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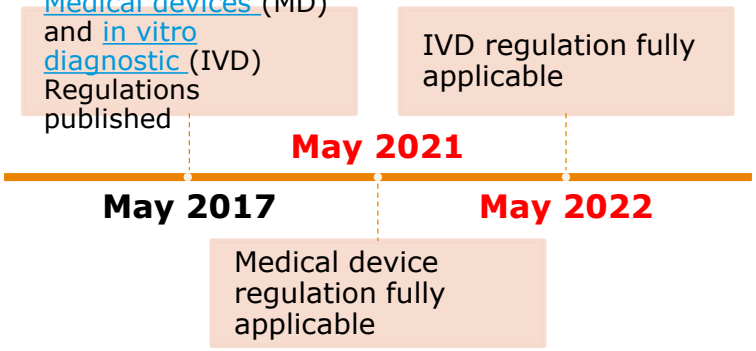
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Multi-stakeholder webinar to support implementation of the Medical Devices Regulation on drug-device combinations

Webinar on the implementation of Article 117 of the Medical Device Regulation
27 November 2020
13:00-17:00 CET

Zaide Frias
Head of the Digital Business Transformation Task Force, EMA

Regulation (EU) 2017/745 on medical devices
Regulation (EU) 2017/746 on in vitro diagnostic medical devices



- New or revised consultation procedures:
  - ✓ ancillary medicinal substances
  - ✓ medical devices composed of substances
  - ✓ companion diagnostics
- **MDR Article 117** amendment to Directive 2001/83/EC impacting medical device - medicinal product combinations (MDR Article second subparagraph 1(8) and 1(9))

Article 117 of Regulation 2017/745

Amendment to Directive 2001/83/EC

In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

'(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council (*), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall **require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body** designated in accordance with that Regulation for the type of device in question.

Approximately 25% of centrally authorised medicines includes a medical device component

Majority of medicine combinations with medical devices:

pre-filled syringes / pre-filled pens
inhalers

Medicinal product with co-packaged device

e.g. spoons, measuring cups, syringes, inhalers, nebuliser

MDR Art 117: Key change for 'integral' drug-device combination

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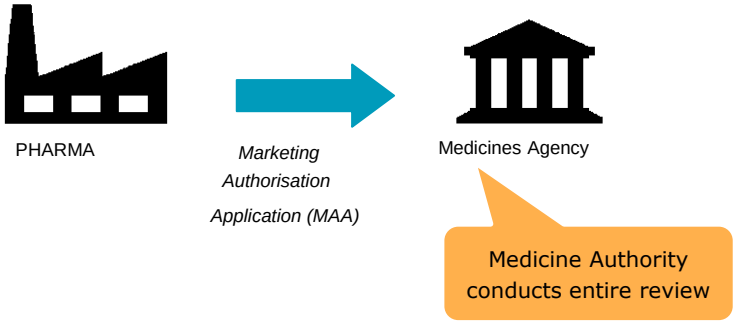
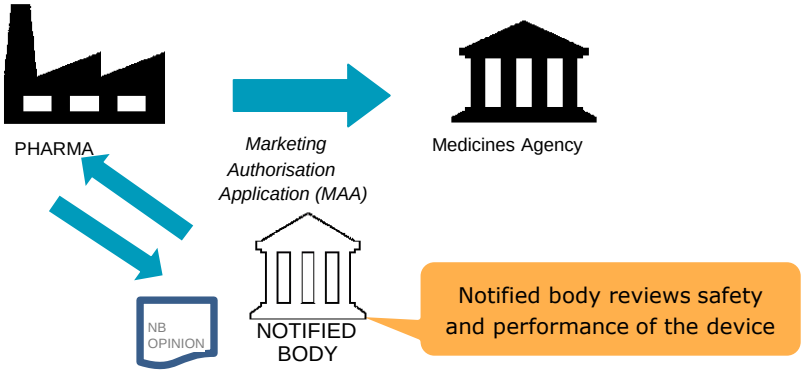
Under current system



Under New Regulation



Single product governed by Directive 2001/83/EC

Compliance with Annex I of **MDD**

No CE marking needed

Single product governed by Directive 2001/83/EC

Compliance with Annex I of **MDR**

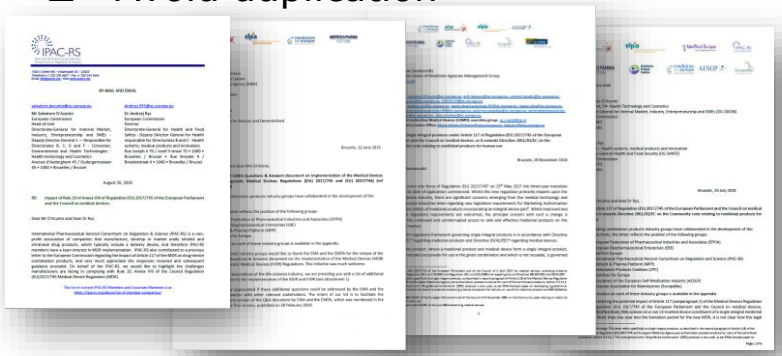
Article 117: CE marking or notified body opinion

Wide-ranging collaborations for implementation

Letters, position papers and comments on guideline

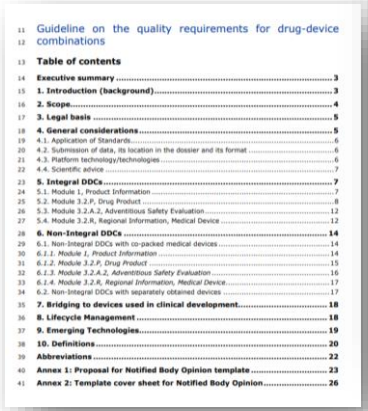
Main issues raised:

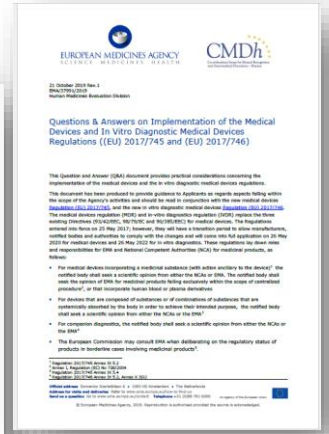
- ❑ Respective roles and responsibilities and scope of NB opinion
- ❑ Avoid duplication



EMA/network guidance

- ❑ Developed in collaboration with competent authorities and EC
- ❑ QWP/BWP GL
- ❑ Q&As





Today's objectives

- **Opportunity** to bring together **all relevant stakeholder** to facilitate a *virtual* interactive discussion between EU Regulators, European Commission, Notified Bodies, pharmaceutical industry and medical device manufacturers
- Focus on **topics** identified as **high priority** by using actual examples
- **Opportunity** to discuss, listen and learn from the still limited experience obtaining a Notified Body opinion
- Discussions and any conclusions from the workshop will be captured and subsequently published
- Outcome of discussions will inform future guidance and/or Q&A

Agenda – Webinar to support implementation of Article 117 of the MDR on drug-device combinations

Item	Agenda	Time
1.	**Welcome / Introductions** Opening remarks and objectives of the meeting *Zaide Frias, EMA*	13:00-13:05 5 min
2.	**Overview of the agenda** *Armin Ritzhaupt, EMA*	13:05-13:10 5 min
3.	**Lessons learned from Notified body opinion process** The Notified Body Opinion - Industry Experience *Bjorg Hunter, EFPIA (NovoNordisk)* Team-NB Feedback on NBOps to date *Jonathan Sutch, BSI and Julia Frese, TÜV SÜD Japan* The Notified Body Opinion – Regulatory Assessor View *Maeve Lally, HPRA*	13:10-14:00 50 min
	Panel discussion All speakers plus representatives from EC, medical device authorities and industry *Session Chairs: Armin Ritzhaupt EMA, Mike Wallenstein, Medtech & Pharma Platform (Novartis)*	14:00-14:50 50 min

Item	Agenda	Time
	Coffee break 	**14:50-15:00** **10 min**
4.	**Lifecycle Management: Considering 'Substantial Design Changes'** • Lifecycle Management: 'Substantial and Non-Substantial Changes' for Drug-Device Combinations *Amanda Matthews, EFPIA (Pfizer)* • TEAM-NB Perspective on Life Cycle Management under Article 117 / MDR *Petra van Leeuwen, DEKRA Certification BV and Colm O'Rourke, NSAI* • EMA considerations on lifecycle management in the context of Article 117 *Pascal Venneugues, EMA*	15:00-15:50
	Panel discussion All speakers plus representatives from EC, medical device authorities and industry *Session Chairs: Ilona Reischl, AGES, Tim Chesworth, Vaccines Europe (AstraZeneca)*	15:50-16:45 55 min
5.	**Concluding remarks and next steps** Quality of Drug-Device Combination Products - Current status *Nick Lee / Maeve Lally, Rapporteur / DG member, BWP (HPRA)* Close of meeting *Armin Ritzhaupt, EMA*	16:45-17:00 15 min
	Close of Webinar 17:00	

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