



[Press release]

EURORDIS regrets missed opportunity to engage patients in EU cooperation on health technology assessment

3 October 2018, Paris - The European Parliament (EP) today adopted the Regulation on EU cooperation on health technology assessment (HTA) with a majority of 576 votes in favor to 56 against and 41 abstentions.

EURORDIS-Rare Diseases Europe congratulates the EP and the Rapporteur, MEP Soledad Cabezón Ruiz, for today's vote. Many of the issues that we flagged in the original legislative proposal were addressed, such as the flexibility given to Member States, without undermining the cooperation, quality of work and transparency of information.

However, MEPs rejected amendments supported by EURORDIS to ensure patients' adequate participation in the EU HTA Coordination Group (as full members) and in joint HTA work.

François Houyez, Director of Treatment Information and Access at EURORDIS, commented, "We are afraid this vote is one step forward, two steps back for patients: we are deeply disappointed that MEPs have today rejected amendments supported by EURORDIS that would have provided for patients' active participation in EU HTA."

He continued, "Patients are best placed to know if a health technology is useful to them or not and they increasingly have a word in all decisions that affect their lives, with their independence of judgement guaranteed, for example, by the strict rules against conflict of interest in place at the European Medicines Agency. Yet, they have just been stripped of this capacity in HTA at the EU level. The rejection of appropriate involvement of patients will affect the overall quality of the joint work, thus undermining the European cooperation on HTA. Whilst we thank MEPs that have supported our inclusion in the development of the legislation, we call on the Council to recognise patients' role in HTA, as is the case in many countries and in all EU regulations on pharmaceuticals".

Mechanisms included in the legislation to ensure patient participation, such as commenting post-hoc in writing, represent only a symbolic effort and are not an adequate approach to involving patients. EURORDIS is therefore calling on the EU institutions to rectify this major drawback during their inter-institutional negotiations.

Apart from this negative outcome for the patient community, the text adopted by the EP today does open the way to productive discussions with the Council. The question is no longer whether or not the European HTA report should be mandatory, but how to make the best use of it. Member States can update European-level HTA assessments if justified, necessary and proportionate. Other provisions that request the highest scientific standards for the joint work and a longer transition period for medical devices are on the same line, increasing chances that the Council, the European Parliament and the Commission adopt the text before the end of the current mandate.

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EURORDIS-Rare Diseases Europe

EURORDIS-Rare Diseases Europe is a unique, non-profit alliance of over 800 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. Follow [@eurordis](#) or see the [EURORDIS Facebook page](#). For more information, visit [eurordis.org](#).

Rare diseases

The European Union considers a disease as rare when it affects less than 1 in 2,000 citizens. Over 6,000 different rare diseases have been identified to date, affecting an estimated 30 million people in Europe and 300 million worldwide. Due to the low prevalence of each disease, medical expertise is rare, knowledge is scarce, care offering inadequate and research limited. Despite their great overall number, rare disease patients are the orphans of health systems, often denied diagnosis, treatment and the benefits of research.

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