Statement in advance of Health Technology Assessment Regulation Trilogues, Monday 31 May

Friday, 28 May 2021

The continuation of trilogues on the Health Technology Assessment (HTA) Regulation are of particular importance given broad support and sustained calls for collaboration from Member States, patients and industry alike. Representing biopharmaceutical and medical technology companies, the American Chamber of Commerce to the EU (AmCham EU) has consistently called for the development of an efficient, high-quality and predictable HTA system that fosters timely patient access to effective treatments and innovation of value to patients, carers and health systems.

The Council's partial mandate for negotiations denotes a significant deviation from the original European Commission proposal. Where European cooperation on the HTA Regulation has previously been moving in a cohesive direction to encourage joint clinical assessment (JCA), the current compromise text risks creating a more inefficient system. Allowing Member States maximum flexibility in how to use JCA dilutes the intent of the approach and will result in a lack of predictability for all parties. JCA risks becoming an additional layer in the assessment process, ultimately resulting in further delaying patient access to innovative treatments. AmCham EU urges the co-legislators to find a more balanced approach aligned with the below principles:

The HTA Regulation should accelerate, not delay access:

- The HTA Regulation should not impose asymmetrical requirements and companies should not be compelled to participate if national uptake of JCA is flexible and until there are reassurances that the system works.
- Properly evaluate the new HTA system to ensure it results in positive impacts for patients, to address knowledge gaps and incorporate new learnings. An expansion of the scope of JCAs under Article 5 should be conditional on a positive evaluation exercise.
- A truly 'joint assessment' requires commitment from Member States to recognise commonalities; the HTA Regulation must strike a balance between creating efficiencies and adapting to national specificities – particularly those specificities which relate to medical technologies. The JCA should be inclusive enough (data, comparators, methodology) to cater to the needs of a majority of Member States, with minimal requirements left to the national level. Deviations for national requirements must be sufficiently limited to support the JCA and avoid duplicative work.
- Provisions preventing the manufacturer from submitting data/evidence at national level that has already been submitted at EU level risk delaying those 'faster' markets/countries (eg. Denmark) where the formal date for national dossier submission is set after the date for JCA dossier submission and prior to publication of the JCA report. The Regulation should include appropriate exceptions.
- JCA evidence requirements for medical devices should be aligned with device development processes, complementing the fast evolutive lifecycle of medical technologies. HTA must guarantee there is no conflicting or duplicative assessment between HTA and the medical technology CE marking regulations (MDR/IVDR) which remain the sole authorisation mechanism in the EU.

The HTA Regulation should generate timely, high-quality and usable outputs:

- As the technology developer, the marketing authorisation holder possesses extensive expertise on the technology and available data. It is essential that the HTA Regulation and implementing acts treat the manufacturer as a partner and protect its procedural rights.

- Early involvement of technology developers through systematic involvement in a 'scoping meeting' is imperative to enhance predictability of JCA and reduce inefficiencies arising from misalignment and is more closely aligned with common national practice. Both Article 6 and the detailed procedural rules to be drawn up by the Commission under Article 11 should explicitly mention involvement of the marketing authorisation holder in the scoping meeting and definition of the PICO (ie. patient population, intervention, comparator, outcomes).
- The manufacturer's procedural rights should be further guaranteed under Article 6c through an opportunity for comments on the draft report including but not limited to factual inaccuracies (as currently stated under the Council position). The five-day turnaround should be extended to a reasonable timeframe.
- A consistent JCA methodology must be developed that is fit for purpose and sufficiently flexible to adapt to technologies which require innovative clinical trial approaches. Uptake of progressive approaches to evidence generation should be encouraged, including clinical trial design in collaboration with global partners. In the case of orphan medicines which have undergone a significant benefit assessment (SBA) by the European Medicines Agency, the outcome of the SBA should be duly considered by the JCA, explicitly referenced in the JCA report and not duplicated unless new evidence has become available.
- Utilise megatrend analysis by the Commission's Joint Research Centre which pertains to health to inform horizon scanning activities.

HTA is noted within both the Pharmaceutical Strategy and Europe's Beating Cancer Plan as supportive of the Commission's goal to increase the EU's global competitiveness and innovation – a duplicative or diluted approach will, paradoxically, hinder these objectives while decreasing the likelihood of increased patient access to new technologies and treatments in the long run.