

Paperwork Reduction Act Statement

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0695 and the expiration date is 2/28/2021. The time required to complete this information collection is estimated to average 45 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

FDA Educating Groups Influencing Generic Drug Use**Telephone Key Informant Interview Guide- Policymakers**

Date:**Participant Number:****Interviewer:**

Overview of Purpose of Call and Introductions

Hello [Name]. My name is [Name]. Thank you for agreeing to participate in our study to better educate groups influencing generic drug use, based on their unique educational needs, sponsored by the US Food and Drug Administration (FDA). The study is being conducted by Auburn University and IMPAQ International. You were selected as a possible participant because you were identified as having a role in the policymaking process for prescription drugs within the previous six months and are age 19 or older.

The interview is expected to take approximately 45 minutes. What I and the research team learn from this study may better inform how information is provided related to generic medications. You will receive \$75 as a token of our appreciation for your participation after completion of the interview.

If you change your mind about participating, you can request to stop at any time during the study. Your participation is completely voluntary. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University, the Department of Health Outcomes Research and Policy, or IMPAQ International.

Do you have any questions about the study or your role in the study? Do you wish to continue with the interview?

Before we begin I would like to ask you if we may audio record the interview. The recordings will be kept private to the extent permitted by law and are intended to assist us in our notetaking and analysis of the information. If you agree to allow the interview to be audio recorded, any data obtained in connection with this study will be made anonymous as soon as possible. We will protect your privacy and the data you provide by de-identifying the data, including assigning pseudonyms and removing any identifiable information from transcripts of the audio file. Notes and transcripts from the study will be saved in password protected folders on a password and firewall protected server at IMPAQ International. Audio recordings will be destroyed immediately upon completion of the project.

Do you have any questions about the recording or how it will be used? May I record?

Appendix F: Interview Protocol - Policymakers

If permission is granted, START RECORDING!

Information Questions

First, I would like to know your thoughts on the information provided in the educational materials. Why don't we begin with...

1. How informative did you find the information in the educational materials on the differences between brand and generic drugs?
 - a. Did you find the information to be innovative with regards to generic drug use?
2. Was there any new information regarding generic drug use that you learned upon your review of the materials?
 - a. If so, what?
 - b. If not, how can the materials be improved for educating policymakers on generic drug use?
 - c. What would you have changed about any of the information provided in the materials, if anything?
3. What information in particular stood out to you after reviewing the materials?
4. How helpful do you find the information in these materials for policymakers like yourself?
 - a. How will you apply this information to your role in the process of getting generic drugs from manufacturers to patients in the future?
5. Do you think these materials may be helpful for other groups involved in the generic drug process, such as large purchasers of drugs or formulary managers?
 - a. If helpful, how?
 - b. If not helpful, do you have any suggestions on how these materials may be better geared towards educating these groups?

Channel questions

6. What would be the best way to provide this type of information in a timely manner to policymakers like yourself?
7. From whom do you prefer to receive an email or newsletter with information regarding generic drugs like this? (such as FDA, professional associations, insurance companies, etc.) Why?

Format Questions

Next, I would like to ask you about your thoughts on the format of the educational materials.

8. What are your thoughts about the format used to present the information in the educational materials?
 - a. What did you like about the presentation of the information?
 - b. Do you have any suggestions on how to make the materials easier to follow for policymakers like yourself?

Satisfaction questions

Appendix F: Interview Protocol - Policymakers

9. Can you please describe if you find the information regarding generic drugs in this email/newsletter to be useful for policymakers like yourself?
10. Can you please describe if you find the information regarding generic drugs in this email/newsletter to be interesting for policymakers like yourself?
11. Can you please describe your overall satisfaction with the information regarding generic drugs in this email/newsletter?
12. How would an email or newsletter with information regarding generic drugs like this help you with your work related to generic drugs (for example, health policies)?
13. Would you recommend this email/newsletter to other policymakers if they are interested in information regarding generic drugs?