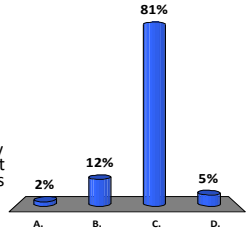
Interchangeability of biosimilars – a financial, ethical, or scientific issue?

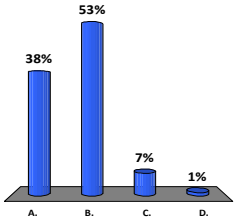
A biosimilar is

A. a drug that is identical to the reference product in every respect
B. a drug that is structurally identical to the reference product and has a clinical efficacy that is highly similar to that of the reference product
C. a drug that is structurally highly similar to the reference product and has a clinical efficacy that is highly similar to that of the reference product
D. none of the above



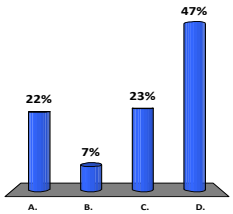
Regulatory requirements for biosimilars are

A. different to those for original biological drugs and generics
B. similar to those for original biological drugs
C. similar to those for generics
D. similar to those for orphan drugs



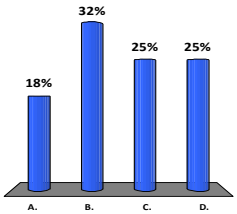
Are two independently developed biosimilars (with the same reference product) interchangeable with each other?

A. yes
B. yes, but only if they have been introduced simultaneously
C. yes, but only if the mode of administration is the same
D. no



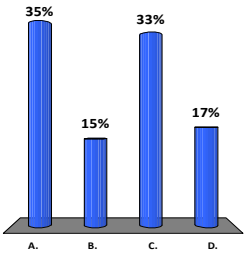
If a biosimilar has been evaluated in one indication, can approval be extrapolated to all other indications for which the reference product has been approved?

A. yes, it will be automatically extrapolated to all other indications
B. yes, but each indication should be considered on a case-by-case basis and particular criteria must be fulfilled
C. yes, but this requires additional safety studies
D. no



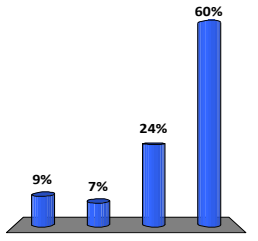
Which statement is true?
Once licensed by the EMA biosimilars

A. can be prescribed for all indications of the reference product
B. can be dispensed interchangeably for all patients
C. can only be prescribed / dispensed to new, drug naïve patients
D. have an increased risk of immunogenicity in patients already treated with the innovative product.



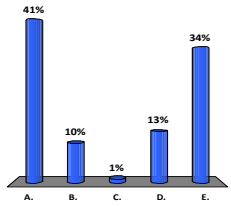
Which statement is true?
Selection of a biosimilar for the drug-formulary

A. can be solely based on the acquisition cost of the product, as everything else is the same;
B. is always advantageous for the hospital-budget
C. should be based on fully powered clinical equivalence trials
D. is a careful multifactorial process



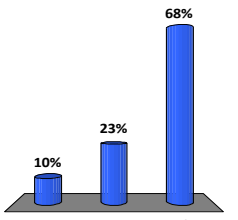
Which statement is true?
What information is required for the responsible use of biosimilars?

A. proof of clinical efficacy in all indications
B. data on consistency of manufacturing for at least 10 batches
C. stock position of the manufacturer (> 3 months)
D. a release-certificate of an eu-qualified person
E. a patient-based registry for all dispensed biologicals, including biosimilars



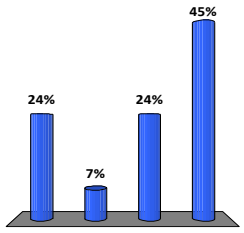
Which is correct?
The rising cost of medical care is caused

A. mainly by the ageing of the population
B. mainly by the increasing costs of new treatments
C. equally shared between the ageing of the population and by the increasing costs of new treatments



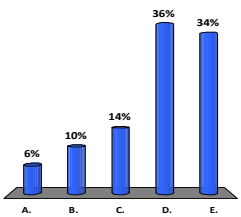
Biosimilar drugs have

A. proven to increase access to treatment
B. enabled treatment to be given to patients with lower risk or earlier stage disease
C. both A and B
D. neither A nor B



The risks of switching to Biosimilar Medicines are greater than the risks from lack of access to targeted biologic drugs

A. strongly agree
B. agree
C. neither agree nor disagree
D. disagree
E. strongly disagree



Introduction to the Synergy Session: Interchangeability of biologicals in Europe

The science, practice, ethics and cost side?

Daan J.A. Crommelin, professor emeritus
Utrecht University, NL
March 2016, Vienna

Disclosing Financial Relationships

Two points

- Terminology re interchangeability and substitution
- Present status on interchangeability-substitution in Europe

Interchangeability / Substitution

What is interchangeability?

- The medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting and in any patient *on the initiative, or with the agreement of the prescriber*[1]

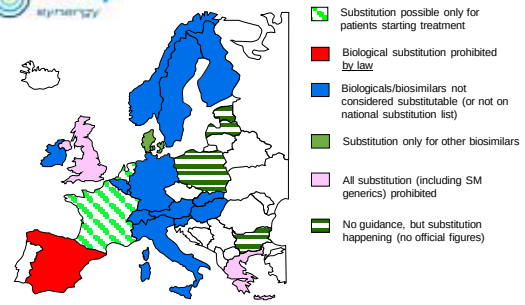
What is substitution?

- Practice of dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level *without consulting the prescriber*[1]

- EMA Guidelines do not include recommendations about interchangeability between a biosimilar and its reference product[2]
  - Implications for clinicians and pharmacists

1. European Commission. What you need to know about biosimilar medicinal products. http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf. 2013. 2. European Medicines Agency. EMA procedural advice for users of the centralised procedure for similar biological medicinal products applications. EMA/940451/2011. www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500125166.pdf. March 2013.

ion / ng policies in several EU countries



DIRECTIVE 2012/52/EU requires brand name prescribing for biologicals

Niederwisser Eur J of Haematology 2011;86:(277–288) updated in 2014, courtesy of Hans Ebbers

Interchangeability of biologicals in Europe
On the programme…..

- The regulatory rules of engagement in Europe
  prof. dr. *Paul Declerck*, Leuven
- The hospital pharmacist's tools to make the choice
  prof. dr. *Arnold Vulto*, Rotterdam
- Is our present system economically sustainable?
  prof. dr. *Paul Cornes*, Bristol
- Panel discussion/questions from the audience