EMA – EUnetHTA 21 Bilateral

Meeting minutes

17 June 2022
10:00-12:00 CEST

Facilitator: EUnetHTA 21 Secretariat (ZIN) **Type of meeting:** Virtual

Chair: Niklas Hedberg, TLV
Michael Berntgen, EMA

Attendees:

First name	Surname	Organisation	Country
Alzbeta	Tuckova	ZIN	Netherlands
Amélie	Meillassoux-Le Cerf	HAS	France
Ana	Hidalgo-Simon	EMA	Netherlands
Andrea	Taft	EMA	Netherlands
Andrej	Segec	EMA	Netherlands
Andriantafika	Gaelle	EMA	Netherlands
Anja	Schiel	NOMA	Norway
Anne Willemsen	Behring	G-BA	Germany
Beate	Wieseler	IQWIG	Germany
Chantal	Belorgey	HAS	France
Michael	Berntgen	EMA	Netherlands
Chantal	Guilhaume	HAS	France
Daniel	Ritter	G-BA	Germany
Paul	De Boissieu	HAS	France
Corinne	De Vries	EMA	Netherlands
Eleni	Pitta	AEMPS	Spain
Elias	Pean	EMA	Netherlands
Emmanuelle	Fouteau	HAS	France
Enrico	Tognana	EMA	Netherlands
Flora	Giorgio	DG SANTE	Brussels
Francesca	Cerreta	EMA	Netherlands
Hanna	Zirath	TLV	Sweden
Hilde	Røshol	NOMA	Norway
Iordanis	Gravanis	EMA	Netherlands
Irene	Urbina	IQWIG	Germany
Irina	Cleemput	KCE	Belgium
Judith	Fernandez	HAS	France
Krystyna	Hviding	NOMA	Norway
Laurent	Brassart	EMA	Netherlands
Lise	Flaunoe	EMA	Netherlands
Marcus	Guardian	ZIN	Netherland
Margaret	Gailbraith	HAS	France
Maria	Mavris	EMA	Netherlands
Maria	Eriksson	TLV	Sweden
Mariane	Cossito	INFARMED	Portugal
Merle	Tenberg	ZIN	Netherlands
Niklas	Hedberg	TLV	Sweden
Philip	Hines	EMA	Netherlands
Roisin	Adams	NCPE	Ireland

Simona	Montilla	AIFA	Italy
Sonia	Ribeiro	EMA	Netherlands
Sonia	Pulido Sanchez	AEMPS	Spain
Stefanie	Prilla	EMA	Netherlands
Stephanie	Said	G-BA	Germany
Thorsten	Olski	EMA	Netherlands
Valentina	Barbuto	DG SANTE	Brussels
Vamvakas Spiros	Vamvakas	EMA	Netherlands
Veronika	Dóczy	NIPN	Hungary
Ziogas	Constantinos	EMA	Netherlands

Minutes

Agenda item #1	Introduction of the day and adoption of the agenda	**Presenter:**	Niklas Hedberg, TLV Michael Berntgen, EMA

The chairs welcome participants to the first bilateral under the new Work Plan between EUnetHTA 21 and EMA. It is the 22nd meeting EUnetHTA and EMA have had during the long-standing collaboration. The joint work plan (2021-2023), which was developed on request of the European Commission to continue and guide the collaboration between the two constituencies, includes activities to support the implementation of the new HTA Regulation. It was noted that the future legally mandated cooperation as reflected in the Regulation is credit to the value demonstrated during the years of voluntary work in a project environment.

The new EMA Chief Medical Officer – Steffen Thirstrup – was introduced and welcomed to the EMA/EUnetHTA bilateral meetings.

Each bilateral will have a focus on a particular area from the work plan. For the first bilateral it was agreed to focus on the topic of horizon scanning including ATMPs.

The agenda was adopted without further changes.

Agenda item #2	Introduction EUnetHTA 21	**Presenter:**	Marcus Guardian

EUnetHTA 21 is a service contract for a duration of 2 years, with the objective to produce deliverables that support the implementation of the HTA Regulation. EUnetHTA 21 is also testing possible governance structures, by mimicking the necessary review flows.

Discussion
EMA emphasises that it is important to recognize there are several deliverables as part of EUnetHTA 21 that might be relevant also for progressing topics under the joint work plan. Therefore, synergies should be created on topics from the deliverables that would benefit from direct interaction, such as the topic on indirect comparisons.

Agenda item #3	Update from the European Commission / DG SANTE on activities related to EMA/EUnetHTA 21 cooperation	**Presenter:**	Flora Giorgio, DG SANTE

The European Commission (EC) pointed out the importance of the collaboration between HTA bodies and EMA, especially to build the new system under the HTA Regulation.

The implementation timelines for the HTA Regulation were presented and it was stressed that the stepwise approach will help building up the system gradually. An important milestone is the establishment of the Stakeholder Network (~Q4, 2022). Next, the governance of the Coordination Group was presented. Lastly, the Commission elaborated on the importance of the establishment of the subgroups.
The preparatory phase will last until 2025. The implementation phase will officially start in 2025 and it will last until 2030, when the Regulation will reach its full scope. An implementation-rolling plan is publicly available and can be accessed here.

The EC concluded that the collaboration between the EMA and the HTA community remains crucial and it has to continue in the years to come.

Discussion
EUnetHTA 21 stressed that, just as for pharmaceuticals the collaboration with EMA is set up, a collaboration with the Medical Device regulators will be important in the future.

EUnetHTA 21 also stated that, while the HTA Regulation is important for the community, also the new pharma strategy will be a great challenge for regulators and perhaps also for HTA bodies (HTAb). Therefore, it was suggested that in a future bilateral the EC may provide an update on the pharma strategy once more details are available.

No action points or decisions recorded.

Agenda item #4	Work plan and its process for monitoring progress	**Presenter:**	Michael Berntgen, EMA Anne Willemsen, ZIN

The joint work plan, which was published in March 2022 (see Joint work plan between EMA and EUnetHTA21), is based on priorities identified during the conclusion of the previous work plan at the end of EUnetHTA Joint Action 3 (May 2021). Additionally,

the activities on the work plan connect to the deliverables from EUnetHTA 21.

The monitoring tool, to keep track of the status of the work plan activities, was presented to collect info on progressing with the work plan.

Discussion
The EC pointed out that the output from the work plan should, where relevant, be incorporated into the EUnetHTA 21 deliverables.

Action Points:

Action point	Responsible	Due date
Status updates on progress with the delivery of the work plan activities at bilateral meetings	EMA and EUnetHTA21	Regularly at each bilateral

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Agenda item #5 Cooperation on "Horizon Scanning" of pharmaceuticals coming into healthcare systems

5a International Horizon Scanning Initiative — Marcus Guardian, ZIN

5b ATMPs and the importance of Horizon Scanning — Enrico Tognana, EMA; Philip Hines, EMA; Chantal Belorgey, HAS; Ana Hidalgo-Simon, EMA

5a – International Horizon Scanning Initiative

The International Horizon Scanning Initiative (IHSI) is a separate legal entity, which is a Member State driven organisation. IHSI has developed a database, which holds pharmaceutical compounds as of phase I of the development. Additionally, IHSI prepares high impact reports, which go into the database to predict which products could be of high impact. Any of this data is in the public domain, without any confidentiality blocking access to the information. The IHSI methodology and process was presented. The collaboration with EMA in this project was found very valuable.

EMA colleagues presented on their preparedness activities, covering Business Analysis & Forecasting as well as horizon scanning'. The latter looks into the near future (3-10 years before submission) and the former anticipates the impact of upcoming Marketing Authorisation Application submissions on the workload and expertise needs of European regulators. Their methods were presented including data acquisition, data management and reporting. EMA produces deep dive reports (including recommendations), short reports, and annual reports.

EMA provides input to EUnetHTA 21 by peer reviewing IHSI impact report against EMA pipeline (Proactive and on demand review EMA pipeline for issues of EUnetHTA-21 concern*).* This is relevant in the context of the work plan item "Increased understanding of future challenges derived from innovative medicines".

Action Points:

Action point	Responsible	Due date
Follow-up discussion how information from EMA can contribute to the process for annual work planning and future reporting under HTA Regulation.	EMA / EUnetHTA21 / Coordina-tion group	Mid-2023
Identification of pharmaceutical compounds that could be suitable for JCA in EUnetHTA 21 or voluntary exchange under the work plan	EMA / EUnetHTA21	Ongoing
Investigate how the IHSI High Impact Reports and EMA's horizon scanning tool could synergistically allow better understanding of future challenges derived from innovative medicines.	EMA / IHSI	End-2022

#5b – Review of upcoming ATMPs and opportunities for cooperation

ATMPs are part of the first pharmaceuticals to undergo a Joint Clinical Assessment or receive a Joint Scientific Consultation, under the HTA Regulation. These compounds bring many challenges to HTA, as randomized controlled trials are very rarely available and often a conditional approval is granted, followed by annual re-assessments. EUnetHTA 21 stressed that this raises the need for Post-Launch Evidence Generation (PLEG). It was also highlighted that the same challenges are becoming more prominent for oncology drugs.

HTA bodies need to be able to anticipate how to proceed with early access authorisation, how to organise the care, how to proceed with early access authorisation (national provision), JSC/JCA/PLEG, and organisation of care (national topic). For this, Horizon Scanning will be very important to anticipate these issues.

EMA agrees that the development and evaluation of ATMPs generally creates new challenges and therefore the establishment of the more relevant evidence base for decision making is crucial. EMA also stressed that PLEG including Real World Evidence is an important element for these products and this is where collaboration across decision makers should take place early. Further, the importance of having Joint Scientific Consultations on ATMPs was stressed.

Action Points:

Action Point	*Who*	*When*
A future EMA-EUnetHTA 21 bilateral will focus on the evidence requirements for ATMPs, so more extensive discussion can take place then.	EUnetHTA 21 Secretariat/ EMA	Q1 2023
There are 4 ATMPs currently undergoing a Marketing Authorisation process. HTA bodies should review which of these are of interest for a discussion on the final regulatory assessment, once available, or the definition of PLEG requirements topics to understand on which of these topics engagement for Real World Evidence would be relevant.	HTA	Q3 2022

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Agenda item #6	Discussion on the rules for cooperation between EMA and EUnetHTA 21 in particular by exchange of information on joint HTA work	**Presenter:**	Anne Willemsen, ZIN Michael Berntgen, EMA

ZIN presented the provisions on exchanges with regulatory bodies under the HTA Regulation for both pharmaceutical and medical device Joint Clinical Assessments.

Key areas for collaboration, such as Horizon Scanning (to prepare the annual work plan under the HTA Regulation), Joint HTA production including Joint Scientific Consultations (JSC) and Joint Clinical Assessments (JCA), were outlined.

Specifically for the JCA on medicinal products, the proposed interaction with EMA during the JCA process was presented building on the experience with cooperation in the context of joint REA production under EUnetHTA JA3. This interaction focussed around regular updates with the EMA and EUnetHTA 21 to flag potential changes in the indication and to anticipate changes in regulatory timelines (i.e. extension of clock-stops) at an early stage. Such interaction would take place on the basis of confidentiality arrangements.

It was stressed that under the HTA Regulation, this interaction between EMA and HTA bodies is foreseen and the fine-tuned operation should be developed through the presented Implementing Acts.

Agenda item #7	Closure of the meeting	**Presenter:**	Michael Berntgen, EMA Niklas Hedberg, TLV

The chairs of the meeting thank the attendees and closes the meeting.