

FAQ

QUESTIONS ABOUT BIOSIMILARS: WHAT PATIENTS SHOULD ASK THEIR DOCTORS

1 | PERSONAL EFFECT OF (CURRENT/NEW) BIOLOGICS

A. BENEFITS

- a. What have been the benefits of the new biologic for me?
- b. Based on experience of patients like me, what benefits can I expect from this biologic?

B. ADVERSE EFFECTS

- a. What side effects have I experienced and how serious/difficult have these been (to adjust to)?
- b. Based on experience of patients like me, what side effects could I expect and how difficult/serious might these be?

C. MONITORING EFFECTS

- a. How do I know the biologic is working? How have I monitored the drug and the side effects? How challenging has this been?
- b. What will I need to do to monitor the drug and to manage any side effects? How challenging might this be?
- c. Is my condition progressive (likely to get worse over time)? How much variation or change do I experience in my condition and my symptoms on a regular basis? If I experience a change in my symptoms, outcomes or side effects, how do I know if it is due to the drug or something else?

D. CONFIDENCE

- a. Overall, how confident do I feel that this biologic is right for me?
- b. Overall, how much confidence do I have that I can manage this biologic?

2 | BIOSIMILARS: SIMILAR TO BUT NOT IDENTICAL TO THE ORIGINAL BIOLOGIC

A. BENEFITS

- a. Were there clinical trials with patients like me comparing the biosimilars with the original biologics? How similar or different were the results?
- b. If clinical trials were not conducted on patients like me, what was the evidence that the biosimilar would work the same as the original, for patients like me?
- c. Based on the experience of patients like me, how likely is it that I will have the same benefits with the biosimilar as with the original biologic?

B. SIDE EFFECTS

- a. Have patients like me been monitored for side effects to the biosimilar, and how do these side effects compare to those for the original biologic? Are they the same, or no worse?
- b. If there has not been enough monitoring to conclude that the side effects are the same (or no worse), what is the evidence that allows for the conclusion that the side effects are the same?
- c. Based on the experience of patients like me, how likely is it that I will have the same or **NO WORSE** side effects with the biosimilar as with the original biologic?

C. CONFIDENCE

- a. How will I know if the biosimilar is working the same as the original biologic? What additional monitoring is provided?
- b. If I feel the biosimilar is not working the same as the original biologic, can I get the original biologic? Under what circumstances can I get the original biologic?

3 | QUESTIONS WHEN DECIDING ON A BIOSIMILAR

- a. Will my clinician and I be informed before I am given (switched to) a biosimilar? Do I have the right to choose or give consent?
- b. Will I get the same or additional support to manage the biosimilar as I received with the original biologic? What difference in support can I expect?
- c. What is the experience of the biosimilar manufacturer? What is the history of safety and quality of the biosimilar?
- d. How many biosimilars to the original biologic are available?
- e. What is the chance that I could be given a different biosimilar at another time?
- f. Based on the experience with patients like me, how safe and effective is it to substitute one biosimilar for another?
- g. Do I have the right to choose or to give consent?
- h. What is the difference in cost of the biosimilar to the original biologic?
- i. If an approved version of the original biologic becomes available, will I qualify for the improved version if I am taking the biosimilar (instead of the original biologic)?
- j. Comparing biologic and biosimilar
- k. How confident am I (is the clinician) that I will have exactly the same benefits with the biosimilar as with the original biologic?
- l. How confident am I (is my clinician) that I will have exactly the same side effects (including immune responses) with the biosimilar as with the original biologic?
- m. How much of a cost saving is there with the biosimilar as compare to the original biologic? What is the cost savings to me?
- n. How similar is the support with the biosimilar as with the original biologic? Is support (administration, testing, monitoring) at the same place?
- o. If I do not feel the biosimilar is not working for me, do I have the option to choose the original biologic?



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