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ECL welcomes the Council of the EU's agreement on a mandate to start negotiations with the European Parliament on the HTA file

The Access to Medicines Task Force of the Association of European Cancer Leagues (ECL) **strongly welcomes the decision of Member States' Ambassadors to the EU to move forward with the latest Health Technology Assessment (HTA) proposal** which paves the way towards a sustainable model of cooperation. We are also **pleased to see that the joint clinical assessments would be starting from cancer drugs**.

After three years of negotiations and discussions, **cancer leagues across Europe very much hope to see this strategic legislative tool adopted and implemented by the end of 2021**. This will have a major relevance and impact on highly specialised cancer diagnostic procedures and treatments.

ECL is convinced that enhanced mandatory cooperation on HTA would:

- Establish a fair pricing framework that encompasses a value-based approach to pricing and reimbursement;
- Enable faster and improved access to high-value treatments for all patients in Europe;
- Strengthen the quality of clinical assessments by pooling expertise from all EU Member States;
- Reduce duplication and ensure efficient use of resources;
- Help payers make better decisions on pricing and reimbursement by providing evidence-based and high-quality assessment;
- Increase transparency across the whole joint HTA process;
- Steer innovation in areas with currently no treatment and improve business predictability.

It is of utmost importance that national health authorities are provided with the necessary scientific information to feed into their policy decisions which ultimately impact millions of patients, families, and carers. **Indeed, there exists a strong connection between the implementation of robust European cooperation on HTA and access to high quality treatment for European patients**, as recognised by the 2016 Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States.

ECL echoes Portuguese Health Minister Temido's recent statement that *"the regulation on health technology assessment, once adopted, will be a major step forward in the field of health. It will constitute a robust framework for cooperation for the benefit of member states, industry and, above all, patients".*

ECL is pleased to see that health technology includes medicinal products, medical devices (eg. pacemakers, dialysis equipment and infusion pumps), **medical and surgical procedures**, as well as **measures for disease prevention, diagnosis and treatment** used in healthcare. **We also applaud the inclusion of the article 3b on transparency and conflict of interest.** For an effective and fair HTA process, it is important to guarantee the complete independence of the Coordination Group.

However, European countries will continue to perform their own national assessments of health technologies, even though they will have to "give due consideration" to joint clinical assessments and include them in the documentation of their own national-level assessments. **The flexibility allowed in the uptake of the joint clinical assessment may undermine the success of this long-awaited step forward**.

Cancer leagues' key priorities going forward

ECL insists on the importance that a number of priorities, which are of particular concern to cancer patients across Europe, be taken into account going forward and when implementing the Plan:

1. **Integration of patient involvement across the entire HTA cycle;**
2. **Effective collection, storage, and analysis of patient reported outcomes (PROs) since the first phases of clinical studies;**
3. **Effective collection, storage, and use of real-world evidence (RWE) following medicines' market access;**
4. **HTA bodies should be able to access clinical trial results and raw data over every clinical trial phase, including unpublished data from failed trials as already highlighted in a joint ECL-EORTC statement on EMA's transparency policy, to enable high-quality assessments.**

ECL stands ready to cooperate with national and European authorities on this important legislative file.

About ECL Access to Medicines Task Force

Established in 2016, the ECL Access to Medicines Task Force connects 30 national and regional cancer societies in 25 European countries, representing over 570 million Europeans. It aims to make safe and effective medicines available to all cancer patients in Europe, by insisting on accessibility, availability, affordability and increased transparency related to medicine prices, ultimately leading to sustainability of healthcare systems. The Task Force strongly believes in the power of constructive dialogue. We urge all stakeholders to push for accessibility to high quality treatments, improving both survival and the quality of life of cancer patients.

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