

**Question for written answer E-007050/2013
to the Commission**
Rule 117
Anna Rosbach (ECR)

Subject: Different definitions of rare diseases

Prevalence in the definition of rare diseases has been consistently applied in EU rare disease legislation and policy. The Council Recommendation of 2009 on an action in the field of rare diseases refers to both the Community action programme on rare diseases and Regulation (EC) No 1411/2000 with regard to prevalence in the definition of rare diseases as 'affecting not more than 5 in 10 000 persons in the Community'.

Despite this figure, countries such as Denmark, Sweden and the UK have defined rare diseases as having a different prevalence. Not only is this contrary to the EU regulatory framework, but this development could be detrimental to patients, as it could result in discrimination between more common rare diseases and other rare diseases when rare disease legislation and policy are applied at national level. Furthermore, it could lead to problems if an EU citizen with a rare disease moves from an EU Member State that applies the EU prevalence to one that does not.

In connection with this, can the Commission please answer the following questions:

1. Does the Commission feel there should be consistency in the definition of rare diseases across Europe?
2. In its assessment report following the implementation of the national plans for rare diseases, will the Commission look at how rare diseases are defined in the national plans across Europe?
3. What implications do the Member States' different definitions of rare diseases have for EU legislation, such as Regulation (EC) No 1411/2000 on orphan medicinal products?