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TLV

European Commission
DG Health and Food Safety
Unit B5 "Medicines – policy,
authorisation and monitoring"

Public consultations on the concept of 'similar medicinal product' in the context of the orphan legislation, response from the Dental and Pharmaceutical Benefits Agency (TLV), Sweden

TLV, The Dental and Pharmaceutical Benefits Agency, is the Swedish pricing and reimbursement authority, a Public Authority under the Government Department of Social Affairs. TLV welcomes the opportunity to comment on the Commission consultation on Concept of 'similar medicinal product' in the context of the orphan legislation: adaptation to technical progress.

TLV:s generally perceives that the current legislation and implementation provisions give orphan pharmaceuticals a high level of protection from competition in the market. On the other hand, certain unanticipated consequences have been identified over time, in particular, regarding pricing of orphan drugs. In some cases, this has resulted in a situation where very high prices are charged for drugs that have been in use for a long time and which were, prior to gaining market authorization with orphan designation, available at much lower prices.

An additional problem is that pharmaceutical companies are allowed to file for orphan status for very narrowly defined treatment groups and later add new orphan designations for different applications of the product, so called "salami slicing".

The increasing prices and numbers of orphan designations cause concern for future developments. The cumulative impact on national healthcare budgets may be that fewer patient treatments can be paid for, that countries cannot afford to pay a reasonable price for a truly innovative drug of high value, or other important innovations that contribute to improved health outcomes.

A further unanticipated outcome of the legislation may be that drug companies who, without much further research, market an already used drug as an orphan drug (and receive higher prices) are in effect favoured against pharmaceutical companies who develop truly innovative new drugs for rare diseases.

Given this background we believe that the intention of the legislation is not met and would suggest a comprehensive review of Regulation 141/2000. As part of a review, it would be helpful if the potential impact of some specific changes to EU legislation could be considered, including potentially changing the Regulation 141/2000 as follows:

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1. Reducing the incentives associated with orphan designation for drugs that are known or already in use.
2. Strengthening the criteria for orphan designation, in order to target incentives where they are most needed.
3. When the orphan drug is on the market: adding a threshold and annual reporting requirements on sales and their value, with market exclusivity being revoked if the total revenue from a drug exceeds the threshold.

TLV is therefore negative to a partial change of the legislation and especially to a broadening of the definition of similar. It cannot be excluded that a broadening of the definition of "similar" will further exacerbate the problems described above. TLV's view is that the protection of orphan pharmaceuticals given by the current legislation is sufficient and that a comprehensive overview of the legislation is needed to ensure that it works towards the intended goals without the described downsides.

Stockholm, 3 November 2016