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The Brussels Centre for Collaboration in Health (BCCH) - support for the HTAR implementation

Abstract

In 2023 European collaboration on health technology assessments (HTA) was elevated from sequential project-based approaches¹ towards a permanent legal framework, the HTA Regulation (HTAR). The HTAR establishes a predictable legal framework for Health Technology Developers (HTD) by defining two main procedures, Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs). European HTA bodies (HTAb) are brought together under the HTA Coordination Group (HTACG), which through its "sub-groups" implement the assessment work. This work is financially supported by the European Commission².

The European Commission introduced the financial support for HTACG members via a tender based Framework Contract. The tender was published in October 2024. The majority of HTACG members came together and formed a consortium that replied to the tender procedure. This "HTA Framework Contract Consortium" (HTA FCC) was formed under the leadership of the Belgian National Institute for Health and Disability Insurance (NIHDI)⁴

¹ Between 2009 and 2023 several EU funded projects of EUnetHTA (European Network for HTA) were implemented leading up to planning and implementing of the HTA Regulation.

² HTAR, Art. 27 "Union Financing".

³ It is important to distinguish the two from each other, even though HTACG and HTA FCC membership overlaps to a large percentage, these are fundamentally different bodies. The HTACG is regulated via the HTAR. The HTA FCC provides the mechanism for the HTACG implementing the HTAR with the help of EU financial support via a framework contract.

⁴ NIHDI is also referred to with the acronym RIZIV-INAMI representing the Dutch and French abbreviations.

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and signed the Framework Contract⁵ in January 2025. The consortium brings together more than 35 European HTA organisations that actively participate in the production of JCAs and JSCs.

For the day-to-day management of the Framework Contract NIHDI established a new legal entity which serves as administrative body to the Lead Partner and as service provider to the consortium. The Brussels Centre of Collaboration in Health (BCCH) in its role as administrative body is a not-for-profit⁶ organisation under Belgian law.

BCCH⁷ provides services to the consortium that benefit from a centralised approach. These services focus on supporting the consortium as a whole and individual consortium partners in their activities under the framework contract. BCCH provides a secure project management infrastructure, sets up meetings for ongoing JCA and JSC procedures, supports the work of the individual assessor and co-assessor (ACA) teams, provides medical editing for JCA and JSC final reports, manages the contractual and financial workflows of the consortium, supports the coordination of consortium member activities and facilitates their joint work.

For both, JCA and JSC, patients and experts are required to provide insights into each individual product assessment. BCCH is charged with contracting selected patients and experts. For this work the "HTA patient and expert hub" was initiated. BCCH collaborates on the hub with European patient organisations in providing relevant information material that helps patients to prepare for their JCA/JSC involvement. The hub provides secure spaces for each individual patient and expert. The secure environment supports the exchange of contract and payment specific information.

The "HTA Patient and Expert Hub" is coordinated in alignment with the HTA Secretariat, the HTA Stakeholder Network, relevant European umbrella organisations and other European initiatives supporting patient and expert contributions to HTAR processes. This joint effort establishes a support mechanism for patients and experts in their participations in European HTA procedures.

The HTA FCC lead-partner, NIHDI, will continue to provide support to consortium members via BCCH in a pragmatic and timely manner. Especially in the early phase of the HTAR

⁵ The framework contract runs for up to 48 months and covers a total of 34 million EUR.

⁶ It carries the status of "association sans but lucrative (asbl)" / "vereining zonder winstoogmerk (vzw)".

⁷ It is important to note that the work of the HTACG is supported by the HTA Secretariat (HTAR Art.27) situated in DG SANTE. The role of the HTA Secretariat is defined in the HTAR. BCCH is not linked to the HTA Secretariat institutionally or otherwise. Both the HTA Secretariat and BCCH collaborate closely in the implementation of the framework contract.

⁸ The European Commission, via its HTA Secretariat, is responsible for identifying relevant patients and experts. The HTA Secretariat, after having checked the individual conflict of interest status, presents a list of candidates to the relevant (JCA/JSC) sub-group which then selects.

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implementation BCCH provides a framework that can address unforeseen obstacles and support developing solutions by consortium members.

BCCH Board of Directors is chaired by Dr. Francis Arickx (NIHDI) and includes members from Ireland⁹ and Portugal¹⁰.

⁹ National Centre for Pharmacoeconomics (NCPE).

¹⁰ Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED).