vfa. Die forschenden Pharma-Unternehmen
Research-Based Pharmaceutical Companies

Comment on the commission implementing regulation (EU) on Joint Scientific Consultation for Health Technology Assessment

Key demands

- Ensure timely joint scientific consultations to all health technology developers that seek advice
- Increase transparency in Member States' contributions to the joint scientific consultations
- Strengthen the protection of confidential business information

Summary

As stipulated by the Regulation (EU) 2021/2282 on health technology assessment (HTA), the European Commission (EC) is seeking feedback on the draft Implementing Regulation regarding the procedures for joint scientific consultations (JSC) on medicinal products for human use at the European Union (EU) level.

The draft provides rules for the submission of requests for JSC, the selection and consultation of stakeholder organizations and patients, clinical experts and other relevant experts (individual experts). It further details the cooperation, by exchange of information, with the European Medicines Agency (EMA) where a health technology developer (HTD) requests the consultation to be carried out in parallel with the scientific advice by EMA.

The JSC is a crucial tool for HTDs. It offers the promise to increase the predictability of European HTA, by creating the opportunity for HTDs to align the evidence generation of clinical development programs for new medicines to European Joint Clinical Assessment (JCA) requirements. This, in turn, should facilitate the national HTA, support pricing & reimbursement processes and ultimately improve access to new medicines in the EU.

To achieve these objectives, JSCs must be offered to all HTDs that seek advice and must be provided in a timely manner to enable informed clinical development.

Neither premise is achieved with this draft implementing regulation. The number of JSC is not aligned to demand, while the provision of timely advice is complicated by lack of a practical rolling timetable with sufficient request periods and necessary lead time.

Further, important specifications are still missing. Firstly, to ensure a timely and predictable process for HTDs, a clear timetable with deadlines for JSC without scientific advice by EMA needs to be specified. Secondly, information is missing about the process of integrating the Member States' inputs into JSC, raising concerns about the applicability of JSC in all the EU Member States. Here, transparency about Member States' contributions to the JSC should be ensured.

The draft regulation also sets new rules for establishing a new template of the briefing package to be used where the JSC is carried out in parallel with scientific advice by EMA. It is important that the process includes the perspective of HTDs as users of the tool, to make it fit-for-purpose. This should be ensured by engaging the industry associations of the stakeholder network.

The draft regulation shows the commitment to protect confidential business information. However, given the highly competitive nature of information shared by HTDs during JSC, these rules should be strengthened. This should include ensuring an equivalent level of protection as EMA, limiting shared information with individual experts to HTA-relevant contents, adding sanctions for non-compliance with professional secrecy and inserting a reference to implemented regulations based on the Directive (EU) 2016/943 that relates to national criminal prosecution for individuals who disclose confidential business information.

Number of request periods

Article 2 stipulates that by 30 November each year, the Coordination Group shall set the dates of request periods for JSC for the subsequent year and the planned numbers of JSC for each of those request periods, while at least two request periods per year should be set.

The low number of request periods and the inflexible date of publication of the JSC timetable are significant obstacles for HTDs in need of a JSC. The request period timetable should be more flexible to accommodate the dynamics of clinical development programs. Inflexible request periods jeopardize the usefulness and acceptance of JSC. This increases the risk of slowing developments and thus delayed patient access to medicines.

A rolling timetable with an increased number of request periods should be established, allowing HTDs to plan and submit a request at least one year in advance. The schedule of EMA's scientific advice stands as a good example. Also in Germany, G-BA offers scientific consultation roughly a year in advance on a rolling schedule with request periods being two to four weeks apart.

Recommendation

A rolling timetable with an increased number of request periods should be established, meeting the demands of the dynamics of clinical development programs.

Number of planned JSCs

Article 2 provides that the Coordination Group shall set the planned number of JSCs for each of the request periods. According to the draft annual work program 2025, the Coordination Group plans to initiate only 5 to 7 JSCs for medicinal products, and 25 JCAs (17 cancer medicines, 8 ATMP).

The number of planned JSCs is alarmingly low, considering the number of expected JCAs in 2025 that are likely to increase further. The number of planned JSCs will therefore not meet demand. In 2021, the G-BA in Germany provided approximately 100 scientific consultations for clinical study design (Link), thus setting an important point of reference for expected JSC demands of a more mature European HTA including updates.

The low number of planned JSCs is very disappointing, considering the critical importance of scientific consultations for HTDs to enable evidence generation along the lines of European HTA-requirements. These low numbers pose a serious risk for predictability, feasibility, and for the long-term success of the JCA process.

The expected high demand for consultation must be matched with higher numbers of planned JSCs. The regulation should align the planned number of JSC to the expected demand, ensuring that all HTDs that seek advice will get it. For this, capacities in HTA-institutions must be increased.

Recommendation

The planned number of JSC should be linked to the expected demand, ensuring that all HTDs that seek advice will get it.

Timetable for JSC

Article 4 provides that the information to the HTD about the JSC should include a timetable. Further, when the HTD requests the JSC to be carried out in parallel with scientific advice by EMA, the timetable should be synchronized with the timing of the process for scientific advice by EMA.

The implementing regulation does not specify the details of the timetable of the JSC, if the HTD does not request parallel scientific advice by EMA. Thus, the timetable for JSC is unclear and HTDs face an unpredictable process. As this regulation intends to lay down detailed procedural rules for JSC, it should also specify a predictable timetable with clear deadlines for JSC without scientific advice by EMA.

For this purpose, it is desirable to establish a timetable for JSC that follows the one for JSC with scientific advice by EMA. The deadlines for the JSC timetable should be identical to those of the EMA scientific opinion to ensure perfect synchronization.

Recommendation

For JSC without scientific advice by EMA, a predictable timetable with clear deadlines should be specified that follows the JSC with scientific advice by EMA.

If JSC is carried out in parallel with the scientific advice by EMA, it must be ensured that deadlines and timetables are identical for both.

Transparency about member states contributions to JSC

The regulation does not contain any information about the process of integrating the Member States' input into JSC. It is unclear whether the Member States' contributions are mandatory or to what extent input is requested and considered. This raises uncertainties about the applicability of the JSC outcome document for the expected European JCA. Without transparency about the process of involving Member States' inputs, it remains unclear to what degree the JSC reflects individual Member States' views.

Therefore, this implementation should make clear provisions about the process of requesting input from the Member States while ensuring transparency about Member States contributions to the JSC outcome document.

It is crucial that the input of all Member States is requested and considered in developing the JSC outcome document to enable a 'complete picture' for the expected European JCA. Further, transparency regarding the involvement of the individual Member States should be ensured and possibly divergent views included in the outcome document. Both can support informed HTD-decisions on HTA-related evidence generation, including for national assessment procedures.

Recommendation

All Member States' inputs should be required in the development of the JSC to ensure full applicability for JCA.

Transparency of Member States' contributions to the JSC should be ensured.

Template of the briefing package

Article 8 holds that the Coordination Group shall, after consulting and reaching an agreement with the EMA, establish a specific template for the briefing package to be used where the JSC on medicinal products is carried out in parallel with scientific advice by EMA.

As the briefing package is provided by the HTD, the development of a template should include the perspectives of industry as users of the tool to make it fit for purpose. It is important to include a consultation option in the process of establishing the template, e.g., by involving the industry associations in the stakeholder network.

Recommendation

The template of the briefing package should be created in consultation with health technology developers.

Protection of confidential information

Article 6 provides that the HTA secretariat shall ensure that only individual experts who have signed a confidentiality agreement are involved in JSC on medicinal products.

The article shows the intention of the regulation to protect confidential business information. However, given the highly competitive nature of information shared by HTDs during JSC, the rules should be strengthened to reduce the risks of disclosure.

The regulation should ensure, in line with Implementing Regulation (EU) on cooperation with the EMA (Link), that the Coordination Group provides an equivalent level of protection as EMA, even when scientific advice by EMA is not requested.

To enhance protection, the briefing package contents provided to individual experts should be limited to HTA-relevant information, thus not including information exclusively relevant for regulatory approval.

Further, sanctions in case of failure to respect the obligations of professional secrecy should be included, in line with Implementing Regulation (EU) on cooperation with EMA (Link) and conflict of interest. Importantly, a reference to regulations based on the Directive (EU) 2016/943 that relates to national criminal prosecution for individuals who disclose confidential business information should be added.

Recommendation

The protection of confidential information should be strengthened by ensuring an equivalent level of protection as EMA, limiting shared information to HTA-relevant contents, adding sanctions for non-compliance with professional secrecy and adding a reference to regulations based on the Directive (EU) 2016/943 that relates to national criminal prosecution.

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