Brussels,

### MINUTES OF THE 10<sup>th</sup> HTA NETWORK E-MEETING TUESDAY 27 OCTOBER 2020

#### 1. INTRODUCTION

These minutes are prepared by the Secretariat of the Health Technology Assessment Network ("HTA Network") in accordance with the rules of procedure<sup>1</sup>.

All Member States (MS), Norway, Iceland and EUnetHTA were present. An EMA representative also attended. In addition, two official representatives for each of the four constituent groups the HTA Network Stakeholder Pool (i.e. patients and consumers, providers, payers and industry) attended the meeting, as following: EURORDIS, BEUC, PGEU, UEMO, AIM, ESIP, EFPIA, COCIR and MedTech Europe. To benefit from the opportunity of an online meeting, other member organisations of the Pool were granted access upon request (i.e. CED, CPME, EAHP, ECPC, EFPC, ESC, ESIP, EUPHA, HOPE, Medicines for Europe, PPTA).

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 and the list of participants will be circulated Presentations were distributed to the participants via AGM and are available on the HTA Network website.<sup>2</sup>

#### 2. WELCOME AND OPENING

The Chair, *Andrzej Ryś*, welcomed participants. The Chair reminded that the agenda of the meeting was circulated in advance, and announced that this meeting's minutes and presentations will be circulated to the participants for approval and subsequently will be published on the DG SANTE website.

# 3. UPDATE FROM THE COMMISSION ON HTA-RELEVANT ACTIVITIES (Topic 1)

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

<sup>&</sup>lt;sup>1</sup> https://ec.europa.eu/health/sites/health/files/technology\_assessment/docs/ev\_20161110\_co03\_en.pdf

<sup>&</sup>lt;sup>2</sup> https://ec.europa.eu/health/technology assessment/events/ev 20170329 en

The first presentation was an update on the European Pharmaceutical Strategy. The audience was informed about its structure, objectives and consultations activities organised by the Commission since the publication of the roadmap in June 2020 (i.e. feedback on the roadmap, stakeholder workshop in July, and an online public survey open until mid-September). Input was analysed by an external consultant and SANTE services and provided useful elements to fine-tune the strategy. Member States were extensively consulted through meetings with the Pharmaceutical Committee held between May and September 2020. The audience was informed that the text of the Commission Communication on the pharmaceutical strategy is in its conclusion phase with the aim to be adopted on 24 November 2020. Issues highlighted by the COVID-19 pandemic will be integrated in the different pillars of the strategy and will be connected to other EU initiatives such as health union package to be adopted on 11 November, the revision of EMA and ECDC mandates in relation to crisis management and the creation of a European agency similar to the US BARDA. The four pillars' structure of the strategy was explained: ensuring greater access to medicines; supporting sustainable innovation, emerging science digitalisation; reducing medicines shortages and securing open strategic autonomy; supporting the EU influence and competiveness globally through promotion of international standards and level playing field for EU actors. The synergy with other EU initiatives such as the HTA proposal was mentioned. Details on the input provided to the consultations activities were also presented, showing the great interest by various contributors to issues related to availability, access and affordability to medicines. More precisely, in relation to HTA, respondents expressed support for alignment of R&D spending with public health needs identified at EU level through a list of essential medicines based on HTA. Industry representatives expressed strong support for an EU-wide HTA assessment process and for patient centred design of clinical trials. Respondents also noted that a harmonised EU HTA process would help with market launch and quicker access to medicines and increase affordability. Some contributors noted that conducting high quality HTA and sharing information about prices and pricing and reimbursement strategies will enhance Member States' ability to prioritise medicines with higher clinical value, review and adjust prices based on new evidence, effectively negotiate prices and get a clear understanding of their added value in real-life settings.

The second presentation focused on the European Health Data Space initiative (EHDS). As underlined in the mission letter to Commissioner Kyriakides, this initiative aims "to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes". EHDS is part of the broader European Data Strategy adopted by the Commission in February this year. EHDS will include a set of rules and services to facilitate safe access to health data for their use and reuse to achieve better healthcare, better evidence-based policy-making and better research and innovation. The four pillars of action (i.e. clear data governance and rules, high quality and semantic interoperability, appropriate infrastructure and technical interoperability, capacity building in the Member States) were presented. Regarding the first one, the Commission plans to adopt next year a legal proposal for the governance framework of the EHDS, also addressing issues related to digital health services where barriers and gaps have been identified. The proposal will be aligned with the proposal developed by DG CNECT including overarching principles and rules for all European common data spaces. For the other three pillars, support activities and projects are planned – using financial support from the new EU4Health Programme, but also from the Digital Europe Programme, ESF and the Resilience and Reform Facility. From an operational point of view, EHDS will be a network of nodes, established by national or trans-national stakeholders, that will provide trust anchors and will follow common policies and interoperability specifications (to be further defined). The data holders will make the health data available for secondary use and the data users will benefit from them for research, policy-making or regulatory purposes. EHDS will take into account existing initiatives such as ERN and the e-health digital service infrastructure. The audience was informed that an inception impact assessment for EHDS should be published in the coming weeks and the Commission will launch an online public consultation early next year to prepare the future legal proposal on EHDS, to which contribution from the HTA community is welcomed. Following a question from a representative from medtech industry, it was clarified that through EHDS, various users including authorities, such as HTA bodies, could benefit from the shared health data.

A representative from DG Research and Innovation (RTD) provided an update on the state of play of the Horizon Europe Research Programme (HE). It was emphasised that HTA has been addressed in the Horizon 2020 Programme, with several funded projects tackling HTArelated issues (e.g. ImpactHTA, PECUNIA, COMED, HTX). However, HE will ensure a boost to this field, with opportunities for the HTA community mainly in the Health Cluster under the second pillar of the programme. Following the publication of the HE legal package and of its strategic plan, DG RTD is currently working on developing the work programmes for the next couple of years, aimed to be published in the spring of 2021 (subject to the finalisation of the co-decision procedure) – these work programmes should include topics relevant for the HTA community. Finally, information on Partnership Candidates under Health Cluster was also provided, with focus on the most relevant partnerships – the Innovative Health Initiative/ IHI (public-private partnership, successor of IMI and IMI2, with the novelty of partners not just representing pharmaceutical industry but also medtech and other health industries) and the partnership on Transforming Health and Care systems (public-public partnership, co-funded). Clarifications on the potential roles of the Innovation Panel as advisory body in the governing structure of IHI were given in response to a question from a representative of a consumer organisation. A representative from medtech industry pointed out that more comprehensive value assessment to guide investments in transformative innovation and care delivery could be addressed by publicprivate partnerships.

The next presentation provided an overview on the development of <u>Europe's Beating Cancer Plan</u>. The Plan will include actions to strengthen approaches at every key stage of the disease: prevention, early diagnosis, treatment, and survivorship and palliative care. The Plan aims for a holistic approach across the entire disease pathway, and across all policies, addressing health inequalities, being developed in close connection with other Commission priorities. The actions proposed for the above-mentioned four pillars of the Europe's Beating Cancer Plan were briefly presented. A list of actions has been drafted following consultations with Member States experts, and is currently being finalised, with the aim to be adopted by the end of 2020. A representative from MedTech industry welcomed the Plan and underlined the support from MedTech industry on actions facilitating access to early diagnosis and screening, with clear potential to improve survival, as well as on actions enabling less severe therapeutic options.

The audience was also updated on the status of the <u>implementation of the Medical Devices Regulation</u> (date of application postponed for May 26, 2021) and the In Vitro Diagnostic Medical Devices Regulation. The audience was reminded about the transitional period for devices certified under the existing legislation. The main Commission priorities were highlighted, such as coordination of the designation of the Notified Bodies by the Member States, setting up of the Medical Devices Coordination Group (MDCG) and its technical subgroups, establishment of the scientific structures (i.e. expert panels, expert laboratories and reference labs), development of the new EUDAMED and of the UDI system, as well as revision of standards. The key guidance documents published in the past six months were

enumerated. Some of the critical issues (e.g. availability of Notified Bodies, establishment of EUDAMED) as well as the work on international aspects were also pointed out.

Finally, the attendees were reminded that the new <u>EU4Health Programme</u> is under the codecision procedure, with actions envisaged to address also the future EU cooperation on HTA

The Chair emphasised that next year will be critical for the initiatives presented, and expressed hope that the HTA community as well as stakeholders will engage and contribute to their development and subsequent implementation.

## 4. PRESENTATION OF THE ACTIVITIES ORGANISED BY THE GERMAN PRESIDENCY IN THE FIELD OF HEALTH (Topic 2)

The Head of Health Unit at the German Permanent Representation to the EU presented an overview of the health-related activities of the German Presidency. He underlined the overarching Presidency' priorities in the field of health (i.e. managing the COVID-19-crisis, creating more resilient health systems, returning to inter-institutional best practices in the EU, covering health priorities not directly linked to the crisis), as well as the main policymaking events organised or planned until the end of the year. He enumerated the files already concluded and those to be finalised until the end of the Presidency (i.e. the Council conclusions on WHO strengthening and the agreements for advance purchasing of vaccines). The HTA file was mentioned among the files under negotiation, together with the Council Conclusions on lessons-learned from COVID-19, Council Recommendations on COVID-19-coordination, and the upcoming Commission proposal on the extension of mandates of ECDC and EMA. Regarding the negotiation of the EU proposal on HTA, some of the core issues examined in the Council, as well as a potential timeline for Council discussions until the end of the year, were mentioned. A progress report on the HTA file may be presented during the EPSCO Health Ministers Council on December 2, report which could represent a starting point for the Portuguese Presidency to possibly finalise the text and start the trilogues.

Following a question from a representative of MedTech industry regarding selection of medical devices for joint assessments, it was clarified that the German Presidency cannot disclose details of the legal text discussed in the Council. A representative from pharmaceutical industry noted the importance of avoiding duplication of work, which currently is an important hurdle for many companies, especially for small ones, when trying to put their products on the EU market; he expressed hope that a solution will be found to appropriately address the non-duplication objective integrated in the Commission proposal. The German representative explained that in some areas, a stepwise approach may be needed, and since the Council proposal will probably propose different approaches than those in the original Commission text, the trilogue will require compromise and agreement from all institutions (i.e. Council, European Parliament, and Commission). A representative from a consumers' organisation expressed appreciation for the German Presidency's commitment to advance the HTA file, underlined the importance of adopting an impactful Regulation, fit for purpose, with HTA reports used by Member States with an acceptable degree of flexibility and expressed hope that a compromise could be reached until the end of the Presidency.

## 5. UPDATE FROM EUNETHTA JA3 – ACHIEVEMENTS, CHALLENGES AND LESSONS LEARNED (Topic 3)

The presentation given by the chief operating officer of EUnetHTA started with a brief overview of the history of EUnetHTA and the specific objectives, participation, governance structures, and work packages of Joint Action 3. He then focused on the changes introduced in the past couple of year, the project' successes, as well as on the limitations and challenges of a project-type cooperation. He mentioned the introduction of the Executive Board as main governing body and of the transversal groups as mechanism to address the main issues for advancing and completion of joint work. He underlined EUnetHTA's lifecycle approach, by carrying out horizon scanning, early dialogues, joint assessments and post-launch evidence generation activities. It was emphasised that EUnetHTA in collaboration with EMA addressed almost all of the topics included in the Synergy Paper developed by the HTA Network in 2018. Some of the key achievements of the project were enumerated, such as the prioritisation list to help selecting the products of interest for all partners, the implementation of the PICO (Population, Intervention, Comparator, Outcome) survey, among partners to understand the needs of individual HTA agencies and reflect them in the joint assessment report, with EUnetHTA being recognised as one-stop shop for HTA in Europe. The volume of joint work carried out so far was highlighted (i.e. 54 joint and collaborative assessments, 34 early dialogues, 5 post-launch evidence generation/PLEG pilots and 18 newly developed rolling collaborative reviews for COVID-19 treatments and rapid collaborative reviews for COVID-19 diagnostic methods). Several limitations of the project-type cooperation were also listed (e.g. limited duration and budget, lack of legal status for the project and legal framework for the cooperation, fully voluntary cooperation which requires not only commitment from partners but also from industry to submit products for joint assessments). He mentioned that by organising meetings of the heads of HTA bodies in the Executive Board, EUnetHTA aimed to test the Coordination Group envisaged in the Commission proposal on HTA. Regarding the period until May 2021 when the project ends, he underlined that EUnetHTA will continue focussing on the planned joint assessments and early dialogues, fine-tuning processes and procedures for joint work, and finalising the White Paper on the future model of EU cooperation on HTA.

The representative of the pharmaceutical industry expressed appreciation to the commitment of EUnetHTA partners and stakeholders, which underpin the achievements of the project. However, he considered that the limits of the voluntary cooperation were reached; he underlined that the next steps should be based on the lessons learned from EUnetHTA and should also provide for more predictability to inform the processes and planning of both HTA bodies and industry. A representative from EURORDIS expressed hope that the Council negotiations will advance and underlined the need for a legal framework delivering high quality and transparent HTA reports for the benefit of all; he also noted that in their assessment a minimum 20 joint assessments per year would create and maintain the critical mass for a high quality system. At his request, it was clarified that EUnetHTA has put in place a quality assurance process included in EUnetHTA Companion Guide. The EMA representative highlighted the value of the cooperation EMA-EUnetHTA, not only on product specific work, but also at the regulatory-HTA interface around market launch. He emphasised the successful collaboration on parallel early dialogues, the importance of webinars between HTA assessors and CHMP rapporteurs, which contribute to improving regulatory output for the subsequent decision-making, as well as the collaboration in the area of post-launch evidence generation. He echoed some of the previous speakers by pointing out to the limitations of a project-type cooperation, which hinders the collaboration with EMA (e.g. limited human resources in HTA bodies for participation in parallel early dialogues; difficulties in sharing information in the market entry phase due to the lack of a clear status of EUnetHTA). As underlined in the EMA regulatory science strategy, the draft strategy of the European medicines regulatory network, and the Commission pharmaceutical strategy, a strengthened EU framework on HTA could contribute to advance the regulatory-HTA cooperation.

## 6. SUPPORTING SCIENTIFIC AND TECHNICAL ASPECTS OF EU COOPERATION ON HTA AFTER MAY 2021 (Topic 4)

As starting point of the discussion, the HTA Network secretariat proposed the areas identified by EUnetHTA where rules and principles are required to support EU cooperation on HTA (see Annex). The rules and principles corresponding to these areas are currently being defined by EUnetHTA in a White Paper on the future model of EU cooperation on HTA (planned for consultation in March 2021). A EUnetHTA expert from NICE presented the objectives and development of the White Paper.

The Commission underlined that the White Paper takes into consideration the directions set up by the HTA Network in its Strategy as well as the Commission proposal for a Regulation on HTA, focusing on scientific/technical aspects and ensuring no contradiction. An agreed set of rules of principles could definitely support the development of a future model of EU cooperation on HTA, like the one in the Commission proposal, therefore the audience was asked the reflect on the completeness of this list and identify the most critical issues to be addressed in the near future.

During the subsequent discussions, representatives from Netherlands confirmed the relevance of the areas included in the list, and identified the areas "relevance - scope and topic identification" - as critical, which would require maximum attention. The EUnetHTA representative clarified a number of areas to be addressed in the White Paper including communication, engagement of all HTA organisations, governance and decision-making and the need to continue supporting capacity building with tailored programmes for interested agencies. Following a question on publication of HTA reports, the expert made clear that they would expect this issue to be addressed under the transparency, communication, and/or fairness areas. It was clarified that the structure presented (i.e. list of areas) is used only for the development phase, and that in case of overlaps, the identified principles and rules will be described in the White Paper only once. A representative from Norway emphasised the importance of tackling independence and conflict of interest, enquiring on how they will be addressed in the White Paper and the future framework. It was explained that the White Paper will address these issues based on EUnetHTA's experience, incorporating also the challenges identified during JA3. In response to a question from a representative from medtech industry, it was clarified that the White Paper will address stakeholder engagement, taking into account the lessons learned from the joint action including previous meetings with stakeholders and the next one planned for December 4, 2020. A representative from healthcare providers flagged the importance of addressing appropriately the communication and language between HTA organisations and patients and clinical experts.

At the end of this session, the Commission informed the audience about the publication of a pre-tender notification on eTED on 27 October<sup>3</sup> of a call for tender to allow for the short-term continuation of some key joint activities beyond May 2021 when EUnetHTA ends.

<sup>&</sup>lt;sup>3</sup> https://ted.europa.eu/udl?uri=TED:NOTICE:509249-2020:TEXT:EN:HTML

#### 7. COVID-19 related activities (Topic 5)

Participants were informed about EUnetHTA's newly developed type of joint work aiming to address the needs of HTA bodies in relation to the COVID-19 crisis.

Information about rolling collaborative reviews (RCR) was presented by a EUnetHTA expert representing the Austrian Institute for HTA. RCR (inspired by the rolling reviews developed by the European Medicines Agency) are the result of continuous monitoring of ongoing clinical trials and studies investigating the safety and efficacy of existing and potential treatments for COVID-19 patients. These publications are living documents, information health provide up-to-date to decision-makers national/regional/European level, to facilitate the development of HTA reports either by EUnetHTA or individual agencies and to support preparations for an evidence-based purchasing if necessary. Once products receive a positive CHMP opinion/marketing authorisation, they are no longer monitored, and could be subject to a rapid review by EUnetHTA. The methodology, as well as the RCR are publicly available<sup>4</sup>. EUnetHTA has published RCR for 15 pharmaceutical and non-pharmaceutical (e.g. convalescent plasma) therapies for COVID-19. Of these products, two have been considered for rapid reviews (i.e. remdesivir, dexamethasone), one will be suspended because randomised clinical trials showed that it has no effects, four will be monitored only bi-monthly because no additional evidence is expected soon, and new medicines will be included in the coming months. These adjustments reflect the rules put in place by EUnetHTA for starting and discontinuing the rolling reviews in order to address only the most relevant therapeutic options. The presenter emphasised that EUnetHTA collaborates with two major European and international initiatives, the EU RESPONSE consortium<sup>5</sup> and the COVID-END initiative<sup>6</sup>, and expressed hope that more EUnetHTA partners will engage in this activity as authoring teams.

An expert from the HTA agency of Emilia Romagna Region, Chair of the EUnetHTA Assembly, gave a presentation on the activities of EUnetHTA's task force on SARS-COV-2 diagnostics initiated in April this year. The aim of this task force is to respond to the needs of various HTA bodies by providing a reliable synthesis of the available evidence on several pressing health policy questions related to screening, diagnosis, and monitoring of the disease's course. A first "Rapid Collaborative Review on the role of antibody tests for novel coronavirus SARS-CoV-2 in the management of the current pandemic" was published in June. This report provides consistent results on diagnostic accuracy estimates and on the strong dependency of these estimates on time since symptom onset, and makes specific and explicit references to the correct use of test results and to the impact they have on the individuals and on public health for a comprehensive risk-benefit evaluation. This report was shared with Commission services, ECDC and WHO, and EUnetHTA experts who developed it provided input during the technical meetings on testing for COVID-19 initiated by these organisations. This collaborative review was also disseminated through the link between EUnetHTA's Covid-19-related repository of publications and outputs and the JRC database on COVID-19 in vitro diagnostic devices and test methods<sup>8</sup>. EUnetHTA works on

<sup>&</sup>lt;sup>4</sup> https://eunethta.eu/covid-19-treatment/

<sup>&</sup>lt;sup>5</sup> "EUropean RESearch and Preparedness netwOrk for pandemics and emerging iNfectious diseaSEs"

<sup>&</sup>lt;sup>6</sup> https://www.mcmasterforum.org/networks/covid-end

<sup>&</sup>lt;sup>7</sup> https://eunethta.eu/wp-content/uploads/2020/06/RCR OT 01- Antibody-tests-for-SARS-CoV-2 23-06-2020.pdf

<sup>&</sup>lt;sup>8</sup> https://covid-19-diagnostics.jrc.ec.europa.eu/eunethta

a similar report on diagnostic accuracy of molecular tests, which should become available by December 2020. During discussions, it was clarified that more information is needed to provide well-defined recommendations on the use of antibody testing, together with the RT-PCR and antigen testing in different settings and that economic considerations were not included in the report.

The last intervention was a presentation of the EU CCP Database by DG SANTE. The COVID19 convalescent plasma (CCP) is usually collected by public blood establishments and made available to hospitals when needed. The advantages of this potential treatment were mentioned (accessible, low cost, no patent, safe, previously used as therapeutic option). While evidence on the effectiveness is still limited, recent publications show some positive results, with data from randomised clinical trials being expected in the near future. More clinical evidence is needed to identify the optimal treatment protocol – results show that early intervention and high antibody titre are key factors for effectiveness. The Commission supports this data gathering effort by funding a project under Horizon 2020 (i.e. SUPPORT-E), and through a RWD database developed by Commission services in collaboration with the European Blood Alliance (EBA), the EU CCP database. This open-access database is gathering and make available data on convalescent plasma donations and patient outcomes following transfusions. It will include data from blood establishments regarding convalescent donors, plasma collection, and plasma components, as well as from clinical trials and from wider monitored use, contributing to consolidate EU evidence on the safety and effectiveness of this therapy. This database could provide additional high quality relevant information to HTA agencies assessing the benefits of this type of treatment; further collaboration could improve the quality and relevance of the data. Furthermore the European Centre of Disease Control is continuously compiling global evidence on this therapy. The Commission representative also informed about the future revision of the EU legal requirements ensuring safety and quality of blood, tissues and cells for human application.

### 8. CONCLUSIONS AND CLOSURE OF THE MEETING

The participants were reminded about the stakeholders meeting organised by EUnetHTA on December 4, 2020. The Commission informed the audience that it may organise a meeting of the HTA Network Stakeholder Pool early next year to address the issue of stakeholders' engagement in the future EU cooperation on HTA.

The Chair thanked for the participation to the 10<sup>th</sup> HTA Network meeting, highlighted the importance of this meeting as potentially the last one in the context of the current legal framework and assured the Network that information about any future meetings will be circulated by the Secretariat.

#### **ANNEX – Cover note for topic 4**



### 10<sup>TH</sup> HTA NETWORK MEETING COVER NOTE BY SECRETARIAT

**Topic 4:** Supporting scientific and technical aspects of EU cooperation on HTA after May 2021

### **Background**

After the establishment of the HTA Network through the Directive 2011/24/EU, EUnetHTA JAs have ensured the scientific and technical EU cooperation on HTA (in line with Article 1.1. of the Rules of Procedure of the HTA Network).

In the last years, EUnetHTA JA 3 made the transition from piloting to production of joint work, developing procedures and carrying out joint assessments (on medicinal products and medical devices) and early dialogues. It also initiated new activities, such as a post-licensing evidence generation and horizon scanning, and developed new quality management guidelines and IT tools to support joint work. Through its joint work plan with EMA (2016-2020), EUnetHTA has been instrumental for putting in practice the recommendations of the "Reflection paper on synergies between regulatory and HTA issues on pharmaceuticals" adopted by the Network in November 2016.

Taking into account that EUnetHTA will end in May 2021, the Network is invited to take stock of the achievements of the current Joint Action and reflect on what immediate scientific and technical issues should be addressed at EU level, and help prepare the next steps.

### **Organisation of the session**

- As starting point of the discussion, the HTA Network secretariat proposes the **areas** identified by EUnetHTA where rules and principles are required to support EU cooperation on HTA. These rules and principles will be further developed by EUnetHTA in a White Paper on the future model of EU cooperation on HTA, which will be finalised early next year.
- The White Paper takes into consideration the achievements of the current and former Joint Actions as well as the Commission proposal for a Regulation on HTA. The focus of the future model and related recommendations is primarily at the **scientific** and technical level.
- The overarching aim of the White Paper is to provide a blueprint for future European cooperation on HTA post-2021 and is the result of a three-stages process:
  - O Stage 1: analysis of the elements of the current model of HTA cooperation, identifying the elements that could be improved or are missing.
  - Stage 2: drafting of a roadmap, recommending next steps in order to improve or develop the elements identified in the first stage.
  - o Stage 3: drafting of the White paper, making reference to the elements

curated over the three phases.

The areas where rules and principles may be required (as identified in stages 1 and 2) are presented below:

Independence and conflict of interest

Transparency and confidentiality

Communication

Evidence and data inclusion in HTA

Involvement (internal, external, interactions between parties)

Relevance (topic identification) – what makes a project of value

Relevance (scope) - what makes a European scope

Use and usability – how far should a joint HTA go

Quality systems approach

**Timeliness** 

Review (up to date-ness)

Fairness of procedure (equal treatment, robustness of procedure)

It is expected that in any possible future framework of EU cooperation on HTA, rules and principles for the areas listed above will be addressed through guidance documents developed by the governing body of the cooperation made up by Member States representatives and/or their experts. Key principles/elements may be also included in any possible legal instrument underpinning the cooperation.

#### Request to the Network

The objective of the session is to gather input from HTA Network Members and stakeholders representatives on the topic above, in particular, they are invited to reflect on the completeness of this list and identify the most critical issues to be addressed in the near future.