EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

HEALTH SYSTEMS, MEDICAL PRODUCTS AND INNOVATION
Medical Devices, Health Technology Assessment

Brussels,

SUMMARY RECORDS

OF THE 11th HTA NETWORK E-MEETING

WEDNESDAY 7 JULY 2021

1. INTRODUCTION

These minutes are prepared by the Secretariat of the Health Technology Assessment Network ("HTA Network") in accordance with the rules of procedure[1].

All Member States (MS) with the exception of Cyprus and Luxemburg were present. Representatives of Norway attended the meeting. EMA, as well as representatives for each of the four constituent groups the HTA Network Stakeholder Pool (i.e. patients and consumers - EURORDIS, BEUC; healthcare providers – ESMO, EAHP; payers - AIM, ESIP, and industry - EFPIA, COCIR and MedTech Europe) were also present. To benefit from the opportunity of an online meeting, other member organisations of the HTA Network Stakeholder Pool were granted access upon request.

The meeting was chaired by Andrzej Ryś, Director, "Health systems, medical products and innovation" DG Health and Food Safety.

With the agreement of all participants to the HTA Network, this meeting was recorded.

2. WELCOME AND OPENING

The Chair, ***Andrzej Ryś***, welcomed the participants. The Chair reminded announced that this meeting's minutes will be circulated to the participants for approval and subsequently will be published on the DG SANTE website. Presentations will be also made available on the HTA Network webpage.[2]

[1] https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co03_en.pdf
[2] 11th meeting of the HTA Network | Public Health (europa.eu)

3. RECENT DEVELOPMENTS AND NEXT STEPS REGARDING EU COOPERATION ON HTA (Topic 1)

The first topic was devoted to Regulation on HTA (HTAR). The Chair recalled the adoption of the cross-border healthcare directive, the setup and work of the HTA network, as well as the successful scientific and technical cooperation through the Joint Actions EUnetHTA – all enabled the exchange of information and expertise among HTA bodies, contributed to capacity building across EU, also facilitating the dialogue and cooperation between HTA bodies and regulators. Based on these collaborative activities, the Commission adopted a proposal for a regulation to further strengthen EU cooperation on HTA. The Chair reminded the audience about the most recent steps of the co-decision procedure, which started with the mandate received by the Portuguese Presidency in March 2021 to start the trialogues. Following 16 technical meetings and three political trialogues, the co-legislators reached a provisional agreement on the 21st of June, which was confirmed by the Committee of the Permanent Representatives of the Governments of the Member States to the EU/COREPER on the 30th of June. The audience was informed that the vote in the European Parliament ENVI Committee is scheduled for the 13th of July 2021, the plenary vote in September 2021, after which the final adoption of the HTAR should follow.

An overview of the provisionally agreed HTAR was given by the HTA team leader in DG SANTE, who outlined its key principles and its main provisions on issues such as organisational framework, areas of joint work, scope of joint clinical assessments (JCA) in the field of medicines and medical devices, involvement in joint HTA work of external experts and stakeholder organisations and a possible implementation timeline. Finally, the audience was reminded about the call for tender on advancing HTA methodology, for which the awarding decision by the Health and Digital Executive Agency/HaDEA is expected in by the end of July. It was mentioned that the service contract, should also ensure continuity of joint work (e.g. joint scientific consultations, joint clinical assessments, joint collaborative assessments), and should organise coordination activities for consulting the broad European HTA community and engaging all relevant stakeholders in its activities.

During the subsequent discussions, the following issues were clarified:

- Stakeholders' involvement in the transition phase from the HTA Stakeholder Pool to the Stakeholder Network laid down in the HTAR (question on behalf of the healthcare providers group). It was explained that the setup of the Stakeholder Network is an important step, which should follow the establishment of the Coordination Group. The service contract, which should start this September, will consult stakeholders when developing its deliverables and thus contribute to ensuring the connection with Member States HTA organisations before the setup of the Stakeholder Network. In addition, The Commission could organise ad hoc meetings with stakeholders, thus collecting their input to its activities during the preparatory phase; while still reflecting on the stepwise implementation of the HTA Regulation, the Commission is committed to ensure a timely communication of the next steps with the broad HTA community and stakeholders.

- EU cooperation on HTA in the field of digital health and implementation date for joint HTA work on medical devices (question on behalf of industry group). It was clarified that digital solutions are not in scope, unless software is part of the medical devices subject to joint clinical assessments covered by the HTAR. However, due to the high interest by MS and recognising the challenges related to assessing this type of products, HTA cooperation in the field of digital solutions may be subject to

voluntary cooperation. Whilst, JCA on medical devices will not start before the application date, work on developing the methodological guidance for joint HTA on medical devices may start earlier, if the future Coordination Group (CG) considers it a priority.

- Connecting HTAR to national HTA processes, in order to allow smooth implementation of the new provisions and avoid delays in access to the market for products assessed jointly at EU level (question on behalf of industry group). It was clarified that the new legal framework aims to provide the JCA reports on medicinal products at the time of marketing authorisation, for the Member States to make best use of them in their national procedures. EUnetHTA JA3 already managed to reach a good timing for its joint assessments, so the new framework will use this experience. In addition, the high interest showed by the HTA community in EUnetHTA and more recently by the Heads of HTA Agencies Group confirms their interest to strengthen EU cooperation on HTA.

- Potential flexibility for the stepwise implementation of the HTAR and the scope of the service contract post-EUnetHTA (question on behalf of patients group). It was explained that the timeline agreed by the co-legislators cannot be changed, but oncology medicines, including orphan medicine for oncology indications, will be subject to JCA in the first step of the implementation phase. In addition, the CG may decide to bring forward and assess earlier than planned, other products considered important to assess (e.g. unmet medical need, public health emergency). Alternatively, voluntary work may cover other products than those laid down in the HTAR for the first phase. Regarding the focus of the service contract, it was clarified that advancing methodological guidance supporting joint HTA work will support the timely implementation of the HTAR by providing robust input to the work of the CG, who is mandated to adopt the guidance for joint work. Concerning joint scientific consultations (JSC), the cooperation between EMA and HTA bodies could supplement the JSCs, which will be carried out by the selected tenderer.

- Decision on the setup of the Stakeholder Network (e.g. timeline, number and categories of stakeholders to be included) and beginning of its activities, possibility of stakeholders to be engaged during the drafting of tertiary legislation (questions on behalf of healthcare professionals group). The reply from the Commission made clear that the detailed steps for setting up the Stakeholder Network and its organisation were not decided yet, but a process similar to the setup of the HTA Network Stakeholder Pool is envisaged. EMA models of engaging with stakeholders will be also considered. The main priority after adoption will be to set up the Coordination Group, and the setup of the Network should follow. Alternatively, until the Network will become operational, the Commission could consider organising ad-hoc meetings to collect input from stakeholders during the preparatory phase. Additionally, the selected tenderer should support the Commission, and engage with all relevant stakeholders and incorporate their input in the methodological guidance they will develop.

- Activities and structures (e.g. CG, CG sub-groups) which could be setup before the application date and the procedure for developing tertiary legislation (question on behalf of MS). It was clarified that after the adoption of the HTAR the Commission will ask MS to nominate their representatives to the CG. A first meeting may be organised in the first half of 2022, to start discussions on matters such as rules of

procedures and process-oriented procedures. The Commission is ready to provide more details on the comitology procedure related to the adoption of implementing legislation to interested MS, upon request, after the meeting.

- Collaboration with payers until the date of application of the HTAR, and afterwards, and handling of conflicts of interest in the context of the new legal framework (questions on behalf of payers group). It was clarified that payers are one of the categories that will be part of the Stakeholder Network. Additionally, DG SANTE is also coordinating the NCAPR meetings, with responsible units working closely together to ensure synergies and avoid duplication of work; after the adoption of the HTAR there will be more discussions on how to coordinate the interactions between the payers group in the Stakeholder Network and NCAPR. Concerning the handling of potential conflicts of interest, it was underlined that the legal text is rather detailed, with an additional provision on how to address this issue included during negotiation.

The Chair reminded the audience that the new framework of cooperation on HTA benefits from the many years of successful cooperation of the HTA Network and the EUnetHTA joint actions, thanked the Member States representatives and stakeholders for their active contribution and expressed hope for a fruitful strengthened cooperation in the future.

4. UPDATE FROM THE COMMISSION ON HTA-RELEVANT ACTIVITIES (Topic 2)

The second topic was devoted to presentations of relevant Commission initiatives led by DG SANTE and DG REFORM.

The first presentation was an update on the European Pharmaceutical Strategy. The audience was reminded about the objective and flagship deliverables of the Pharmaceutic Strategy adopted last November, with the HTAR as one of its main deliverables for this year. The presentation focused on the deliverables of the Pharmaceutical Strategy more relevant for the HTA community. Under the deliverables related to improving access and affordability to medicines, HTA could provide relevant input in the areas of on unmet medical needs and evidence generation, with the new HTAR playing a supporting role though its provisions on joint work. Regarding sustainable innovation, enhancing the dialogue between regulators, HTA authorities and other relevant authorities is one of the actions aiming to streamline to process and enable innovation in key desired areas. The main legislative agenda related to the Pharmaceutical Strategy was presented, as well as the indicative timeline for the revision of basic pharmaceutical acts, with the Commission aiming to adopt a legal proposal by the end of 2022. In this regard, among other preparatory actions, a broad online public consultation will be carried out by the Commission in the fourth quarter of this year. In parallel, the Commission is working with an external contractor on a study evaluating the current pharmaceutical legislation and supporting the future impact assessment. Additionally, Pharmaceutical Committee meetings, conferences organised by the Portuguese and Slovene presidencies, and five thematic workshops allowed to collect input on all areas relevant for the revision. Concerning the latter, the participation and the valuable contribution from HTA authorities was highlighted, especially on issues such as unmet medical needs, access and affordability, and sustainable innovation. Finally, the audience was asked to further reflect on policy developments necessary in terms of pharmaceutical incentives and cooperation among national authorities so that the new EU HTA mechanism reaches its full potential. A MS representative called the Commission to continue fostering synergies between the new HTA

framework and the EU pharmaceutical legislation. A patients' representative called for more ad-hoc meetings to be organised by the Commission in order to increase input from civil society and patients' organisations to the Pharmaceutical Strategy.

The second presentation focused on the European Health Data Space initiative (EHDS). It was reminded that the EHDS initiative is one of the components of the European data strategy presented by the Commission in February 2020, in close connection to the Data Governance Act. By facilitating timely and simplified exchange of and access to health data, EHDS aims to support healthcare delivery (so-called primary use of data/EHDS1), as well as health research and health policy making purposes (so-called secondary use of data/EHDS2). EHDS will be developed using a combination of instruments, and will cover rules for data governance and data exchange, data quality, infrastructure, as well as capacity building. The key challenges for both primary and secondary use of health data at EU level were highlighted. Concerning the legislative work, the Commission aims to adopt a legal proposal in the first quarter of 2022. The legal proposal will build on the elements developed under current legal framework (e.g. for EHDS1, expanding the existing cross-border exchange of patients' data). For the EHDS2, by means of EU4Health funding, the Commission will launch pilots, to provide the proof of concept for the cross-border exchange of health data involving data permit authorities, research infrastructures and other public authorities, addressing important technical issues, as well as questions related to the future governance and IT data ecosystems. In parallel, the ongoing Joint Action TEHDaS[3] will develop the joint European principles for the secondary use of health data and will feed into the impact assessment for the legal proposal and the overall development of the EHDS. The audience was encouraged to provide input to the ongoing public consultation (open until July 26) and if interested to collaborate to the other actions preparing the EHDS. The Chair reminded the audience that the DARWIN (Data Analytics and Real World Interrogation Network) project, initiated by EMA, will also contribute to EHDS.

The next presentation provided an overview of the European strategy on COVID-19 Therapeutics, published in May 2021. The strategy complements the successful EU strategy for COVID-19 vaccines, and aims building an EU portfolio of therapeutics to enhance the response to COVID-19 (i.e. ten promising therapeutics by October, of which five identified by end of June; three new therapeutics authorised by October 2021, and possibly two more by the end of the year) and increasing Member States' capacity to meet the demand for therapeutics during the pandemic. The Strategy is based on the lessons learned from the pandemic and includes clear actions and targets, addressing all relevant areas: research, development and innovation; ensuring access to and swift approval of large-scale clinical trials in the EU; scanning for candidate therapeutics; securing supply chains and the delivery of medicines; ensuring a rapid and flexible regulatory process; flexible, fit-for-purpose and well-resourced financing and procurement capacities; reinforcing international cooperation. For each area, the main deliverables were highlighted (e.g. establishing a 'therapeutics innovation booster' platform by July 2021, organization of an EU matchmaking event on COVID-19 therapeutics for industrial production on 12-13 July 2021**,** launching a pilot project to facilitate the EMA's and national medicine agencies' access to real-world data to check the safety and efficacy of therapeutics planned for the third quarter of 2021, launching new joint procurements of COVID-19 authorised therapeutics in the EU on behalf of Member States by end of 2021). Following a question from a representative of the patients and consumers group regarding APAs for COVID-19 therapeutics, the Commission clarified that for the moment only joint procurement procedures are planned according to existing

[3] Joint Action Towards the European Health Data Space – TEHDAS - Tehdas

agreements, with APAs not yet covered, but not excluded either. In response to a question from MS on the potential contribution from HTA experts to the identification of products to be included in the EU portfolio of COVID-19 therapeutics, the Chair clarified that this issue has been signaled to colleagues working on recruiting experts for the panel mandated with this task, confirming the value of the HTA perspective for this action.

The last presentation was given by a representative from DG REFORM on the Technical Support Instrument/TSI. TSI offers technical, tailor-made support to all EU Member States (but not EEA countries) upon demand for designing and implementing structural reforms. It may address a wide range of reforms, covering entire life cycle of the reforms and does not require any co-financing. In the field of health, several MS benefitted from TSI projects in areas such as primary care, eHealth, hospital care and other horizontal reforms. With the next deadline for submitting requests to the Commission approaching (i.e. 31 October 2021), HTA representatives were invited to reflect and contact their national Coordinating Authority, for any potential needs which may benefit from the TSI. For interested Member States, DG REFORM representative offered to provide the contact details of their national coordinating authority upon request. It was clarified that DG REFORM has a good experience with also with multi-country projects, especially when they show complementarity and synergy of actions. Concerning the potential timeline from request until implementation, it was explained that after the submission deadline, DG REFORM analyses all proposals in the following 5 weeks, with the selection board ensuring informal feedback on the results by the end of the year, and official publication of the Commission decision by end February. Potential implementation of the successful projects may start in the following 4 to 6 months.

5. CONCLUSIONS AND CLOSURE OF THE MEETING

The Chair reminded the audience that this was the last meeting of the HTA Network (in light of the adoption by the Council and the European Parliament of the HTAR expected by the end of year), thanked for the active and valuable contribution of all representatives throughout the existence of the HTA Network and called for an equally fruitful cooperation under the future new EU HTA legal framework. The members of the HTA Network and of the Stakeholder Pool will be timely informed about any future developments and meetings by the HTA team in SANTE B6.