EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

“Reflection on similarity assessment”

Industry stakeholder platform on research and development support

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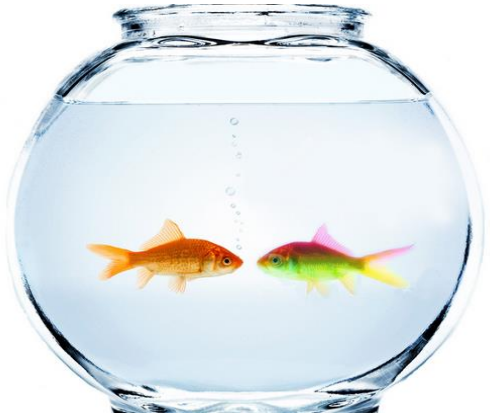
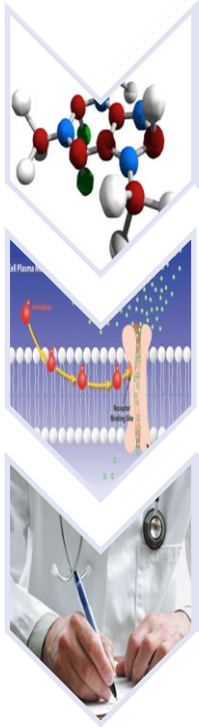
Similarity – When?

- Can apply to any Product
  - Whenever there is an orphan product authorised already for a condition related to the proposed therapeutic indication
- For applications:
  - New MAA
  - Line extensions incl. Quality LE
  - Type II – extension of indication
- By the CHMP not by the COMP
  - Assessment in parallel with the Q/S/E assessment during the procedure



Similarity assessment



- Similar molecular features?
- Similar mechanism of action?
- Similar therapeutic indication?

If yes to all questions, then SIMILAR PRODUCT

- Accept another MAA*
- Grant a MA
- Accept application to extend existing MA (variation/Line extension)

* **Unless any derogation applies**

Derogations

- Consent
- Unable to supply sufficient quantities
- Clinically superiority

- **If one of derogations applies => then 2nd product can be authorised.**

SHARING the MARKET

Revision of Orphan Regulation (EC) No 847/2000

- Definition of similar medicinal product and in particular the examples foreseen in Art 3(3)c of Regulation 847/2000.
- The definition required adaption to technical progress due to major developments in the field of biological medicines including advanced therapy medicinal products.
- Definition for Principal molecular structural features(PMSF) for each of chemicals, biological medicinal products and advanced therapy medicinal products
- More notable changes for biologicals: PMSF definition offers the possibility of including an additional structural element to the therapeutic moiety contributing significantly to the functionality of the therapeutic moiety
- ATMPs: Allowing to take 'features' stemming from structure, starting material or manufacturing when significantly impacting the efficacy/safety profile.

Feed-back

- The Agency would welcome feed-back on industry experience with similarity assessments and any points for discussion


Thank you