AIM Healthcare and social benefits for all

First general AIM Response to the European Commission Proposal on HTA

AIM is an international association of non-profit healthcare payers. Its members provide healthcare coverage to around 200 million people within Europe. Sustainable access to high quality medicines for all is an important objective of the association and its members.

The present document is a general reflection on the European Commission's proposal for a regulation on health technology assessment (HTA). More detailed comments and suggestions for amendments will follow in due course.

AIM welcomes efforts at EU level to improve the quality and timeliness of health technology assessments, and to ensure through Union-wide collaboration that the assessor has timely access to relevant high quality data to carry out meaningful comparisons between the assessed products and the most appropriate comparators. AIM is pleased to see that the European Commission proposes to give HTA collaboration at EU level a more permanent status. With this regulation, the Commission proposes that clinical assessments are no longer carried out by individual HTA bodies. After a transitional period, all countries would be forced to use the joint clinical assessment for most new expensive drugs and certain classes of medical devices that come to the market. Clinical assessments of those technologies would no longer be allowed at Member State level. According to AIM, this approach is probably not the best way forward. If the joint assessment was based on solid and relevant endpoints, Member States would voluntarily consider its results.
In addition, AIM is concerned that, with only one clinical assessment in the EU, there would be more pressure to produce this clinical assessment as quickly as possible, to the potential detriment of the quality and safety of care. AIM wonders why, in its proposal, the Commission did not choose the Coordination Group, but the Commission itself to publish the finalized clinical assessment reports. AIM is not in favour of funding collaboration on HTA through industry fees, as it would lead to conflicts of interest.

AIM understands the choice of the European Commission to focus its proposal on clinical effectiveness. The ultimate pricing and reimbursement decision is nevertheless not only based on clinical effectiveness, but also on (relative) cost-effectiveness. The Commission argues rightly that that decision should take country specific circumstances into consideration and AIM agrees with the Commission that it should remain a national competence. AIM sees nevertheless great added value in technical collaboration in this field. Non-clinical assessments remain difficult to make for individual Member States and inscrutable for the general public. It is important that countries are being supported in the strengthening of this part of the HTA process. Member States should give priority to collaboration in this field, in strengthening methodologies for (relative) cost-effectiveness studies and transparency of the pricing and reimbursement decision. Jointly developed methodologies should then be tailored to national contexts and priorities, also to ensure that Member States do not lose their independence on how to organize their healthcare system and how to allocate funds.

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