Authorized Generics: Guide for focus group with physicians/pharmacists

INTRODUCTION

Thank you for attending this focus group discussion today. My name is Joshua Gagne and I will be leading this discussion with my co-facilitator, Michael Fischer. You are all here because you are [physicians who spend at least 50% of your time practicing in primary care/pharmacists who practice in retail settings]. During this 120-minute session, we will ask you to talk about your thoughts about generic drugs and brand-name drugs.

Before we begin, I would like to go over a few ground rules:

- First, we hope that you will feel comfortable discussing your views in this format. However, we realize that it is possible that some of you may feel uncomfortable or uneasy sharing your thoughts and understandings. If you feel that you do not want to answer a question or participate in the discussion we fully respect your decision.
- It is important that this discussion remains confidential. Please use only your first name and please refer to others by first name only. That will allow us to maintain as much anonymity on the tape recording as possible.
- We expect that people might have different experiences and opinions and we would like to hear all viewpoints. Please feel free to share your feelings and opinions, even if you disagree with what has already been said.
- I would also like to remind you that today's discussion will be tape recorded. We record all conversations so that we have an accurate and complete report of what was said. You will not be identified on the tape other than by your first name. The tape will be transcribed into a written form, although your name will not be part of the written form. The tapes and transcripts will be available only to the research team, will not be used for any other purpose than this project, and will be destroyed at end of the project.
- It is important that only one person speaks at a time, and please speak up so we can capture all of your comments. If there is more than one person speaking at a time, it is very difficult to transcribe. We need to be able to hear what everyone says so that we can produce an accurate report of the discussion.
- Because this is a group discussion, I will try to make sure that everyone has a chance to speak but that no one dominates the discussion; so please don't be offended if I gently interrupt.

Finally, before we begin, I need to ask you whether you consent to participate in the focus group. Because we are not capturing any personal information, we will not record individual responses. We will only record that all participants provided verbal consent. We will go around the table. Please respond to the following questions with a 'Yes' or a 'No'. Do you consent to participate in this focus group?

[If anyone does not consent, they will be asked to leave]

Are there any questions before we begin? We have a lot to discuss, so let's get started.

First, please tell us your first name. If it is all right, I will turn on the recorder and begin the

discussion.

The first questions are to understand your knowledge of authorized generic drugs.

1. How familiar are you with the concept of an authorized generic?

After discussion of #1: To ensure that we are all on the same page about what authorized generic drugs are, I will briefly describe brand-name drugs, generic drugs, and authorized generic drugs, in particular. Brand-name drugs are FDA-approved drugs that are usually approved through a new drug application and are protected by a patent for some period. Brand-name drugs are typically produced by a single manufacturer.

Generic medications contain the same amount of the same active ingredient as their brand-name counterparts and can be approved by the FDA after the brand-name drug's patent has expired. Generic drugs are approved through an abbreviated new drug application in which the manufacturer must demonstrate bioequivalence to the approved brand-name product, but do not need to repeat all of the lengthy and costly pre-approval clinical trials. As a result, generic drugs are much less costly than their brand-name counterparts and therefore reduce overall health system spending.

An "authorized generic drug" is a listed drug as defined in § 314.3 that has been approved under subsection 505(c) of the act and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark that differs from that of the listed drug.

Another way to think about authorized generics are that they are brand-name drugs that are marketed, sold, or distributed as generic medications, usually either by a subsidiary of the brand-name manufacturer or by another company licensed to do so. Since they are produced by the brand-name manufacturer, authorized generics are chemically-identical to the brand-name versions because they contain exactly the same active and inactive ingredients as the brand-name version, but they may differ in labeling, packaging, product code, labeler code, trade name, or trademark. Authorized generic are different from so-called "branded generics" which are actually independent generics approved under the abbreviated pathway that the generic manufacturer assigns a proprietary name to. We will not be talking specifically about branded generics.

2. Are there any questions about brand-name drugs, generic drugs, and authorized generic drugs?

3. How frequently are you aware that your patients are using authorized generics?

The next set of questions are intended to understand your opinions about authorized generic drugs based both on your prior knowledge and experience with these products, if any, and based on the discussion we just had.

4. Would you prefer that your patients use an authorized generic instead of another generic product? If so, under what circumstances? Why?

5. In what ways do you think the safety and effectiveness of authorized generics, non-authorized generics, and brand-name drugs differ?

6. What would be appropriate copayments for brand-name drugs, authorized generics, and non-authorized generics?

7. To what extent do prescription drug costs impact patients' adherence to prescribed therapy? If at all, to what extent do you think that differences in price between brand-name versions, authorized generics, and other generic drugs affect adherence?

One distinction between authorized generic drugs and other generic drugs is that the authorized generic drugs typically share the same appearance as the brand-name products. In particular, authorized generic drugs usually have the same color, size, and shape as the brand-name product. In contrast, independent (non-authorized) generic drugs typically look different from the brand-name products. Also, generic versions produced by multiple manufacturers typically look different from each other. Research has shown that patients who refill the same dose of the same medication experience changes in pill appearance in up to 30% of refills.

8. Does this information change whether or when you would prefer that your patients use an authorized generic instead of a brand-name product? If so, how?

9. How important is it that patients receive pills that look the same with each refill?

10. How important is it that patients receive pills from the same manufacturer with each refill?

That concludes our questions. Are there any questions we should have asked about that we did not cover? Do you have other comments or thoughts you wish to share?