FORS|MARSH GROUP

Biosimilar and Interchangeable Products—Healthcare Professional Interviews

SEMI-STRUCTURED INTERVIEW GUIDE

Summary Page

Research Objective: Conduct interviews with 30 healthcare professionals (HCPs) who currently prescribe or dispense biologics or biosimilars or have in the recent past to gain insight into the thoughts and feelings of healthcare professionals likely to prescribe or dispense biosimilars and interchangeables toward the educational materials FDA developed as resources for healthcare professionals.

Discussion Guide Format: The discussion guide is developed for a 90-minute session.

SESSION OVERVIEW: 90 minutes
Introduction (5 min) The moderator will explain the purpose of the research, present the ground rules, allow the participant to ask any questions, and get to know the participant.
Baseline Knowledge and Experience (5 min) The purpose of this section is establish baseline understanding of the topic, ease the participant into the conversation, and start getting them into the mindset of the materials.
Educational Materials Testing (70 min) The purpose of this section is to answer the research questions related to the materials.
Educational Materials Comparison (5 min, if time permits) The purpose of this section is to examine and compare the participant's perceptions of all the materials they see during the session.
Conclusion (5 min) The moderator wraps up the discussion and ensures that all questions have been answered and all comments have been heard. If time permits, the moderator will employ a false close in which observers can communicate with FMG support if there are specific topics for the moderator to follow up on with the participant.

Introduction (5 min)

Thank you for taking the time to talk with me. My name is [Moderator name], and I'll be leading our discussion today. I am part of an independent research company, Fors Marsh Group. We are conducting a study sponsored by the Food and Drug Administration. I'm here to talk with you and understand what you think. Specifically, I am going to be asking you to review and comment on some educational materials about biological products called biosimilars and interchangeables. Your feedback will inform FDA's communications about these products. This discussion will last about 90 minutes.

There are a few things I'd like to go over to help make our discussion productive:

- I have a discussion guide in front of me that includes all the points of discussion I need to raise, and helps me keep the discussion on track. It is important that we cover all the topics so I may have to break off the conversation to move the discussion on to another area.
- We are audio recording this session for use in preparing a report with our findings. Because we are recording this meeting, I ask that you speak loudly and clearly.
- I know you received and signed a consent form. As a reminder, this discussion will be private to the extent allowed by law, and your name will not appear in the summary report. Likewise, I will not share any of our discussion from today with others who are not actively working on this project.
- Your participation is voluntary. Therefore, you can choose not to answer any question you do not wish to answer.
- Some people from my team as well as the FDA may be viewing remotely. They want to hear what you have to say about the topics we'll discuss, so please do not feel constrained by their presence.

Do you have any questions before we begin?

Warm-Up

You are a healthcare professional working in [Medical Specialty]. Tell me where you practice and how long you have been practicing.

Baseline Knowledge and Experience: 5 min

To get us started, I want to ask you a few questions about your experience with today's topic. [IF NEEDED: It's okay if you're not familiar with this topic; we will provide information later in this interview.]

- What do you know about biosimilar products?
- Have you ever prescribed a biosimilar and if so, for what conditions? The 3 biosimilars currently on the market are Renflexis, Inflectra and Zarxio.
- What do you know about interchangeable biological products?

Educational Materials Testing: 70 min (20-22 mins pe handouts A,B,C; 5 mins Graphic if time permits)

Now, we have some information about biosimilars and interchangeables that we'd like to get your reactions to, which I'm going to put up on the screen now for you to look at. Please take a few minutes to read this now and then I'll ask you some questions about it. Can you see it on my screen? I'm going to hand over control to you so you can browse through the handout. Please let me know when you are done.

[Handouts will be administered in following order: Handout A (Biological Product Definitions), Handout B (Prescribing Biosimilar and Interchangeable Products), Handout C (Biosimilar Product Regulatory Review and Approval)]; Overview graphic.

[Moderator and notetaker will observe how participant interacts with handout (e.g., if they scroll, how long they spend reading the hand out). If participant exceeds 7 minutes while reading, moderator will politely stop participant and begin discussion questions.]

[Moderator will ask the below questions for each handout, except where handout specific questions are annotated.]

Let's jump in. Remember there are no wrong answers. I did not develop these materials and have no stake in the outcome of this testing.

- What are your initial thoughts after reading the handout?
    - What do you like about this information?
        - What do you dislike about it?
    - What are the main ideas that you took away from this information?
- How easy or difficult was it for you to understand this information?
    - What would make it easier to understand?
- What is unclear or confusing about this information?
    - What would make it clearer or less confusing?
    - How does this information compare to what you understood about [see below list before reading this]
        - A: About …biological products? Biosimilars? Interchangeables?
        - B: About prescribing biosimilar products? About prescribing interchangeable products?
          C: About the biosimilar regulatory review and approval process?

        - Did you learn anything new from this material? If so, what?
        - What questions or concerns did you have about [biosimilars/interchangeables] that this information helped answer?
            - What unanswered questions or concerns do you still have?
    - How complete is this information?
        - What's missing? What should be added?
        - What information is unnecessary?
    - [IF APPLICABLE: Probe on any behavioral cues/vocalizations observed during review of materials that do not come up naturally in conversation]

*(See handout A for question to be added here)

- What got your attention about this information?
    - What would make this information better able to get your attention or make you more likely to read it?
    - Is the most important information placed where it should be?
- Who is the target audience for this information?
    - How user-friendly is this information? What would make it more user-freindly?
    - What do you think about the format of this information?
- How believable is this information?
    - What, if anything, would you change or add to make this information more believable?
    - What or who would be the most credible source for this information?
- How do you think this information would help prescribers/pharmacists?
- How would this information influence your practice, including discussion with patients, when prescribing/dispensing biosimilar and/or interchangeable products? Why?

Handout A: Definitions ONLY (20-22 minutes)

- *How does this information help you distinguish between the biologic reference product and biosimilars? Between biosimilars and interchangeables? Between biosimilars and generics?
- How would this information help you communicate with patients about biosimilars? About interchangeables?
    - How easy or difficult is it to find the specific information you would need to explain biosimilars to your patients on the handout? To explain interchangeables to them?
    - How would you use this information to communicate with patients?
    - How likely is it that you would use this information to communicate with them about biosimilars?

    - What would need to be changed about this information so it could be used as a resource to provide to patients?

Handout B: Prescribing biosimilars and interchanegables ONLY (20-22 minutes)

- How did this information help you understand the indications for prescribing biosimilars compared to the reference product?
- How did this information help you understand the indications for prescribing interchangeables compared to the reference product?

Handout C (Biosimilar Product Regulatory Review and Approval) ONLY: (20-22 minutes)

- How does this information influence your understanding of the regulatory approval process for biosimilars?
- How does this information change your understanding of biosimilar products?
- How would this information help you communicate with patients about [biosimilars/interchangeables]?
    - How would you use this information to communicate with patients?
    - How likely would you be to use this information to communicate with patients?
    - What would need to be changed about this information so it could be used as a resource to provide to patients?

Infographic: (5 mins if time permits)

- What are your initial thoughts after reading the handout?
    - What do you like about it? Dislike?
- Does this graphic capture the key information from the other handouts you reviewed?
    - How complete is this information?
- Who is the target audience for this information?
- How user-friendly is this information?
    - What would make it more user-friendly?
    - What do you think about the format of this information?
- How do you think this information would help prescribers/pharmacists?
- How would this information help you communicate with patients about biosimilars?
    - How likely would you be to use this information to communicate with patients?
    - What would need to be changed about this information so it could be used as a resource to provide to patients?

Educational Materials Comparison (5 min if time permits)

Before we wrap up, let's take a minute to think about all of the information you saw today.

- Which handout did you like the best for your own information and why?
    - Which handout did you like the least and why?
- After they are modified to be suitable for consumers, which handout do you think would be the best resource to provide to patients receiving biosimilars and why?
- Which handout was easiest to understand and why?

Section 5: Conclusion (5 min.)

Thank you very much for participating in this interview. I appreciate you sharing your time and valuable feedback. Is there anything that you would like to share that you did not have a chance to share yet?

[The moderator will check with the research team for any remaining questions.] If you will excuse me for just a moment, I would like to check with my team to see if they have any follow-up questions for you.

I believe we are all done here. Thank you so much for your time. Per the usual process, you will receive your incentive through your All Global Circle account. If you have any problems, please follow up with Lightspeed Health or use the contact information for the researcher cited on the consent form you were provided.