EUROPEAN HIGHLIGHT | 04.07.2019

CONSULTATION ON DRAFT GUIDELINE ON QUALITY REQUIREMENTS FOR MEDICAL DEVICES IN COMBINATION PRODUCTS

On 3 June 2019, the European Medicines Agency ("**EMA**"), which protects and promotes human and animal health by evaluating and monitoring medicines within the EU and the EEA, has released a draft guideline on the quality requirements for medical devices in human medicines that include a medical device, known as drug-device combinations, for a three-month public consultation.

The guideline, which can be consulted here, addresses the new obligations in the new Medical Device Regulation ("**MDR**") requiring that the marketing authorization application should include a CE certificate or declaration of conformity for the device or, in certain cases, an opinion from a notified body on the conformity of the device.

The guideline covers devices that are necessary for the administration, dosing or use of the medicine. They can be integral, co-packaged or referred to in the product information of the medicine but obtained separately. It specifies which information about the device needs to be submitted as part of the initial marketing authorization application and subsequently during the product lifecycle. It also contains a proposed template for the notified body opinion on the conformity of the device to the relevant general safety and performance requirements laid down in the MDR.

With this guideline EMA intends to increase transparency and consistency of information in regulatory submissions, reducing work for all stakeholders and ultimately improving patient safety.

Stakeholders are invited to send their comments by 31 August 2019 to qwp@ema.europa.eu using the template provided.

EMA will take into account comments received during the consultation, with a view to finalizing the guideline before the MDR fully applies on 26 May 2020.

We hope this information is useful. You should not hesitate to contact us should you have any questions or require further information.

Kind regards,

Sarah – Evi

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