AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Strengthening Member State cooperation on Health Technology Assessment

Driving collaboration in the right areas to promote access to innovation

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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Executive summary

The American Chamber of Commerce to the EU (AmCham EU), which represents companies operating across the life sciences sector, supports the European Commission's proposal on Health Technology Assessment (HTA) in its aim to harmonise the assessment of clinical evidence and avoid duplication of HTA processes across EU Member States. Fostering timely patient access to effective, safe and reliable treatments is at the centre of this objective, a priority shared by our member companies. In this regard AmCham EU encourages the Commission to adopt a balanced approach and methodology reflecting the specificities of each sector of the healthcare industry, in line with the principles outlined in this paper.

Introduction

In the face of budget constraints and demographic pressures, innovative healthcare technologies can generate efficiencies in Europe's healthcare systems to make them more accessible, safe and sustainable[1]. The speed of innovation is accelerating across the entire life sciences industry, and making sure that patients across Europe can gain access to these ground-breaking new treatments is key. The regulatory environment needs to adapt to keep up with these changes, and the assessment of the added value of healthcare technologies is fundamental to informing this process.

Health Technology Assessment (HTA) plays a key role in value assessment for medicinal products by providing information regarding the short- and long-term implications of using a health technology and measuring the added value of a new health technology compared to an existing one. Health 'technologies' encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment. As a horizontal association representing various parts of the life sciences industry, including pharmaceutical, medical device, diagnostic technology and eHealth companies, AmCham EU is well placed to share its members' experiences with HTA from a cross-sectoral perspective.

Health technology assessment is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. (EUnetHTA[2])

HTA processes in Europe are currently fragmented, undertaken in different ways and with different requirements across 28 Member States, which contributes to inequalities in access. While the organisation, financing and delivery of healthcare services is a national competence (Art. 168, 7, TFEU[3]), it is widely recognised that cross-border collaboration on how some of these innovative technologies are assessed and introduced into the different national systems can contribute to improving their efficiency and addressing disparities in access across the continent, by informing national policy-making.

[1] New Health Technologies. Managing Access, Value and Sustainability (OECD (2017), http://dx.doi.org/10.1787/9789264266438-en

[2] https://www.eunethta.eu/services/submission-guidelines/submissions-faq/

[3] Consolidated version of the Treaty on the Functioning of the European Union - PART THREE: UNION POLICIES AND INTERNAL ACTIONS - TITLE XIV: PUBLIC HEALTH - Article 168 (ex Article 152 TEC) , https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:12008E168

The European Commission's proposal on health technology assessment and amending Directive 2011/24/EU seeks to introduce a new regulation to establish a support framework and procedures for cooperation on health technology assessment (HTA) at EU level and to establish common rules for the clinical assessment of health technologies.

Strengthening collaboration to promote access to innovation

AmCham EU generally welcomes the objectives of the European Commission's proposal to strengthen Member State cooperation on HTA. The use of HTA to assess the added value of different healthcare technologies has been developing over the last thirty years and significant progress has been made to integrate different approaches to value assessment and improve clinical evidence generation and methodological processes.

The voluntary collaboration on HTA that has been running since 2006 through the EUnetHTA, and its subsequent Joint Actions have demonstrated success. However, the HTA systems remain fragmented across the EU, thereby posing a challenge to clinical trial design and data collection across Europe, which also has implication for timely patient access. Further efforts to reinforce sustainable cooperation will boost the uptake of innovation, benefitting European industries, patients and healthcare services.

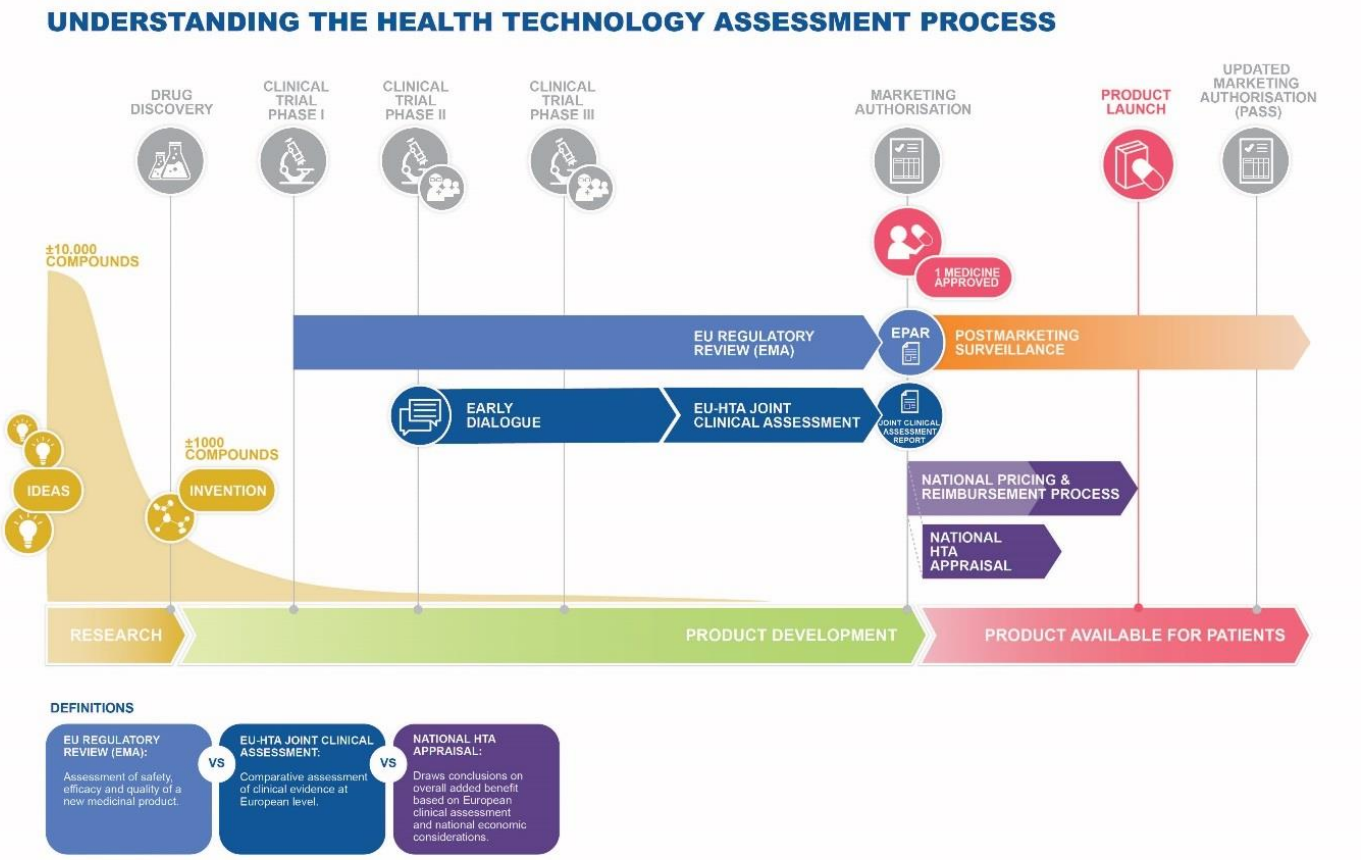
AmCham EU supports the European Commission's aim to increase alignment on clinical evidence requirements and generation in order to reduce duplication, pool expertise and speed up access to new pharmaceutical treatments, while preserving Member States' autonomy to perform their own country-specific socio-economic appraisals and make decisions regarding pricing and reimbursement (P&R). The new system set up by the Regulation will also provide the opportunity for health technology developers to streamline evidence requirements and create greater predictability.

Limiting the scope of the Regulation to joint clinical assessment and scientific consultation for pharmaceutical products will allow for the centralised provision of scientific information to inform national decision-making, while respecting subsidiarity. In this regard, AmCham EU has some concerns regarding the voluntary cooperation on non-clinical elements as set out in the proposed Regulation. Indeed, such cooperation would risk encroaching on areas that are specific to individual Member States and diverting limited resources away from the priority areas.

A tailored approach that recognises the reality of market access models

The role that HTA can play in healthcare reform differs significantly according to the type of technology being assessed. While for centrally authorised pharmaceutical products, the benefits to be gained by greater Member State cooperation are significant, the reality for medical technologies (medical devices, in vitro diagnostics, imaging equipment and e-health solutions[4]) is different, as they rely on a greater variety and diversity of market access models. This is reflected in the specific CE marking regulations for medical devices and in vitro diagnostics (IVD) as laid out by 2017/745, 2017/746 which differ from pharmaceutical legislation.

[4] http://www.ub.edu/medicina/grauEB/2013%20Eucomed%20brochoure.pdf



As the figure above demonstrates, HTA is one element of a lengthy and complex development process for pharmaceutical products (European Federation of Pharmaceutical Industries and Associations (EFPIA))

It is advised to exclude medical technologies from the scope of the proposal until the new EU Regulations on medical devices and IVD – and the associated increase in requirements that will come to bear on the clinical assessment of these products – have been implemented. The medical technologies industry in Europe (80 per cent of which is SMEs) is adapting to the increased costs associated with these Regulations, which require higher standards in data collection for certification before product launch. Introducing an additional HTA requirement before these Regulations are implemented risks overburdening a largely SME-based industry.

Simplified medical device market access model (MedTech Europe, 2016[5])

[5] *Patient Access Model for Medical Devices in Europe : Reflecting the reality localised healthcare delivery*, Eucomed (now MedTech Europe) https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20160922_co02_en.pdf

For medical technologies, HTA is only performed in a few countries and in limited cases (less than 1%). Unlike pharmaceutical products which tend to undergo a national HTA to inform initial pricing or reimbursement, the access model for devices is decentralised and Member State decisions are made at differing times and for differing purposes. Medical devices have a shorter life cycle, with value often heavily dependent on associated procedures. Furthermore, some medical devices are multifunctional (e.g. CT, MRI and Ultrasound) which are used in a vast array of clinical care setting, with evaluations always context-specific, related to 'clinical pathways', often only relevant within the context of nationally defined healthcare practices and priorities. In addition, conducting HTA at the point of market entry is not optimal, as full value and effectiveness can only be assessed by real world evidence (RWE) that takes into account contextual factors, care pathways, diagnostic information, and the learning curve of professionals or patients using the new technology. Well-established procurement and hospital procedures have played a large role, with assessment often ex-post.

Using HTA inappropriately in access pathways risks increased burden and significant delays to accessing some types of medical innovation. For this reason, AmCham EU urges policymakers to adopt a tailored approach to value assessment that recognises the fundamental differences between different healthcare technologies and the way they enter the market. This means developing and using methods, data requirements and outcome measures that are appropriate for and tailored to the specificities of medical technologies.

Ensuring the uptake and use of joint clinical assessments

In the case of pharmaceutical products, AmCham EU supports the mandatory uptake of joint clinical assessments (JCA) in national HTA processes, which is central to the objectives of the Regulation in order to reap the benefits of reducing duplication and fragmentation. This will guarantee that the market distortion and barriers posed by the current situation, which this Regulation aims to overcome, are firmly avoided. In that respect, if all centrally authorised medicinal products will be subject to JCA, it is important to ensure that the use of the JCA reports will be mandatory for national authorities as it will create more certainty for all stakeholders.

As noted, Member States will continue to be able to perform their own assessments on non-clinical aspects, and draw on the factual clinical evidence from the joint report to make national decisions around pricing and reimbursement (P&R). Mandatory uptake ensures that this clinical evidence is obtained in a consistent and efficient way as a basis for further Member State appraisal. To that effect, AmCham EU welcomes the relevant safeguards included in the Commission's current proposal, allowing Member States to conduct their own clinical assessments in situations justified on public health grounds and agreed by the Commission. Additionally, a specific system of sanctions in case of Member States' non-compliance should be foreseen.

Stakeholder involvement

Cross-stakeholder consultation is the heart of successful HTA, including participation from patients, clinicians and health technology developers. The proposal would benefit from greater clarity and structure around the roles and participation of involved stakeholders in the joint clinical assessments, ensuring a multi-stakeholder perspective in the stakeholder network.

Methodology and quality criteria

AmCham EU believes it is important that the evidence requirements for the joint clinical assessments are clearly defined, coherent and transparent, and that the scientific evidence used is of the highest possible quality available. The methodology and procedures as set out in the current proposal require further clarification, building on EUnetHTA guidelines and agreed best practices.

To ensure timely access to medicines, the assessment process should also involve a clearly established procedural timeframe with defined clock stops established in the legislation. This timeframe should ensure JCA reports are available at time of marketing authorisation so as not to further delay national P&R processes and therefore patient access. This should include a scoping meeting with the developer at the beginning of the assessment process, of which the outcomes would be endorsed by the Coordination Group.

While marketing authorisation and joint clinical assessment remain separate processes, increased information sharing and alignment on procedural timing and data requirements would promote early access to medicines while still allowing for flexibility in the system.

On the other hand, the appropriate time to conduct a clinical assessment for medical technologies is after CE marking approval, when effectiveness data are available to demonstrate the full value of the technology. HTA assessments on medical devices inform on the relative (cost-) effectiveness compared to a current practice. Given these important differences and distinct roles, HTA and CE regulations should remain disentangled for medical devices.

The current proposal also lacks an appeal mechanism, which is present in most national HTA systems. As the mandatory joint clinical assessment will be central to informing Member States' decision making, it is important that an appropriate, independent appeal process that includes the opportunity for hearings is in place to challenge decisions where a potential discrepancy in the interpretation of evidence has been observed. Decisions on appealed cases should also be reached as quickly as possible before the report is communicated to Member States.

With a view to ensuring the highest quality clinical assessment, the following elements should therefore characterise a JCA report:

- Conform to the highest scientific standards;
- Be transparent with robust procedures and formalised stakeholder input;
- Be dynamic and open to periodic review – with formal consultation procedures with regards to definition of and amendments to its methodologies;
- Provide for an open and robust process for the selection of comparators;
- Be flexible to allow for different approaches for specific treatments and technologies (e.g. treatment as prevention or cell and gene therapies);
- Provide for companies to re-submit on the basis of new data or analyses as well as appeal a JCA in certain circumstances.

The evidence requirements placed on manufacturers as well as the patient access timelines should be evaluated through an impact assessment at an appropriate time following the application of the legislation.

Throughout this process, AmCham EU wishes to underline the importance of the confidential handling of data.

Joint scientific consultations

AmCham EU supports the possibility for health technology developers to request joint scientific consultation in order to obtain scientific advice as to the data and evidence likely to be required as part of the joint clinical assessment. Such early dialogue, which should be entirely voluntary, non-binding, non-restrictive towards separate national early dialogue and confidential, would positively contribute to a convergence in terms of clinical data requirements.

Emerging health technologies

AmCham EU is supportive of the proposal to identify emerging health technologies (horizon-scanning) during the implementation period, provided this is conducted in an efficient and balanced way. However, once the process is fully operational, there should be no need for horizon-scanning to prioritise products as all centrally authorised medicinal products will undergo joint clinical assessments.

Conclusion

AmCham EU, representing members across the life sciences sector, is supportive of the proposed EU Regulation in its aim to harmonise efforts and avoid duplication of HTA across EU Member States, in order to improve timely patient access to safe and effective promising treatments. In this regard, AmCham EU encourages the Commission to adopt a balanced approach and methodology reflecting the differences of each sector of the healthcare industry in line with the principles outlined above. This implies creating the possibility of a learning curve by targeting selected centrally authorised medicines and awaiting the implementation of the EU regulations for medical devices and IVD. Our members remain willing and available to share their experiences with HTA or to provide additional information and look forward to a constructive dialogue on this issue with all stakeholders.