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Deutsche Sozialversicherung
Europavertretung | DSV

Opinion from German Social Insurance issued on 23 October 2024

European Commission's consultation held on 1 October 2024 about health technology assessment (HTA) - joint clinical assessments of medicinal products - draft implementation regulation covering joint scientific consultations on medicinal products for human use

I. Preliminary remarks

As a result of the joint clinical assessment of health technologies (EU HTA), the European Commission introduced a significant reorganisation of the scientific assessing of health technologies in 2021 through Regulation (EU) 2021/2282 . The EU HTA harmonises the benefit assessment of health technologies, including those for medicinal products and medical devices. Tighter European coordination will make cooperation between the member states more binding. EU HTA is to be implemented gradually from 2025.

On 1 October, the European Commission presented the third of a total of six drafts of an implementing regulation for health technology assessment (Commission Implementing Regulation (EU.../...) of XXX laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medicinal products for human use at Union level).

The planned implementing provisions are intended to regulate joint scientific consultations regarding medicinal products. Specifications are to be stipulated that describe how developers of health technologies can obtain early guidance on the evidence and data required to conduct a joint scientific assessment of their product.

II. Opinion

From the perspective of the DSV, the regulations proposed in the draft implementing regulation are necessary and, for the most part, reasonable. The DSV expressly welcomes the fact that the draft presented does not include any restrictions that would make it even more difficult for the national HTA organisations and their committees to process the briefing package provided by the health technology developer.

However, from the DSV's point of view, the proposed provision in Article 13 (1) covering scientific consultation is inadequate. The planned provision proposes that updates made by the health technology developer after submitting the final version of the information package due to a modified development plan will be considered by a subgroup from the Joint Scientific Consultation in the outcome document, provided that it is submitted at least 10 days before the respective meeting.

However, the DSV does not consider it feasible for HTA organisations to conduct a thorough consultation on significant changes to the development plan within 10 days

if these changes are relevant to the joint assessments. The obligation to consider documents submitted at such short notice could jeopardise the proper Joint Scientific Consultation procedures.

In principle, expanding the range of services for joint scientific consultations sought by the pharmaceutical industry will require these procedures to be subject to fees. This is analogous to the scientific consultations that are already subject to a fee and are provided by the European Medicines Agency (EMA) within the framework of national procedures.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and long-term care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group 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 (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and long-term care insurance with 75 million insured persons, pension insurance with 57 million insured persons and accident insurance with more than 70 million insured persons in 5.2 million member companies offer effective protection against the consequences of major risks of life.