



[Press release]

## EURORDIS calls on MEPs to support active participation of patients in European cooperation on health technology assessment

**1 October 2018, Paris** - Ahead of the upcoming European Parliamentary plenary session, EURORDIS-Rare Diseases Europe is calling on MEPs to support amendments to the Regulation on EU cooperation on health technology assessment (HTA) so that the legislation:

- Guarantees adequate participation of **patients** in EU HTA cooperation, and
- Avoids **unnecessary bureaucratic burden** and provides for the creation of an efficient and quick HTA procedure at the European level.

On 13 September, the ENVI (Environment, Public Health and Food Safety) Committee voted on the first draft of the Regulation, which aims to strengthen cooperation between Member States (MS) on HTA. EURORDIS welcomes progress made by compromise amendments adopted at this meeting, which respond to the expectations of some MS. For example, that when using the EU HTA report, MS will be allowed to complete this report with additional information from the national context under certain conditions.

However, **EURORDIS is concerned by compromise amendments adopted by the ENVI Committee that nullify decades of progress regarding the involvement of patients in discussions around medicines development**, and that might render the EU HTA cooperation extremely slow, costly and unnecessarily bureaucratic.

EURORDIS regrets that, in a world where patients are increasingly implicated in all aspects of the development and evaluation of treatments, the [ENVI report](#) does not provide for adequate patient participation in the new EU HTA cooperation. The ENVI Committee systematically replaced the active consultation of patients and other stakeholders by a post-hoc submission of comments.

**François Houÿez, Director of Treatment Information and Access at EURORDIS**, commented, "Requesting HTA to be conducted according to the highest quality standards and simultaneously rejecting the quality participation of patients is a marked contradiction, counter-productive, and an offence to European patients and their organisations. For years, patients have provided invaluable contributions to the evaluation of medicines where their participation is statutory, thus leading to quality results."

A series of amendments that, for example, request developers to submit all information and all results of studies they have carried out, even if not relevant for HTA, will also add an unnecessary bureaucratic burden to the EU-level HTA cooperation.

The objectives of the Regulation are to make HTA faster, higher quality and in the interest of patients. On the contrary, measures introduced by the ENVI Committee make the procedure longer, more complex and costlier.

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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.

## Press contact

Eva Bearryman,  
Communications Manager, EURORDIS-Rare Diseases Europe  
[eva.bearryman@eurordis.org](mailto:eva.bearryman@eurordis.org)  
+33 1 56 53 52 61