



PRESS STATEMENT

EURORDIS welcomes Dutch EU Presidency's conclusions on strengthening the balance in the EU pharmaceutical system but identifies major challenges

Paris, 17 June – EURORDIS-Rare Diseases Europe welcomes the Council of the European Union's [conclusions](#) on strengthening the balance in the pharmaceutical system in the EU, published today, but **expresses reservations about a statement** that proposes the wrong solutions to problems surrounding access to medicines, which affect people living with a rare disease.

EURORDIS is eager to recognise the continued efforts of the Dutch Presidency of the EU and of Dutch Health Minister Edith Schippers to find a new balance between innovation and fair prices, and patient access to medicines and sustainable healthcare, and involving smaller Member States. The Netherlands, in partnership with Belgium and Luxembourg, has played a pioneering role in establishing new ways in which increased cooperation, dialogue and exchange of information between EU Member States can help improve access to safe, effective and affordable medicines while preserving the sustainability of national healthcare systems.

EURORDIS is pleased that the Council Conclusions acknowledge such progress and encourage more Member States to follow a similar path and strengthen their EU-level cooperation, something which EURORDIS has been calling for since the **May 2015** [Call to Payers](#), jointly published with the European Patients' Forum (EPF).

In **May 2016**, EURORDIS and EPF wrote to national authorities in Belgium, the Netherlands and Luxembourg to call upon them to extend their agreement for joint negotiation of orphan medicines pricing to other Member States expressing an interest.

Earlier this month, European rare disease patients then [called](#) for more collaboration between all relevant national/ European authorities and the pharmaceutical industry with the aim of streamlining the medicines pricing process so that patients can access the medicines they need. EURORDIS also observes and welcomes growing collaboration between Member States at the regional level, for example in Benelux, the Nordic countries, Central Europe and the Western Balkans. But for rare diseases it is the European level that is of most relevance.

However, EURORDIS finds extremely worrying the disproportionate focus in the Council conclusions that is placed on the incentives foreseen by existing EU legislation for the development of innovative medicines (particularly those in Regulation EC 141/2000 on orphan medicinal products and Regulation EC 1901/2006 on medicinal products for paediatric use), as well as the implied view that such incentives could form, to an undefined extent, part of the problems around access and affordability that are observed today.

Such a view is short-sighted and inaccurate. The incentives contained in the Regulation on orphan medicines are the very reason this groundbreaking legislation has proved to be a genuine success, and has helped increase the number of orphan medicinal products approved in Europe from 8 before 2000 to over 120 today.

In response to the proposal contained in the Council conclusions to "consider revision of the regulatory framework on orphan medicinal products", EURORDIS argues that:

- It is irrelevant and misguided to revise and weaken a piece of legislation that has worked and continues to work effectively.

- Such a proposal will most likely be counterproductive if the weakening of existing incentives eventually translates (as can be realistically expected) into a much lower pace of discovery, development and commercialisation of new orphan medicinal products, and ultimately in the decrease of the number of new treatments available to patients living with a rare disease. This would set us back 15 years in time. The suggestion to revise the regulation ‘without discouraging the development of medicinal products needed for the treatment of rare diseases’ is wishful thinking. Such revisions will undoubtedly have a detrimental impact on the development and delivery of orphan medicines and send the wrong signal to investors, entrepreneurs, patients and their families.
- By focusing so much on incentives, the Council Conclusions do not sufficiently address the real problem –**the fragmentation of an EU system in which decisions on the pricing and reimbursement of orphan medicines are contained within national silos** (while market exclusivity for an orphan medicine is granted in all Member States at once, decisions about the price of these medicines are made on a national level). The right and effective solution is rather for Member States to invest greater effort in the pursuit of cooperation between each other. By doing so, Member States will be able to cooperate to strengthen the common position they take when in pricing negotiation discussions. This is what EURORDIS and EPF called for as early as last year. This is what EURORDIS and EPF are still calling for today.

The European Patients’ Forum has also issued a [press release on the Conclusions](#).

EURORDIS’ work on improving European collaboration on medicines pricing and patient access continues throughout 2016 with numerous position papers in the pipeline and the development of a new call for action proposing a detailed structured approach to improve patient access.

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EURORDIS-Rare Diseases Europe

EURORDIS-Rare Diseases Europe, the European Organisation for Rare Diseases, is a non-governmental patient-driven alliance of patient organisations representing over 700 rare disease patient organisations in 63 countries. EURORDIS represents the voice of an estimated 30 million people living with a rare disease in Europe. Follow [@eurordis](#) or see the [EURORDIS Facebook page](#). For more information visit: www.eurordis.org

Rare Diseases

The European Union considers a disease as rare when it affects fewer than 1 in 2,000 citizens. Over 6000 different rare diseases have been identified to date, affecting over 60 million people in Europe and the USA alone. 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.