Dutch government response to Consultation Document on the concept of 'similar medicinal product' in the context of the orphan legislation (adaptation to technical progress).

Introduction

This document contains the response of the Dutch government to the European Commission's draft Public Consultation on amendments to **Commission Regulation (EC) No 847/2000 of 27 April 2000** laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'.

Position of the Dutch government

The Dutch government agrees with the proposals for change as presented by the European Commission in the consultation document. This response has been prepared by the Ministry of Health, Welfare and Sport with input from the Dutch Medicines Evaluation Board. In our view, the proposed changes may have a positive impact on the availability of orphan medicinal products for comparable therapeutic indication. As a consequence, patients may be provided with more alternative treatment options.

Furthermore, we deem it important that the European Commission has started various discussions and initiatives to further streamline the content and application of the EU orphan legislation. Indeed, there is a growing concern in the Netherlands and in other European countries that this legislative framework has some unintended and/or unwanted adverse consequences that challenge its purpose and that may jeopardize future availability and affordability of orphan medicinal products for EU citizens.

Suggestions for possible changes

Even though we agree to the proposed changes, a few additional remarks on the text of the Consultation Document may be relevant:

- One should be careful with examples in the legal text, as they will become part of legislative text of Commission Regulation 847/2000 and therefore create limitations. Moreover examples may become outdated in the future.
    - Examples can therefore be better part of an Annex to the legal text.
- The Dutch government feels that an update of the concept of similar medicinal product and clinical superiority (like the current consultation) should be carried out more often (e.g. once every three years), as pharmaceutical developments and changes especially in the realm of biologicals happen at an increasingly faster pace.
- It is to be expected that also in future, the legal text as well as explanatory memorandums will continue to be subject of scientific debate. For example, phrases like 'activity relevant for the intended therapeutic effect of the product' (lines 106 – 114) could provoke interpretative questions and therefore give room for various interpretations and decisions on a case by case basis.