10 December 2020
EMA/386443/2020

Minutes of EMA/EUnetHTA virtual meeting

13 July 2020

Role	Name
Co-chairs:	Hans-Georg Eichler and Niklas Hedberg
Present:	EUnetHTA: Simona Montilla (AIFA), Regina Skavron (G-BA), Irena Guzina (HAS), Chantal Bélorgey (HAS), Chantal Guilhaume (HAS), Alex Correia (INFARMED), Joerg Lauterberg (IQWiG), Beate Wieseler (IQWiG), Alric Ruether (IQWiG), Krystyna Hviding (NOMA), Niklas Hedberg (TLV), Marcus Guardian (ZIN), Anne Willemsen (ZIN), Merle Tenberg (ZIN), Chaienna Schreuder-Morel (ZIN), Wim Goettsch (ZIN). EC: Flora Giorgio, Ioana Raluca-Siska, Julia Schmitz. EMA: Michael Berntgen, Falk Ehmann, Hans-Georg Eichler, Harald Enzmann, Lorenzo Guizzaro, Dominik Karres, Xavier Kurz, Maria Mavris, Thorsten Olski, Chrissi Pallidis, Sabine Scherer, Bruno Sepodes, Spiros Vamvakas.

Item	Draft agenda	Name	Time
1.	Welcome and introduction to the day and adoption of the draft agenda	Hans-Georg Eichler and Niklas Hedberg	10 min 15.00-15.10
2.	Update from DG SANTE on activities related to the EMA/EUnetHTA collaboration	Flora Giorgio	10 min 15.10-15.20
3.	Update from EUnetHTA including the priorities for the final phase of JA3	Marcus Guardian	15 min 15.20-15.35
4.	Refinement of the operations of the Parallel Consultation platform	EUnetHTA: Representative from WP5 EMA: Thorsten Olski, Iordanis Gravanis	15 min 15.35-15.50
5.	Application of the extrapolation concept in practice – development of assessment tools	EMA: Dominik Karres, Chrissi Pallidis, Sabine Scherer	25 min 15.50-16.15

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6.	EUnetHTA-EMA Work Plan Jan 2017-2021: review of activities in view of the last year for completion and plans for reporting Short topic update: • Optimise utilisation of post-licensing evidence generation for decision making • Provision of guidance on evidence needs for regulators and HTA bodies • Better utilization of patient-reported outcomes as part of evidence generation plans • Share practices and experiences with combination products/companion diagnostics	Michael Berntgen / Anne Willemsen Topic leads for selected items	30 min 16.15-16.45
7.	Publication of clinical reports on COVID-19 treatments and vaccines	Beate Wieseler	5 min
8.	Closing remarks	Hans-Georg Eichler and Niklas Hedberg	5 min 16.45-16.55

This was the 19th meeting between the European Medicines Agency (EMA) and representatives from the European Network for Health Technology Assessment (EUnetHTA). As usual, the meeting was attended by the European Commission.

Such bilateral meetings are held between EMA and EUnetHTA since 2010. On this occasion, due to the COVID-19 pandemic, it was decided to arrange the bilateral in a virtual format and of shorter duration. The primary focus of the meeting was to review the status of specific items from the EMA/EUnetHTA workplan 2017-2021.

The draft agenda was adopted without changes.

Update from DG SANTE on activities related to the EMA/EUnetHTA collaboration

The Commission provided an update on the legal proposal for HTA collaboration. A progress report from the Croatian Presidency was presented in June and the expectation is for continued discussion at Council level under the German presidency.

Furthermore, the Commission highlighted the development of the Pharmaceutical Strategy and the online workshop in June 2020 with participation from a number of stakeholders including regulators and HTA bodies. Key sessions from HTA perceptive are on Roadmap; Innovation and access; Availability and shortages; Affordability. Also, to note in this context the EU4Heath programme, which provides the new financial framework for public health programmes.

Update from EUnetHTA including the priorities for the final phase of JA3

For EUnetHTA the predictability, awareness and continuity of collaboration with EMA remains high priority even in times of uncertainty. It is in this context that the formal approval of a 12-month extension of EUnetHTA Joint Action 3 (JA3, until May 2021) was positively noted. The objectives of the prolongation remain consistent with the objectives of JA3; however, the focus is different. The eight areas of focus for the remaining duration of JA3 are: prioritising COVID-19 related work; completion of ongoing Joint Assessments; acquisition of new Pharmaceutical Joint Assessments; finalisation of

assessment procedures and methodologies; continuation of Early Dialogues activities; completion of PLEG pilots; finalisation of work on the Future Model of Cooperation on HTA; completion of the final technical and financial report.

As JA3 is coming to an end soon, it is the responsibility of the EUnetHTA Secretariat to ensure that the knowledge on the experience with HTA collaboration is documented. In the absence of clarity concerning a potential future legal framework, work is ongoing to produce relevant records. In this context it was agreed to jointly produce a technical report with achievements and lessons learned from the EMA/EUnetHTA collaboration, similar to what was done at the end of JA2.

Turning to the COVID-19 pandemic, it was noted that this has highlighted the importance of EU cooperation to safeguard the health of EU citizens, and that the HTA community should contribute to the efforts to make sure that the response to the crisis is based on the best available scientific evidence collaboration. In practice, this means amongst others prioritising COVID-19-related Joint and Collaborative Assessments and Early Dialogues and PLEGs, tying together all key products - including the work on PLEG - to conduct work on the complete lifecycle of treatments, and exploring the potential use of "Rolling Collaborative Reviews" for monitoring COVID-19 treatments. EUnetHTA has recently published a dedicated webpage detailing its activities in relation to the pandemic.

ACTIONS:

- Production of technical report with lessons learned from the EMA/EUnetHTA collaboration, which will later also be published

Refinement of the operations of the Parallel Consultation platform

HAS as lead partner for parallel consultation presented on EUnetHTA's recently initiated refinement of the operations of the parallel consultation platform. After a pause by EUnetHTA in April 2020, their Executive Board has recognized the interest to continue offering Early Dialogues (ED) through the EUnetHTA prolongation period of JA3. The aim is to conduct 1 ED per month with a maximum 8 EDs during this time.

From HTA perspective, there would be an Open Call during 6 weeks in July/August 2020 to be considered for any of these 8 slots. Rather than two types of procedures for HTA collaboration on ED (consolidated and individual), there will be one type with two different formats, written-only and face-to-face meeting. In any case all EDs would receive consolidated HTA advice. The EUnetHTA ED Request Form, submissions calendar, briefing book template, and Guidance for Parallel Consultations were published, in collaboration with EMA.

Initial feedback from prospective applicants was reported positive in terms of the reopening of the activity, the new focus on post-licensing evidence generation (PLEG) and patient-reported outcomes (PRO), as well as the format of the briefing book template. It was agreed that further feedback should be collected systematically.

ACTIONS:

- Joint development of communication material to provide information to prospective applicants
- Systematic collection of feedback from applicants on the new procedure for preparation of "lessons learned"

Application of the extrapolation concept in practice – development of assessment tools

EMA provided an overview of ongoing implementation work regarding the reflection paper on the use of extrapolation in the development of medicines for paediatrics, which is driven by the Paediatric Committee (PDCO). The objective is to create a structured and practical guidance to facilitate the common presentation of the extrapolation framework from industry to the regulators and to drive a common approach assessing the acceptability by regulators across the life cycle. A draft guidance template has been developed to serve as assessment tool. The application of the concept was exemplified on a medicine for a rare paediatric condition. A challenge is that in some cases data to be generated as part of an agreed extrapolation plan might only be fully established post-marketing authorisation, e.g. specific obligations, post-authorisation efficacy studies. This leading to the challenge that not all assumptions are necessarily fully confirmed at time of HTA assessment. It was therefore highlighted that sharing views on extrapolation (or evidence transfer) between regulators and HTAs is important to ensure that products authorised based on extrapolation are later also accessible to patients.

From HTA perspective the documentation of the assumptions in the EPAR was highlighted. It was agreed that with increasing clarity of the extrapolation framework more information can be provided in these reports. The invitation to collaborate further on this topic was therefore appreciated with the expectation that this leads to similar positive experience as with the discussion on the therapeutic indication and the related reflection paper.

ACTION:

- Initiate an exchange to increase understanding around application of extrapolation (e.g. discussing the approach using cases; sharing the draft guidance document)

EUnetHTA-EMA Work Plan Jan 2017-2021: review of activities in view of the last year for completion and plans for reporting

In order to ensure the delivery of the EMA/EUnetHTA work plan, a review of the current status was presented jointly by EMA and EUnetHTA. As of July 2020, following further review 9 activities were considered on track or completed, 6 activities showed progress but some obstacles are expected, 2 activities were not progressing as planned and would require additional effort, and 3 activities were closed.

Reflecting specifically on the activity to collaborate on the provision of methodological guidance on evidence needs, it was noted that the guidance on indirect comparison was considered of mutual interest; as another area the methodological learnings for the assessment on antimicrobials were highlighted given a recent joint production by EUnetHTA in this space. However, it was agreed that any such work can currently not progress due to resource constraints. It was therefore agreed that any contributions will be limited to the contribution as part of the respective public consultation on draft documents for the time being.

ACTION:

- The topic leads from EMA and EUnetHTA will be asked to provide a mid-year report for their item, which will be recorded as basis for the above-mentioned technical report

Publication of clinical reports on COVID-19 treatments and vaccines

EUnetHTA enquired about the publication of clinical study reports for COVID-19 treatments and vaccines under EMA's Policy 70. Particularly, the possibility to accelerate publication of clinical reports for COVID-19 treatments and vaccines in parallel to acceleration of other regulatory processes was raised to support HTA and the scientific community working towards development of COVID-19 treatments and vaccines. EMA confirmed its general commitment to transparency. During the COVID-19 pandemic, the EMA is implementing exceptional measures to maximise the transparency of its regulatory activities on treatments and vaccines for COVID-19 that are approved or are under evaluation. EMA is achieving this by shortening its standard publishing timeframes and publishing information it does not normally publish for other medicines. This includes the publication of clinical trial data. However, due process will need to be followed by all actors including the sponsor in order to facilitate such progressive degree of transparency.

Closing remarks

The next meeting will be hosted by EMA and will be scheduled for **Q4 2020**, most likely again in the virtual format.