الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS – G018

# Guidance on Saudi Food and Drug Authority Policy for Collection of Patient Experience Data

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# SFDA Policy for Collection of Patient Experience Data

## Policy Goal

The collection of patient experience data is important to SFDA in providing a means by which SFDA can better understand how patients in all therapeutic areas experience treatment with medicines and medical devices to promote the informed regulation and approval of medical devices and medicinal products in the KSA.

## Patient Experience Defined

Patient experience is the lived experience of a patient with an illness undergoing treatment. Specifically, this policy is focused on the patient experience with treatment for the disease with medicines and/or medical devices.

## Key Principles

- Patients are the experts about their lived experience with treatment of a disease or health condition
- Patient experience has value and can make a meaningful contribution to advancing medical product development
- Patient-generated health data can complement and fill in the gaps of traditional clinical data

## Establish Saudi Patient Experience Data Program

SFDA will establish a Saudi Patient Experience Data Program to collect and disseminate patient experience data. SFDA will encourage and solicit data directly from patients regarding their experiences with pharmaceutical drugs, medical devices and other medical therapeutics (all considered “health interventions” regulated by the SFDA. The program will promote better understanding of patients’ experience with medicines and medical devices in all therapeutic areas and promote the informed regulation and approval of medical devices and medicinal products in the KSA.

## Prioritizing Therapeutic Areas for Data Collection

SFDA will conduct a prioritization exercise that includes input from drug and medical device regulators, HCPs, and patients to determine therapeutic areas for which patient experience data is particularly needed. SFDA may also consider upcoming regulatory decisions or known therapeutics in the regulatory pipeline to help prioritize topics.

When a clear area of priority is not immediately obvious, or there is debate about what areas should be prioritized, SFDA may use the Delphi method to prioritize topic areas for survey of patient experience. Relevant SFDA stakeholders would be invited to submit anonymously all of their proposed topics to a group moderator. Once the moderator has received all of the topics, he or she will compile them into a list to be returned to the stakeholders who are asked to rank their top 5 topics. This method assures all stakeholders are given the opportunity to both identify and prioritize topics.

Once priority areas for patient experience data have been prioritized, SFDA may use the template for submission of patient experience data into the Saudi Patient Experience Data Program based on the SFDA Patient Experience Survey Template.

## Tools for Data Collection

## SFDA Patient Experience website

The SFDA Patient Experience program will collect patient information via a secured, patient-accessible website. The website will be established as an entry point to the patient experience data collection program. The survey website should be useable in mobile format such that patients can complete the survey from a smartphone or tablet if desired.

The website will be designed in collaboration with the SFDA cybersecurity and IT departments to assure adequate data protection and regulatory and legal compliance. The text and photos for the website will be developed with the assistance of the SFDA communications team. Special emphasis will be placed on using plain language for the text of the website, that is, text that is easy to understand for the general population and free of technical jargon.

SFDA will equip the website with both qualitative and quantitative mechanisms for collecting patient experience data. SFDA may decide to work with a third-party administrator to collect both

quantitative and qualitative data collection. Such third-party administrators have specific expertise in the design of patient data collection mechanisms and will be able to work with SFDA to identify priority topics and therapeutic areas for development. Third party administrators would be vetted by SFDA, including cybersecurity, IT and the Research Executive Directorate.

Patients may submit quantitative data, qualitative data or both. Quantitative data collection will be done by means of patient surveys using the SFDA Patient Experience Template, or modified versions thereof, which may be customized to achieve the needs of SFDA in capturing specific patient experience with medicines or medical devices. The purpose of these surveys will be to collect basic demographic information, basic health information, patient experience with current medicines and/or medical devices, and expectations for new medicines and/or medical devices.

Qualitative data collection will include a set of open-ended questions, to which patients can write responses with as much detail as they care to share. Such qualitative questions can be a valuable source of information as they may reveal topics of areas of interest to patients that have not been previously identified by SFDA.

## Interviews

SFDA may decide to conduct follow-up interviews to obtain additional information on a specific topic or from a specific patient. For instance, if a patient submits a particularly compelling or surprising report about an adverse drug event, SFDA may want to follow-up with the patient for additional detail. That additional detail can help SFDA to assess whether more widespread, systemic investigation of that event is warranted or if additional assessments of patient experience in that topic area should be prepared. SFDA and the third-party partners would collaborate on the development of an interview guide in advance of any such interview to determine the scope of the interview and to confirm all topics of interest are included. Interviews should be recorded and transcribed for analysis.

Because interviews are very resource intensive, and results are often not generalizable, they should only be utilized in special cases, where there is a compelling need for additional, firsthand data.

## Additional Qualitative Data Collection Methods

- Focus groups, a guided discussion with three or more participants plus a facilitator, can help identify key themes and topics of interest to the patient community that can be followed up with more detailed quantitative assessments. Focus group facilitation guides should be developed in conjunction with relevant teams at SFDA to ensure discussion around the specific topics of interest. An external facilitator may be appropriate, as patients may not be as candid with a facilitator from the SFDA.
- Ethnographies allow for more in-depth exploration of a particular aspect of patient experience, and can be drawn from qualitative data submitted by the patient and follow-up interviews when needed and appropriate.

## Additional Quantitative Collection Methods

- Online surveys can be administered through the SFDA Patient Experience Data website and are an effective means to capture information across a large set of the patient population.
- In-person surveys can be collected from patients in healthcare professionals' offices at the time of a healthcare appointment. This can be particularly effective for brief surveys to capture information at the moment of the healthcare interaction. These should be administered online at the Patient Experience Data website to ensure consistent data collection from all survey participants.

## Recruitment of Patients to Submit Patient Experience Data

SFDA will engage in recruitment to the Saudi Patient Experience Data Program by means of direct and indirect patient contact. Direct patient recruitment will be conducted via social media, web sites, mailings, posters in hospitals and other provider facilities. Additional patient recruitment will be facilitated by outreach to health care professionals, who may distribute fliers or informational cards to patients to encourage them to participate. Health care professionals may also encourage patients to complete the survey during clinic visits.

Both direct and indirect recruitment materials will be developed in conjunction with SFDA Communication staff who have expertise in communication with local patient populations.

## Types of Patient Experience to Collect

Ultimately, the SFDA will prioritize therapeutic areas for which patient experience data is needed. Regardless of the therapeutic area, the following types of information are particularly relevant to SFDA and the goals of the Patient Experience Program.

- **Usability**

Patients may have differing experiences with regard to the usability of medicines or medical devices. The surveys will address patients' experience using medicines and/or medical devices, their perceptions of how usability affects their ability to treat their condition, and their expectations for usability of new products.

- **Side effects**

While clinical trials collect information about patient side effects, often we learn additional important information once the product is broadly available to the public. The survey will address which side effects patients experienced from a medicine or medical device product and the severity and frequency of these effects.

- **Risk tolerance**

Patients may have different levels of tolerance for risk, which may be influenced by age, disease progression, and severity of illness. Understanding different patient populations risk tolerance is an important consideration for regulatory assessment of a new medical product.

- **Expectation of benefit**

Patients and physicians may not agree on what is a meaningful benefit. The patient can provide the unique perspective of what level of benefit would allow them to return to the activities of life that are most important to them.

## Analysis and Delivery of Patient Experience Data to SFDA

All data collected from patients, whether quantitative or qualitative, will be synthesized by therapeutic area or product and provided to relevant stakeholders at SFDA. At SFDA request, interim reports can be delivered on request and/or once a minimum sample size is achieved.

For quantitative data, statistical summary data will be provided, as well as a guide to survey questions that were given to patients.

For qualitative data, thematic analysis will be provided in the reports, along with representative quotes and relevant patient stories.

## Communication of Patient Experience Data

Final reports will be disseminated to SFDA leadership, SFDA regulators and SFDA product reviewers. These reports will contain information about how and when the patient experience data was collected, how information was analyzed, and key findings relevant to the assessment of the medical treatment or therapeutics under review.

Results will also be shared with other relevant SFDA departments, including medical affairs, legal affairs and communication. Legal Affairs will review results before they are publicly shared. Communications will provide patient-friendly materials to the public to further educate the public about SFDA, what SFDA does and how patients can support SFDA's mission. Sharing the results will increase public understanding of how patient experience data is evaluated and used by SFDA. Results should also be shared with pharmaceutical companies and medical device manufacturers so that they understand how patient experience data is informing the regulatory process.