Platinum Sponsor Seminar

Presenter: Krystel Limouzin

Decoding Article 117 of Medical Device Regulation 2017/745: Known Information and Future Challenges for Drug-Device Combination Products

Introduction

Replacing Medical Device Directive (MDD) 93/42/EEC, the Medical Device Regulation (MDR) 2017/745 will come into force on May 26, 2020 with new provisions that provide enhanced patient safety and transparency for both the patient and Industry. All device manufacturers must apply this regulation to maintain or bring their technologies on the market, including manufacturers of drug delivery devices (where used in a drug-device combination product with a Principal Mode of Action (PMOA) linked to drug) according to Article 117. Article 117 introduces new requirements which include compliance to General Safety and Performance Requirements (GSPR) for the device part of a single integral drug-device combination product, and the involvement of a Notified Body (NB) as a new stakeholder in the EU Marketing Authorization Application (MAA) process.

Description

This presentation will focus on the challenges introduced by Article 117 as much from the Authorities' point of view as from Industry. Due to the current low level of information available from EMA, several questions were raised by Industry, such as:

- How the different stakeholders (Industry, National Competent Authorities (NCA), European Medicines Agency (EMA), NB) will collaborate together in a MAA context (i.e. attributed role and responsibilities, communication, documentation, lifecycle management)?
- How the industrial parties involved in a drug-device combination product development (Marketing Authorization Holder (MAH), Device Manufacturer, Suppliers) could respond to GSPR while keeping the data confidential?

To delineate organization and help industry, EMA has published a draft Guideline (May 29, 2019) that provided an initial overview of proposed solutions to match the incoming regulatory requirements in a pragmatic industrial context. Within this scope, EMA currently proposes a collaborative workshop on March 31, 2020 between all stakeholders to eventually clarify requirements for Article 117 implementation and establish clear guidance. Outcomes related to this work will be included in this presentation.

Outcome for Participants

Attendees will leave the presentation with a better understanding of the impact of MDR's Article 117 on all stakeholders involved in the drug-device combination product development and approval process, and of the current situation in Europe from the perspectives of industry and regulatory authorities.

Aptar Pharma – the go-to drug delivery expert

When pharmaceutical companies around the world want to develop safe, efficient and compliant medicines, they turn to Aptar Pharma for proven drug delivery solutions.

Leveraging our therapeutic insights, over 25+ years of regulatory expertise and the widest portfolio of solutions and services in the industry, we accelerate and derisk our customers' drug development process, helping them transform bright ideas into new market opportunities to improve and save patients' lives.

Let's partner together on your next bright idea. Visit **www.aptar.com/pharma** to get started.

Delivering solutions, shaping the future.

Aptar pharma