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Editorial

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EUnetHTA's contribution to the new legal framework for health technology assessment cooperation in Europe

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The history of the European cooperation on health technology assessment (HTA) has reached an important milestone with the adoption of the European HTA Regulation (HTA R) 2021/2282 in Dec 2021 (1). Its publication in the Official Journal of the European Union means a lot to those of us who wish to give HTA a stronger role in supporting health policy in favor of sustainable healthcare systems in Europe. The HTA R was prepared well by the European Commission with an impact assessment on policy options for enhanced EU cooperation on HTA (2) in 2017, followed by 3 years of negotiations with Member States. Now the ratified document stipulates that the European Cooperation on HTA will be based on a legal mandate and no longer stay a voluntary project-based initiative. It also means sustainability, since a permanent Secretariat at the European Commission will be set-up under the HTA R.

The European Network for HTA (EUnetHTA) always had among its objectives, from its inception in 2006, to facilitate the establishment of a permanent and sustainable European cooperation on HTA. With the Regulation, it can be emphasized that EUnetHTA laid the foundation of a stable cooperation structure, though often EUnetHTA has been criticized of being slow and stolid in its activities. In any case, we are facing a new stage of HTA in Europe: the European collaboration has been put on legal grounds and will act on that.

The HTA R establishes a framework that is in line with the recently published, consensually developed HTA definition (3). It creates a structure to carry out joint HTA at the European level in order to inform decision making. It establishes a mode of cooperation that must be formal, systematic, and transparent. In addition, it considers health technologies—with special focus on pharmaceuticals and high risk medical devices—along their lifecycle and aims to use state-of-art methods to evaluate the best available evidence.

EUnetHTA has been, and continues to be, the scientific and technical space for HTA cooperation across borders in Europe: the state-of-art methodology is permanently updated, for living-up to the highest standards. Throughout the three Joint Actions (JAs) and previous projects, EUnetHTA has built and tested pragmatic tools that allow joint HTA work to be conducted (4). The HTA R establishes in its article four (Art. 4) that the methodology and procedural guidance developed by EUnetHTA must be taken into account (1). The lyrics sound good, but it will be the facts that judge whether the HTA R succeeds in meeting the expectations: It will be the responsibility of the European Member States to establish the Coordination Group that will direct and oversee the quality and relevancy of the work carried out under the HTA R and the uptake of the results on national level.

This collection of articles brings together some key elements resulting from the third and final EUnetHTA Joint Action. It shows how the EUnetHTA methodology broadly covers many of the steps in the lifecycle of health technologies and is able to adapt to a disruptive crisis such as COVID-19. The collection starts with the article of Ruether et al., which reviews the history of EUnetHTA but at the same time, reports and discusses the current and future landscape of European cooperation in HTA.

Early dialogues between developers and HTA-institutions have started already many years ago and are now an established activity within EUnetHTA. Galbraith et al. describe the process, results, and experiences with early dialogues, highlight opportunities for still improving the current processes, and stress the importance—in the context of the HTA R—to focus the consultations toward future Joint Assessments.

During the EUnetHTA Joint Action 3 (JA3) the procedures to perform joint relative effectiveness assessments (REA) were refined. The article of Luhnen et al. describes the EUnetHTA Quality Management System developed for the production of joint REAs, which can play an important role in the development of the HTA R. The methodology and procedures of the system are incorporated in a web-based platform, the EUnetHTA "Companion Guide," and this article presents and discusses experiences and lessons learned of the use of the guide that could also be of relevance for other networks.

Willemsen et al. evaluated the EUnetHTA processes of elaboration of forty-three joint REAs during the JA3 and the changes made in comparison with previous JAs. The evaluation resulted in a set of recommendations for a future model of cooperation and perceived improvements in

terms of usability, transparency, and inclusiveness of the REA production. Ballini et al. describe the process and output of coordinated and collaborative activities in the COVID-19 pandemic, with speeding up the production and release of high quality EUnetHTA reports with introducing a new format of "rolling reviews."

Postlaunch evidence generation (PLEG) studies are at an advanced stage of the technology life cycle. EUnetHTA has experience in coordinating European PLEGs, but this is a particularly open topic and the article of Puñal-Rioboo et al. can help us understand how national HTA bodies are approaching this methodology and where the spaces and topics for future cooperation can be found. Formoso et al. investigated new forms of presenting results from systematic reviews of multiple health interventions based on their experience in EUnetHTA. The paper proposes a new tool to show in single table information of multiple comparisons that usually is included in multiple figures/tables. An integral part of HTA is information management often not adequately represented in smaller HTA agencies within EUnetHTA. In order to meet these different conditions, information specialists in EUnetHTA's partner institutions have created various products and defined processes. Waffenschmidt et al. describe the newly established Information Specialist Network and the Standard Operating Procedures for complex information retrieval processes for EUnetHTA REAs.

Inclusiveness is one value of EUnetHTA and with it the involvement of stakeholders, be it payers, patients, healthcare providers or technology developers (industry). Elvsaas et al. present the approaches to patient involvement and analyze the experiences, the improvements and the remaining challenges in timely patient involvement and visibility of the patients' input to assessments. Tafuri et al. report about the annual Forum with stakeholders to receive feedback on EUnetHTA's activities, processes, and outputs produced. The authors emphasize that synergies, pragmatism, and inclusiveness across Member States and stakeholders are the leading factors to put in place a collaboration that serves the interest of patients and public health.

The collection ends with an article about the EUnetHTA model of cooperation. In this article, Garrett et al. extract some of the learnings and elements of the EUnetHTA model of cooperation that have a general applicability to a broader audience and presents the EUnetHTA White Paper. The EUnetHTA White Paper is a consensual and thorough description of the scientific and technical principles and elements that the EUnetHTA community recommends to follow in the next phase of the development of the European HTA cooperation (5). The White Paper was elaborated with participation of all eighty-four EUnetHTA partners plus a wide variety of stakeholders. It represents a solid ground to build-on a future network based on the highest quality standards and mutual trust.

The EUnetHTA has come to stay. The Regulation will have—as any Regulation in Europe—a transitional phase of 3 years and will fully be implemented in 2025. In the meanwhile—2021–23 a small consortium of thirteen European HTA agencies, EUnetHTA 21 (6), supported by a larger group of European HTA-institutions, will develop the final procedures, templates, and methodologies guaranteeing a seamless implementation on the national as well as the European level thereafter. Beliefs in HTA, persistence and patience complemented by strong political will and amply funding, in the format of European JAs and projects, have led to this development.

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Conflicts of Interest. The authors declare that they have no conflict of interest.

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