A very important legislative proposal from the European Commission is under scrutiny for approval by the European Parliament and the European Council of Member States: a **Regulation on "Health Technology Assessment" (HTA)**.

What HTA consists in?

HTA, in this context, consists in the collection and assessment of the clinical information about a new therapy (medicinal product or medical device) and in particular the information about its added benefit compared to the standard therapeutic solutions already available (or not).

In other words, we are talking about a Report which is carried out by HTA Agencies in almost every country (some countries are not in condition of doing such a work).

The aim of a HTA Report is to collect and identify clinical information of good quality; that Report can then be used by the Government to decide about the price and the coverage of the therapy in question.

Generally, HTA includes also economic analyses linked to the decision on pricing and reimbursement. However, that field is not touched by the Regulation, which leaves financial analysis and political decisions at National level (according to the "Subsidiarity principle" and to the Treaties).

The Regulation establishes the framework of a permanent European Cooperation on HTA among Member States, which will therefore be structured and sustainable (which is not the case today).
Indeed, a cooperation on a voluntary basis has been running for more than 20 years between EU Members States (acronym: EUnetHTA). However, at present, due to this voluntary-basis model, opportunities are lost because most of those involved are still thinking and working in their own corner.

Why this Regulation is important for patients: higher quality of information and more transparency

With the new Cooperation, Member States will pool expertise and therefore increase the quality of their HTA work. Moreover, that will avoid that 27 Member States repeat the same work 27 times for each product, with different methods and different outcomes, which is currently creating a lot of confusion, notably among patients as they cannot understand how clinical value of therapies can diverge across countries.

By accepting the new cooperation, Member States will also accept to use the *Joint HTA Report* as a basis for their own national HTA analyses. So, they can add new information related to their national context but not duplicate the work already done together: that is called *the Mandatory uptake of the Joint Report*.

a. This rule is the best guarantee for patients to have the best ***quality*** HTA possible (if a country is allowed to decide not to use the Joint Report, no reason to work at its best on it).
b. This rule will also make HTA process more ***transparent***, as Member States will assess and share (so, reuse) the same information. Then, National debates on reimbursement will gain in transparency as well.

c. More specifically, *in the rare diseases' field*, where there are small populations and sometimes limited evidence or information, the new Cooperation would represent a great improvement
d. The new Cooperation will *facilitate patient consultation and involvement* across Europe, in particular for rare diseases (see the case of the Patient Engagement at the European Medicines Agency).

Benefits of the Regulation for health systems

By joining forces with others, the authority and the quality of big countries' HTA Agencies will not be diminished, but on the contrary will increase. At the same time, small countries with no HTA capability or expertise will benefit from a good quality HTA and will learn over the years to bring a greater contribution to the joint work.

The new Cooperation will be hosted by the European Commission, while the work will be practically carried out jointly by Member States, via their main body: the *Coordination Group*.

We need patients to advocate for the Regulation in their own country

The European Council of Member States has to approve this Regulation by a vote, but many countries has shown their opposition because of the engagement required in transparency and solidarity among Member States.

Solidary between Members States is a fundamental principle of the EU. The same applies to the solidarity among patients across Europe.

A press release from your organization and a letter to the Ministry of Health will be the best way to let your Government know that patients are aware of matters that affect their lives and they have strong expectations.

That is why we have to support such a Regulation and advocate for this.