الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Good Review Practices

Version 1.0

Date of issue	07 September 2025

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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

Version	Author	Date	Comments
1.0	Drug Sector	07 September 2025	Final

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Glossary

Terminology	Definition
Applicant	The company or its representative that submits a request for marketing authorization of a new medical product, or proposes updates or variations to an existing marketing authorization
Application	A drug application includes the application form and the product file, which contains the information provided by the applicant to the SFDA for evidence-based review and marketing authorization decision.
Inquiry	A questions or clarifications posted in Saudi registration system to be responded by the applicant.
Marketing authorization	Also referred to as product license or registration certificate. A legal document issued by the SFDA that authorizes the marketing or free distribution of a pharmaceutical product in Saudi Arabia after evaluation of product's safety, efficacy and quality.
Good review practices GRevPs	Best practices that guide the process, format, content, and management of medical product reviews to ensure consistency, transparency, and high-quality outcomes.
Good review management principles and practices (GRMPs)	Good Review Management Practices involve the structured planning, organization, and allocation of resources to ensure that the review of an application is completed thoroughly, efficiently, and within the established timeframe.
Good Submission Practices	An applicant practice for any aspect related to the process, format, contents and management of application submission of medical products.
Good Regulatory Practices	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
Good review principles	The important GRevPs elements for SFDA to implement in order to achieve successful review outcomes
Product file	The electronic version of the product file.
Review	A highly complex, multidisciplinary assessment of product applications to assess whether they meet scientific and evidentiary standards for safety, efficacy and quality. It forms the scientific foundation for regulatory decisions. The first stage of the review process, validation occurs before the scientific review with the aim of ensuring completeness of the application in order to subsequently facilitate the scientific review.
Review strategy	The approach or plan of action that a reviewer or a review team uses to review a product application.
Standard operating procedure (SOP)	An authorized written procedure giving instructions for performing operations (both general and specific).

1. Introduction

Most regulatory authorities are increasingly adopting strategies to improve performance and ensure the quality of their regulatory systems. At the same time, they face ongoing challenges in reviewing medicinal products for quality, safety, and efficacy in a transparent and timely manner.

To address these challenges, an effective and efficient regulatory review process – supported by continuous improvement strategies - is essential. One such strategy is the implementation of Good Review Practices (GRevPs), which form the foundation of high-quality regulatory review.

GRevPs are a key component of broader Good Regulatory Practices. When applied alongside Good Submission Practices, they can help to enhance the quality and consistency of regulatory decisions.

1.1 Objective

This guideline was developed and adapted based on international regulatory best practices and contextualized for SFDA's purpose. It provides guidance on the principles and processes of - GRevPs related to reviewing applications submitted to the SFDA. It is not intended to provide detailed instruction on how to conduct a scientific review of these applications.

The goal of this guideline is to ensure consistently high-quality, efficient, and transparent reviews of submitted applications, thereby promoting clear, well-justified decision-making throughout the regulatory review process.

This document provides the industry with information on GRevPs used by the SFDA to optimize regulatory processes. While not directed at the industry for action, understanding GRevPs can support more transparent and collaborative interactions with the SFDA.

1.2 Scope

This guideline applies to the review of safety, efficacy, and quality data in human medicinal product applications submitted to the SFDA for marketing authorization. The concepts outlined apply to new applications, variations to existing marketing authorizations, and product renewals.

1.3 Related guidelines

This document should be read in conjunction with the latest versions of the following Drug sector documents:

- Good Regulatory Practices.
- Regulatory Framework for Drug Approvals.
- Data requirements for human drugs submission: Content of the Dossier.
- Guidance for Priority Review of Product Registration.
- Registration according to verification and abridged.
- Guidelines for variation requirements.
- Data Requirements for Herbal & Health Products Submission.
- Requirements for Formal Meeting between Drug Sector and Applicants
- Data Requirements for Human Drugs Submission
- Guidance on Publication of Assessment Reports for Medicinal products for Human Use (Saudi-PAR)

2. Good review practices (GRevPs)

GRevPs are documented best practices that guide the process, format, content, and management of medical product reviews to ensure consistency, transparency, and high-quality outcomes.

GRevPs are designed to ensure timely, predictable, consistent, transparent, and high-quality reviews, and are continuously refined to incorporate new scientific knowledge, regulatory changes, and lessons learned. Implementation of GRevPs is achieved through the development of review tools (e.g., Standard operating procedure (SOPs), checklists, and templates) and reviewer learning activities (e.g., training, mentoring, and discussions). To maintain relevance and effectiveness, GRevPs must be continuously evaluated and updated in response to new science, regulations, and experience.

3. Good review management principles and practices (GRMPs)

The principles of a good review describe elements of essential GRevPs to be implemented by SFDA to achieve successful review outcomes. Listed in alphabetical order in Table 1, the 10 key principles offer a general guide to the review process

1. Balanced	A good review is objective, unbiased, and fair. It ensures that all evidence is considered impartially, without influence from external pressures or preconceived notions.
2. Considers context	A good review considers the data and the conclusions of the applicant in the context of the proposed conditions of use and storage, and may include perspectives from experts and other regulatory authorities' analyses and decisions, ensuring that conclusions are relevant to the specific context.
3. Evidence-based	A good review is evidence-based and reflects both the scientific and regulatory state of the art. It integrates legislative, regulatory and policy frameworks with emerging science.
4. Identifies signals	A good review comprehensively identifies and highlights potential areas of concern identified by the applicant and the reviewers. It ensures that no significant issue is overlooked.
5. Investigates and solves problems	A good review involves both the applicant's and the reviewers' in-depth analyses of key scientific data, utilizing problem-solving, regulatory flexibility, risk-based analyses and synthesis skills to propose solutions and alternatives when necessary.
6. Makes linkages	A good review integrates all aspects of the application: preclinical; clinical; chemistry/biocompatibility; manufacturing; and risk management plan, into a cohesive analysis. It includes timely communication and consultation with applicants, internal/external stakeholders.
7. Thorough	A good review reflects thoroughness by ensuring an adequate follow-through, addressing all relevant issues identified by the reviewers. SFDA and reviewers may adopt a risk-based approach, prioritizing follow-up on issues that present a potential risk to patients or other critical factors.
8. Utilizes critical analyses	A good review thoroughly evaluates the scientific integrity, relevance, and completeness of the data, as well as the proposed labeling and its interpretation. This ensures the review captures the

	full scope of the applicant's submission, addressing any gaps or inconsistencies.
9. Well-documented	A good review provides a well-written and thorough report of the evidence-based findings and conclusions provided by the applicant in the dossier, and the reviewers' assessment of the conclusions and rationale for reaching a decision. It contains clear, succinct recommendations that can stand up to scrutiny by all the parties involved and can be leveraged for future review processes.
10. Well-managed	A good review applies effective project and quality management principles. This includes clearly defined steps, specific activities, and measurable targets, ensuring that the review process is efficient, well-structured, and aligned with SFDA's goals.

Table 1: 10 key principles of a good review

SFDA actively manages the review process of medicinal product applications to ensure both a positive public health impact and the efficient use of review resources. SFDA clearly defines the separate steps in the process, each with specific activities and goals, as outlined in the *"Regulatory Framework for Drug Approvals".*

The SFDA's goal is to ensure that its review and approval process is managed in a consistent and efficient manner and seeks the highest levels of quality in submitted applications, reviews, processes, and final regulatory decisions.

The principles of project management and quality management are critical to a well-functioning review process. The practices of planning and monitoring review activities, along with timely, informative communication within the drug sector and standardized processes and procedures for the reviewers, can maximize the efficiency and effectiveness of the review, ensuring both quality outcomes and timely decision-making.

A well-managed review process allows SFDA reviewers to accommodate and adequately consider unexpected events and findings. It also takes ongoing workload and public health priorities into consideration.

The relevant teams within regulatory affairs and evaluation departments are responsible for overseeing the progress of applications throughout the review process. Routine data collection and

analysis help assess the effectiveness of the review strategy, track individual application progress, and evaluate workload distribution across multiple applications. This information supports decision-making for balancing available resources and ensuring adequate capacity to handle the volume of applications under review within the specified time frame.

The application review should be performed in accordance with standardized procedures and checklists to ensure a well-written and thorough assessment of findings and conclusions. Key documents such as SOPs, checklists and approved assessment templates, play a critical role in maintaining the quality of the review process. Furthermore, decision-making processes, such as decision frameworks, time frames for completion and communication of reviews, use of external experts are well defined.

Moreover, improvements are frequently introduced to the review and decision-making process, and are achieved through mechanisms such as internal assessments of a reviews (i.e. peer reviews), internal quality audits, self-assessments, and analysis of feedback from stakeholders. Lastly, they ensure that review procedures and templates are being consistently interpreted and applied through the assessment of various inputs, such as internal and external feedback, and periodic evaluation of practices by internal and external experts.

4. Communications

The SFDA is committed to clear, transparent, and effective communication across all stages of the regulatory review process. Effective communication plays a critical role in ensuring that the review process is well-managed and that all stakeholders are informed of progress, findings, and outcomes. To support this commitment, the SFDA ensures that essential information is readily accessible to the public and stakeholders. The SFDA publishes policies, laws, guidelines, templates, checklists, review summaries, and other non-confidential and relevant information on its website. All communications are guided by regulations, standard procedures, memoranda, or other similar mechanisms.

Communication can take place within the agency (intra-agency), between agencies (inter-agency), and with external parties including industry representatives, applicants, external experts, and the general public.

4.1 Intra-agency Communications

Intra-agency communications refer to exchanges between reviewers conducted in a collaborative and efficient environment. These communications often involve consultations and coordination across various organizational units within the SFDA, such as pre- and post-marketing disciplines. Communications should be open, clear, constructive, and timely – covering review progress, findings, data interpretation, and discussions on potential solutions and actions. This collaborative process ensures that reviewers effectively share insights, leading to a more cohesive and well-informed review outcome.

4.2 Interagency Communications

Interagency communication is primarily intended to inform and support the SFDA's independent regulatory decision-making. It enables the SFDA to benefit from the experiences and expertise of other regulators while ensuring that final decisions are firmly based on its own scientific assessments and regulatory standards. The SFDA engages in various forms of interagency communication, including accessing publicly available information from stringent authorities, sharing assessment reports, participating in joint assessments, and contributing to international working groups for guideline development. These interactions enhance the SFDA's review processes while fully respecting its independent regulatory decisions. All collaborations are conducted within established confidentiality frameworks and legal agreements to ensure the protection of sensitive and proprietary information. These include formal information-sharing arrangements and procedures such as memoranda of understanding, confidentiality agreements, applicant consent, redaction of sensitive content, and non-disclosure provisions. Such measures are essential to safeguarding commercial data, trade secrets, and personal information while enabling effective regulatory cooperation.

4.3 Industry stakeholders and Applicants

Another important form of communication aimed at improving transparency is the interaction between the SFDA and industry stakeholders or applicants. This includes providing scientific advice, publishing guidelines on submission and registration requirements, and soliciting stakeholder input on draft guidelines. This approach ensures that applicants understand SFDA's current thinking and expectations, enabling them to be compliant with regulatory requirements, and submit robust data and higher-quality applications, ultimately supporting better public health outcomes

Feedback from applicants is considered not only during review of guidelines but also in other areas where SFDA seeks to enhance its processes. For example, SFDA may request feedback during application evaluations or post-market oversight. To ensure that applicants' concerns are thoroughly addressed, SFDA actively solicits their feedback through consultations, surveys, or meetings. This feedback is carefully tracked and reviewed, and any relevant issues or recommendations are addressed and incorporated into the SFDA's decision-making processes to improve the regulatory framework.

The SFDA is committed to ensuring that industry stakeholders and applicants are fully informed of the requirements, timelines, and procedures for submission, thereby enhancing the efficiency and quality of the entire review process.

4.4 External Experts and Public Communication

Communication with external experts—such as academic institutions, industry associations, patient organizations, and medical and scientific societies—provides valuable expertise and additional perspectives that can support the SFDA's review process.

These interactions help address knowledge gaps and enhance decision-making. However, maintaining confidentiality and avoiding conflicts of interest are paramount. This can be ensured through transparent procedures for managing confidential information and screening for potential conflicts.

The SFDA also maintains transparency in its public communications through web-based information, product approvals, and recalls. By keeping the public informed, the SFDA fosters trust, promotes accountability, and strengthens confidence in the regulatory process.

5. Review personnel

5.1 Reviewer expertise, competencies

Scientific reviewers should be qualified by appropriate education, training, and experience, or any combination thereof, to conduct and manage reviews in scientific disciplines relevant to the assessment of the safety, efficacy, and quality of medicinal products. Reviewers should possess both technical and scientific knowledge to understand and assess concerns that may be associated with the product under review. To build the required expertise, reviewers may participate in a various of professional development activities through which such expertise can be acquired,

including attending relevant courses, international meetings, workshops, internal lectures, mentoring programs, and collaboration with both internal and external experts

In addition to continuous professional development, scientific reviewers should hold at least a bachelor's or master's degree in a relevant discipline. Furthermore, each scientific reviewer must possess the following competencies:

- Foundational competencies: Personal attributes and behaviors developed through experience (e.g. adaptability, diligence, critical and analytical thinking, communication, etc.).
- Functional competencies: Skills gained through experience that are essential for performing Scientific and regulatory reviews (e.g. time management, teamwork, effective use of information technology, etc.).
- Technical competencies: Unique skills developed through experience and specific knowledge tailored to the specific scope of the reviewer's responsibilities and assigned tasks (e.g. regulatory requirements, risk assessment, device subject matter expertise, etc.).

By equipping reviewers with the necessary education, training, and competencies, the SFDA ensures that regulatory decisions are scientifically sound and based on up-to-date knowledge.

5.2 Reviewer Training

The SFDA ensures that scientific reviewers maintain and enhance their competencies through structured, continuous training programs, supporting high-quality, consistent, and efficient regulatory reviews in line with international best practices, evolving scientific and technological advancements, and innovations in drug development. This training addresses updates to regulatory requirements, relevant guidance documents, standards, internal policies, procedures, and business support systems. Such continuous development strengthens the SFDA's review quality and ensures that industry stakeholders can trust their submissions are evaluated in accordance with the most current scientific and regulatory standards. This contributes to enhanced predictability, transparency, and overall review efficiency, supporting timely access to safe, effective, and high-quality medical products.

Beyond formal training, reviewers are also encouraged to participate in professional development events which includes attending local, regional, national, and international meetings, conferences and workshops, presenting papers at conferences and having the opportunity to attend continuing education classes both within and outside of the SFDA.

Moreover, training needs are tailored based on the specific interests and performance areas of each reviewer, identified through reviewer's job performance and review outcomes. This personalized training approach ensures that reviewers stay highly specialized in areas critical to product submissions, improving the overall quality and relevance of their assessments for the industry.

To further strengthen internal expertise, reviewers are encouraged to share their acquired knowledge with colleagues, promoting a culture of continuous learning and collaboration. This not only builds internal knowledge but also contributes to more efficient and effective scientific and regulatory reviews. Regular evaluation of training effectiveness ensures SFDA's programs continue to meet the evolving needs of both reviewers and applicants, upholding high standards throughout the review process.

6. Review process

6.1 Review pathways

The SFDA establishes the main stages in the medicinal product review process, including application submission, screening, verification, and scientific assessment. To ensure transparency and applicant preparedness**,** the SFDA communicates its review expectations through clear guidelines, templates, checklists, and defined target timelines**,** which are publicly accessible on the SFDA website**.** These resources provide applicants with a comprehensive understanding of the requirements at each stage of the review process, promoting consistency and facilitating compliance.

Beyond published resources, the SFDA may offer pre-submission guidance, such as consultations, meetings or webinars, to address applicant queries and clarify regulatory expectations. Throughout the review process, applicants receive regular updates on their application status and any additional information requests, with established deadlines and response protocols in place to ensure timely progression.

To support the efficiency of the review process within defined timelines, applicants are responsible for submitting high-quality applications and well-prepared product dossiers. Submissions containing incomplete, deficient, redundant, or irrelevant information may result in delays or potential rejection. Therefore, applicants are strongly encouraged to thoroughly review SFDA guidelines and familiarize themselves with the relevant regulatory requirements prior to submission. The applicant can also seek SFDA advice on the dossier content and identify possible review issues and address any difficulties.

The review process depends on the eligibility of the application for different registration pathways, including the Regular Registration Pathway, Priority review, and expedited programs, which address products intended for urgent public health needs, such as breakthrough therapies and orphan drugs. Reliance approaches which incorporating and relying on the recommendations and decisions from other regulatory agencies, including Abridged and Verification pathways, may also be applied where appropriate.

This reliance can help align the review process, reduce duplication, and improve overall decision-making, For further information on reliance please refer to*"* Registration according to verification and abridged".

6.2 Review stages

There are two main stages in the process of reviewing medical product applications, which are validation and scientific review.

a) Validation review

The review process of the application starts with the validation stage, in which the application completeness and the arrangement of documents are reviewed prior to conducting the scientific review to facilitate the reviewing process. The application must comply with SFDA requirements to proceed to the scientific review.

b) Scientific review

The subdivisions of SFDA's are responsible for reviewing the safety, efficacy and quality dossiers of the medicinal products. While each subdivision follows its own internal review process, templates and checklists all are aligned with Good Review Practices. Furthermore, the SFDA reviewer will conduct a full review on a new applications and variations, and a limited

review for renewal applications. Depending on the circumstances, the reviewer may also apply an expedited or reliance review process for certain applications.

The application review is assigned to one or more scientific reviewers, from cross-scientific review departments, who assess the quality, safety, and efficacy data at each stage of the marketing authorization process, as well as any post-marketing modifications. Following the review, the reviewers convene to discuss their findings and conclusions.

The assessment report serves as the formal outcome of the review process, summarizing the reviewer's findings and justifications for the final decision. In preparing the report, the reviewer(s) must demonstrate key competencies such as critical thinking, scientific writing, and data analysis. To formulate an evidence-based opinion, the reviewer(s) consults to a range of reliable resources, including scientific literature, SFDA and international guidelines, pharmacopoeia monographs, reports from other international agencies relevant to the assigned product and other relevant references. The reviewer(s) then compiles their findings and conclusions into the assessment report, which is subsequently shared with the applicant for their response.

According to the Regulatory Framework for Drug Approval guidelines, the review process may involve multiple waves, depending on the type of submission, during which the applicant is expected to respond to and addresses SFDA’s inquiries. This collaborative and multi-step approach ensures the thorough evaluation of the product's quality, safety, and efficacy.

6.3 Decision-making

The reviewer is responsible for conducting the primary evaluation of the application, which includes assessing the overall quality, safety, and efficacy data and preparing the review report. However, if concerns arise that require more specialized knowledge, the reviewer will seek consultation from the assigned expert—an external professional temporary engaged to provide specialized expertise for the review process. The assigned expert contributes their knowledge to ensure the decision-making process is informed by the most current and accurate scientific data. This supports a high-quality, objective, and well-rounded review, particularly in areas requiring deep technical or clinical expertise such as not limited to as advanced biostatistical modeling, cutting-edge therapeutic modalities, or unconventional molecular target interactions. For highly complex cases, or when additional expertise is needed beyond the assigned expert and reviewer, the advisory committee may be consulted to provide broader perspectives.

Throughout the review process, communication with relevant SFDA departments—such as Scientific Review, Pharmacovigilance, Regulatory Affairs, and Clinical Trials— may also be sought before a final decision on the approval or rejection of the drug application is made. The findings and conclusions of the review must be documented in a comprehensive review report, and once a final decision is reached, it should be promptly communicated to the applicant.

Moreover, the post-approval actions and decisions, such as the monitoring of the drug's performance in the market, any variations, or safety concerns identified post-approval, should be well-documented and traceable. This ensures continuous regulatory compliance and safeguards public health by enabling ongoing evaluation of the drug's safety, efficacy, and quality throughout its lifecycle.

7. Publication and transparency

As part of the commitment to transparency, the SFDA publishes information relating to the evaluation of applications via Saudi public assessment reports (Saudi-PAR) database. The Saudi-PAR shall include a summary of information that has a certain value for healthcare providers, pharmaceutical manufacturers and the public. In addition, it includes the approved Summary of Product Characteristics (SPC) and Patient Information Leaflets (PILs) in Arabic and English language which is easily accessed through Saudi Drug Information System (SDI).

Publishing SFDA's assessment reports (after redacting commercially confidential information) and giving reasons for decisions to the public can build greater public awareness and confidence in SFDA's processes. For further information on redacted content, refer to *Guidance on Publication of Assessment Reports for Medicinal products for Human Use (Saudi-PAR)).*

SFDA also releases and communicates information on medicine and regulatory actions through the SFDA website. The following are examples of published information:

- List of registered human, herbal and veterinary drugs
- Approved clinical trials on drugs
- Drug safety updates:
    - Approved Risk Management Measures (RMMs)
    - Most commonly reported drugs and medication errors
    - Safety communications and safety alert

- News regarding recent drug designation and approvals
- Monthly electronic bulletin: Saudi Drug Updates (SDU)

8. References

1. Good review practices: guidelines for national and regional regulatory authorities, World Health Organization, Technical Report Series No. 992, 2015, Annex 9.
2. Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications Guidance for Industry and Review Staff, Good Review Practice, Draft Guidance, U.S. FDA, Sept 2018.
3. Good Reliance Practices in Regulatory Decision-Making: 6 high-level principles and recommendations: Draft Working Document, World Health Organization, 2020
4. Competence, Training, and Conduct Requirements for Regulatory Reviewers, IMDRF Good Regulatory Review Practices, 2017.