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Press release

The EP's position on HTA improves the Commission proposal to a great extent by outlining evaluation needs and improving transparency and independence

On 3 October in plenary session, the European Parliament (EP) adopted by a large majority Ms. Cabezón Ruiz report on the proposed Regulation on health technology assessment.

Prescrire welcomes the EP position as it improves the European Commission proposal on several key aspects: transparency, independence, governance and the introduction of a framework for high-quality evaluation standards. As we already stated in the past, HTA should rely on high standards, robust methodologies and be carried out in an independent and transparent manner.

Mandatory framework while having the right to conduct complementary assessments

Since the beginning of the discussions, in contrast to Member states, the EP expressed its support to the Commission's proposal to establish a framework for mandatory European joint clinical assessments and a ban of duplication of assessments at Member state level (article 8). In the position adopted, the EP makes a step towards the Member states. While still calling for a mandatory system based on non-duplication, we are pleased that the EP provides Member states with greater flexibilities to conduct complementary clinical assessments addressing national specificities.

Introduction of high-quality evaluation standards

We are relieved to notice that instead of relying on future and uncertain delegated and implementing acts, the EP filled the gap of the proposed Regulation by introducing comparative assessment, methodology criteria and procedures for joint clinical assessments.

Methodology and high-quality standards: we welcome and fully support the EP statement that European collaboration should guarantee the highest quality standards and not lead towards the lowest common denominator.

Comparative trials: in line with the objective of the proposed Regulation to assess the added value of a health technology in comparison with other technologies (recital 2), the EP calls for the conduct of at least one comparative trial against standard treatment and the provision of related data and results. Since many years, Prescrire consistently advocated for the conduct of comparative trials and access to their results. We are convinced that comparative trials data will facilitate the activities of HTA bodies, save time and resources. Health professionals, patients and the public at large who use and pay for medicines need to know whether a new drug is or is not an improvement over existing treatments, in terms of benefits and harms.

Improved transparency
Prevention of conflicts of interest, transparency, public access and disclosure of safety information as well as comparative data are essential to make informed decisions. The EP adopted many amendments laying down clear rules for transparency and disclosure of data and documents including minority and diverging positions as well as the publication of scientific consultation reports (upon the completion of the joint clinical assessment). We would underline that full transparency and public access to assessment outcomes and underlying comparative date is needed to ensure accountability and public trust.

Independent funding
We also welcome the request of the EP that the EU should ensure stable and permanent public funding for the joint work (without funding by health technology industries).

Commercial confidential information
While calling for a high level of transparency, the EP also provides for the protection of commercial sensitive data in several articles. We would like to emphasize that the clinical trial Regulation No 536/2014 (article 81 (4)) states that the protection of commercial confidential information represents an exception to the principle of disclosure, public access and transparency. Commercial information may be protected unless there is an overriding public interest in disclosure. Confidentiality should thus be strictly limited and duly justified.

Orphan drugs flexibilities
The EP calls for the consideration of specificities for orphan drugs or products with conditional authorization. Amendment 85 considers that there may be no reason to support further clinical analysis beyond the significant benefit assessment already carried out by EMA. We are afraid that such disposals might pave the way for making EMA responsible for HTA assessments for orphan drugs. While EMA might consider that there is a positive benefit-risk ratio, the role of an HTA assessment is to stick to the available data and facts and if applicable highlight the uncertainty when robust evidentiary data are missing. This is tremendously important information for pricing and reimbursement decisions as well as for patients and healthcare professionals. We demand that HTA assessments are done by HTA bodies also for orphan drugs.

To conclude, we do believe that the EP position represents a valuable discussion basis to start the negotiations with the Member States. We encourage them to take momentum for building-up a robust framework for joint clinical assessments fitted for national evidence-based pricing and reimbursement decisions. Timely available genuine comparative trials data would represent an undeniable support to streamline HTA bodies' remit.

For more information

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