eunethta

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DG Research and Innovation
European Commission

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Dear Dr. Ruxandra Draghia-Aklia,

Health Technology Assessment (HTA) organisations across Europe have come together to collaborate via the European network for HTA (EUnetHTA) (*www.eunethta.eu*) which is currently co-funded by the European Commission in a Joint Action until the end of 2015 performing the tasks of the scientific and technical cooperation of the HTA Network established as per the Directive 2011/24/EU. The European Commission (DG SANTE) is likely to propose a new Joint Action on HTA in its Health Programme, and EUnetHTA will re-apply to continue its activities from 2016 until the end of 2019.

As stated by DG R&I (in the Horizon2020 Work programme of 2015), there are "opportunities for real breakthrough research and radical innovation to improve health outcomes, reduce health inequalities and to promote active and healthy ageing". EUnetHTA firmly believes that Horizon2020 is in a position to support European cooperation on HTA, by facilitating further development of an HTA methodology that will be necessary in order to move forward with the aim of conducting joint European HTA assessments and support sustainable health care in the European Union. We feel it is therefore of high importance that EUnetHTA informs you of the latest scientific developments and shares with you the scientific needs of the HTA community to facilitate strong support from Horizon2020 in this domain, in which the European Commission has already invested significant resources.

EUnetHTA has identified a number of methodological issues that are of high importance and require further research to develop successful solutions to these challenges. We consider it highly relevant that these issues are taken into consideration in the development of the upcoming Horizon2020 implementing work plans and calls including SC1 work plan (2016-2017). Below, we would like to shortly introduce and address each of these issues:

1. **Alignment of HTA use at different levels:** HTA is currently used in a number of different settings and levels within Europe. HTA can be used for hospitals' decision-making on the availability and pricing of new technologies, to the regional and national level where HTA information is used for decisions on reimbursement of health technologies (the AdHopHTA project supported by DG R&I initiated work in this area of HTA methodology development where further complementary research action is needed). Developments of the past 10 years in the European cooperation on HTA indicate that joint assessments performed by cross-border teams have great potential to make the national HTA production process more efficient thus contributing to improving effectiveness of the national decision-making processes. As the statement goes, 'evidence is global, decision is local', it is highly important that the use of HTA can be aligned across these differing levels in order to maximize the flow of information, reduce unnecessary duplication, and facilitate informed decision-making towards purchasing or reimbursement in European healthcare. From a methodological viewpoint, the description and classification of determinants for which HTA is currently able (and not able) to provide evidence-based information is essential. Additionally, determinants that are currently informed by other disciplines (outside the scope of HTA) and that may become relevant in the process of local adaptation can be identified. Such further scientific examination can help clarify why joint/international HTA production may lead to different conclusions at the national/local level, while maintaining scientific coherence. This need is identified in a number of SC1 co-

ordination activities such as the activities on co-ordinating personalised medicine (HCO5) and towards an ERA-NET on public health research (HCO6)

2. **The importance of additional patient data collection for HTA:** New technologies more commonly receive conditional market approval and may also simultaneously receive conditional reimbursement. As a part of these conditional pathways, additional data collection and data analysis beyond data for, e.g. regulatory approval and initial reimbursement decisions are requested in many European countries in order to decrease the uncertainty on the real world effectiveness and value (economic and otherwise) of these technologies. While there are some Commission funded activities such as the Parent Joint Action (DG SANCO 2012-15), the IMI-GetReal project and the ENCePP activities by the EMA, more action must be taken in order to address this need. Specifically, further developments in the methodology of using real world data will be necessary in order to fine-tune the data collection from patients and to create a robust link to HTA assessments. There are uncertainties about the exact role, definition and methodological quality of real world data and HTA has a crucial role in developing the process and methodologies to clarify and guide the use of real world data. This issue closely aligns with some of the topics in the SC1 working plan on big data (PM22) and digitalised healthcare records (PM23).

3. **Synergy between HTA and clinical guideline development as incentives for appropriate use of healthcare:** Appropriate use of health technologies may be ensured by different pathways such as clearly defined reimbursement decisions built upon health technology assessment, as well as by clinical guidelines developed by the clinical practitioners, patients and other stakeholders. A closer methodological alliance of those activities may ensure more consistency in reporting and should subsequently lead to more consistent promotion of appropriate use including control of over- and underuse of care. This may be organised by strengthening collaboration between HTA organisations and clinical excellence centres that are responsible for developing guidelines. All these issues are in line with some Personalised Medicines aims in SC1 draft work plan for instance on rare diseases (PM7); comparing existing healthcare interventions (PM9) and implementation research and good practice (PM24).

4. **Research into organisation of care and systems research:** Increasingly, a successful implementation of technologies with proven efficacy depends on research-based assessment of the context, i.e. the specific system and organisation of care, where it is introduced. Health interventions have become more complex and integrated across health systems (the INTEGRATE-HTA project supported by DG R&I initiated research in this area of HTA methodology development). The practice of HTA constantly confirms that healthcare organisation and systems is an under-researched field. Thus, more empirical research and development of applied methodology is needed. This issue is in line with, e.g. comparing existing healthcare interventions (PM9) and implementation research and good practice (PM24).

5. **Specific attention to advanced innovative medical devices and other advanced technologies:** In contrast to pharmaceuticals, the market entrance and reimbursement of many advanced innovative, but also invasive, technologies is not very clearly controlled. Knowing that the first actions to support research in this area were initiated by DG R&I (MedTecHTA and AdvanceHTA projects), we firmly believe that additional methodological research is necessary to target technology-specific issues and develop guidance that can support the conduct of more robust, but feasible studies by the technology producers. This may also include methodologies to assess the role of advanced diagnostics in the identification of patients that should receive a specific treatment. Finally, we also support research into how advanced technologies spread in health systems without rigorous evaluation.[1] These issues fit well, e.g., the Personal Medicines aim on implantation research and good practice (PM24) but also a co-ordination activity on the standardisation of pre-analytical and analytical procedures for in vitro diagnostics in personalised medicine CHCO 2).

[1] Understanding the adoption dynamics of medical innovations: affordances of the da Vinci Robot in the Netherlands. Abrishami P, Boer A, Horstman K. Soc/ Sci Med 2014: 117:125-133.

6. **Transferability of cost-effectiveness data:** European collaboration in the field of research on economic evaluations has several potential advantages and may help to solve several sustainability issues that Member States are now dealing with individually. Pooling of expertise will avoid duplication of efforts and resources for industry, HTA bodies and payers. EUnetHTA has developed an overview on the current practices for performing cost-effectiveness assessments in Europe. Currently however, member states are still separately developing methodology regarding budget impact and economic evaluations. European collaboration on topics such as the use of economic evidence in decision making, transferability of data, the development of dynamic disease models and more advanced budget impact models would therefore be very useful. Cross-border research supported by Horizon2020 programme can strengthen the methodological quality and rigour of economic evaluations and give a better understanding of barriers for the generation of the cost-effectiveness data and transferability limitations. Standardisation of economic evaluation studies would be a logical next step that needs to be explored. We propose that Horizon2020 provides an opportunity to structurally fund research that supports these developments and feel that this is currently insufficiently addressed in the SC1 working plan for 2016-2017.

7. **Research methodologies to better capture patient perceptions and preferences:** Clinical data about the patient play a key role in the estimation of efficacy, benefit and harm of health technologies. However, there are also important patient perspectives which capture the daily life and the social environment (e.g. family and caregiver) beyond the clinical aspects of health and disease. Such perspectives play an increasing role in the decision-making on uptake of technologies which are dependent on accept, adherence and cooperation from the patient for successful implementation. The patients have an increasing voice, and HTA needs better applied research methods and results to capture the patient perceptions and preferences. The research domains to involve in meeting these needs should include social sciences (qualitative and quantitative methodologies) and anthropology (qualitative humanistic research methods). These issues could be, for instance, addressed in Personalised Medicines Aims such as new therapies for rare diseases (PM7) and patient-centred therapies for chronic diseases (PM8).

We believe that there are great opportunities to bring the scientific development of HTA methodology further in order to advance European collaboration, and support mechanisms that assist with early and sufficient access to new and innovative technologies while, at the same time, ensuring health care sustainability. We acknowledge that DG R&I previously funded research projects as part of the European Commission's Seventh Framework Programme (FP7/2007–2013) which produced a number of HTA research trends and future priorities that are in harmony with EUnetHTA's priorities[2]. Furthermore, we recognise that DG R&I already initiated research in the area of HTA in the past 3 years (AdHopHTA, MedTecHTA, AdvanceHTA and IntegrateHTA projects). However, we think that further attention should be given to developing the scientific basis of HTA by building on the results achieved so far by European collaboration and by involving research centres of excellence with a focus on specific scientific and policy challenges.

We hope that our ideas can be taken into account when developing new calls in the implementation of the Horizon2020 programme. We are happy to discuss our suggestions with you in more detail and to establish contact to explore opportunities to work together.

Yours Sincerely,

Finn Børlum Kristensen
Chair, Executive Committee of EUnetHTA

[2] Nielsen CP, Funch TM, Kristensen FB. Health technology assessment: research trends and future priorities in Europe. *J Health Serv Res Policy*. 2011;16 Suppl 2:6-15.