MDS – G 017

Guidance on Saudi Food and Drug Authority Policy for Engagement with Healthcare Practitioners

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SFDA Policy for SFDA Engagement with Healthcare Practitioners (HCPs)

Policy Goal

The SFDA seeks to enhance engagement with healthcare practitioners to ensure the safe use of medical devices and drugs, improve reporting of adverse events, evaluate the post-market experience with medical devices and drugs, and include the input and advice of healthcare practitioners in the regulation of medical devices and drugs.

Definition of Healthcare Practitioners (HCP)

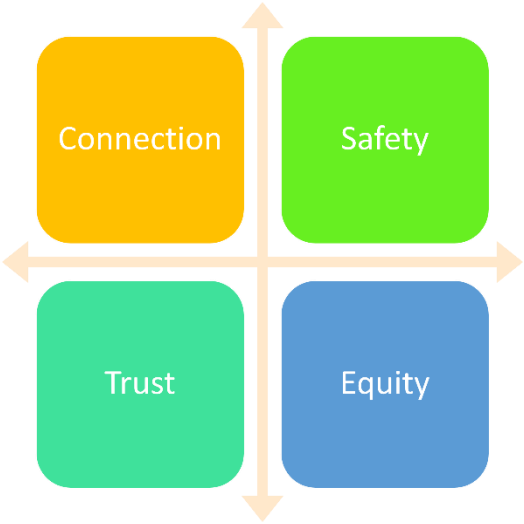
A healthcare practitioner (HCP) is anyone who delivers patient care as part of any government or private establishment that provides healthcare services. For example, a HCP could be a doctor, surgeon, nurse practitioner, physician assistant, therapist, or other type of healthcare practitioner providing patient care. All HCPs are covered by this policy document.

Key Principles

SFDA's healthcare practitioner engagement policy is based on key principles that ensure trust, transparency, and communication between HCPs and regulators. SFDA is committed to enhancing communication with HCPs to ensure the safety of public health with respect to the use of medical devices and drugs within Saudi Arabia. The following four principles guide all HCP engagement activities and provide a roadmap for regulators and HCPs who participate in these activities.

The four guiding principles for the SFDA's healthcare practitioner (HCP) engagement policy are:

- **Connection**: Engaging with HCPs to gain access to real-world practice experience can enhance regulators' ability to effectively regulate medical products by supplementing clinical data with the real-world data and insight from HCPs.
- **Safety**: Enhancing the relationship between HCPs and regulators can improve HCPs safe and rational use of medical products by understanding how HCPs manage patients and make treatment decisions.
- **Trust:** Engagement with HCPs by regulators enhances trust, promotes integrity in the regulatory process, and improves transparency.
- **Equity:** Including the perspectives of diverse HCP stakeholders ensures equity and the opportunity for SFDA to obtain a variety of HCP perspectives.



SFDA policies for engagement with healthcare practitioners across the KSA are designed to serve all review branches of SFDA, including medical devices and drugs. Oversight for the HCP Engagement Program will be housed in the SFDA. HCP engagement policy will cover several programs. These programs will include the following:

1. Saudi HCP Expert Network
2. Healthcare Officer Nominations
3. SFDA HCP Training Program
4. Special Interest Working Groups
5. Adverse Event Reporting & Surveillance Studies
6. Evaluation of HCPs for Safe Use of Medical Devices
7. HCP Engagement Portal

These programs will provide different avenues by which SFDA and HCPs engage and exchange information. Each program will have a process by which engagement activities occur, criteria for participation, and expectations for outcomes of the activity.

The HCP Engagement program will remain flexible in its ability to create new engagement opportunities should the need arise to address a specific therapeutic area or medical product need. Any program developed this policy shall be based on the Key Principles and, whenever possible, developed with input from HCPs.

Types of HCP Engagement

The SFDA HCP Engagement programs will include the following engagement opportunities in which HCPs may participate.

- **Saudi HCP Expert Network.**

The Saudi HCP Expert Network is a network of healthcare practitioners with expertise in specific therapeutic areas or treatment modalities. For example, one HCP may be an orthopedic surgeon with expertise in treatment of trauma injuries, while another may be a Nurse Practitioner with expertise in management of infectious disease or a Physician Assistant who has expertise in dialysis treatments. The HCP Expert Network should encourage HCPs with particular expertise to apply to participate and be identified as part of a “pool” of experts who might be invited to specific meetings with regulators, complete surveys on a particular topic, or participate in focus groups.

HCPs will apply via the HCP Engagement Portal and will be vetted by the SFDA, using criteria established by this department. At a minimum, HCP experts must be licensed medical professionals in good standing with authorization to practice medicine in the KSA. They must also be willing to devote the needed time to participate in the activities for which the expert is recruited, understand the need for confidentiality, and be able to confidently share their experiences and expertise with regulators. HCPs may be entitled to compensation for their time and reimbursement for expenses related to participation in the Saudi HCP Expert Network. Rewards for participation will be at the discretion of the SFDA.

- **Healthcare Officer Nominations**

The Executive Department of Surveillance and Biometrics will establish policies and procedures for the nomination by HCPs of Healthcare Officers who will be responsible for registration in The National Center for Medical Device Reporting (NCMDR). HCPs must nominate individuals who meet the criteria for a Healthcare Officer, namely that the person shall be scientifically qualified in biomedical engineering/biomedical technology or any medical/health specialty. NCMDR is responsible for reviewing nominations and approving individuals for this role. Training for HCPs on the role of the Healthcare Officer and their role in adverse event reporting for medical devices will be provided in the SFDA HCP Training Program.

- **SFDA HCP Training Program**

The HCP Training Program will be available to all healthcare providers in the KSA. This program will be offered online using a web-based platform. HCPs will be provided with several training options that enhance their understanding of how SFDA regulates medical devices and drugs in the KSA, the role of SFDA and HCPs in protecting public health, requirements and procedures for reporting adverse events, the conduct of post-market clinical evaluations and surveillance studies, and introductions to the various programs in which HCPs may participate to engage with SFDA. SFDA may develop training that is mandatory for all HCPs practicing in the KSA. Oversight and enforcement of these training requirements will be in collaboration with the Saudi governing body responsible for licensing healthcare providers in KSA and the SFDA.

- **Special Interest Working Groups**

HCP experts may participate as part of Working Groups with SFDA to address benefit/risk determinations for specific medical products, provide feedback on SFDA policies and programs, and engage with regulators to identify areas of unmet medical need in the KSA. Participation in a Working Group may require HCPs to have specific scientific knowledge, training, or experience. Criteria for participation in the Working Group will be determined by the SFDA. The criteria may vary depending on the topic of the Working Group. In general, HCPs should meet the minimum criteria for participation in the Saudi HCP Network, while being willing to commit to the additional time and effort that participation in the Working Group might entail. The SFDA may desire to provide HCPs with additional training to enhance the ability of HCPs to contribute to a particular Working Group. HCPs may be entitled to compensation for their time and reimbursement for expenses related to participation in a Special Interest Working Group. Rewards for participation will be at the discretion of the SFDA.

- **Adverse Event and Surveillance Studies**

HCPs throughout the KSA will be required to participate in reporting of adverse events for all medical devices and drugs. The SFDA will establish policies and procedures for the required reporting of adverse events to SFDA by HCPs. Training for HCPs on the proper reporting of adverse events to SFDA will be part of the SFDA HCP Training Program. SFDA will be

responsible for investigation of adverse events and responding to safety signals or other evidence of an increased risk to public health.

SFDA may choose to conduct a post-market clinical evaluation studies of a medical device or drug, which may require the participation of HCPs in a clinical study or survey. Training for HCPs on their role and participation in post-market clinical evaluations will be included in the SFDA HCP Training Program. HCPs will complete surveys or provide other clinical experience data as requested by SFDA to address post-market clinical evaluation and surveillance study needs. HCPs may be entitled to compensation for their time and reimbursement for expenses related to participation in a post-market clinical evaluation and surveillance study. Rewards for participation will be at the discretion of the SFDA.

- **Evaluation of HCPs for Safe Use of Medical Devices**

The SFDA will establish policy and procedures to ensure HCPs are comply with the requirements for safe use of medical devices. This program will include remote workshops and on-site evaluations. A standard presentation will be used to communicate the safe use of medical devices requirements. HCPs will be required to provide evidence of compliance with the program within 10 days of receiving the post-workshop survey. For on-site visits, the evaluations will take place the same day as the workshop. HCP participation in this program will be determined by the monthly evaluation plan developed in the SFDA.

- **HCP Engagement Portal**

The SFDA will establish a web site that serves as a resource to the HCP community by providing details about HCP engagement programs, means by which to participate in those programs, and delivery of results from HCP engagement activities. The web site will also solicit input and feedback from the HCP community by enabling HCPs to complete surveys on specific topics and provide general feedback to SFDA. Survey topics might include soliciting input about a specific therapeutic area, medical product, or regulatory issue. SFDA may also use the HCP Engagement Portal to obtain feedback on new policies or programs for which HCP input is a critical component. The HCP Engagement Portal should facilitate two-way communication between the SFDA, HCPs, and other stakeholders, thus enhancing engagement between SFDA and the community.

Selection of HCPs to the SFDA HCP Engagement Programs

The SFDA will oversee recruitment of HCPs to the various HCP Engagement Programs while ensuring a commitment to diversity and attention to the program's Key Principles. The HCP Engagement Portal will be the main avenue by which HCPs will be recruited, though HCPs with specific expertise may be invited to participate if desired. Individuals interested in participating in one of the HCP Engagement Programs will use the Portal to learn about the types of engagement activities available to them, the criteria by which HCPs will be chosen for participation, and how to apply to be part of the HCP Engagement Program activities.

HCP Engagement Program activities should be evaluated on a yearly basis at a minimum. Specific initiatives, projects, Working Groups, research activities, or other focused efforts should be evaluated upon completion of the activity using metrics based on the factors listed above. Annual and specific program evaluations should be summarized and reported to SFDA leadership.

Saudi HCP Network

Mission

To provide a pool of HCP experts who can provide regulators with input and understanding of living with a particular illness, accessing care, or experiences with treatment.

Objectives

To support or inform regulatory decision making, facilitate HCP-SFDA communication, maintain inclusiveness and diversity of HCP input, achieve all engagement timelines, and expand, uphold and enhance the reputation of SFDA in the HCP community.

Resources required

The SFDA will reach out to HCPs, who have applied, and been approved, to join the network. HCP Network participants should be provided onboarding materials to orient them to the program. For example, materials focused on training and education about the regulatory system should be available. HCPs will also need to be provided with informational materials on confidentiality, as well as any background materials on relevant topics. The SFDA will need dedicated staff to generate the materials needed to educate network participants. In addition, dedicated staff will be needed to plan and facilitate engagement with Saudi HCP Network participants. This may include development and distribution of surveys, scheduling phone interviews between participants and regulators, arranging HCP attendance at meetings with regulators, or other activities to be determined by the needs of the SFDA. HCPs may be entitled to compensation for their time and reimbursement for expenses related to participation in the Saudi HCP Network. Rewards for participation will be at the discretion of the SFDA.

Criteria for Participation

Participation in the network will be determined by meeting several criteria based on the following definitions of potential network participants:

- A healthcare practitioner (HCP) is anyone who delivers patient care as part of any government or private establishment that provides healthcare services. For example, a HCP could be a doctor, surgeon, nurse practitioner, physician assistant, therapist, or other type of healthcare practitioner providing patient care.

To participate in the network, individuals must meet the definition of a HCP and be willing to participate as needed in activities defined by the SFDA. At a minimum, network participants must be willing to devote the needed time to participate in the activities for which the HCP expert is recruited, understand the need for confidentiality, and be able to confidently share their experiences with regulators

Recruitment of Participants

The SFDA will be responsible for recruiting participants to the Saudi HCP Network. Recruitment will ensure a diverse group of HCPs are brought into the network. Recruitment might occur by way of:

- Advertising opportunities for HCP participation
- Direct mail or email to HCPs
- Open call for applicants on the HCP Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

The HCP Engagement Portal will provide HCPs with details about all the available HCP engagement programs, as well as the option to apply to participate in any of the available programs. HCPs will apply via the HCP Engagement Portal and will be vetted by the SFDA. Review of eligibility for participation may include completion of a Conflict of Interest Disclosure. Full criteria for participation in the Saudi HCP Network are established by the SFDA based on the activity to which the participants are being recruited.

Methods of Engagement

Engagement will include, but is not limited to, the following: participation in focus groups, completion of surveys, and provision of feedback regarding HCP experience and HCP needs. Participation would be on an as-needed basis when regulators have a particular desire to learn more about a specific therapeutic area.

- Types of input might include: HCP experience with a specific medical device or drug treatment, their experience with a particular patient population, the occurrence of adverse events or device failures, unmet medical need in a particular therapeutic area, or HCP's perceptions about access to therapy.
- Types of output from these activities might include: a report summarizing the subjective experience of participants, recommendations for regulatory policy or decisions about a new or existing therapy, investigation of the occurrence of failures or adverse events, changes to access or reimbursement for specific treatments, or requests for new regulatory science to be developed around novel devices or drugs.

Duration of Engagement

Participants must agree to participate in the network for one-year increments. For each year, the HCP must apply to be part of the network. A HCP may participate in the network for as many years as they like. There is no guarantee a HCP will be needed by regulators in any given year. However, HCPs agree to participate in at least 2 – 3 phone calls, 1 – 2 surveys, and at least one focus group for any year in which they have applied and been accepted to participate in the network.

Evaluation of the Saudi HCP Network

1. **Expected Outcomes:**
    - Fulfill stated objectives
    - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
    - Monitoring outcomes:
        - Has there been a meaningful impact on regulatory decision making
        - Have engagement deadlines and quotas been met for the year
        - Yearly feedback (including ratings, feedback, and suggestions) from SFDA sources collected through surveys and interviews
        - Yearly feedback (including ratings, feedback and suggestions) from HCP members collected through surveys and interviews
    - Evaluating Outcomes:
        - How well is the program meeting the objectives: HCP empowerment, inclusiveness and diversity of HCP experts, effect on decision making, reputation
        - Standards of operation:
            - Quality of program
            - Efficiency of program
            - Ethics review

3. **Learnings and Changes:**
    - Assessment of gaps
    - Steps to improve
    - Continual assessment of the relevance of outcomes alongside long term vision

Healthcare Officer Nominations

Mission

To accept and approve nominations by HCPs for Healthcare Officers who will be responsible for registration in the National Center for Medical Device Reporting (NCMDR) and who will be responsible for adverse event and failure reporting for medical devices.

Objectives

To ensure Healthcare Officers are in place at all healthcare facilities for the purpose of engaging with SFDA and for reporting adverse events and failures for medical devices.

Resources required

The SFDA will need dedicated resources to manage the policies and procedures associated with HCP nomination of Healthcare Officers. In addition, resources may be necessary to engage with HCPs to provide training and information about the process to nominate Healthcare Officers and the criteria by which potential Healthcare Officers will be evaluated. Ongoing maintenance of the Healthcare Officer program and updates to policies and procedures over time may also require dedicated resources. Healthcare Officers will need to be compensated for their work. There is no expectation that HCPs will be compensated or rewarded for the nomination process.

Criteria for Participation

Healthcare Officers shall be scientifically qualified in biomedical engineering/biomedical technology or any medical/health specialty. Criteria for becoming a Healthcare Officer is established by the national center of medical devices reporting (NCMDR). HCPs must nominate individuals for the Healthcare Officer role who meet all of the criteria set by SFDA.

Recruitment of Participants

The HCP Engagement Portal will provide HCPs information about the requirements for a Healthcare Officer, the criteria by which these nominees will be evaluated, and how to nominate individuals for the role. SFDA may also engage in recruitment for Healthcare Officers by way of:

- Advertising opportunities for HCP nominations for the role
- Advertising the need for Healthcare Officers
- Open call for applicants on the HCP Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

HCPs should follow SFDA procedures for the nomination of Healthcare Officers. SFDA should provide information about the program requirements, criteria for nomination, and how to nominate individuals. This information should be available on the HCP Engagement Portal.

Duration of Engagement

Effort by HCPs in the nomination process should be minimal. Healthcare Officers will be employed as SFDA representatives for the duration of their tenure based on criteria for employment with SFDA.

Evaluation of Healthcare Officer Nomination Program

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - Has there been a meaningful impact on regulatory decision making
     - Have engagement deadlines and quotas been met for the year
     - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from HCP advisors, healthcare providers, and other stakeholders if applicable collected through surveys and interviews
   - Evaluating Outcomes:
     - How well is the program meeting the objectives: HCP empowerment, inclusiveness and diversity of HCP experts, effect on decision making, reputation
   - Standards of operation:
     - Quality of program
     - Efficiency of program
     - Ethics review

3. **Learnings and Changes:**

- Assessment of gaps
- Steps to improve
- Continual assessment of the relevance of outcomes alongside long term vision

SFDA HCP Training Program

Mission

To provide HCPs with training and resources that enhance their understanding of SFDA's role in the regulation of medical devices and drugs, educate HCPs about their role in partnering with SFDA in protecting public health, and provide policies and procedures for reporting adverse events and product failures to SFDA, and explain methods for the conduct of post-market clinical evaluations and surveillance studies.

Objectives

To enhance the regulatory and compliance knowledge of HCPs within the KSA and promote greater communication and collaboration between HCPs and SFDA to protect public health.

Resources required

Dedicated resources will be required to develop, implement, and maintain the training programs needed to make this initiative a success. Web-based educational program support will be required, as will dedicated program evaluators who will be responsible for ensuring the content of all programs is up-to-date and accurate. Technical support for HCPs engaging with the training program will also be required. Experts in the development of educational materials may be required on an as-needed or permanent basis depending on the depth and breadth of programming offered. Instructors for on-site training at local medical colleges or in healthcare facilities may be needed. SFDA may develop training that is mandatory for all HCPs practicing in the KSA. Oversight and enforcement of these training requirements will be in collaboration with the Saudi governing body responsible for licensing healthcare providers in KSA and the SFDA. HCPs may be entitled to continuing education credit for completing courses through the HCP Training Program. Rewards and continuing education credit for participation will be at the discretion of the Saudi governing body responsible for licensing healthcare providers in KSA and the SFDA.

Criteria for Participation

All HCPs practicing patient care in the KSA will be eligible to participate in the SFDA HCP Training Program. SFDA may develop training that is mandatory for all HCPs practicing in the KSA. Oversight and enforcement of these training requirements will be in collaboration with the Saudi governing body responsible for licensing healthcare providers in KSA and the SFDA. Should new training requirements be implemented for all HCPs, a rational time period of compliance should be allowed for existing HCPs to meet the new requirements (e.g. 1-year from the time they are notified of the new requirements). This timing and roll-out of new HCP training requirements will be overseen by the Saudi governing body responsible for licensing healthcare providers in KSA and the SFDA.

Recruitment of Participants

The HCP Engagement Portal will provide information about available training opportunities and requirements. SFDA may also choose to implement requirements for participation in the HCP Training Program at local colleges, such that recruitment for completion of the training occurs as a matter of the medical college curriculum. Should any of the training become required in the KSA, the SFDA may choose to directly inform HCPs by way of direct mailings, email, or other correspondence. Recruitment might occur by way of:

- Advertising opportunities for HCP participation
- Direct mail or email to HCPs
- Open call for participants in the training program on the HCP Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

The HCP Training Program will be primarily web-based with online learning modules available on a dedicated educational web platform. On-site training may take place at medical colleges for new HCPs or at healthcare facilities when needed.

Duration of Engagement

The HCP Training Program will be an ongoing commitment by the SFDA to educate HCPs in the KSA. SFDA may decide to set minimum annual (or biannual) training requirements for HCPs. These requirements may vary based on healthcare modality. For example, medical doctors and surgeons may have more training requirements than nurses, though rationale for these differences must be documented. HCPs may be entitled to continuing education credit for completing courses through the HCP Training Program. Rewards and continuing education credit for participation will be at the discretion of the Saudi governing body responsible for licensing healthcare providers in KSA and the SFDA.

Evaluation of HCP Training Program

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - Has there been a meaningful impact on regulatory decision making
     - Have engagement deadlines and quotas been met for the year
     - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from HCP advisors, healthcare providers, and other stakeholders if applicable collected through surveys and interviews
   - Evaluating Outcomes:
     - How well is the program meeting the objectives: HCP empowerment, inclusiveness and diversity of HCP experts, effect on decision making, reputation
   - Standards of operation:
     - Quality of program
     - Efficiency of program
     - Ethics review

3. **Learnings and Changes:**
   - Assessment of gaps
   - Steps to improve
   - Continual assessment of the relevance of outcomes alongside long term vision

Special Interest Working Groups

Mission

To provide the HCP perspective to Special Interest Working Groups led by SFDA staff. HCP advisors along with HCP experts, and other stakeholders as required may participate as part of Working Groups with SFDA to address benefit/risk determinations for specific medical products, medication use and dissemination, provide feedback on SFDA policies and programs, and engage with regulators to identify areas of unmet medical need in the KSA. A Working Group might deliver a written recommendation, a report, a presentation, or other form of deliverable for consideration by SFDA leadership.

Objectives

To support or inform regulatory decision making, facilitate HCP engagement, maintain inclusiveness and diversity of HCP input, achieve all engagement timelines, and expand, uphold, and enhance the reputation of SFDA in the greater community.

Resources required

HCPs who participate in the Working Groups may need to have specific expertise, knowledge, training, or experience to participate in a particular Working Group. In addition, the SFDA may desire to provide HCPs with additional training to enhance the ability of HCPs to contribute to a particular Working Group. Additionally, materials focused on training and educating about the regulatory system, the topic of the Working Group, and any other information the participants will need to successfully contribute will need to be developed and disseminated to all Working Group participants. Information about the purpose of the Working Group and the associated tasks will need to be developed to facilitate recruitment of participants to the Working Group. Meetings of the Special Interest Working Group will need to be planned and facilitated. Deliverables from the Special Interest Working Group (such as a written recommendation, a report, a presentation, or other form of deliverable for consideration by SFDA leadership) will need to be managed and delivered to SFDA leadership. HCPs may be entitled to compensation for their time and reimbursement for expenses related to participation in a Special Interest Working Group. Rewards for participation will be at the discretion of the SFDA.

Criteria for Participation

HCPs in a Special Interest Working Group may be required to meet more rigorous criteria for participation depending on the topic being addressed. These HCPs will function as experts or advisors who, in addition to disease-specific expertise, have the technical knowledge in medical device and drug research and development and/or regulatory affairs through training or experience. The specific criteria for the HCP experts may include a college education, specialized training in clinical research, engineering, or medicine, and/or have completed training provided by SFDA on policy development, regulatory affairs, or SFDA administrative practices. The team may additionally include regulators, HCPs or caregivers, academic researchers, and other stakeholders as required. Each Special Interest Working Group will need to be defined by the SFDA with specific criteria for recruitment to ensure all stakeholders can contribute equitably to the assigned task.

Recruitment of Participants

The HCP Engagement Portal will provide potential working group participants with details about all of the available HCP engagement programs, as well as the option to apply to participate in any of the available programs. Specific information about a given Working Group task will be disseminated as needed to recruit participants. HCPs who participate in a Special Interest Working Group may be identified from the Saudi HCP Network or may be recruited by the SFDA to serve specifically on a Working Group. The SFDA may proactively solicit participation

of HCP and academic researchers and other stakeholders if needed for a particular working group. Recruitment might occur by way of:

- Advertising opportunities for HCP participation
- Direct mail or email to HCPs
- Open call for applicants on the HCP Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

Participation would be on an ongoing basis for a specified period of time. The SFDA may desire to provide HCPs with additional training to enhance the ability of HCPs to contribute to a particular Working Group. The team, consisting of HCP experts, regulators, HCPs, and other stakeholders will meet several times throughout the year, and will create deliverables consisting of a written recommendation, a report, a presentation, or other form of deliverable for consideration by SFDA leadership.

Duration of Engagement

The work to be completed by a Special Interest Working Group should be achievable in 6 – 12 months. HCP advisors on a working group should not be required to serve for more than 12 months. The working group should meet no more than 1 – 2 times per month. Virtual participation should be available. Participation in a working group should not interfere with the HCP's work or home life commitments.

Evaluation of Special Interest Working Groups

1. Expected Outcomes:

- Fulfill stated objectives
- Upholding high standards of operation including efficiency, quality, and ethics.

2. Monitoring and Evaluating Outcomes:

- Monitoring outcomes:
  - Has there been a meaningful impact on regulatory decision making
  - Have engagement deadlines and quotas been met for the year
  - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
  - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews

- Yearly feedback (including ratings, feedback and suggestions) from HCP advisors, healthcare providers, and other stakeholders if applicable collected through surveys and interviews

- Evaluating Outcomes:
  - How well is the program meeting the objectives: HCP empowerment, inclusiveness and diversity of HCP experts, effect on decision making, reputation

- Standards of operation:
  - Quality of program
  - Efficiency of program
  - Ethics review

3. Learnings and Changes:

- Assessment of gaps
- Steps to improve
- Continual assessment of the relevance of outcomes alongside long term vision

Adverse Event and Post-Market Clinical Evaluations and Surveillance Studies

Mission

To ensure adverse events and failures of medical devices and drugs are consistently and thoroughly reported to SFDA by HCPs, Healthcare Officers, and healthcare facilities and all safety signals are thoroughly examined by means of robust post-market clinical evaluation and surveillance studies.

Objectives

To achieve compliance with SFDA regulations requiring the timely, consistent, and complete reporting to SFDA the occurrence of adverse events and failures of medical devices and drugs by HCPs and their Healthcare Officers in the KSA. To partner with HCPs in the clinical evaluation of safety signals and the protection of public health.

Resources required

Dedicated resources will be required to establish, implement, and maintain the policies and procedure necessary to meet all regulatory requirements for the reporting of medical device and drug adverse events and failures by HCPs and their Healthcare Officers to SFDA. A web-based reporting mechanism that facilitates ease of reporting by HCPs, Healthcare Officers, and healthcare facilities to SFDA is necessary. Dedicated resources for the development, implementation, and maintenance of this reporting portal are required. Training materials for HCPs on how to report adverse events and failures should be developed and implemented by means of the HCP Training Program. SFDA resources for follow-up and investigation of trending adverse events or failures must be provided and SFDA administrative oversight structure established to ensure full compliance with all adverse event and failure reporting requirements.

When a safety signal is detected, SFDA must have resources available for the conduct of post-market clinical evaluations or other types of post-market surveillance studies to be conducted in partnership with HCPs. At a minimum, annual reporting of aggregated adverse event and failure data should be made available to HCPs by SFDA on the SFDA web site or through direct mail or email to HCPs in the KSA. Similarly, the results of post-market clinical evaluations and surveillance studies should be made available to HCPs. Other resources may be needed for inspections, investigations, on-site training, or other needs associated with implementing and maintaining a robust adverse event reporting program. HCPs may be entitled to compensation for their time and reimbursement for expenses related to participation in post-market clinical evaluations and surveillance studies. Rewards for participation will be at the discretion of the SFDA.

Criteria for Participation

All HCPs, Healthcare Officers, and healthcare facilities are required to participate in adverse event and failure reporting for medical devices and drugs based on the requirements set forth in SFDA regulations. As part of a post-market clinical evaluation and surveillance study, HCPs may be asked to complete surveys or provide other clinical experience data as requested by SFDA to address post-market clinical evaluation needs.

Recruitment of Participants

The HCP Engagement Portal will provide information about requirements for adverse event and failure reporting for medical devices and drugs. Similarly, information about participation in post-market clinical evaluations and surveillance studies will be provided on the HCP Engagement Portal. In addition, training modules in the HCP Training Program should address these topics to ensure HCP understanding of their role and requirements in reporting events to SFDA and participating in post-market clinical evaluations and surveillance studies. SFDA may choose to directly inform HCPs,

Healthcare Officers, and healthcare facilities of the requirements or the need for clinical data by way of direct mailings, email, or other correspondence. Other notifications about this program might occur by way of:

- Advertising opportunities for HCP participation
- Open call for participants in the training program on the HCP Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

The adverse event and failure reporting process should be primarily web-based with an easy-to-use portal by which HCPs, Healthcare Officers and healthcare facilities may report adverse events and failures to SFDA. SFDA may decide to implement other means of reporting, including a telephone hotline or paper-based forms that can be mailed to SFDA. Post-market clinical evaluations and surveillance studies may be conducted via a web-based or paper survey, collection of clinical data at the healthcare facility, or submission of clinical data by an HCP at the request of SFDA.

Duration of Engagement

Adverse event and failure reporting will be an ongoing requirement for HCPs by SFDA. As regulations are modified or updated over time, SFDA will communicate reporting changes in requirements as needed to all stakeholders.

Evaluation of Adverse Event Reporting and Post-Market Clinical Evaluations and Surveillance Studies

1. **Expected Outcomes:**

- Fulfill stated objectives
- Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**

- Monitoring outcomes:
    - Has there been a meaningful impact on regulatory decision making
    - Have engagement deadlines and quotas been met for the year
    - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews

    - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
    - Yearly feedback (including ratings, feedback and suggestions) from HCP advisors, healthcare providers, and other stakeholders if applicable collected through surveys and interviews
- Evaluating Outcomes:
    - How well is the program meeting the objectives: HCP empowerment, inclusiveness and diversity of HCP experts, effect on decision making, reputation
- Standards of operation:
    - Quality of program
    - Efficiency of program
    - Ethics review

3. **Learnings and Changes**
    - Assessment of gaps
    - Steps to improve
    - Continual assessment of the relevance of outcomes alongside long term vision

Evaluation of HCPs for Safe Use of Medical Devices

Mission

To ensure HCPs are using medical devices safely and in accordance with their approved indications for use.

Objectives

To protect public health by partnering with HCPs and healthcare facilities to ensure medical devices are used safely and in accordance with their approved indications for use.

Resources required

Dedicated resources are required to manage the compliance program needed to monitor HCPs for the safe use of medical devices. Systems for managing inspections and tracking safe use of medical devices by HCPs will be needed as will reporting mechanisms and structure. The Executive Department of Surveillance and Biometrics will establish policies and procedures by which the safe use of medical devices program is administered and implemented. Personnel will need to be trained and available to conduct the workshops and on-site evaluations as well as administer follow-up and tracking of HCP use of medical devices.

Criteria for Participation

All HCPs are required to be available for evaluation of the safe use of medical devices used in their practice of medicine.

Recruitment of Participants

The HCP Engagement Portal will provide information about requirements for the safe use of medical devices program for inspecting and evaluating this use by HCPs. In addition, training modules in the HCP Training Program should address these topics to ensure HCP understanding of their role and the Executive Department of Surveillance and Biometrics expectations and requirements for safe use of medical devices. SFDA may choose to directly inform HCPs, Healthcare Officers, and healthcare facilities of the requirements for safe use of medical devices, or the need for an evaluation or inspection by way of direct mailings, email, or other correspondence. Other notifications about this program might occur by way of:

- Advertising opportunities for HCP participation
- Direct mail or email to HCPs
- Open call for participants in the training program on the HCP Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

The SFDA will directly engage with HCPs, either remotely or on-site, for evaluation or inspection of the safe use of medical devices.

Duration of Engagement

Safe use of medical devices in accordance with their approved indications for use will be an ongoing requirement for HCPs by SFDA. SFDA has requirements, namely 10-days, for timely responses to a remote SFDA inquiry about the safe use of medical devices. As regulations are modified or updated over time, SFDA will communicate reporting changes in requirements as needed to all stakeholders.

Evaluation of Evaluation of HCPs for Safe Use of Medical Devices

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - Has there been a meaningful impact on regulatory decision making
     - Have engagement deadlines and quotas been met for the year
     - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from HCP advisors, healthcare providers, and other stakeholders if applicable collected through surveys and interviews
   - Evaluating Outcomes:
     - How well is the program meeting the objectives: HCP empowerment, inclusiveness and diversity of HCP experts, effect on decision making, reputation
   - Standards of operation:
     - Quality of program
     - Efficiency of program
     - Ethics review

3. **Learnings and Changes:**
    - Assessment of gaps
    - Steps to improve
    - Continual assessment of the relevance of outcomes alongside long term vision

HCP Engagement Portal

Mission

To establish a web site that serves as a resource to the HCP community by providing details about SFDA engagement programs with HCPs, means by which to participate in those programs, SFDA requirements that apply to HCPs, information about HCP training programs, and delivery of results from HCP engagement activities. The HCP Engagement Portal may also be used to elicit participation in post-market clinical evaluations and surveillance studies. The website will also solicit input and feedback from the HCP community.

Objectives

To support or inform regulatory decision making, facilitate HCP engagement, ensure HCP compliance with all SFDA requirements, educate HCPs on topics related to SFDA policies, procedures, and programs, achieve all engagement timelines and expand, uphold and enhance the reputation of SFDA in the greater community.

Resources required

The planning and development of the HCP Engagement Portal will be required. Designated resources will be needed for copywriting and content development related to details about HCP engagement programs, means by which to participate in those programs, and delivery of results from HCP engagement activities. Surveys on specific topics, HCP training resources, policies and procedures related to adverse event reporting, and other SFDA requirements for HCPs will also need to be developed, implemented, and maintained on the HCP Engagement Portal. Survey topics might include soliciting input about a specific therapeutic area, medical product, or regulatory issue. Obtaining feedback on new policies or programs will require regular website maintenance and a review of surveys and feedback. Additional resources may be needed to analyze survey data, generate reports from HCP engagement activities conducted by way of the HCP Engagement Portal, and to provide updated information to HCPs, Healthcare Officers, healthcare facilities, and stakeholders. For some activities, HCPs may be entitled to compensation for their time and reimbursement for expenses related to participation. Rewards for participation will be at the discretion of the SFDA.

Criteria for Participation

The HCP Engagement Portal should be easily accessible and freely available to all HCPs, Healthcare Officers, and healthcare facilities in the KSA.

Recruitment of Participants

The HCP Engagement Portal will provide potential HCP engagement participants with details about all of the available HCP engagement programs, as well as the option to apply to participate in any of the available programs. Recruitment of participants into the many possible HCP engagement programs or notification of new requirements for HCPs might also occur by way of:

- Direct mail or email to HCPs
- Advertising opportunities for HCP participation
- Open call for applicants on the HCP Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

HCPs may interact with the HCP Engagement Portal whenever they like. The web site should be easily accessible and designed to enhance engagement with all HCPs, including those with special needs (e.g. larger font for vision impaired). The HCP Engagement Portal should facilitate two-way communication between the SFDA, HCPs, Healthcare Officers, healthcare facilities, and other stakeholders. The portal will provide HCPs with details about all of the available HCP engagement programs, as well as the option to apply to participate in any of the available programs.

The portal will also provide the results of HCP engagement activities. HCPs will be able to use the portal to provide feedback and input in several ways. The web site will enable HCPs to complete surveys on specific topics and provide general feedback to SFDA. Survey topics might include soliciting input about a specific therapeutic area, medical product, or regulatory issue. HCPs will also be directed to policies and procedures that apply to them such as adverse event and failure reporting, training requirements, and post-market clinical evaluations and surveillance studies. SFDA may additionally use the HCP Engagement Portal to obtain feedback on new policies or programs for which HCP input is a critical component.

Duration of Engagement

The HCP Engagement Portal will be an ongoing effort by SFDA to engage with the HCPs, Healthcare Officers, healthcare facilities, and other stakeholders. The website will be maintained and updated regularly by the SFDA.

Evaluation of HCP Engagement Portal

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - Is there regular meaningful interaction between HCP members and the SFDA
     - Does the exchange of information have an effect on regulatory decision making
     - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from academic, industry, and medical research collaborators collected through surveys and interviews
   - Evaluating Outcomes:
     a. How well is the program meeting the objectives
     b. Standards of operation:
        i. Quality of program
        ii. Efficiency of program
        iii. Ethics review

3. **Learnings and Changes:**
   - Assessment of gaps
   - Steps to improve
   - Continual assessment of the relevance of outcomes alongside long term vision

Rules for Engagement with HCPs

The following are guidelines for engagement of SFDA with HCPs within all of the HCP engagement programs described in this policy. These "rules for engagement" are based on the values of the HCP engagement program to promote connection, safety, trust, and equity between SFDA and the public. These rules of engagement may be expanded or modified as the HCP engagement programs in the KSA evolve.

1. **Identify the Issue**: prior to initiating a HCP engagement activity, the issue to be addressed by the activity must be identified, clearly defined, and documented. Clear identification of the issue will allow for a determination of which HCP engagement activity is best suited to address the issue, what the objectives of the activity should be, and what the desired outcome from the activity is.

2. **Communicate Clear Objectives:** the objectives and desired output of HCP engagement activities should be clearly defined and communicated to all stakeholders involved in the activity.

3. **Establish Structure:** the structure of the HCP engagement activity should be clearly defined and communicated to all stakeholders. This structure should include roles and responsibilities for each participant and clearly defined accountability for the activities being undertaken by the participants.

4. **Create Space for Expression:** the mission of the HCP engagement program is to encourage input from HCPs. As such, participants in HCP engagement activities should feel empowered to speak their experience, express their views, and provide their perspective in a respectful, open, safe, and positive environment.

5. **Define Expectations:** each participant should have a clear understanding of the amount of time they will be expected to participate in the activity, what their role is, how they will be asked to communicate, what the type of work is they will be expected to complete, and what the activity should accomplish when it is complete. These expectations should also include details of any required travel, training, or other requirements expected of the participants. Expectations should be provided in writing to participants, who may be asked to sign an agreement indicating they understand the activity in which they will be engaged.

6. **Address Conflict Resolution**: each HCP engagement activity should have a means by which conflict is addressed and resolved. Conflict resolution should be based on acceptable codes of conduct for the organizations involved. For example, the standards for conflict resolution at SFDA may be the model applied to HCP engagement activities if appropriate. Alternatively, if a research organization is leading a HCP engagement activity, the research organization's standards for conflict resolution may take precedence.

7. **Implement Standards for Compensation:** each of the HCP engagement activities should have associated compensation standards applied to it based on local laws, regulations, or other applicable requirements. HCPs should be aware whether or not they will be compensated for their time and expenses. Compensation policy should be made available for consideration by anyone being asked to participate in a HCP engagement activity prior to them making a commitment to do so.

8. **Maintain Confidentiality:** each HCP engagement activity will have a level of confidentiality associated with the activity and the outputs. Participants should be made aware of the requirements for confidentiality and may be asked to sign confidentiality agreements depending on the nature of the content or level of confidentiality required. All participants should adhere to confidentiality requirements of any HCP engagement activity in which they participate. Confidentiality should not be used unnecessarily to impede transparency of the HCP engagement program.

9. **Provide Support:** participants in the HCP engagement program should be provided with support for logistical issues, questions regarding the programs, their participation, or compensation, help with travel arrangements and accommodations, or other needs. This support should be easy to find and contact information for the support team should be provided to all participants involved in the HCP engagement program.

10. **Evaluate and communicate:** the HCP engagement program activities should be evaluated annually, and a report should be generated and made publicly available. This report should highlight the success and achievements of the program activities. The report should also identify areas for improvement, lessons learned, and proposals for change. Further, the report should summarize recommendations from HCPs collected as part of the program evaluation portion of each HCP engagement program. Finally, those who participate in one of the HCP engagement programs should have access to information about how their participation had an impact. This may be included in the annual assessment report, or in reporting following individual HCP engagement activities (e.g. a Working Group summary report).