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CONCEPT OF 'SIMILAR MEDICINAL PRODUCT' IN THE CONTEXT OF THE ORPHAN LEGISLATION: ADAPTATION TO TECHNICAL PROGRESS

REPLIES TO THE PUBLIC CONSULTATION

This document summarizes stakeholders' responses to the Commission's public consultation on the concept of 'similar medicinal products' in the context of the orphan legislation.

1. BACKGROUND TO THE CONSULTATION

Regulation (EC) No 141/2000 on orphan medicinal products was developed to promote the research, development and marketing of medicinal products for rare diseases. The Regulation calls on the Commission to adopt the necessary provisions for implementation and definitions.

The Commission has recently launched a number of initiatives to improve the implementation of the regulatory framework. Amongst these initiatives, the Commission has decided to launch a targeted review of Commission Regulation (EC) No 847/2000 on the concept of similarity.

The cornerstone of the orphan rules is the principle of market exclusivity. When a marketing authorisation for an orphan medicinal products is granted, the Union and the Member States shall not for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation for the same therapeutic indication, in respect of a similar medicinal product

Commission Regulation 847/2000 provides a definition of 'similar medicinal products' and a number of examples defining what kind of products are to be regarded as similar for the purposes of the application of the incentives provided under Regulation 141/2000.

The definitions of Regulation 847/2000 require adaption to technical progress due to major developments in the field of biological medicines including advanced therapy medicinal products. The purpose of the public consultation was to receive feedback from stakeholders on this matter.

2. RESPONDENTS

The Commission received 17 responses from stakeholder organisations representing pharmaceutical undertakings, patient organisation or individual companies, as well as public institutions including regulatory agencies and national ministries. Healthcare professionals, academia, research networks and other associations also contributed.

All responses and comments provided useful information for the Commission. In some cases however, they went beyond the scope of the public consultation and could therefore not be taken into account.

3. SUMMARY OF RESPONSES

This document presents a factual short summary of the responses to the public consultation. It does not present the views of the European Commission.

In general, most of the respondents welcomed the consultation and the initiative to revise the definition of similar active substance. A clear and unequivocal definition of similarity with regards to Principal Molecular Structural Features is of utmost importance. However, some respondents criticized the use of ambiguous terms, which are open for interpretation and do not give adequate guidance to determine the actual boundaries of the definition.

The respondents were positive as regards the division of similarity in respect of different categories of products comprising chemical medicinal products, biological medicinal products and advanced therapy medicinal products (ATMPs) covered by the review. The degree of technological progress in each area is advancing at different rates. Therefore, many respondents agreed that the requirements for demonstrating similarity will differ from product type to product type.

As regards the three categories of products, the majority of the comments support the proposal for the chemical medicinal products. Most of the respondents commented in detail on the biological medicinal products and ATMPs, including line-by-line comments.

Some respondents highlighted that predictability is a key component for therapeutic development by pharmaceutical companies. It is crucial that the issue of similarity is addressed as early as possible in a dialogue between the developers and the regulators.

The above summary of comments is not exhaustive. The Commission services will carefully analyse all the responses in consultation with experts in the European Medicines Agency and Member States. All the public responses have been published on the pharmaceuticals website.