Why EURORDIS supports the proposal for a Regulation on Health Technology Assessment (HTA) Cooperation in Europe

What patients are advocating for

What is the legislative proposal?

After more than 30 years of voluntary cooperation on HTA funded by the European Commission, the European Commission is now proposing a permanent and sustainable scientific secretariat for high quality and transparent HTA cooperation in the European Union that will benefit 508 million EU citizens.

A Regulation aiming to improve health of EU citizens, most welcome at a time when 70% of EU citizens expect the EU to intervene more in health and social policies, while 49% feel current EU action is insufficient (Eurobarometer June 2017). Health and social aspects are the third pillar of EU policy where EU citizens expect the construction of the European Union to restart in the next years, together with actions to protect them from terrorism and unemployment.

The proposal for a Regulation on the Cooperation on HTA, by pooling the best European expertise will contribute to increase the scientific quality of the HTA reports and will avoid duplication of the work in 28 Member States. Moreover, it will certainly improve the transparency of the HTA process for EU citizens, putting scientific evidence at the centre of decision-making.

The Regulation proposes to create a permanent scientific secretariat hosted by the European Commission that will host future Health Technology Assessment (HTA) activities of national and/or regional HTA agencies¹. It will assess new health technologies (clinical aspects only) and its conclusions will serve as a basis for Member States (MS) to add country specific elements (such as costs and economic aspects, national healthcare characteristics or specific treatments used in the country).

¹ See the summary description of the proposal in the annexe
Why do we need a European cooperation on HTA?

1. Decision-making based on scientific and medical evidence, transparent processes and facts, everywhere in the EU
   • When a new health technology comes in, each MS has its own process to decide whether to reimburse/cover it or not.
   EU citizens can accept that different decisions are made in different countries, as different MS invest different budgets in healthcare, and health is not awarded the same budget priority in all MS: across EU Member States, the healthcare expenditure varies from 5.9 to 11.9 % of Gross Domestic Product (GDP)
   • However, different agencies use different sources of data and different methods to assess the exact same technology, and frequently reach different conclusions. This leads to confusion among the patient community and, in many cases, a lack of transparency in methods exacerbates this effect. European citizens cannot understand this pandemonium and do not accept it.
     a) By carrying out scientific assessment separately, there is no possibility to benefit from each other’s work and the current system is wasteful of what are very scarce resources
     b) High quality HTA reports can be best produced by pooling together the best European expertise and the highest scientific standards, leading to a raising of the overall quality of HTA
     c) In rare diseases in particular, some MS cannot generate high quality reports for technologies for conditions for which no expert exists in the country
   Currently, the situation authorises MS to cherry pick which data they want to consider, which methods they want to use, depending on which decision they want to make. Is there a political willingness to reimburse a treatment for disease A, or a budget available for this? Thereafter, HTA bodies select which data and which methods justify an a priori made reimbursement decision.
   With the transparent process of the EU cooperation in HTA, the clinical evidence will be rigorously assessed, it will not be the truth but as close to the truth as possible, and then costs and economic aspects will be considered for the subsequent reimbursement decision.

2. Solidarity between Member States is a founding principle of the European Union
   • The Schuman declaration, 9 May 1950, stated that “Europe will not be formed overnight, nor through a singular construction: instead, it will be formed through concrete actions to create a de facto solidarity.”
   • EU Cooperation on HTA is a major step in the direction of increased solidarity, and it will make national decision making more efficient and more transparent, in the interest of citizens
   • Without close cooperation, no MS can assess clinical aspects for all health technologies for which decisions need to be made each year
     a) At present, each HTA agency in each of the 28 MS needs to spend an average 30,000€ on each HTA report and this is then multiplied by the number of new technologies for which an HTA report is needed. Unnecessary duplication of work inevitably results from this process, and no
meaningful exchange of expertise can take place
b) In 2013, the Commission proposed to revise the Transparency Directive 89/105/EEC to improve the transparency of the reimbursement/coverage decision and to accelerate the procedure, and this proposal was largely adopted by the European Parliament (559 in favour, 54 against, 72 abstentions). However it was subsequently rejected by MS
c) MS typically do not respect the mandatory 180 days legal period to decide on the reimbursement/price or not of a newly authorised medicine

• In light of the above, the Subsidiarity Principle under Article 5(3) TEU applies, as three preconditions for intervention by Union institutions are respected:
  a) the area concerned does not fall within the Union’s exclusive competence
  b) the objectives of the proposed action cannot be sufficiently achieved by the Member States
  c) the action can therefore, by reason of its scale or effects, be implemented more successfully by the EU.

3. HTA cooperation on a voluntary basis has its limits

• EUnetHTA, the European Network of HTA agencies, has made valiant efforts to develop joint HTA reports on a voluntary basis since 2010, but as it is only voluntary collaboration and uptake of the joint work, its effectiveness has been strictly limited
a) Scientific guidelines adopted by the network are not fully used by all members of the network
b) For joint assessments, in the best-case scenario ten Member States are using them partly or fully, but in average it is more around five
c) As a result, few patients and consumers in Europe see the promised evidence based decision-making to which they should be entitled
d) EUnetHTA has been funded since 2010 to the extent of 35.5 million €, funded by EU citizens’ taxes. It is now time to see the logical extension of this cooperation and a sustainable long-term solution in the best interest of patients and all Member States. Else, efforts and resources invested in HTA cooperation would have been wasted.

4. The proposal introduces fairness, equity, high scientific standards and efficiency in the decision-making process, in the interest of all patients

• EURORDIS acknowledges that in this Regulation, the interests of people living with a rare disease and the wider patient community are in harmony

• The European Union is committed to equality of care, and MS stressed the “paramount” need for “equity and solidarity” of care between orphan and common diseases², as well as requiring “delivery of high-quality, accessible and cost-effective healthcare” for those suffering from rare diseases³.

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a) National Courts of Justice have also affirmed the legal duty to promote equality of opportunity and to consider disabilities even where that involves treating the disabled more favourably⁴, which presupposes allocating a larger per capita share of the health care budget to those affected by rare diseases

5. The objectives are complementary with the European policy⁵ to create and develop European Reference Networks

- European Reference Networks are a source of knowledge for health technology assessment: not only these networks can provide both the clinical experts and the patient experts needed when assessing a new or an obsolete technology, but the registries and databases they operate are another source of real world evidence to be used in HTA reports, both on safety, efficacy and quality of life
- The European HTA reports and the ERNs are interdependent and they will reinforce each other. HTA reports that compare different technologies used to treat a particular disease and that rank the level of evidence, are essential information needed for the development of evidence-based Treatment and Care Management Guidelines by the European Reference Networks. Consensus-based Treatment and Care Management Guidelines developed by the European Reference Networks lead to improved and uniform quality of care in European medical centres
- European Reference Networks and HTA cooperation are complementary aspects of patients’ rights for cross-border care, illustrating the importance of exchanging medical and scientific information both ways

About EURORDIS

EURORDIS - Rare Diseases Europe is a unique, non-profit alliance of over 700 rare disease patient organisations from more than 60 countries that work together to improve the lives of the 30 million people living with a rare disease in Europe. By connecting patients, families and patient groups, as well as by bringing together all stakeholders and mobilising the rare disease community, EURORDIS strengthens the patient voice and shapes research, policies and patient services. EURORDIS works across borders and diseases to improve the lives of people living with a rare disease.

The EURORDIS vision is better lives and cures for people living with a rare disease. Follow @eurordis or see the EURORDIS Facebook page. For more information, visit www.eurordis.org

⁴ EWHC 3064 2007 (Admin): para 40 (concerning access by elderly disabled persons to community care).
⁵ Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare
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EURORDIS Statement

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