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Revised Q&A on Combinations of Medicinal Products and Medical Devices

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On May 2024, a new revision of the question-and-answer document ("Q&A") concerning the implementation of the Regulation (EU) 2017/745 on medical devices and of the Regulation (EU) 2017/746 on in vitro diagnostic regulations for combinations of medicinal products and medical devices was published by the European Medicines Agency ("EMA"). Taking into account that, depending on the main mode of action the products combining a medicinal product or medicinal substance and a medical device are regulated either under the pharmaceutical framework or under the medical device framework, this revised version of the Q&A provides regulatory and procedural guidance in combination with the EMA Guideline on quality documentation for medicinal products when used with a medical device.

Besides the revision of the answers already included thereto, the revised version of the Q&A incorporates a few additional and helpful questions/answers/clarifications summarized as follows:

- As regards borderline products, namely of products that it is unclear whether they are regulated by the pharmaceutical or medical devices regime, the national competent authorities for medicinal products and/or medical devices should be responsible for their qualification/classification. Any dispute between manufacturers and notified bodies on the classification of product is to be referred for a decision to the national competent authority for medical devices. Informal input may also be requested from the Innovative Task Force (ITF) of the EMA for innovative drug-device combinations.

- The MAH of the integral combination is responsible for obtaining an up-to-date notified body opinion or EU certificate in case of major changes as regards the device used in the integral combination. Minor changes that do not impact the safety or performance of the device (part) or its intended use but still require an update of the registered information shall be submitted with the corresponding variation application. The Q&A provides examples of minor changes/variations.

- Changes to the medicinal product may impact on the safety or performance of the device or on its intended purpose. Since the change to the medicinal product may trigger a variation or line extension, a new or updated EU declaration of conformity/ EU certificate /notified body opinion may be needed.

- As regards co-packaged medical devices (class I and class II) and the required product information (e.g. SmPC, labelling and package leaflet) of the medicinal product the following solutions are provided in the Q&A:

- Including in the packaging two (2) separate leaflets, namely a package leaflet of the medicinal product and a leaflet with the medical device's administrative information.

- Attaching the leaflet with the medical device's administrative information to the package leaflet of the medicinal product and place it within the secondary package of the medicinal product as one single folded component.

- Affixing a fold out vignette/sticker with device-specific information directly onto the device itself, or on the packaging of each device.

In summary, the recent revision of the Q&A document by the EMA represents a crucial step toward clarifying the implementation of the Regulation (EU) 2017/745 on medical devices and the Regulation (EU) 2017/746 on in vitro diagnostic regulations. These updates are particularly significant for the integration and combination of medicinal products and medical devices.

While the revised Q&A document aims to address various complexities and provide clearer guidance, its practical effectiveness in streamlining regulatory compliance remains to be seen. Stakeholders across the medical and pharmaceutical industries are keenly observing how these revisions will influence the application and interpretation of these regulations in real-world scenarios.

On the basis of the above, our dedicated Health & Life Sciences team will continue to monitor the developments closely, and it will be interesting to observe how the revision of the Q&A will impact in practice the implementation of the medical devices and in vitro diagnostic regulations concerning the combinations of medicinal products and medical devices. As always, staying informed and adaptable is key to navigating regulatory landscapes successfully.

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