Brussels, 3 October 2018

Cabezón Report on HTA Regulation adopted by the European Parliament: much more meat on the bones that still needs a bit more cooking

AIM supports the overall objective of the EC proposal on HTA and welcomes the set of amendments the European Parliament adopted today. We thank Ms Cabezón Ruiz and her colleagues for all the work done. The Parliament substantiated some concepts in the initial draft regulation presented by the Commission. AIM now looks forward to the Council position on the same proposal and hopes that significant progress can still be made before the European Parliament elections of May 2019.

Pricing and reimbursement authorities and payers should be part of the coordination group!

Pricing and reimbursement authorities and healthcare payers are important end users of health technology assessments. They should be directly involved in discussions about methodologies to be used, data requirements, priority setting etc. The role of healthcare payers is not well identified in the Commission proposal and Parliament amendments do not sufficiently address this omission either. We call on all the European institutions to specify the role of this important authority in the proposal.

How to measure whether something is justified, necessary and proportionate?

The European Parliament adopted amendments, which introduces a more detailed description of the possibility to do context-specific additional clinical assessments at national level. AIM welcomes those changes, although we do ask to reconsider the text that indicates that such assessments at national level should be justified, necessary and proportional and should not unduly delay access. Although we would fully agree with such requirements in principle, we would foresee difficulties deciding which measure may, or might not, be justified, necessary and proportionate. A regulation demanding proof of this necessity will inevitably cause extensive litigation and insecurity for all parties involved.

What to do when there is hardly any evidence available?

AIM very much welcomes the efforts of the members of the European Parliament to create more clarity about the methodology of the assessment. Assessments should indeed be carried out timely, using the best available scientific evidence. AIM would like to raise the question, what should be done when an assessment cannot be carried out because available scientific evidence cannot be considered sufficient.

Transparency and preventing conflict of interest should be guaranteed!

We would like to reiterate our earlier statement that the transparency of assessment outcomes and the data used as well as solid conflict of interest policy are of utmost importance to AIM and its members and should be further substantiated in implementing acts and coordination group practices.