The Cost of Bringing a Biosimilar Product to Market—Expert Interviews

Generic Information Collection Request under OMB No. 0990-0421

Supporting Statement B

May 10, 2023

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B. Generic Collection of Information Employing Statistical Methods If statistical methods will not be used to select respondents and item 17 on Form 83-I is checked "No" use this section to describe data collection procedures.

The purpose of this information collection is to elicit expert information that will enable the contractor, ERG, to structure a dynamic model of biosimilars market entry decision making process. A statistical survey is impractical because many of the questions and issues that will arise during these interviews will be influenced by the information obtained during the interview itself. The need to develop the relative costs associated with developing different types of biosimilars; the costs associated with different clinical trial designs, the costs of *in vitro* analyses of pharmacokinetics and pharmacodynamics v. costs of assessing these through clinical trials, and for what types of drugs *in vitro* studies may be appropriate; the relative costs of ongoing quality control measures during manufacturing; the costs of defending against lawsuits for patent infringement, and the probability and costs associated with delaying market entry due to settlement of such lawsuits—these are a few of the areas in which we seek expert feedback.

1. Respondent Universe and Sampling Methods

Table 1 presents the intended distribution of interviewees across 11 categories of organizations and individuals with expertise in various areas of biologic/biosimilar market entry and competition.

Table 1. Distribution of Expert Interviewee Types

Type of respondent	Number of Respondents
Manufacturer of Biosimilars	10
Manufacturer of Biologics	8
Contract Development & Manufacturing Organization	2
Wholesalers/ Distributors	3
Academic and other Researchers	3
Pharmacy Managers	2
Pharmacy Benefit Managers	2
Intellectual Property Attorneys	2
Health Systems	3
Prescribing Physicians	3
Trade Groups	2
Total	**40**

The identities of all interviewees and their employers will be closely held by the ERG project team, and interviewees' comments will not be specifically attributed to them, nor attributed to their companies by name, in any written or oral report. All personally identifying information (PII), including contact information, will be stored securely. No information that would enable an interviewee to be identified will be presented in any oral or written communication by ERG,

2. Procedures for the Collection of Information

The contractor, ERG, will first contact representatives of two major trade groups—the Association for Accessible Medicines (AAM) and the Biosimilar Forum—who have expressed willingness to facilitate scheduling interviews with knowledgeable individuals at several large and small biologic and biosimilar manufacturers and contract development and manufacturing organizations specializing in biologics/biosimilars.

With the advice and assistance of AAM and Biosimilar Forum personnel, ERG will develop a roster of potential interviewees knowledgeable about several areas of biosimilar/biologic manufacturing. ERG will email potential interviewees, explain the nature of the project, and request them to schedule an approximately one-hour virtual interview with two or three members of the ERG research team.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Because this is not a statistical survey, issues regarding response rates and nonresponse bias are limited. Nevertheless, we do anticipate that many of the companies represented by our prospective interviewees will be well-disposed toward participating in a project that is intended to inform policies that facilitate biosimilar competition with brand biologics. Further, the minimal 1.75 hours of burden per respondent (sum of 0.75 hours for reading and responding to outreach emails and 1 hour of interview time) and the contractor's commitment to maintain the anonymity of interviewees and their employers should lessen potential hesitation on the part of interviewees.

4. Tests of Procedures or Methods to be Undertaken

ASPE and ERG have previous experience implementing structured and semi-structured interviews of industry employees and other experts to elicit information and data that would be difficult to obtain from other sources or by other methods. The interview outline for manufacturers of biosimilars has been revised based on input from senior ERG project team members, an outside consultant prominent in the biosimilars/ biologics industry, and the project advisory group (PAG) that includes staff from ASPE and FDA. While we will be obtaining responses to a consistent set of core questions, the interview guide is likely to evolve as interviews progress and important details and issues emerge.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

This data collection was designed by the following ERG personnel in consultation with the PAG. The ERG team will collect, compile, and anonymize the data, and then analyze the data in conjunction with the PAG team members.

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