HEADS OF HTA AGENCIES GROUP

The Heads of Health Technology Assessment Agencies Group (HAG) welcomes the Commission's proposal for a revised pharmaceutical legislation in the European Union, as it marks the most significant reform in over 20 years in this domain. As an independent group of European healthcare agencies collaborating to advance strategic cooperation on health technology assessment (HTA), we particularly appreciate the Commission's commitment to promoting timely and equitable access to safe, effective, and affordable medicinal products across all European countries.

The HAG specifically wants to highlight the following areas of particular interest to our network:

The appraisals issued by HTA bodies are necessarily linked to the evidence generated by health technology developers for gaining marketing authorization. Consequently, the HAG would like to stress the importance of the Article 162 of the proposed Regulation that foresees a consultation mechanism with HTA bodies for the development of scientific guidelines related to the unmet medical need definition, comparative clinical trials, and other topics related to evidence generation along the medicine life cycle legislation. This consultation must ensure useful and relevant guidelines for all stakeholders concerned with these critical aspects of evidence generation. It will be particularly important to involve the HTA Coordination Group, responsible for endorsing methodological guidelines and joint clinical work on the relative effectiveness and relative safety of health technologies as per EU Regulation 2021/2282. On the other hand, the HAG identifies challenges with the large number of alternative and accelerated regulatory pathways mentioned in the proposal, which should not increase uncertainties surrounding the added value of some pharmaceuticals.

The Joint Clinical Assessments that will be conducted by the HTA Coordination Group from 2025 need to occur in parallel and in close connection with the regulatory pathway. The HAG supports the early approval of new medicinal products that are safe and have demonstrated their added clinical benefit particularly when patients do not have alternative treatment options. Nevertheless, the impact of reduced marketing authorization timelines on the processes outlined in the HTA regulation and its implementing acts must be anticipated. The reduction of the time to EC authorization will ultimately impact the time to perform Joint Clinical Assessments for medicinal product as this procedure is based on this key milestone.

Finally, the HAG welcomes the introduction of the Joint Scientific Consultation between the EMA and the HTA Coordination Group in the proposed pharma legislation, mirroring the HTA regulation. These Joint Scientific Consultations have been successfully established. To support evidence generation that informs decisions for both regulators and HTA bodies, advice on comparative effectiveness studies needs to be implemented with higher priority, also considering the criteria established in the HTA Regulation. Therefore, Joint Scientific Consultations must be preserved throughout the ongoing negotiations in the Council and European Parliament.

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