Reshaping rheumatology – the era of biosimilars

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1. Biosimilars are chemically identical to their reference biologic.

- ☐ **A** True
- ☐ **B** False

2. Which statement is incorrect? A 52-week safety and efficacy trial of an etanercept biosimilar versus the reference biologic in RA showed:

- ☐ **A** Comparable efficacy
- ☐ **B** Similar safety profile
- ☐ **C** Lower immunogenicity profile at week 24 for reference biologic
- ☐ **D** A and C
- ☐ **E** B and C

3. Which statement is correct? The PLANETAS study of biosimilar and innovator infliximab in patients with AS found, up to week 30:

- ☐ **A** Equivalent pharmacokinetic profiles
- ☐ **B** Similar efficacy and safety profiles
- ☐ **C** The biosimilar was well tolerated
- ☐ **D** All of the above
- ☐ **E** B and C

4. Biomimics, or intended copies, are those agents that were developed using the same target antigen but have not demonstrated comparability to the biosimilar or the reference product.

- ☐ **A** True
- ☐ **B** False

5. Due to the molecular complexity of recombinant proteins, small differences in manufacturing processes can affect:

- ☐ **A** Efficacy
- ☐ **B** Safety
- ☐ **C** A and B

6. Which statement is correct? In terms of recombinant proteins:

- ☐ **A** Comparable clinical profiles do not automatically follow from physicochemical likeness
- ☐ **B** Even a minor change in any component of a quality system could lead to product drift, evolution and divergence
- ☐ **C** A and B

7. Data from the DANBIO registry indicates that numerically more ___ patients experienced flare when making a non-medical switch from originator etanercept to biosimilar etanercept.

- ☐ **A** RA
- ☐ **B** PsA
- ☐ **C** AxSpA
- ☐ **D** All of the above
- ☐ **E** A and B

8. Which statement is correct? The nocebo effect is important because:

- ☐ **A** There is the potential for misattribution of adverse events
- ☐ **B** Patient safety may be compromised
- ☐ **C** There is an economic and humanistic impact
- ☐ **D** All of the above
- ☐ **E** A and C

9. Which statement is incorrect? Upon development of immunogenicity to a biologic:

- ☐ **A** Switch to a biosimilar of the originator
- ☐ **B** Switch to a different molecule in the same class
- ☐ **C** Switch to a molecule with a different mechanism of action
- ☐ **D** A and B
- ☐ **E** B and C

10. Unique INNs are important for:

- ☐ **A** Minimising risk of unintentional prescribing and inappropriate substitution
- ☐ **B** Enabling more effective track and trace pharmacovigilance
- ☐ **C** A and B

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