



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Medicinal products in combination with medical devices

---

Practical arrangements under the Medical Device Regulation

R&D platform – 4 June 2021

Presented by Christelle Bouygues / Pascal Venneugues  
Human Medicines Division

An agency of the European Union



# MDR implementation regarding pharmaceuticals - state of play

## HIGH PRIORITY

- Q&A – update to provide key clarifications on requirements for integral, co-packaged and ancillary medicinal substances in medical devices
  - Q&A - published versions in Feb 2019 & Oct 2019
  - Q&A update developed in 2020 and reviewed in collaboration with the EC and Art 117 Task Force
- Update of application forms for MAA and variations
- Quality guideline on quality documentation for medicinal products when used in combination with a medical device – final version



# Current published Q&A

# Planned scope of the 2nd update

## Table of contents

<b>1. Medicinal product medical device combinations ('combination products')</b>	<b>4</b>
1.1. What regulatory framework does a product incorporating both medicinal product and medical device fall under? New Oct 2019	4
1.2. How do I choose a notified body for my co-packaged /integral device? New Oct 2019	4
<b>2. Medicinal product with an integral medical device (integral DDC)</b>	<b>5</b>
2.1. When is my medicinal product considered to form an integral product with the administration device?	5
2.2. What is Article 117 and what does it mean for medicinal products? Rev. Oct 2019	5
2.3. How will the medical devices Regulation and in particular Article 117 impact new marketing authorisation applications? Rev. Oct 2019	6
2.4. When is it required to provide the notified body opinion/ EU certificate / declaration of conformity with my Marketing Authorisation Application (MAA)? Rev. Oct 2019	6
2.5. At what stage do I need to submit the notified body opinion?	6
2.6. How does Article 117 of the medical devices regulation impact currently authorised integral DDCs? Rev. Oct 2019	7
2.7. Will I need to provide a (new or updated) EU certificate / declaration of conformity / notified body opinion if there are changes to the device submitted through a variation /extension?	7
2.8. What is the impact of the MDR on medicinal products including an integral medical device for a Mutual Recognition Procedure submitted on or after the 26 May 2020? New Oct 2019	8
2.9. Are the requirements for UDI (unique device identifier) applicable to integral DDCs? New Oct 2019	8
<b>3. Medicinal product with a co-packaged device</b>	<b>9</b>
3.1. How will the implementation of the Medical Device Regulation affect the device? New Oct 2019	9

- Update with 2021 implementation date
- Clarifications on existing questions inc.
  - At what stage do I need to submit the notified body opinion?
  - Will I need to provide a (new or updated) DoC/EU certificate/ NB opinion in relation to the device changes?
- Addition of 7 new questions



# Outline of new Questions

## **Integral drug-device**

Q - Is it possible to submit a notified body certificate issued under the MDD to comply with Article 117?

Q - How will the notified body opinion be reflected in the European Public Assessment Report (EPAR)?

Q - Do the requirements of MDR Article 117 also apply to an application for medicinal products to be used outside of the European Union (Article 58 / EU-M4all )?



# Outline of new Questions

## **Co-packaged**

Q - What requirements for medical device labelling are applicable to medical devices “co-packaged” with medicinal products ?

Q - Do I need to submit a CE certificate / declaration of conformity as part of the dossier for a co-packaged medical device?

Q - What actions if any do I need to take if my co-packaged device is up-classified and requires to be certified by a notified body for the first time?



# Outline of new Questions

## **Ancillary substances in medical devices**

Q - What type of consultation procedure needs to be submitted for an ancillary medicinal substance that has already been consulted under the medical device Directive 93/42/EEC?



# Update on current published Q&A

## **Changes impacting published version**

- To refocus terminology Drug-Device Combination to integral medicinal product / device.
- Clarification of Art 117 requirements
- Revision of question on life cycle management for integral medicinal product / device as regards to device changes



# Update of application forms for Initial Marketing Authorisation and Variation applications

- To have more granularity on the device presentation type i.e. integral, co-packed, referenced in PI (medical device or companion diagnostic) and information on documentation (declaration of conformity, CE certificate or NB opinion) provided in the application
- Same changes to be introduced in both MAA and variation AFs





**HIGH PRIORITY**

**Scope:** Product-specific aspects of a medical device relevant to the quality, S&E of a medicine

→ Scientific guideline focusing on quality dossier requirements

→ Integral, co-packaged and separately-obtained devices referenced in the SmPC

- Sept 2019 - Feb 2020: review of 400+ pages of comments from public consultation
- March 2020: revised guideline circulated to QWP, BWP and CAT
  - ➔ Limited comments received were addressed. **Technical input from QWP, BWP and CAT finalised**
- **Since March 2020: ongoing discussions with EC**, including Art 117 TF (since Nov 2020)
- **The guideline has not fundamentally changed after public consultation**
- Points of interest:
  - ❖ Duplication of review by EMA/NCAs vs Notified Bodies minimised
  - ❖ Platform concept replaced with use of supportive data
  - ❖ Proposal for Notified Body Opinion template removed



## Next steps

- Q&A update: publication targeted in course of June
- Application forms: update to come soon
- Quality guideline (final): publication targeted as soon as possible after Q&A publication



# Any questions?

## Further information

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

Follow us on  **@EMA\_News**