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EU HTA – Procedural Insights & First Learnings

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The new European-level regulatory/HTA interface

Procedural Insights & First Learning: Insights from EMA Perspective

Abstract:

The new European HTA Regulation, applicable since January 2025, recognises the value of collaboration at the regulatory/HTA interface. The aim is to build synergies between regulatory evaluation and HTA along the medicine lifecycle.

Building on detailed and forward-looking implementation work, first experiences with the operations at the regulatory/HTA interface are now made. This particularly concerns the provision of information from the assessment of Marketing Authorisation Applications (MAAs) that are subject to Joint Clinical Assessment (JCA). The latter is conducted in parallel to the regulatory review resulting in a procedural connection that requires operational management. Several products are currently undergoing such European-level parallel reviews (see ongoing Joint Clinical Assessments). To facilitate the timely JCA preparation, well-defined elements from the ongoing regulatory review are to be provided by EMA to the HTA secretariat, ensuring that the respective remits are respected. With the progress of the various applications, this by now already includes the provision of information from the adopted list of questions.

Furthermore, the first four requests for parallel Joint Scientific Consultations (JSC) under the new Regulations are identified. Whilst this work builds on several years of project-level experience, the new legal framework provides specific requirements. Other exchanges of information at the interface include the provision of forecast data to inform the planning for future HTA work, as well as the identification of potential experts (patients, carers and clinicians) to support such nominations for JCA and JSC, respectively.

The experiences are also relevant for better prospective evidence planning by developers. Here the Joint HTAb/regulatory position paper on robustness of evidence and uncertainty management (see Position paper) provides valuable insights for the design of clinical development programmes and serves as framework for future topics of mutual interest.