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Deutsche Sozialversicherung
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Feedback from German Social Insurance dated 2 April 2024

Consultation of the European Commission on 5 March 2024 on Health Technology Assessment (HTA) – Joint Clinical Assessments of Medicinal Products – draft of an Implementing Regulation

I. Preliminary remarks

With its Joint Health Technology Assessment (EU-HTA) that the European Commission introduced in 2021 through the Regulation (EU) 2021/2282, the European Commission has undertaken a sensible reorganisation of the scientific assessment of health technologies. The EU-HTA harmonises the benefit assessment of health technologies, including medicinal products and medical devices. Stronger European coordination will make cooperation between the Member States in this area more binding. EU-HTA is to commence gradually from 2025.

In the view of the German Social Insurance (DSV), the draft of the Implementing Regulation, including the annexes, makes it clear that there is still insufficient clarity regarding the content and scope of joint clinical assessments of medicinal products, further compounded by the absence of guidelines still to be developed, including the methodology. This jeopardises the timely implementation of the EU-HTA at national level. As exact methodological requirements are missing, it can be assumed that not all assessments to be regularly submitted in Germany will be included in the joint HTA report and that additional assessments will therefore have to be submitted at national level.

II. Opinion

_ The problem resulting from change of indication of the medicinal product during the authorisation procedure is addressed for the first time in the Implementing Regulation. The DSV assumes that the European Medicines Agency (EMA) is only obliged to provide information on potential indication changes at the time of the "List of Questions" (day 120) or the "List of Outstanding Issues" (day 180) **[Art.3 para.4]**. The deadlines to be applied in the event of a necessary revision of the scope and the dossier **[Art. 16 para. 2]** are not specified. Although this is understandable due to the wide range of constellations, it remains unclear how the procedural steps should be carried out if the finalisation deadline remains unchanged.

_ In the selection and participation of patients as well as clinical and other experts **[Art. 6],** priority shall be given to those who have extensive expertise in the therapeutic area of joint clinical assessment in several Member States. However, it is unclear how this expertise is to be obtained and documented.

- An assessment scope proposal with a set of the parameters for the joint clinical assessment in terms of patient population, intervention, comparators and health outcomes ("PICO") is to be drawn up by the assessor. This can be useful in individual cases, provided the proposal is not binding. A consolidated assessment scope is then to be drawn up on the basis of the feedback provided by the Member States **[Art. 9];** the DSV assumes that this assessment scope will remain inclusive and must meet the needs of the Member States **[Recital 17]**. The DSV assumes that the consolidation meeting on the assessment scope serves solely to check whether the result meets the requirements of the individual Member States and that there is no risk that individual PICOs will be questioned and possibly cancelled. Against this background, it is unclear what purpose the involvement of patients and experts serves in this phase of the procedure **[Art. 10 para. 1]**.

- If new clinical data for the authorisation procedure are submitted by the Health Technology Developer (HTD) during the ongoing assessment, these data can also be included in the Joint Clinical Assessment (JCA) **[Art. 12 para. 7],** provided they were submitted no later than 7 days after the decision of the Committee for Human Medicinal Products (CHMP) **[Art. 14 para. 5]**. This poses a challenge, as the time for the implementation of the JCA is reduced to approximately 60 days (possibly even less if the European Commission issues its authorisation decision before the expiry of the statutory period of 67 days); therefore, the HTD must submit the data without delay.

- DSV sees risks in the requirements for handling potential business secrets of HTD. As part of its fact check of the HTA report **[Art. 14 para. 4 in conjunction with Art. 20]**, the HTD should note any inaccuracies and indicate which information it considers to be confidential. The possibility for the HTD to correct the report as provided for in the Implementing Regulation is questionable. In addition, only personal data in documents (for example, study reports, individual patient data) that would not be part of the report can be confidential. It should therefore be clarified that redactions can only concern personal data, but not data, results and analyses relevant for the assessment.

- The Implementing Regulation gives the HTD the option of proactive submission of new data **[Art. 18 para. 2]**. Since this is usually associated with the hope of an improvement in the HTA result, a distortion arises without a simultaneous obligation to submit potentially negative findings. Art. 18 para. 2 should therefore be deleted. In addition, the decision on the allocation/selection and appointment of experts should be the responsibility of the coordination group.

_ **[Annex 1, section 4.2.1]** It remains unclear why only the National Library of Medicine's bibliographic database (MEDLINE) and the Cochrane Central Registry of Controlled Trials database are used for bibliographic research and not, for example, Embase (Excerpta Medica Database). It also remains unclear why the study registers are not further specified.

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 74 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.