Bio-hybrid medicinal products – Widening access or product differentiation?

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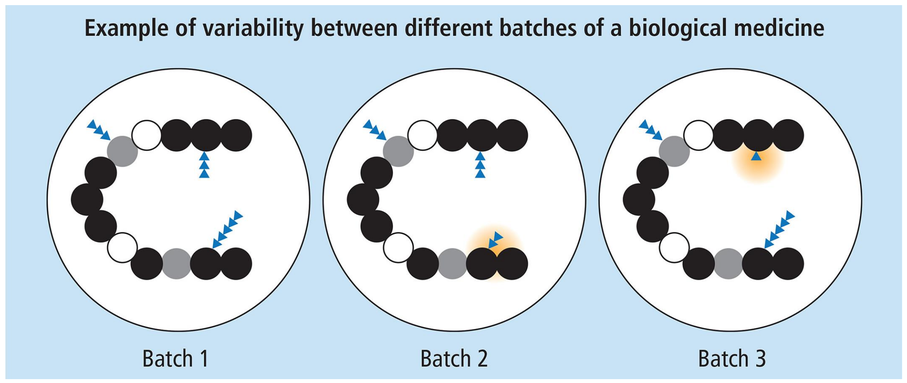
What is the difference between biosimilar and bio-hybrid medicinal products?

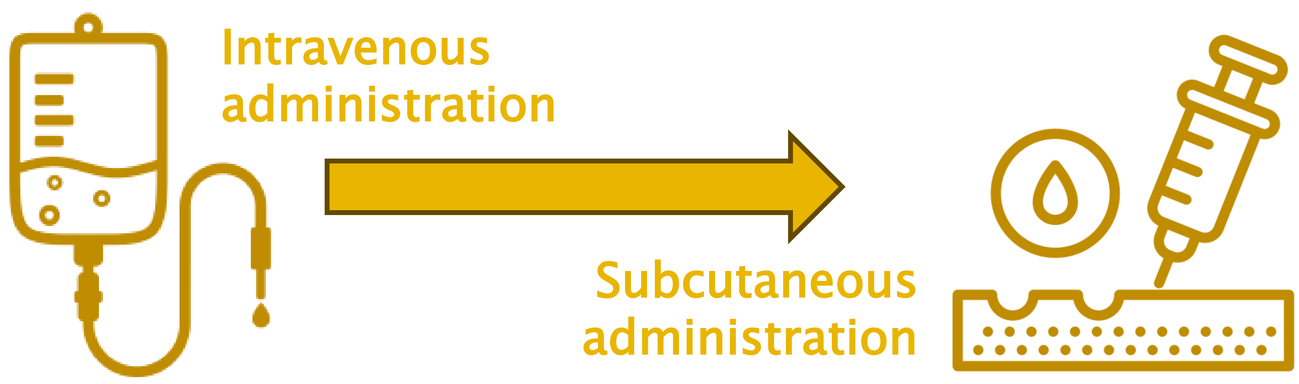
What is a biosimilar medicinal product?



Source: Chaplin, S. (2021), Biosimilar insulins: will switching soon be the norm?

A biosimilar is a biological medicine highly similar to another already approved biological medicine (the 'reference medicine')

What is a bio-hybrid medicinal product? *(example)*



A bio-hybrid is a follow-on product to a biological reference product, but in contrast to a biosimilar it may differ in strength, pharmaceutical form, route of administration or immediate packaging.

Research question and methods

- Authorisation of hybrid medicines has already been possible within the framework for marketing authorization of generic medicines
- Revision of the EU pharmaceutical legislation aims to facilitate marketing authorisation for hybrid medicines for biological medicines

Bio-hybrids have the potential to **widen access** → off-patent biological products enables treatment of more patients

Bio-hybrids can be considered a form of **product differentiation** which allows suppliers to charge price premiums

BUT: What data do we need to assess the impact of bio-hybrids?

The aim of the study is to assess if current ways of routine data collection through the EURIPID database are sufficient to assess the impacts of bio-hybrids and to support the development of functionalities for monitoring.

What are the expected results?

Since bio-hybrids mostly address the administration of biological medicines in ambulatory settings, their price information will be routinely collected

Measuring affordability poses a particularly difficult challenge → bio-hybrids often come with a shift in the point of administration

EURIPID

- **Routine data collection** within the EURIPID databases can capture impacts related to list prices of pharmaceutical and support policy makers
- Access to medicines has several dimensions; in order to efficiently monitor impacts **data gaps** in the scope of data that are routineley collected **need to be closed**

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