Share your opinion on the EU Regulation on orphan medicinal products

The European Commission is currently evaluating the EU Regulation on Orphan Medicinal Products ahead of a possible revision of the regulation, together with the similar legislation on Paediatric Medicines, and we invite EURORDIS members to participate in the consultation, to express your individual views.

As part of this evaluation, the European Commission is conducting a public consultation. Watch a video in which Simone Boselli, EURORDIS Public Affairs Director, explains why EURORDIS thinks it is important to maintain this regulation and see our position below.

Take part in the consultation by filling out the online questionnaire.

EURORDIS position on the EU Regulation on orphan medicinal products:

- EURORDIS, together with other organisations, successfully advocated for the establishment of such a regulation, to create the necessary environment to channel investment in Europe for the development of treatments for people living with a rare disease, under-served by the traditional development.
- The Regulation firstly established the principle that 'patients suffering from rare conditions should be entitled to the same quality of treatment as other patients', thus creating a system of incentives to increase investments in research and treatment development in rare diseases, like in the US in 1983 and later on in Japan in 1993.
- Twenty years after its adoption, the European Regulation on orphan medicinal products can be considered a success, with more than 170 new therapies adopted for people living with rare diseases. As of September 2018 there have been:
    - 2,067 orphan designations
    - Of which 171 orphan designations included in authorised indication (representing 153 new medical entities)
    - and 61 for use in children.
- As the number of orphan medicinal products approved centrally at European level has increased, so has the number of orphan medicinal product available in individual European countries. However, the availability grows at an unequal pace across European countries.
- The great majority of people living with a rare disease at this very moment have delayed or no access at all to the medicine they need, or there is no existing medicine.
- The current outlook is that a very positive trend is set to continue in the near future, with between 30 to 50 new orphan medicinal products coming to market per year by the year 2020. Many of the therapies will fundamentally change the course of lives of many people living with a rare disease.
- At EURORDIS we are working hard to protect the spirit of the Regulation whilst at the same time improving it and reducing the hurdles to access across Europe.
- If you have any more question, please contact Simone.boselli@eurordis.org.