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Deutsche Sozialversicherung
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Statement of the German Social Insurance from 26 September 2023

Initiative to revise the variation framework for medicines

The European Commission intends to adopt a delegated regulation in the fourth quarter of this year to make the current legal framework more efficient for changes in the contents of marketing authorisations for medicinal products that have resulted, for example, from technological developments. The legal act would thus take place years earlier than the conclusion of the legislative initiatives on European medicinal products legislation.

The DSV welcomes the planned delegated regulation in principle. However, the intended short-term changes must be placed in the context of the medicinal product review. In the draft directive [COM(2023)192final], it is planned, among other things, to shorten the regular authorisation procedure from 210 days to 180 days. In the opinion of the DSV, this must not be at the expense of the quality of the authorisation procedure. The same requirement must also apply to the planned delegated regulation on variations to the marketing authorisation of the medicinal product.

The current regulations essentially link the classification of marketing authorisation changes to their risk to public health and the extent of the impact on the quality, safety and efficacy of the medicinal product concerned. In addition, they ensure that in particular those changes are made promptly that affect the up-to-dateness of the product information and thus in turn the medicinal product therapy safety. In order to combine the high level of safety with the desired bureaucracy relief and efficiency gains, the existing risk-adapted approach should be further strengthened.

In addition, the impact of the planned delegated regulation on national healthcare systems must be considered. In Germany, for example, the procedures for early benefit assessment and exemptions from price regulations depend on whether a marketing authorisation change is associated with the addition of a new therapeutic indication or the change of an existing indication (major variation of type II according to Annex II No. 2 a) of Regulation (EC) 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human and veterinary use.

Therefore, firstly, it is of great importance that a consistent distinction is made between the following situations when classifying the changes: Changes that lead to an extension or restriction of the indication and those that do not.

In the past, it was observed for some antivirals (for example for Harvoni®) that the indication of the medicinal product as derived from section 4.1 of the SmPC was relevantly extended - namely by the use for additional genotypes - by amendments to sections 4.2 and 4.4 without the relevant amendment being classified as a major type II change. Therefore, secondly, it should be ensured in future that all changes to sections 4.2 and 4.4 of the SmPC that lead to a relevant change in the

indication (and are therefore usually based on new study data) are classified as a major variation of type II and are thus also subject to the corresponding procedural and transparency requirements.

A third reference concerns the "skinny labelling" according to Article 11(2) of Directive 2001/83/EC (Community code relating to medicinal products for human use), which provides for exemptions from the labelling obligation for generic medicinal products in the case of still existing patents for use of the original medicinal product. Here, the authorisation of generics or biosimilars should be extended to include the initially omitted indications of the reference medicinal product after the discontinuation of the application patent with as little change as possible.

Finally, it should be noted that where several variations are grouped together in accordance with Article 7 of Regulation (EC) No 1234/2008, the public documents concerning those variations shall continue to clearly indicate the classification of each individual variation.

About us

The German Pension Insurance Association (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the associations of statutory health and long-term care insurance funds at federal level, and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance Association Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e.V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union as well as other European institutions and advises the relevant actors in the context of current legislative projects and initiatives. As part of a statutory insurance system, health and long-term care insurance, pension insurance and accident insurance offer effective protection against the consequences of major life risks.