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

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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

Table of contents

Planned scope of the 2nd update

- 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

Guideline on quality documentation for medicinal products when used in combination with a medical device

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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

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