2 March 2020
EMA/464742/2019
Human Medicines Evaluation Division

Workshop to support implementation of Article 117 of the MDR on drug-device combinations

31 March 2020, European Medicines Agency, Amsterdam

Purpose

Medicinal product-medical device combinations where the device and the medicinal product form a single integral product, are intended exclusively for use in the given combination, and which are not reusable, are regulated as medicinal products (Directive 2001/83/EC). However, with the adoption of the new Medical Device Regulation (MDR, Regulation (EU) 2017/745), Annex I to Directive 2001/83/EC, point 12 of section 3.2 has been amended by Article 117 of the MDR which introduces new requirements for medicines with an integral device. As of 26 May 2020 onwards, a marketing authorisation application should include a CE certificate or declaration of conformity for the device or, if it is not CE marked but would need to be certified if marketed separately, the applicant must include an opinion from a notified body on the conformity of the device.

Concerns have been expressed to date from various stakeholders on the impact of the new requirements on marketing authorisations applications. The aim of this workshop is to facilitate an interactive discussion on practical examples and exchange of views between EU Regulators, European Commission, Notified Bodies, pharmaceutical industry and medical device manufacturers to further clarify expectations in relation to respective roles and responsibilities in the future regulatory review process, as well as dossier requirements for marketing authorisation applications and post-authorisation submissions. The Workshop is planned to have two parts:

a) a general discussion to understand the changes introduced by MDR Article 117, new roles and responsibilities and development of drug-device combinations under the new legal framework and

b) discussion of specific industry case studies in light of the draft quality guidance on drug-device combinations.

Key Topics

- Changes introduced by Article 117 of MDR and impact on MAA and lifecycle management
- Clinical and quality requirements for medicine-medical device combination products

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- Roles and responsibilities in relation to medicine assessment vs device conformity

The conclusions from the workshop will be captured in a report, which will be published. The development of further follow-up guidance may be considered.

Location

European Medicines Agency
Domenico Scarlattilaan 6,
1083 HS Amsterdam
The Netherlands
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Draft Agenda

31 March 2020, Time: 09:00-17:00

Timings	Topics
8.30-9.00	Arrival and registration
9.00-9.10	**Welcome & Introductions** *Zaide Frias (EMA)*
1. Background & Scope *Session leads: Armin Ritzhaupt, Ivana Hayes, Sonia Ribeiro, Pascal Venneugues (EMA)* This session will serve as providing background to the topic to set the scene for the workshop and goals of what is to be achieved on the day;	
9.10-10.30	**Goals of Workshop and Problem Statement, EMA** (10') Each stakeholder has 10 min to briefly share their perspectives on Article 117; e.g. preparations done ahead of implementation, remaining challenges, what they want to take out of meeting. **EC** (10') *TBC (EC DG SANTE)* **Pharma industry** (10') *TBC* **Device industry** (10') *TBC (MedTech Europe member company)* **Notified Body** (10') *TBC (Team-NB representative)* **Panel Discussion** (30')
Coffee break 10:30 – 10:45	
2. Considerations for development of medicine-medical device combination products	

Timings	Topics
	Session leads: Ilona Reischl (Biologics Working Party, EU) and Nick Lee (Quality Working Party, EU) This session will primarily focus on the quality requirements for drug device combination products in light of the guidance released by EMA. It will also aim to touch on relevant clinical considerations. This session will provide further information to industry on what requirements are relevant to MAA. - What are the regulatory expectations? What has been done so far? - What has been the industry approach; how justified? Focus on general industry perspective rather than specific case studies - Existing approaches/use of existing experience and how it could be adapted
10:45-12.00	**Regulator's perspective** (15') *Pascal Venneugues (Quality Office, EMA)* **Industry** (15') *TBC* **Notified Body** (15') *TBC (Team-NB)* **Panel discussion** (30')
	Lunch break 12:00 – 13:00
	3. Case studies *Session leads: Maeve Lally (Biologics Working Party, EU)* and TBC *(Quality Working Party, EU)* Three case studies will be discussed to illustrate the approach to meet the requirements of Article 117 for a specific DDC product and how the review/assessment will be carried out by EMA and NB. Industry will present the case studies and notified bodies and Regulators will give their perspective.
13:00-16:00	1. **Industry case study 1** (30') *(EFPIA)* Speaker: Amanda Matthew, Pfizer *Title: Lifecycle approaches for DDC and substantial change* 2. **Industry case study 2** (30') *(IPAC-RS & EuropaBio)* Speakers: Bjorg Hunter - GSK; Krystel Limouzin - Aptar Pharma; Lesley Hoe - 3M; Nicky Ellis - Vectura *Title: Provision of Notified Body Opinion for Devices/device constituents used by multiple customers* 3. **Industry case study 3** (30') *(Parenteral Drug Association)* Speaker: Lee Leichter, President, P/L Biomedical *Title: Relevant requirements for pre-filled syringe & on-body delivery system (or example of MDR Article 1(8))*

Timings	Topics
	Panel discussion: (60') ***Coffee break 16:00-16:30***
5. General discussion, summing up and way forward *Session leads:* EMA	
16:30-17:00	The outcome of the workshop and next steps will be summarised at the end of the meeting *Speakers from the previous sessions*
Close of meeting 17:00	

Workshop organising committee

Quality Working Party

Nick Lee	Health Products Regulatory Authority

Biologics Working Party

Ilona Reischl	Austrian Medicines and Medical Devices Agency
Maeve Lally	Health Products Regulatory Authority

EMA

Pascal Venneugues	Quality Office, *Human Medicines Division*
Armin Ritzhaupt	Regulatory Affairs Office, *Human Medicines Division*
Ivana Hayes	Regulatory Affairs Office, *Human Medicines Division*
Marie-Helene Pinheiro	Industry Liaison – *Stakeholders and Communication Division*
Monika Hewitt Katonova	Regulatory Affairs Office, *Human Medicines Division*
Sonia Ribeiro	Regulatory Affairs Office, *Human Medicines Division*

Speakers & Panellists

Regulators

Notified Bodies

Industry