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

Comment on the commission implementing regulation (EU) on Cooperation of EMA and Member States HTA Coordination Group

Key demands

- Ensure robust protection of confidential business information
- Inform about legal consequences of breach of confidentiality and increase sanctions
- Ensure the inclusion of the health technology developer in information exchange

Introduction

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 (IR) that lays down detailed procedural rules concerning cooperation, in the form of exchange of information, of the Member State Coordination Group on Health Technology Assessment ('CGHTA'), with the facilitation of the secretariat of the Coordination Group ('HTA secretariat'), with the European Medicines Agency (EMA) on the joint clinical assessment (JCA) and joint scientific consultation (JSC).

The draft IR provides rules concerning cooperation, in the form of exchange of information regarding the planning and forecast of the JCA and JSC, identification of patients, clinical experts and other relevant experts to be involved in JCA and JSC, regarding general scientific and technical matters related to JCA and JSC and security of sharing and protection of confidential information exchanged between the EMA and the HTA secretariat and CGHTA or its subgroups and their members within the context of JCA and JSC.

Cooperation and exchange of information between EMA and CGHTA with meaningful involvement of the HTD are a prerequisite for a successful European HTA. Thus, the vfa supports a policy that aims for good cooperation and exchange of information between the EMA and CGHTA that includes the HTD in the information exchange, while preserving the separation of the respective remits of the EMA and CGHTA. To ensure that trade and business secrets are not disclosed, strict rules on the protection of confidential business information must be implemented. To ensure high-quality, transparent and efficient JCA and JSC, the HTD should be included in the information exchange between EMA and CGHTA on aspects of the individual product of the HTD.

The vfa welcomes the EC's clear intention to protect confidential business information. However, the proposed rules do not go far enough to ensure effective protection. The EC should ensure that the CGHTA provides an equivalent level of protection as EMA by specifying necessary technical and organizational measures the CGHTA must implement to ensure protection. For instance, a mechanism for CGHTA should be implemented to restrict access to protected information based on the individual's role, thus increasing the level of protection. Further, EMA should only share aggregate product formation related to the planning and forecast of JCA and JSC with the HTA secretariat, while HTD should be responsible to share individual product information directly with the HTA secretariat. The EC must also ensure that exchanges on general scientific or technical issues related to JCA and JSC do not contain references to

individual product information or share confidential information with the stakeholder network.

Importantly, the sanctions in case of failure to respect the obligations of professional secrecy appear not strong enough to deter the misconduct regarding the disclosure of confidential business information, by orienting the punishment on the case of a failure to declare a conflict of interest. Here, a stronger sanction is needed. Importantly, a duty for the CGHTA to inform about legal consequences of disclosing confidential information should be implemented, including 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. The disclosure of trade secrets can have serious consequences under data protection and criminal law. Germany imposes heavy fines and even prison sentences of up to 5 years for offences.

The exclusion of the HTD from the information exchange of EMA and CGHTA is a major risk for European HTA process, as it makes the preparation and participation of the HTD in the process more difficult. Thus, the EC must ensure the inclusion of the HTD in information exchange of EMA, HTA secretariat and CGHTA.

Protection of confidential business information

Article 8 provides that information received from the EMA within the context of JCA and JSC shall be used exclusively for the purposes of planning and conducting the JCA and JSC. The EMA shall clearly indicate the level of protection that it attributes to the information shared with the HTA secretariat. Before providing the information received from the EMA to the CGHTA and to its relevant subgroups, the HTA secretariat shall attribute to this information at least an equivalent level of protection. The members of the CGHTA or its subgroups shall implement necessary and appropriate technical and organizational measures to ensure and protect the confidentiality of the information received from the EMA in the context of JCA and JSC within their organization.

The vfa welcomes the intention to ensure an equivalent level of protection of confidential information for EMA and CGHTA as well as the fact that CGHTA or its subgroups should implement technical and organizational measures to ensure and protect the confidentiality. However, further provisions must be made to ensure effective protection. The EC should specify possible measures CGHTA must implement to ensure protection. For instance, a mechanism should be provided for the CGHTA to restrict access of CGHTA representatives, subgroup members or individual experts and patients to protected information, based on the individual's role and information needs. In that way, confidential information can be better protected by appropriately restricting the access to it.

Article 6 provides that the CGHTA and its subgroups should ensure, via the HTA secretariat, an appropriate exchange of information with the EMA on general issues of scientific or technical nature related to JCA and JSC and that the CGHTA may involve the stakeholder network in the exchange. It is important that this exchange is not addressing specific issues of scientific or technical nature related to individual pharmaceutical products. The EC must ensure that exchanges on general scientific or technical issues related to JCA and JSC do not contain information about specific products or share confidential information with the stakeholder network.

Article 2 provides that the EMA shall provide the HTA secretariat with information concerning medicinal products related to the planning and forecast of JCA and JSC. However, these information concern highly competitive information, such as the expected submission date of the application for marketing authorization. To increase the protection of these confidential business information the EMA should share only aggregate information rather than individual information about products with the HTA secretariat. The aggregated information would be sufficient for CGHTA’s planning and forecast of JCA and JSC.

In principle, the HTD should be responsible to share individual product information directly with the HTA secretariat, in a similar way as the HTD shares product information directly with the EMA.

This would enable the HTDs to submit the confirmation of eligibility for centralized procedure the same way they share their letter of intention to submit, providing more reliable and timely information for JCA planning.

Recommendation

The EC should ensure that the CGHTA provides an equivalent level of protection as EMA by specifying concrete measures the CGHTA must implement to ensure protection.

The EC should ensure that exchanges on general scientific or technical issues related to JCA and JSC do not include information on specific products or exchange confidential business information with the stakeholder network.

To increase protection of confidential business information the EMA should only share aggregate information related to the planning and forecast of JCA and JSC with the HTA secretariat.

The HTD should be responsible to share individual product information directly with the HTA secretariat.

Sanctions and legal consequences of breach of confidentiality

Article 9 provides that the EC may exclude the CGHTA representative or the individual expert from the joint work for a period up to 2 years, if the representative or the individual expert failed to respect the obligations of professional secrecy intentionally or by gross negligence.

The vfa considers that these sanctions are not strong enough to deter the misconduct regarding the disclosure of confidential business information. These low sanctions, that reflect those expected for individuals that fail to declare a conflict of interest, are surprising, given the strong legal protection of confidential business information in the European Union in Directive (EU) 2016/943 (Protection of undisclosed know-how and business information [trade secrets] against their unlawful acquisition, use and disclosure). Thus, a stronger sanction is needed.

To further improve protection, complementary measures should be taken. A duty for the CGHTA to inform about legal consequences of disclosing confidential should be implemented, including 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. The disclosure of trade secrets can have serious consequences under data protection and criminal law. Germany imposes heavy fines and even prison sentences of up to 5 years for offences (§ 23 law on the protection of trade secrets [GeschGehG], § 203 infringement of private secrets, German Criminal Code, [StGB]).

Recommendation

Sanctions for failure to respect the obligations of professional secrecy should be increased.

Individuals involved in the joint work must be informed about the legal consequences of disclosing confidential information in the European Union.

Inclusion of the HTD in information exchange

Cooperation and exchange between EMA and CGHTA with meaningful involvement of the HTD are a prerequisite for a successful European HTA. However, the draft IR does not provide for the possibility of including the HTD in the information exchange.

Involving the HTD in the information exchange between the EMA and CGHTA is crucial for several reasons. The inclusion of the HTD can streamline the flow of information, reduce delays and misunderstandings, and enable the HTD to respond promptly to requests of the CGHTA or provide additional data, resulting in a more efficient and

effective JCA process with higher quality. Further, involvement helps HTD in identifying potential risks and concerns early in the assessment process, allowing for timely mitigation strategies. Finally, involving HTDs ensures they are aware of how their confidential business information will be handled, which is crucial for protecting trade secrets and maintaining competitive advantage. Therefore, the EC should provide the possibility for inclusion of the HTD in the information exchange of EMA with the CGHTA on the aspects of the HTD's individual product.

Recommendation

To ensure high-quality, transparent, and efficient JCA and JSC, the HTD should be included in the information exchange between EMA and CGHTA on the aspects of the individual product of the HTD.

In summary, while the draft IR shows promise in protecting confidential business information and fostering cooperation, it needs further enhancement to ensure robust protection and effective participation of the HTD in the European HTA process.

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