EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA considerations on lifecycle management in the context of Article 117

Pascal Venneugues

Webinar on the implementation of Article 117 of the Medical Device Regulation
27 November 2020

EUROPEAN MEDICINES AGENCY

What is a substantial/significant change?

- Change affecting performance, safety characteristics or intended purpose of the medical device
- Impact on QTPP, DDC CQAs, DDC overall control strategy, delivery, instructions for use

BUT:

- No legal definition of a substantial/significant change to a medical device
  - ➔ Applicability of MDCG 2020-3 on significant changes or ISO 20069? Dedicated guidance is preferable
- Different perspectives on the importance/relevance of a change
- Product-specific considerations
- In any case, MAHs are expected to comply with the EU Classification guideline on variations

EU Classification guideline on variations

B.IV.1 Change of a measuring or administration device	Conditions to be fulfilled	Documentation to be supplied	Procedure type
a) Addition or replacement of a device which is not an integrated part of the primary packaging			
1. Device with CE marking	1, 2, 3, 6, 7	1, 2, 4	IA_{IN}
2. Device without CE marking for veterinary products only		1, 3, 4	IB
3. Spacer device for metered dose inhalers or other device which may have a significant impact on the delivery of the active substance in the product (e.g. nebuliser)			II
b) Deletion of a device	4, 5	1, 5	IA_{IN}
c) Addition or replacement of a device which is an integrated part of the primary packaging			II

Article 5 (Reg. 1234/2008) / z scopes for unforeseen variations ➔ not ideal

EMA considerations for possible review of the EU Variations regulatory framework

- Consider for example **design changes** to the device that could impact the quality, safety, efficacy of the medicinal product
- B.IV.1 category **currently limited to "measuring or administration" device**
  - ➔ Consider Art 1(8) 2nd sub-paragraph (e.g. tablet with embedded sensor) and new technologies
- Uncertainty over applicable variations for integral devices acting as container closure system (B.IV.1 vs B.I.c/B.II.e)
- Considerations to establish a process for interactions between EMA/NCAs and Notified Bodies
  - ➔ Changes requiring a variation **and/or** a review by a Notified Body
- ICH Q12 implementation: **Established Conditions** for DDCs?
  - ➔ Requires in-depth consideration

General recommendations / expectations

- The medical device manufacturer should notify the MAH of changes to their devices
- **The MAH determines whether a variation is needed**
  ➔ In case of doubts (variation category, grouping, etc) liaise with EMA/NCA
- **Advising on the need for a new or updated Notified Body Opinion (NBOp) is outside EMA/NCA remit**
  ➔ MAHs expected to liaise with Notified Bodies
  ➔ New or updated NBOp, if required, expected in the variation package at Day 0
- Consider changes to the drug product potentially impacting the device
- Changes in the intended use or target population may require an additional usability study
- QWP/BWP DDC guideline to be read in conjunction with EMA Q&A on MDR implementation and post-authorisation guidance

Further information

www.ema.europa.eu/en/human-regulatory/overview/medical-devices
https://ec.europa.eu/health/md_newregulations/overview_en

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

Follow us on **@EMA_News**