الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Good Regulatory Practice

Adopted from World Health Organization (WHO) and edited by SFDA

Version 1.0

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Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

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1. Introduction

Because of the wide diversity of medical products available, the difficulty in evaluating their quality, safety, efficacy, or performance, and the complexity of their design, production, supply, and surveillance, the medical products industry is one of the most heavily regulated of all sectors. It is consequently critical that the public's interests and safety be entrusted to a regulating agency appointed for ensuring that only legal trade products are available and that marketed products are safe, function as claimed, and are of assured quality.

A robust legal framework, adoption of international norms and standards, and recruitment and development of qualified employees are all required but not sufficient conditions to establish "effective regulatory oversight". These measures must be combined with good regulatory practices (GRP), which guide all individuals in organizations charged with overseeing medical product regulation in making decisions that are clear, transparent, consistent, impartial, proportionate, timely, and based on sound science and legislation.

GRP is a collection of principles and practices that are used to the development, implementation, and revision of regulatory instruments - laws, regulations, and guidelines – in order to fulfill public health policy objectives as efficiently as possible. A modern, science-based, responsive regulatory structure in which regulations are converted into desirable outcomes is characterized by the successful application of GRP. As a crucial aspect of health system performance and sustainability, GRP provide a means of designing and implementing sound, affordable, and efficient medical product regulation.

1.1. Objective

This document presents the high-level principles of GRP and considerations in the development and use of the regulatory instruments that underpin regulatory activities. They are designed to serve as benchmarks, guiding the Saudi Food and Drug Authority (SFDA) in the use of best practices in medical product regulation. Moreover, they assist in keeping the SFDA's regulatory systems current as the technologies and systems in which they are employed evolve. GRP's ultimate goal is to serve and preserve the public's health and the interests of patients while adhering to all applicable ethical norms.

1.2.Scope

SFDA employees are guided by GRP principles in setting appropriate requirements and formulating clear, transparent, consistent, impartial, proportionate, and timely decisions based on sound science.

2. Principles of Good Regulatory Practice

2.1. Legality

SFDA was established to achieve its objectives believed by the government to be in the public interest. It operates within and in accordance with the powers conferred by the Law of the Saudi Food and Drug Authority. The law clearly states the objectives of the SFDA, the powers of the authority, the scope of the regulated products, the regulatory, executive, and monitoring roles and duties that the authority is mandated to perform, and the provisions for making regulations.

The Board oversees the SFDA management and the conduct of its affairs and making decisions necessary to achieve its objectives. The Board may delegate some of its powers and responsibilities to different levels of the regulatory system in an explicit and clear manner.

SFDA cooperate with other regulatory authorities which is essential to manage increasingly complex and cross-jurisdictional issues, our legal framework for medical products supports various forms of cooperation, including convergence, harmonization, information- and work-sharing, reliance and recognition. This allows the exchange of good practices and may save resources and avoid duplication.

SFDA is accountable to the public, the regulated entities and the government for its actions and decisions as part of good governance and accountability. In the context of GRP, SFDA is responsible for acting according to certain standards and commitments, answerable for their actions and willing to face the consequences when standards or commitments are not met.

SFDA’s Regulatory actions and decisions are consistent with the controls provided for by the legal framework. SFDA’s Processes are in place for review of regulatory decisions, such as the grounds of product registration and pricing, in addition to internal appeals and judicial appeals of the decisions of SFDA.

2.2. Consistency

Regulation of medical products should be performed in the context of and in ways coherent with the national legal framework, general government policies, and public health policy objectives. SFDA is keen to be coherent with any regional or international agreements to which the country is a party.

SFDA avoids any overlap or conflict with existing laws and regulations, as this causes confusion, duplication of mandates and unnecessary regulatory work and increases the likelihood of noncompliance. All regulatory functions and activities are efficiently integrated to ensure the uniformity of the SFDA's regulatory system.

Consistency is upheld when the regulatory framework provides an impartial appeal to regulatory decisions. SFDA adopts an appeal policy that assures consistency among regulated parties by allowing them to appeal any regulatory decisions. Moreover, SFDA performs internal reviews and audits and sets performance-based indicators that help in ensuring consistency in the application of regulations and regulatory operations.

SFDA ensures consistency by sufficient, clear regulatory guidance, based, when possible, on international guidelines; orientation and training for staff; and regular and transparent interactions with regulated parties and other stakeholders.

SFDA established formal procedure for proper coordination during the drafting and execution of regulatory instruments and operations of medical products.

2.3. Independence

The SFDA was established under the Council of Ministers resolution no (1) dated 07/01/1424 H, as an independent body corporate with an autonomous budget that directly reports to The President of Council of Ministers. SFDA undertakes the procedural, executive, and supervisory, which was carried out by the currently existing agencies. The main objectives of the SFDA is to ensure safety of food, drug for human and animal, safety of biological and chemical substance as well as electronic medical devices that are related to human health.

Good governance and anti-corruption measures are built into SFDA's regulatory framework to avoid actual or perceived conflicts of interest, unfounded bias, or improper influence by stakeholders. SFDA operates independently, authoritatively, and impartially to maintain public

confidence.

The nomination and appointment of the SFDA's leadership are based on transparent and accountable processes. Clear rules to avoid conflicts of interest should be in place to ensure independent behavior during and after employment.

2.4. Impartiality

The SFDA works impartially, discharging its duties independently of the regulated entities (see section 3 Independence). SFDA adopted a well-written code of ethics that governs the organization's decisions and behavior and serves as a central guide and reference for employees to support day-to-day decision-making. Declarations of interest defined and reviewed for each employee to maintain integrity and impartiality. This principle extends to external researchers and other experts sitting on scientific and advisory committees that make recommendations on regulatory policy or the authorization of medical products.

As an independent body corporate the SFDA directly reports to The President of the Council of Ministers and does not engage in the activities it regulates nor be hierarchically subordinate to the institutions that perform the regulated activities. Regulatory activities and decisions are legitimate, evidence-based, and ethical. To maintain competitive neutrality, regulated parties are treated equitably, with the same principles and framework.

The SFDA is open and transparent about its decisions and decision-making process. The scientific and technical basis for regulatory oversight is objective and accessible. Public consultation and transparency throughout decision-making are well established to ensure impartiality, better regulatory outcomes, and greater public confidence in SFDA and the use of regulated medicinal products.

2.5. Proportionality

SFDA's oversight and decisions should be proportional to the risk and to its capacity to implement and enforce the decisions. A proportionate, risk-based approach allows SFDA to allocate resources where the need is greater. It also ensures that the cost of complying with a regulation is proportionate to the nature of the risk.

The principle of proportionality demands that an action not exceed what is necessary to achieve the intended objective. This principle should be applied to all elements of a regulatory system.

Regulation should be created only when necessary and should be adequate for the aim and not excessive. The content and form of regulation should be appropriate to both the issue being addressed and the risk it poses. SFDA executes its actions based on the current strategic plan (2018-2022) to meet the regulatory challenges by making informed decisions based on scientific evidence and building effective partnerships with the private sector, other government agencies, and our international partners.

The principle of proportionality also applies to the policies and processes by which regulations are made. Regulation making should be flexible and proportionate to the complexity and/or impact of the problem that it addresses. For instance, the investment department will perform a cost–impact analysis to estimate the strengths and weaknesses of a new regulation or guidance and ensure that it does not exceed our national capacity before the implementation.

Assessment of medical products should be based on a benefit–risk evaluation based on the evidence submitted on the quality, safety and efficacy or performance of the product. SFDA has specialized committees that evaluate benefits of the medical products against the identified risks. In addition, SFDA maintains a system for post-marketing surveillance and risk assessment programs to monitor and evaluate benefit–risk profile of a medicinal product and to take any actions required.

2.6. Flexibility

In order to respond to a changing environment and unforeseen occurrences, SFDA's regulatory framework and regulatory system is flexible to accept the advancement of science and technology. The SFDA's regulatory system is a meaningful, intelligible, and enforceable system and is detailed enough to provide clarity. The SFDA will also provide flexibility in responding to new technologies and innovation, as well as the changes in the regulatory environment, as well as a quick response to unexpected public health hazards. The SFDA's oversight flexibility is risk-based and doesn't risk a product's quality, safety, efficacy, or performance.

Responsiveness at the SFDA is a broader concept of flexibility. It denotes the ability to reply more rapidly than normal in particular circumstances. In a public health emergency, for example, an accelerated response or evaluation may be required.

In urgent cases such as a public health emergency, severe shortages of a medical product with no alternative, an unmet medical need or rare disorder, and medicinal products for compassionate use,

responsiveness is time-bound and temporary. The SFDA's regulatory systems are properly prepared and equipped with the tools needed to respond to and handle such circumstances (e.g. for priority review the evaluation time is reduced by 40%). Flexible and responsive provisions are essential for ensuring that the SFDA may make choices based on the best available data and benefit–risk evaluations, therefore when data is unavailable (e.g. compassionate use and conditional approval).

When regulatory responsiveness is crucial, the SFDA does consider using a risk-based approach to prioritize its tasks. The goal of the SFDA's regulatory framework flexibility and responsiveness should be to accommodate the growth of science and technology. The language of supporting regulations is usually performance-based rather than prescriptive, allowing regulated parties to utilize different techniques to achieve the same result.

The most thorough, flexible, and amendable regulatory instruments are guidelines and other guidance documents. These attributes ensure that the regulatory framework can adapt to emerging risks quickly and that future medical products can benefit from developments in regulatory science and technology.

To promote best practices, a common regulatory understanding, and international convergence while laying the groundwork for eventual guidelines in science that is rapidly evolving but has not yet matured enough to justify regulatory guidelines. When developing new guidance documents, international guidelines and standards are always taken into consideration to support international harmonization and convergence. National requirements that go above and beyond international standards must be well-founded.

Medical product regulation is complicated and ever-changing. Our regulatory systems will continue to be challenged by new technologies and behaviors, which will redraw the bounds of what can and should be governed. Before drafting regulations to address new technologies or particular activities, SFDA has the flexibility to revise or remove an existing regulation or guideline when it is no longer needed.

2.7. Clarity

Compliance with regulatory requirements and processes, as well as consistent application of those regulations, generally requires a clear understanding of what is expected. The SFDA and the regulated party are both aware of the SFDA's future activities and the consequences of non-

compliance through the publication of the annual plan for standards directorate and the penalties according to executive regulation on SFDA's website.

The SFDA's proposed regulatory instruments is easily obtained and written in a language that the intended users can understand. Collaboration with legal affairs and investment departments in evaluating the legal instrument's objectives, the target audience, other stakeholders who may be impacted, and feedback from internal and external consultations, including subject matter experts, is how this is achieved. SFDA striving to develop the drafts in clear, straightforward, precise language that is consistent with other laws and regulations, reducing the likelihood of misunderstanding and promoting compliance.

The SFDA drafts medical product regulations as an initial step, which conducts a review to identify any unclear areas and resolve any inconsistencies in the regulation or with other regulations. This step also allows us to assess and determine whether any regulatory requirements need to be updated or better integrated in order to eliminate inconsistencies, redundancy, and complexity, or to adapt to new requirements.

Interested parties, including the public, are kept informed of regulatory development and regulatory impact analysis and are invited to participate in these processes through Istitlaa (a public consultation platform), formal meetings, workshops and training in order to improve the quality and language of the SFDA and assist in the quality of the applications submitted, ensuring clear understanding of what is intended and increasing the likelihood of buy-in and future compliance.

Regulatory impact analysis is valuable for assessing the expected effects of regulatory proposals in a systematic manner. It is often undertaken by policy analysts in the regulatory department of the SFDA that is supporting the proposal, with the purpose of assisting decision-makers in their considerations. A regulatory impact analysis produces a document that summarizes the regulation proposal, potential alternatives, and the aspects and impacts of implementing the policy.

To avoid ambiguity or misinterpretation, terms are defined and are consistent with internationally recognized norms, standards, and guidelines. International standards and guidelines, as previously noted, are particularly important vehicles for promoting common regulatory language, convergence, and international cooperation.

The SFDA has applied the principle of clarity to its regulatory and administrative guidelines, which are fundamental for understanding and applying regulations. Good guidance practice ensures that guidelines are written clearly and concisely, and that they are consistent with other guidelines and

the underlying regulations. Standard templates and formats, style guides, editors, regulatory experts, and user feedback acquired through established tools (such as forms, webinars, public consultation platform, and institutional polls) are all applied.

Draft guidelines, like regulations, are submitted forward for internal and external consultation to ensure that the language is clear or that it needs to be revised to improve comprehension. The goal is using simple language and sentence structure, using illustrative examples whenever possible. When introducing or updating regulations and guidelines, particularly when they are complex, education, awareness sessions, and training are considered, along with clear timelines for adoption of new regulations and guidelines.

Regulations and supporting guidelines are reviewed periodically (every three years, according to the SFDA's Policy and Procedure for Issuing or Amending External Documents) to ensure that they reflect the SFDA's current practices and expectations, are updated to reflect developments, and, where applicable, are aligned with current international standards and guidelines. The review and revision of a guideline considers the changes that occur in other guidelines that are being revised simultaneously.

The SFDA's process and framework for making regulatory decisions and enforcing them are clear and accessible to those who are directly or indirectly affected. SFDA's oversight to have the desired effect, clarity is essential in all aspects (requirements, procedures, decisions, and communications).

2.8. Efficiency

The SFDA's regulatory system aims to achieve the desired outcomes in a reasonable amount of time and at a reasonable cost.

The SFDA's regulatory system is founded on science and evidence, as well as risk assessment and management concepts, and incorporates an international regulatory cooperation strategy into daily operations. The SFDA's regulatory framework generates sound decisions in a timely and consistent manner. Its effectiveness is determined not just by the availability of sufficient resources, but also by the type of resources available and how effectively they are used, regardless of size. The integrity of the SFDA in the entire regulatory system allows for regulatory efficiency.

The SFDA facilitates the medicinal product access, trade or international regulatory cooperation. A number of factors influence the effectiveness of regulatory control of medical products, including:

- consideration of alternatives, with input from stakeholders who would be impacted;
- regulations that are directly proportionate to the perceived risk, promote innovation, and do not restrict trade; and
- early planning for implementation and future enforcement practicalities.

The SFDA develops "strategies for education, assistance, persuasion, promotion, economic incentives, monitoring, enforcement, and sanctions" while developing new regulatory instruments and evaluating their impact. In addition to the threat of penalties, the SFDA determines which compliance strategies to establish and whether consumer awareness and market forces can be appropriately utilized.

By establishing and maintaining regulatory systems, the SFDA incurs costs. Industry and other regulated parties incur costs in order to comply with regulations, such as conducting studies, preparing application dossiers, keeping records, and paying fees — this is all part of the cost of doing business. Short and/or determinable product review timeframes result in successful revenue and scheduled orders in product availability for patients, with potentially significant positive implications for morbidity, mortality, health care expenses, and the economy. A healthy economy requires a healthy population.

Efficiency also has a favorable impact on a regulatory authority's resources, reputation, and job satisfaction, as well as a reduction in the time spent dealing with performance complaints. The SFDA's regulatory framework is more likely to be efficient because it embodies the concepts of proportionality, flexibility, and consistency, which allow resources to be allocated to the regulatory activities that are most in need.

The SFDA is always looking for ways to improve efficiency while maintaining high standards for evaluating medical product quality, safety, efficacy, and performance. Introduction or refinement of good review practices and a quality management system; greater, more effective use of information technology; consultations with industry, health care professionals, and patients on common deficiencies and how to best address them; risk-based criteria for scheduling and conducting inspections; addressing gaps in guidance; performance measurement; and regulatory cooperation (e.g. membership with ICH to raise the international harmonization of regulatory requirement) and reliance (e.g. abriged and verification pathways/procedures in evaluating the medicinal products) are all examples of this.

In a regulatory impact analysis, the SFDA looks for the most efficient, least burdensome way to achieve the regulatory purposes at the minimum amount of cost possible. The SFDA takes into account the overall burden and resources required for cumulative regulation in its regulatory approach.

KPIs are set annually to increase performance as a SFDA strategic plan is carried out as tools to measure the actual efficiency of the SFDA's regulatory instruments in order to guarantee that the anticipated benefits are realized and, if so, the direct and indirect costs.

2.9. Transparency

"Informed opinion and active cooperation on the part of the public are of the utmost importance in the improvement of the people's health," the WHO Constitution states. Patients, consumers, governments, health-care personnel, and manufacturers all benefit from transparency because it promotes public trust and confidence in the SFDA's regulation of medical products. Transparency in the SFDA's regulatory requirements and actions leads to better-informed investment decisions in both the public and private sectors, as well as a reduction in discriminatory, corrupt, or abusive practices.

All affected and potentially interested parties – domestic and foreign, public and private – have a meaningful opportunity to be informed of new or amended SFDA regulations and guidelines and to express their views before they are enacted if there is transparency. Once the guidance/regulation is drafted, it is published in Istitlaa (a public consultation platform) before issuing the final version. The SFDA's medical product regulations and guidelines are readily available and accessible to companies and the general public. The SFDA’s website contains and maintain the basic information such as:

- the roles, responsibilities, organization and contact information of the SFDA;
- access to the laws, regulations, guidelines and procedures necessary to satisfy regulatory requirements and improve the efficacy, safety and quality of medical products;
- a searchable registry of approved products;
- product information for health care professionals and patients;

- health advisories, safety information, alerts on quality or on substandard or falsified medical products, advisory notices, recalls and other time-sensitive information of public health interest;
- proposed new regulatory instruments, including periods for comment and how to provide input; and
- public assessment reports

The SFDA's assessments (both positive and negative), decisions, and actions are documented and made publicly available, along with the rationale for the decisions, ideally through the issuing of a Saudi public assessment report. This information is very valuable to a range of companies, including industry, researchers, health professionals, patients, and consumers, who utilize it for a variety of purposes. It is also essential to establish trust and confidence in SFDA's regulatory system.

The full reports of a product assessment are accessible to regulated parties. This not only provides insight into the reasoning behind comments and decisions, but it also serves as a teaching tool, aiding regulatory compliance and the quality of future submissions. The SFDA benefits from this practice because it fosters a culture of transparency and accountability at the operational and management levels. Additionally, it ensures that reports are of higher quality by ensuring that they clearly explain how such assessments led to decisions. Before publication, the manufacturer is given the opportunity to redact any trade secrets or confidential personal or commercial information.

The findings of all audits or oversight reviews of the SFDA's performance and operation are made public. Such reviews, as well as reports on performance against targets and annual reports, are essential aspects of public accountability.

The SFDA follows the Regulations For the Protection Of Confidential Commercial Information *(issued by the decision of the Minister of commerce and industry no.(3218) dated 25/03/1426h (may 4, 2005)),* TRIPS Agreement and the Kingdom of Saudi Arabia E-Government Implementation Rules, Council of Ministers Resolution No. 40 Dated 27/2/1427H (27/3/2006) statement no.8 which clarify the confidential data protected as per Confidential intellectual property, 'know-how' and trade secrets (for example formulas, programs, process or information contained or embodied in a product, unpublished aspects of trademarks, patents and similar);

commercial confidences Trade secrets or proprietary commercial knowledge, such as medical product compound or material specifications or manufacturing processes, are examples. There are protocols in place to prevent the disclosure of such information, as well as a process for resolving disputes over the proprietary nature or confidentiality of the information.

In general, national laws and regulations favor transparency and public access to the regulatory decision-making process and criteria. The SFDA's disclosure policies are in line with national laws concerning public access to government information, by establishing a database in the field of the SFDA’s work and exchanging information with local, regional and international authorities. The SFDA's procedures and contact points for obtaining information are easily accessible and clear.

The SFDA utilize transparency to adopt new, more efficient ways of conducting regulatory operations. Transparency in regulatory operations and decisions is essential for SFDA regulators, not only as a fundamental principle of GRP, but also to build trust and maximize opportunities for cooperation and reliance as part of the regulatory community's shared responsibility.