Biosimilars in immune-mediated inflammatory diseases

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First Name		**Profession**	
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1. Which of these biological DMARDs is/are an IL-12/23 receptor blocker?

- ☐ **A** Tocilizumab
- ☐ **B** Ustekinumab
- ☐ **C** Sarilumab
- ☐ **D** Infliximab
- ☐ **E** Adalimumab
- ☐ **F** All of the above

2. Which of these biological DMARDs is/are an IL-6 receptor blocker?

- ☐ **A** Tocilizumab
- ☐ **B** Ustekinumab
- ☐ **C** Sarilumab
- ☐ **D** Infliximab
- ☐ **E** A and C
- ☐ **F** A, C and D

3. Which of these biological DMARDs act(s) against TNF-α?

- ☐ **A** Etanercept
- ☐ **B** Infliximab
- ☐ **C** Adalimumab
- ☐ **D** Golimumab
- ☐ **E** Certolizumab
- ☐ **F** All of the above

4. Biosimilars of which anti-TNF-α biologic are available in South Africa?

- ☐ **A** Infliximab
- ☐ **B** Adalimumab
- ☐ **C** Golimumab
- ☐ **D** Certolizumab
- ☐ **E** All of the above
- ☐ **F** A and B

5. There is no clinically meaningful difference in terms of safety, potency and purity between biosimilars that are highly similar to reference biologics.

- ☐ **A** True
- ☐ **B** False

6. Which of these criteria are necessary for the development pathway of biosimilars to meet requirements for SAHPRA registration?

- ☐ **A** Analytical studies
- ☐ **B** Nonclinical research
- ☐ **C** Clinical pharmacokinetic and pharmacodynamic studies
- ☐ **D** Additional clinical studies
- ☐ **E** All of the above
- ☐ **F** A, B and C

7. Which statement is correct? Prior to registering a proposed biosimilar, SAHPRA requires:

- ☐ **A** A comparative clinical trial against the reference biosimilar
- ☐ **B** Clinical switching studies
- ☐ **C** A and B

8. In South Africa, pharmacy-based switching of RPs to biosimilars or between biosimilars is allowed.

- ☐ **A** True
- ☐ **B** False

9. Which statement is incorrect? In terms of biosimilars:

- ☐ **A** Extrapolation is an accepted scientific and regulatory principle that many clinicians support based on real-world experience derived from registries
- ☐ **B** Switching studies must be undertaken for each clinical indication of the RP prior to considering its use in related conditions
- ☐ **C** Clinical experience in IMIDs currently exceeds 700 million patient-days

10. Systematic review of switching studies revealed no important efficacy or safety signals associated with the biosimilar used relative to the RP in which of these IMIDs?

- ☐ **A** Crohn's disease and ulcerative colitis
- ☐ **B** Rheumatoid arthritis and ankylosing spondylitis
- ☐ **C** Psoriatic arthritis and plaque psoriasis
- ☐ **D** All of the above
- ☐ **E** A and B
- ☐ **F** A and C

11. Which biosimilar, available in South Africa, is approved for the treatment of juvenile idiopathic arthritis?

- ☐ **A** Infliximab
- ☐ **B** Adalimumab
- ☐ **C** A and B

12. Which biosimilar, available in South Africa, is approved for the treatment of hidradenitis suppurativa?

- ☐ **A** Infliximab
- ☐ **B** Adalimumab
- ☐ **C** A and B

13. Which biosimilar, available in South Africa, is approved for the treatment of uveitis?

- ☐ **A** Infliximab
- ☐ **B** Adalimumab
- ☐ **C** A and B

14. Which biosimilar, available in South Africa, is approved for the treatment of paediatric Crohn's disease and paediatric ulcerative colitis?

- ☐ **A** Infliximab
- ☐ **B** Adalimumab
- ☐ **C** A and B

15. Worldwide, registries provide important real-world evidence related particularly to adverse events, e.g. increased risk of infections, lymphoproliferative malignancies, and cardiovascular disease related to the use of biologics, both RPs and biosimilars.

- ☐ **A** True
- ☐ **B** False

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