the timeframe** for the conduct of JCA and updates;

(f) adopt **detailed procedural steps and the timeframe** for the conduct of JSC

(g) adopt **guidance on the appointment of assessors and co-assessors** for JCA, JSC;

European Commission

HTA Regulation
MS Coordination Group on HTA (Article 3.7)

(h) **coordinate and approve the work of its subgroups**;

(i) **ensure cooperation with relevant Union level bodies** established pursuant to Regulations (EC) No 726/2004, (EU) 2017/745 and (EU) 2017/746 to facilitate the generation of additional evidence necessary for its work;

(j) **ensure appropriate involvement of stakeholder organisations and experts** in its work;

(k) **establish subgroups**, in particular for the following:

(i) joint clinical assessments;

(ii) joint scientific consultations;

(iii) identification of emerging health technologies;

(iv) development of methodological and procedural guidance

HTA Regulation
MS Coordination Group on HTA (Article 4,5)

The Coordination Group shall

Input from EunetHTA21

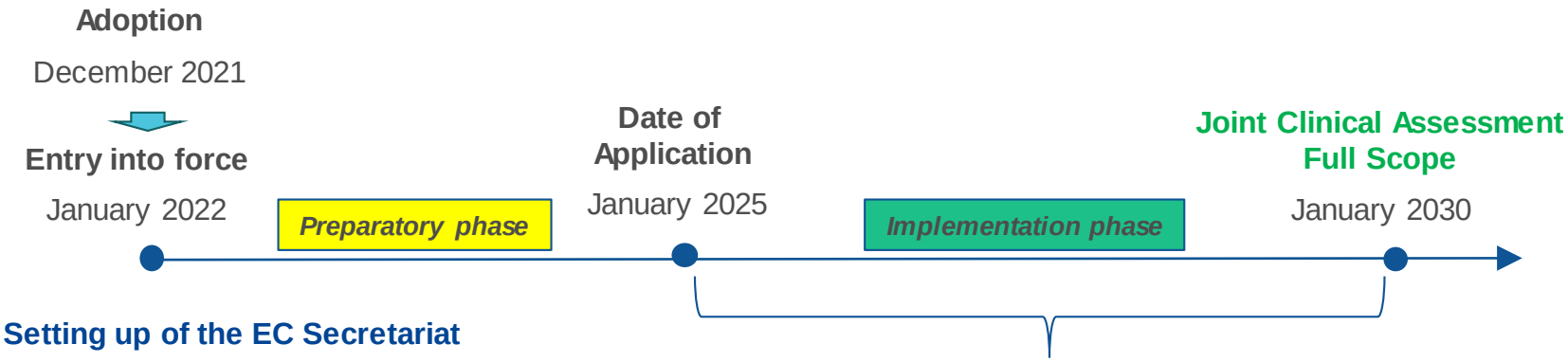
- ensure that the **joint work carried out follows international standards of evidence-based medicine**, and is delivered in a timely manner
- **establish and regularly review SOPs**
- **regularly review, and where necessary update, methodological and procedural guidance**

Input from EunetHTA21

- carry out its activities in an **independent, impartial and transparent manner**
- **not have any financial or other interests** in the health technology developers' industrial sector which could affect their independence or impartiality

European Commission

HTA Regulation
Timeline of implementation



- **Setting up of the EC Secretariat**
- **Setting up the Coordination Group/CG (EC)**
- **Setting up Stakeholders' Network (EC)**
- **Drafting implementing and delegated acts (EC)**
- **Drafting guidance documents (CG)**

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Service contract EUnetHTA21

Joint Scientific Consultations (JSC)
+
Stepwise build-up of
Joint Clinical Assessments (JCA) scope for medicines:
- From Jan. 2025: cancer drugs, ATMPs
(from date of application)
- From Jan. 2028: orphan drugs
(3 years after date of application)

European Commission

HTA Regulation
Implementation rolling plan

Latest update: March 2022

	SUBJECT	LEGAL BASIS HTAR	DESCRIPTION	EXPECTED TIMELINE	STATUS/ NEXT STEPS
1.	Setup of the publicly accessible webpage IT Platform supporting the HTAR	Article 30	Publicly accessible webpage on ec.europa.eu Publication by the Commission of the list of the members of the Coordination Group and their appointed representatives, together with their qualifications and areas of expertise and their declarations of conflict of interest after the finalisation of the joint work	Q2 2022	Ongoing
2.	Setup of a secure intranet for the exchange of information between members of the Coordination Group and its subgroups	Article 30	First release of the IT Platform made available to Coordination Group members	Q3 2022	Ongoing
3.	Setup of the Coordination Group		Designation of member institutions and their representatives by Member States and observer institutions and their representatives by EEA countries	Q2 2022 (by 25 March and 31 March respectively)	Ongoing
			First meeting of the Coordination Group	21 June 2022	Planned
4.	Raise awareness of Member States authorities and stakeholders about the HTAR		Conference on the HTAR Dissemination activities	22 June 2022	Planned

Submission of CG designated members and their representatives
(reply received from 23 MS + 2 EEA)

Rolling plan - Implementation of the Regulation on health technology assessment (europa.eu)

European Commission

HTA Regulation
Implementation rolling plan

	SUBJECT	LEGAL BASIS HTAR	DESCRIPTION	EXPECTED TIMELINE	STATUS/NEXT STEPS
5.	Setup of the Stakeholder Network	Article 29	Open call for applications addressed to all eligible stakeholder organisations, in particular patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals	Q4 2022	Planned
			Evaluation by the Commission of applications and publication of the list of stakeholder organisations included in the Stakeholder Network (including the declarations of those organisations on their membership and sources of funding, and the declarations of interest of representatives of stakeholder organisations)	Q4 2022/ Q1 2023	Planned
6.	Setup of the sub-group for the development of joint methodological and procedural guidance	Articles 3.3; 3.7 (k)	The members of the Coordination Group shall designate their national or regional authorities and bodies as members of subgroups of the Coordination Group. The members of the subgroup shall appoint their representatives, who shall have the appropriate HTA expertise, in the subgroups on an ad hoc or permanent basis and inform the Commission of their appointment and any subsequent changes.	Q4 2022	Planned*

Setup of sub-groups on JSC, JCA, Emerging health technologies planned for 2024

European Commission

HTA Regulation
Implementation rolling plan

	SUBJECT	LEGAL BASIS HTAR	DESCRIPTION	EXPECTED TIMELINE	STATUS/NEXT STEPS
10.	Preparation and adoption of implementing acts	Articles 15.1 (a), (b), and (c); 20.1 (a), (b) (c) and (d); 25.1(a) and (b); 26.1(a), (b) and (c)	Preparatory work (e.g. analysis of deliverables from EUnetHTA 21 and other relevant sources of information) Drafting and adoption of the implementing acts	Q4 2024	Ongoing
		Article 7.4		Q4 2026	Planned

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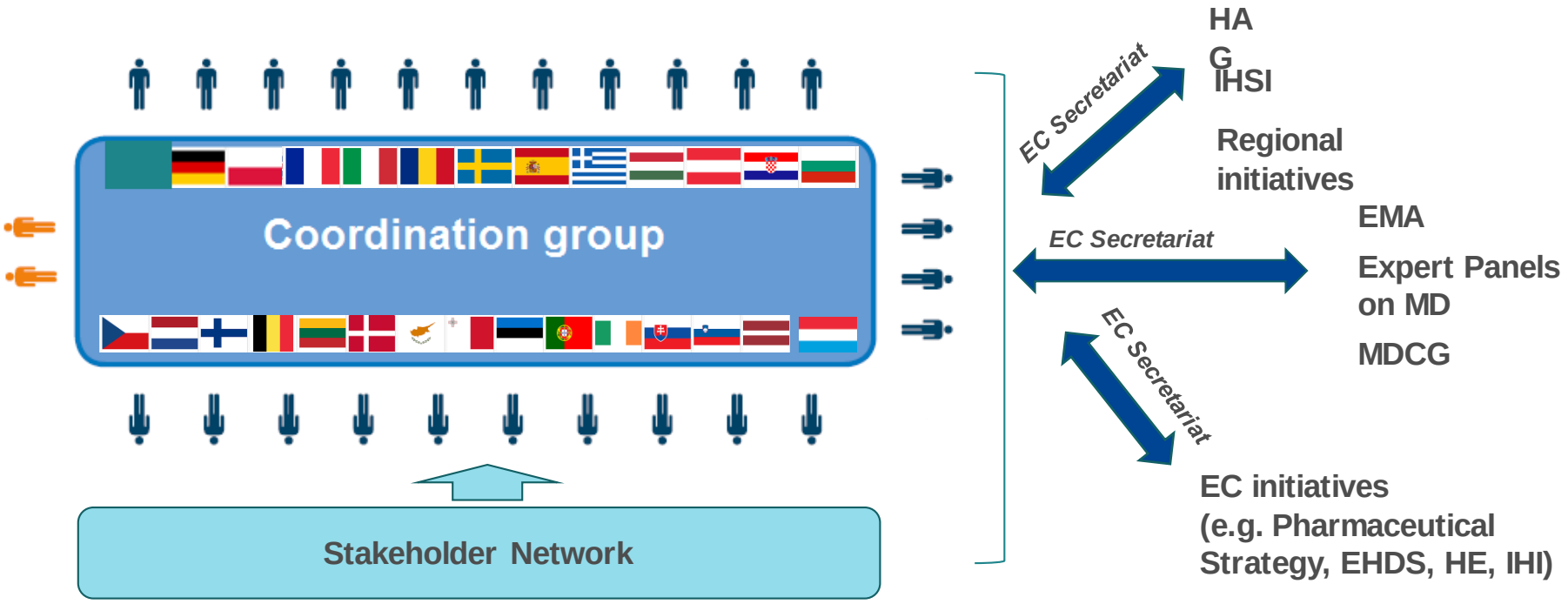
European Commission

HTA Regulation Synergies



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Thank you

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5. **Q&A**

Niklas Hedberg, TLV

6. **Closing remarks**

Niklas Hedberg, TLV