Joint pharmaceutical industry statement

on the Commission's proposal for a Regulation on health technology assessment (HTA)

The pharmaceutical industry represented by AESGP[1], EFPIA[2], EUCOPE[3], EuropaBio[4], Medicines for Europe and PPTA[5] – henceforth referred to as 'the pharmaceutical industry' – **generally welcomes the European Commission (EC)'s Proposal for a Regulation on HTA**[6]. We understand the scope of the joint clinical assessments foreseen in the proposal is limited to medicinal products subject to the centralised marketing authorisation, and exempting generic, biosimilar and non-prescription medicines[7].

We believe that EU cooperation on joint clinical assessments and joint scientific consultations has the potential to contribute to expedite patients' access to medicines in Europe. **It is a unique opportunity for greater alignment** on clinical evidence generation requirements, ensuring consistency, transparency and synergies in clinical assessments by Member States and evidence that is relevant for Europe. It can also reduce the burden faced by companies, which is particularly important for the competitiveness of small-scale biopharmaceutical companies active in Europe.

For the future system to work, we agree it is crucial that the joint clinical assessment replaces the equivalent step in the national HTA process. However as experienced in EUnetHTA, in a purely voluntary framework joint clinical assessment reports are not sufficiently used at the Member State level. **The pharmaceutical industry therefore strongly supports the requirement to apply and not repeat joint clinical assessment reports at the national level (article 8)**. Member States should of course continue to be solely responsible for drawing conclusions on the value of the health technologies concerned as part of national appraisal processes and should retain full competence when it comes to national pricing and reimbursement decision-making.

We believe that **strengthening the process and methodology framework within the main body of the Regulation** can contribute to a balanced debate on the merits of the Commission Proposal on HTA. In particular, a **scoping meeting** between the health technology developer and the assessors, the outcomes of which would be endorsed by the Coordination Group, would ensure that all Member States' requirements are appropriately reflected in the assessment, and hence avoid controversies downstream. Such scoping would also contribute to the timely availability of reports at marketing authorisation in order to avoid any delays in national decision-making. It also needs to be clarified that **methodologies** that will support joint clinical assessment will build on existing EUnetHTA methods, be up to date with scientific development and be regularly reviewed; methodologies and evidence also need to be sufficiently flexible in order to ensure a level playing field for different types of medicines, including medicines for rare diseases that have limitations resulting in unavoidable evidential uncertainty.

We look forward to a constructive dialogue with all stakeholders, including patients, healthcare providers and representatives from Member States and EU institutions to ensure that the Commission Proposal achieves our shared goal of improving the availability of innovative treatments and therapies for patients across Europe.

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[1] The Association of the European Self-Medication Industry (AESGP)
[2] The European Federation of Pharmaceutical Industries and Associations (EFPIA)
[3] The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
[4] The European Association for Bioindustries
[5] Plasma Protein Therapeutics Association (PPTA)
[6] 2018/0018 (COD)
[7] As outlined in article 5.1(a), to the exclusion of medicinal products authorised under Articles 10 and 10a of Directive 2001/83/EC. As a consequence, we also understand this would exclude medicinal products composed of off-patent molecules authorised under Article 10b of Directive 2001/83/EC.