Comments on EUnetHTA 21's D4.3.2 Methodological Guideline on Direct and indirect comparisons

Ecker + Ecker GmbH, a healthcare consultancy based in Germany with strong expertise in the early benefit assessment, welcomes the establishment of a European Health Technology Assessment (HTA) fostering closer cooperation between member states (MS) on health technology assessment by introducing a permanent framework for this joint work.

The legal requirements for a European HTA have been determined as a legislative act by the end of 2021 with the EU regulation 2021/2282. From 2025, before placing innovative medicinal products on the market, oncology products and ATMPs are subject to a European joint clinical assessment. In the next step, Orphan Medicinal Products (OMPs) will follow beginning in 2028 and from 2030, all medicinal products will have to go through the European assessment.

While the regulation does not come into force until 2025, the process of implementation is already ongoing to ensure effective application from January 2025 onwards. At present, the development of a methodology for joint HTA work is facilitated by the European Network for Health Technology Assessment (EUnetHTA) 21 consortium.

On May 2, the EUnetHTA 21 draft deliverable "D4.3.2 Methodological Guideline on Direct and indirect comparisons" was published and is now available for public consultation. While this guideline provides an excellent summary of current HTA methodology on direct and indirect comparisons, guidance is needed on how to resolve (potentially) conflicting requests between European HTA and national HTA bodies of involved member states.

Comment
According to HTA Regulation (EU) 2021/2282 "*Member states shall (…) not request at the national level information, data, analyses or other evidence that has been submitted by the health technology developer at Union level in accordance with Article 10(1) or (5)*". However, this proposition becomes potentially irrelevant once MS have methodological requirements on a MS-level which are different from the methodological requirements for EU HTA. Hence, guidance is needed how to resolve (potentially) conflicting requests between EU HTA and national (MS) HTA bodies. To give an example: Evidence synthesis conducted via a Bayesian method using a specific prior is accepted in EU HTA. However, national HTA bodies of member states consider the prior insufficient and require evidence synthesis conducted using a different prior or frequentist methods.

The guideline is available here:

D4.3.2 Methodological Guideline on Direct and indirect comparisons

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