Federal Institute
for Drugs
and Medical Devices

Bridging aspects in terms of Medical Devices – a regulator‘s perspective

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Disclaimer

This presentation reflect‘s the presenter‘s personal view, not necessarily the view of BfArM or EMA

What‘s on our desk?
Fixed combinations of drugs and medical devices (DDC) – Issues

Development of drug and device in parallel, however, timelines often not aligned

(to be noted: terminology of Medical Device and Medicinal Product regulation similar but different, e.g. „validation“ acc. to ISO 9000: Confirmation, through the provision of objective evidence, that the requirements for a specific intended purpose or application have been fulfilled ≠ meaning of validation in context of medicinal products)

- Ideal situation: pivotal clinical trials for DDC with final device (part)
- But often: device development not ready at time of phase III clinical trial (CT), similar but not to-be-commercialised device (part) used in the CT, or even completely different presentation, e.g. vial instead of prefilled syringe (PFS), particular case insulin (clamp study): pen device not used in CT at all

Development of two DDC presentations, i.e. two devices in parallel, e.g. PFS and Autoinjector in which PFS is assembled

- In CT only PFS used

What‘s on our desk?
Fixed combinations of drugs and medical devices (DDC) – Issues (ctd.)

Development of Generics/ Biosimilars to DDCs:

- Numerous Scientific Advices on comparability of test product‘s device to originator‘s device,

- however, in Europe, device is regarded as Applicant‘s own development, hence, self-standing => compliance to MDR 2017/745 as main requirement for the device (part)

Increasing number of applications to switch from IV to SC administration – sometimes with limited supporting/bridging data

DDC development / bridging is a multidisciplinary task

Quality-related aspects if device is introduced late in development

- Stability of DP in DDC (if device = primary packaging), e.g. when bridging from vial to PFS, stability data of vials only supportive

Quality-related aspects for **device bridging**

- Properties of new vs old device (e.g. needle dimensions)
- Performance and functionality (e.g. dose accuracy, break-loose and glide force, injection time…)
- critical functional parameters properly identified/ justified? Stability data for new device component?

Clinical aspects

- Do differences in device features/ performance translate into differences in PK?
- Human factor studies

Use of Prior Knowlegde

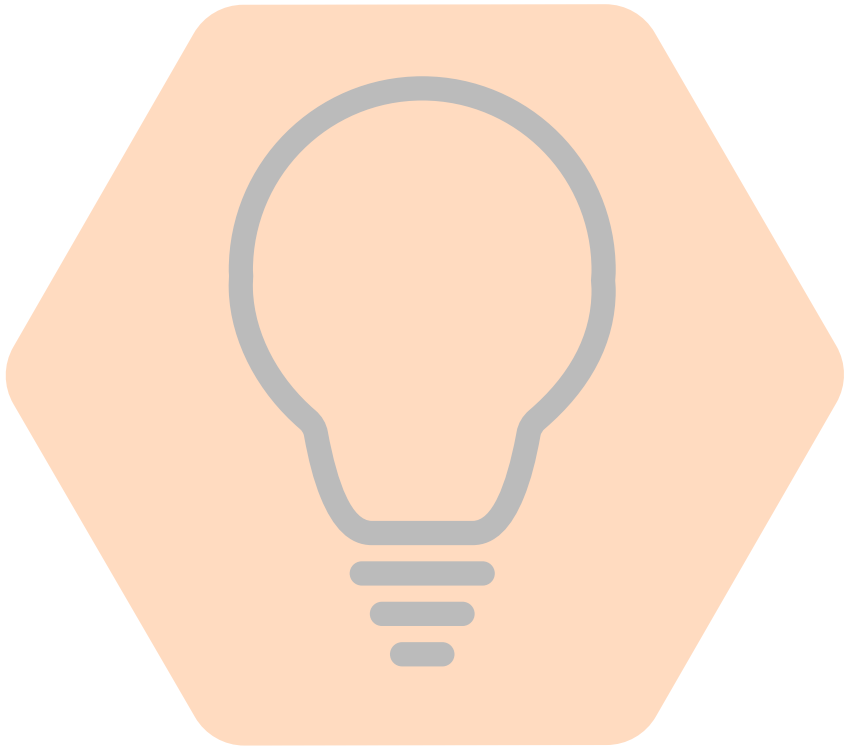
Prior knowledge available?
Only Applicant‘s own data from same/ similar devices can be used

How to justify it‘s representative?

- Device comparability (features, intended purpose of device?): transparency at appropriate level of detail needed to substantiate comparability of different device versions

- Drug product related aspects:
  - Viscosity of the solution
  - Dose to be administered (accuracy)
  - Functionality
  - …
- Patient population (human factor studies representative?)

Conclusion



Bridging exercise/ amount of data needed highly individual (case-by-case), depends on:

- Which question needs to be answered (bridging from pivotal CT to commercial, one device to another post-marketing,…)
- Similarity of new vs. old device (features, performance characteristics, patient population,…)
- Availability and relevance of prior knowledge
- Representativeness of availble data for same/ similar devices
- Criticality of the device performance with regard to overall risk of DDC
- Drug product in question
- …

Bridging is multidisciplinary!

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Thank you ☺!

Request Scientific Advice at your NCA and/ or EMA in case of uncertainties

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