



Jordan Food and Drug Administration (JFDA)

Comprehensive Guideline on Good Review Practices (GRevP)

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1. Glossary

Term	Definition
Applicant	The legal entity 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	The complete dossier of information provided by the applicant to the JFDA for evidence-based review and marketing authorization decision.
Good Review Practices (GRevP)	Documented best practices for the process, format, content, and management of a medical product review to ensure consistency, transparency, and high-quality outcomes.
Registration Certificate	A legal document issued by JFDA that authorizes the marketing of a medical product in Jordan, based on the evaluation of its safety, efficacy, and quality.
Quality Management System (QMS)	The coordinated activities to direct and control an organization with regard to quality.
Regulatory Authority (RA)	The agency (e.g., JFDA) responsible for regulating medical products.
Review	A multidisciplinary, evidence-based assessment of a medical product application to determine if it meets scientific and regulatory standards.
Review Strategy	The comprehensive plan of action that a reviewer or review team uses to evaluate an application.
Standard Operating Procedure (SOP)	An authorized written procedure giving instructions for performing operations.
Validation	The initial administrative check to ensure an application is complete and admissible before scientific review begins.

2. Introduction

2.1 Document Objective

This document establishes a comprehensive framework for the implementation of Good Review Practices (GRevP) at the Jordan Food and Drug Administration (JFDA). The objective is to create systematic, consistent, and high-quality processes for the review of medical product applications. This guideline encompasses both main principles and detailed procedures intended to achieve timely, predictable, consistent, transparent, efficient, and high-quality regulatory reviews, thereby facilitating clear and well-justified decision-making throughout the regulatory review process. The objective of this document is to provide high-level guidance on the principles and processes of good review practice (GRevP). It is not intended to provide detailed instruction on how to conduct a scientific review. This document is envisioned as one building block in a set of tools and is sufficiently expandable to accommodate additional annexes or ancillary documents in the future

This guideline provides the overarching principles, governance framework, and quality measures for regulatory review and is not intended to replace detailed technical assessment procedures or scientific review SOPs

2.2 Global Context and Rationale for JFDA

Global regulatory authorities encounter significant challenges, including the complexity of novel therapies, a rising volume of submissions, and an increased public demand for timely access to medical products. The World Health Organization (WHO) advocates for the adoption of structured GRevPs as a fundamental element of robust regulatory systems. This document aims to provide the industry with pertinent information regarding the GRevPs employed by the JFDA to enhance regulatory processes.

For the JFDA, the adoption of GRevPs is critical to:

- Enhancing the scientific rigour and consistency of benefit-risk assessments.
- Fostering regulatory convergence and facilitating collaboration with international partners.
- Increasing predictability for applicants, thereby encouraging high-quality submissions.
- Strengthening public and stakeholder confidence in the decisions made by the JFDA.
- Optimizing the utilization of limited resources through efficient review management.

2.3 Definition of Good Review Practices

GRevPs are documented best practices for any aspect related to the process, format, content and management of a medical product review. The objective of GRevPs is to help achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality in both the content and management of reviews. This is done through the development of review tools (for example, standard operating procedures (SOPs) and templates) and reviewer learning activities (for example, training courses, mentoring, orientation packages and discussion sessions). To promote continuous improvement, all aspects of GRevPs should be continuously evaluated and updated.

2.4 Scope

This guideline applies to the regulatory review of safety, efficacy, and quality data for all medicinal products, encompassing both pharmaceuticals and biologicals, submitted to the JFDA for marketing authorization approvals. The principles contained within this document may also be adapted for other medical products and throughout the product lifecycle from investigational testing to new product applications, updates or variations to existing marketing authorizations and maintenance of the product.. The principles described in this guideline may also be applied, where relevant, to other regulatory review functions.

3. Principles of a Good Review

The Jordan Food and Drug Administration (JFDA) conducts reviews based on a set of ten guiding principles, which have been adapted from the World Health Organization's Good Review Practice (GRevP). These principles are designed to ensure a thorough and fair evaluation process.

1. **Balanced:** Reviews are conducted impartially, objectively and without bias, ensuring that there are no conflicts of interest involved.
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 patients, health-care professionals and other RAs' analyses and decisions.
3. **Evidence-Based:**

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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.

Identifies signals A good review comprehensively highlights potential areas of concern identified by the applicant and the reviewers.

4. Identifies Signals: The review process actively seeks to highlight potential concerns, inconsistencies, or gaps in the data.
5. Investigates and Solves Problems: Reviewers use critical thinking, regulatory flexibility, and risk-based methodologies to address scientific challenges. and synthesis skills to devise and recommend solutions and alternatives where needed.
6. Makes linkages A good review provides integrated analysis across all aspects of the application: preclinical; nonclinical; clinical; chemistry/biocompatibility; manufacturing; and risk management plan. It includes timely communication and consultation with applicants, internal stakeholders and, as needed, with external stakeholders who have expertise relevant to the various aspects of the application.
7. Thorough: A good review reflects adequate follow-through of all the issues by the reviewers.
8. Utilizes Critical Analyses: The review assesses the scientific integrity, relevance and completeness of the data and proposed labelling, as well as the interpretation thereof, presented in the application.
9. Well Documented: Every 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 could be leveraged by others.
10. Well-Managed: The JFDA applies project and quality management techniques to guarantee a timely and efficient review process, prioritizing submissions based on public health considerations and safety.

The principles outlined herein serve to ensure that the Jordan Food and Drug Administration (JFDA) maintains a stringent and efficient review process that prioritizes public health and safety.

The objective of the JFDA is to manage its review and approval processes with consistency and efficiency, while striving for the highest standards of quality in the submissions received, the reviews conducted, the processes implemented, and the final regulatory decisions made. Specific teams within the regulatory affairs department are tasked with overseeing the progression of applications throughout the review process. Regular data collection and analysis are conducted to assess the efficacy of the review strategies, monitor the status of individual applications, and evaluate the distribution of workloads among multiple applications. This data is instrumental in guiding decision-making regarding the allocation of resources and ensuring sufficient capacity to manage the volume of applications under review within the designated timeframes.

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The review of applications is to be executed in accordance with standardized procedures and checklists, ensuring a comprehensive and precisely documented assessment of findings and conclusions. Essential documents such as Standard Operating Procedures (SOPs), checklists, and approved assessment templates are pivotal in sustaining the quality of the review process. Moreover, the frameworks for decision-making, including timelines for completion, communication of reviews, and the engagement of external experts, are well-defined to further enhance the integrity of the review process.

4. Managing the Review

JFDA actively manage the process of reviewing medical product applications in order to maximize both the potential for a positive public health impact and the effective and efficient use of review resources. Regulatory authorities should clearly define the separate steps in the process, each with specific activities and targets. The principles of project management and quality management are critical to well-functioning regulatory authorities.

4.1 Project Management

Project management for the review process refers to the planning, organization, prioritization, monitoring, and resourcing necessary to achieve a complete and high-quality review of an application within a specified timeframe. Techniques used by JFDA to monitor review progress shall support interpretation of the progress of individual applications and the overall workload, and shall support decision-making with respect to balancing workload against available resources

Jordan Food and Drug Administration (JFDA) has established a comprehensive project management framework for applications to ensure a thorough and high-quality review process within defined timeframes.

- Timelines: Clear, risk-based timelines will be established and communicated for standard, priority, and reliance-based reviews. Specific timelines for particular submission types, such as National Security-listed drugs and emergency use authorizations, are detailed in separate guidelines and internal Standard Operating Procedures (SOPs). It is understood that resource constraints may influence the full execution of these timelines.
- Tracking: The use of dashboards and tracking systems, including the electronic JFDA Workflow System (eJDWS) and the e-services portal, will facilitate the monitoring of individual application progress and the overall workload.
- Resource Allocation and Team Continuity: Reviewers will be assigned based on their expertise, the complexity of the applications, and their current workload.
- Prioritization: Applications will be prioritized according to their relative importance to subject safety and public health needs, followed by the order of submission date.

Submissions for chemicals and biologicals will be organized into separate tracks. Additionally, products will be classified as either local or imported, along with a distinct track for fast-track products, with each track assigned to a different team.

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- Escalation Pathways: Clear procedures will be defined for escalating complex scientific, procedural, or timeline-related issues to both technical and higher-level committees.

4.2 Quality Management System (QMS)

The Jordan Food and Drug Administration's (JFDA) Quality Management System (QMS) for reviews is founded on the continuous "Say-Do-Prove-Improve" cycle (refer to Appendix A):

- Say What You Do: Develop and maintain Standard Operating Procedures (SOPs), review templates, and decision-making frameworks.
- Do What You Say: Implement the defined procedures, adhere to established timelines, and maintain accurate records.
- Prove It: Demonstrate consistency through internal audits, peer reviews, supervisory checks, and analysis of stakeholder feedback.
- Improve It: Regularly update procedures, templates, and training based on performance data, audit findings, and advancements in scientific knowledge.

4.3 Standard Operating Procedures (SOPs), Templates, and Checklists

- Standard Operating Procedures (SOPs) must comprehensively detail each step of the review process, from the receipt of applications to the final decision, including the roles, responsibilities, and communication protocols of involved parties.
- Templates, including those for submission evaluations, external expert assessments, and final decisions, are essential for ensuring structured, consistent, and thorough evaluations.
- Checklists, such as those for validation and submission completeness, are utilized to ensure that all required elements are accounted for and that all tasks are completed satisfactorily.
- These documents are dynamic resources and shall be updated routinely to reflect the ongoing evolution of regulatory standards and scientific advancements.

4.4 Key Elements in Defining a Review Strategy

Before initiating the comprehensive review, the review team shall formulate a specific strategy that encompasses the following considerations:

- Public Health Priority: Assessing the product's potential impact on the disease burden and healthcare system in Jordan.
- Actions of Other Regulatory Authorities (RAs): Utilizing reviews and decisions made by other authorities, while noting any variations in product, population, or indication.
- Major Scientific Questions: The early identification of critical issues pertaining to safety, efficacy, or quality that will guide the assessment process.

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4.5 Implementation of the Review Strategy

The review process is characterized as an iterative endeavor conducted by a multidisciplinary team.

- **Fundamental Principle:** The interactive engagement between applicants and the Jordan Food and Drug Administration (JFDA) is essential to ensure the efficient progression of product development.
- **Reviewer Responsibility:** Reviewers are tasked with the obligation to offer guidance on significant issues, extending beyond the specific inquiries of the applicant, in order to safeguard public health and facilitate optimal product development.
- **Information Sharing:** The JFDA fosters a culture of transparent communication from applicants and may share pertinent class-based concerns or design insights, within the limits of confidentiality, to enhance development programs.
- **Documentation:** All reviews, ranging from a simple electronic sign-off to a comprehensive report, must be meticulously documented in the official archives. The rationale for recommendations, especially those deemed critical, must be recorded clearly and communicated effectively.
- **Consistency and Support:** The JFDA is committed to supporting its critical recommendations throughout the product lifecycle, unless new scientific evidence necessitates a change. Such changes will be communicated in writing, accompanied by a rationale.

5. Communications

The Jordan Food and Drug Administration (JFDA) is dedicated to promoting clear, transparent, and effective communication throughout all phases of the regulatory review process. Effective communication is instrumental in ensuring that the review process is managed efficiently and that all stakeholders are kept informed of developments, findings, and outcomes. In alignment with this commitment, the JFDA guarantees that essential information is readily accessible to both the public and relevant stakeholders. The JFDA publishes policies, regulations, guidelines, templates, checklists, and various other non-confidential and pertinent information on its official website. All communications are conducted in accordance with established regulations, standard operating procedures or similar frameworks.

5.1 Intra-agency Communication

Product reviews are conducted in a collaborative environment. They often require expertise from and coordination with different Departments within JFDA. With Open, clear, constructive and timely communications regarding the progress of the review, review findings, differing data interpretations and discussion of possible solutions and actions.

Regular cross-disciplinary meetings and shared digital platforms, including the electronic JFDA Workflow System (eJDWS) and electronic Common Technical Document (e-CTD), are critical for aligning clinical, quality, and safety assessors.

Establishing clear communication channels is essential for ensuring efficient information flow and facilitating collaborative problem-solving.

5.2 Interagency Communication

communication is primarily aimed at informing and supporting the Jordan Food and Drug Administration's (JFDA) independent regulatory decision-making process. This communication allows the JFDA to benefit from the experiences and expertise of other regulatory agencies while ensuring that its final decisions are firmly rooted in its own scientific assessments and regulatory standards.

The JFDA will actively pursue regulatory convergence by:

- Utilizing publicly available assessment reports from Stringent Regulatory Authorities (SRAs).
- Engaging in work-sharing and joint review initiatives whenever feasible.
- Participating in international harmonization forums, such as the World Health Organization (WHO) and the International Council for Harmonisation (ICH), and contributing to international working groups for guideline development.
- All communications will be conducted under confidentiality agreements to protect proprietary information. Information-sharing arrangements and procedures have been used to ensure confidentiality of commercial data, trade secrets and personal information.

5.3 Communication with Applicants and Industry Stakeholders

The Jordan Food and Drug Administration (JFDA) is committed to providing scientific guidance, establishing comprehensive guidelines for submission and registration requirements, and petitioning input from stakeholders regarding draft guidelines. This methodology ensures that applicants are well-informed about the JFDA's current perspectives and expectations, thereby facilitating compliance with regulatory requirements and the submission of robust data alongside high-quality applications. Ultimately, this initiative supports enhanced public health outcomes.

To foster transparent dialogue, the JFDA implements the following strategies:

- Pre-submission Meetings: These meetings are conducted to discuss developmental plans and regulatory expectations.
- Scientific Advice for complex, value-added, or innovative products.
- Structured Feedback: The JFDA clearly articulates issues, recommendations, and responses in writing, along with a rationale to enhance understanding.
- Timely Status Updates: Applicants receive regular updates to keep them informed about the progress of their reviews.
- Meeting Management to address any issues that may arise during the review process.

5.4 Engagement with External Experts

JFDA may seek input from external experts where specialized scientific or technical expertise is needed to support the assessment of an application or a specific scientific issue arising during review. External expert input may be sought when the required expertise is not sufficiently available internally, or when additional specialized opinion is needed to support scientific evaluation.

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External experts shall provide **advisory scientific input only** and shall not replace the responsibilities of the designated internal reviewer or assessor. The internal reviewer remains responsible for conducting the review, documenting the assessment, and preparing the review conclusions and recommendations in accordance with applicable JFDA procedures.

All engagement of external experts shall be subject to applicable confidentiality and conflict of interest requirements, and their role, scope of input, and any advice provided shall be appropriately documented and managed in accordance with JFDA procedures.

Committee members shall have a role distinct from that of external experts.

Committee members participate in committee deliberation and in the recommendation or decision-making process in accordance with the mandate of the committee, whereas external experts provide specialized advice where needed. Committee members shall not be treated as external reviewers in a manner that blurs accountability or bypasses the structured assessment pathway.

The governance, recommendation, and decision-making accountability of committees and final decision-making bodies shall remain with the legally and/or administratively designated body in accordance with the applicable legal and procedural framework. Advisory consultants may be engaged to provide specialized expertise within JFDA committees, such as those focusing on safety, efficacy and quality aspects. These interactions help address knowledge gaps and enhance decision-making.

A comprehensive process for screening and managing any conflicts of interest is mandatory.

5.5 Communication with the Public

To improve transparency and foster public trust, the JFDA will publish, in a timely manner:

- Safety alerts and recalls.
- Lists of approved products.
- Guidelines and regulatory decisions.
- other open-source data's according to JFDA transparency policy

6. Review Personnel

6.1 Reviewer Expertise, Competencies, and Training

In order to ensure rigorous scientific review, it is imperative that reviewers possess appropriate qualifications, including relevant education, training, and experience. They must demonstrate both technical and scientific insights to effectively understand and evaluate potential concerns related to the products under assessment. Reviewers are required to embody a comprehensive range of attributes, which include:

- **Behavioral Competencies:** The personal attributes, professional behaviors, and practical work skills required to support effective scientific and regulatory review, including adaptability, diligence, critical and analytical thinking, effective

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communication, time management, teamwork and a commitment to ethical standards.

- **Technical Competencies encompassing:**
 - **Scientific Expertise** According to JFDA competency framework - external expert : Professional qualifications in relevant fields such as medicine, pharmacy, toxicology, and associated disciplines. , and proficient use of information technology
 - **Regulatory Knowledge:** A well-informed understanding of national regulations and legal frameworks, as well as regional and international guidelines, including, but not limited to, ICH, EMA, and FDA standards.
 - **Professional Development:** Reviewers are strongly encouraged to enhance their expertise through ongoing education and training. This can include participation in international harmonization initiatives, attending scientific conferences, engaging in internal lectures, joining mentoring programs, and collaborating with both internal and external experts, as well as other relevant professional development activities. Continued development improves the quality of reviews and ensures that industry stakeholders can trust that their submissions are evaluated against the most current scientific and regulatory standards.

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.

By equipping reviewers with the requisite education, training, and competencies, the JFDA ensures that its regulatory decisions are scientifically sound and grounded in current knowledge. This approach contributes to increased predictability, transparency, and overall review efficiency, ultimately supporting timely access to safe, effective, and high-quality medical products.

6.2 Critical Thinking and Decision-Making

Reviewers must engage in objective, evidence-based critical thinking. It is imperative that data is not accepted at face value; instead, its validity, relevance, and significance must be rigorously assessed in accordance with established scientific references and guidelines. Regulatory decisions should be grounded in the best available scientific evidence, accompanied by a well-documented rationale that clearly explains the process through which the benefit-risk profile has been evaluated.

7. Review Process

Key Elements in Defining a Review Strategy

Before initiating the scientific review, JFDA shall define a review strategy that may be shaped by the following considerations:

a) Public health priority of the medical product application

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Each medical product application poses unique and varied scientific questions, challenges, and opportunities for public health in Jordan, and these, in turn, determine the public health priority of the application. Given the limitations of resources within JFDA, prioritization based on public health needs may be helpful in setting and communicating review timeframes, determining the extent of involvement of management and other regulatory authorities, assigning resources to the review team, identifying the need for public input, and planning other review activities.

b) Understanding other regulatory authorities’ action on the application

The use of reviews and decisions reached by other regulatory authorities is expected to become increasingly important in making the review process more efficient in the face of pressures on resources. To implement the optimal and consistent use of other regulatory authorities’ reviews and decisions, the development of a policy framework and review strategy is critical. Such strategies should consider both the use of publicly available information, for example decisions, review reports, and summaries, and confidential information obtained directly from applicants or other regulatory authorities, where applicable. Clear direction and support from senior management on the use of regulatory outputs from other regulatory authorities is also essential. The goal is to consider how to achieve efficiencies and improve the quality of the review through the use of other regulatory authorities’ reviews and/or decisions in appropriate situations. When considering another regulatory authority’s action, JFDA shall take into account whether there are differences in the product reviewed, for example formulation or final container presentation, and any differences in the proposed indications or conditions of use in the Jordanian population.

c) Understanding specific intrinsic and extrinsic factors

Whether or not a medical product is authorized by another regulatory authority, the review should focus on available information that may be clinically relevant to the population of Jordan where the product is being authorized. Such information could include identification of potential differences in genotypes and phenotypes, disease manifestation, and comparison of available alternatives and medical practice in both the study population relevant to the application and the Jordanian population.

d) Identification of major scientific questions and their possible resolution

Early identification of complex, precedence-setting, or high uncertainty issues in the application is important and can lead to faster and more efficient resolution. Major scientific application-specific questions are likely to relate to product safety, efficacy, or quality. If problems are identified early, reviewers can

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formulate a plan to first review the data in the application that are of greatest relevance to these problems, JFDA can develop a plan to seek external advice if desirable, or, if the application does not permit a conclusion about benefits and risks, JFDA can avoid spending time and resources altogether. Understanding what information is needed to reach an acceptable level of certainty to resolve scientific questions and meet regulatory standards for marketing authorization, versus what information can be collected in the post-marketing period, is an important aspect of regulatory decision-making

Jordan Food and Drug Administration (JFDA) defines clear and structured stages for the medicinal product review process, beginning from application submission and continuing through screening, verification, and comprehensive scientific assessment. To promote transparency and ensure applicant preparedness, the JFDA provides publicly accessible guidelines, templates, checklists, and defined target timelines. These resources enable applicants to fully understand the requirements at each stage, supporting consistency and facilitating regulatory compliance.

Applicants play a critical role in maintaining the efficiency of the review process. They are expected to submit high-quality applications supported by complete, well-organized, and relevant dossiers. Submissions that are incomplete, inconsistent, or contain unnecessary information may lead to delays or possible rejection. Applicants are therefore strongly advised to thoroughly review JFDA guidelines, ensure familiarity with the relevant regulatory frameworks, and, where necessary, seek JFDA scientific or regulatory advice to clarify dossier expectations and anticipate potential review challenges.

7.1 Review pathways

The review pathway is determined by eligibility criteria and may include the Regular Registration Pathway, Priority Review, or Expedited Programs designed for urgent public health needs, such as national security medicines or emergency-use products. Reliance pathways may also be considered when appropriate. These reliance approaches leverage assessments conducted by other stringent regulatory authorities, reducing duplication of effort and enhancing regulatory alignment. Further guidance on reliance pathways is published by JFDA.

7.2 Review Stages

The medical product review process consists of two primary stages: Validation and Scientific Review.

a) Validation Review

The review process begins with a validation stage, during which the application's completeness, structure, and document arrangement are assessed. This administrative

evaluation ensures that the dossier complies with regulatory requirements before transitioning to the scientific review phase. Applications that do not meet the required standards will be rejected.

b) Scientific Review

During the scientific review, specialized JFDA subdivisions evaluate the product's quality, safety, and efficacy. Each subdivision follows structured internal procedures based on Good Review Practices, using harmonized templates and checklists. Reviewers conduct a full assessment for new applications and evaluate relevant sections for variations or renewal applications. Where justified, expedited or reliance-based review models may be applied.

Applications are typically assigned to one or more scientific reviewers from cross-disciplinary departments —such as Pharmacovigilance, Regulatory Affairs, Validation, and Pricing—to ensure alignment across all regulatory considerations.

These reviewers thoroughly analyze all technical and clinical data, consult relevant resources—including scientific literature, national and international guidelines, pharmacopoeias, and assessments from other regulatory agencies—and document their conclusions in an assessment evaluation template. This report outlines the evaluators' findings, supporting evidence, and the rationale for the proposed regulatory decision.

In line with the Regulatory Framework for Drug Approval, the review process may involve several rounds of communication. During these rounds, applicants are required to respond to questions or address any deficiencies identified by the reviewers. The final assessment decision from each department is communicated to the applicant through the electronic JFDA Workflow System (eJDWS) for their feedback.

This iterative process helps ensure a thorough and evidence-based evaluation of the product's safety, efficacy, and quality.

7.3 Decision-Making

The primary reviewer is responsible for conducting the initial scientific evaluation and preparing the assessment evaluation template. When issues arise that require deeper technical expertise, the reviewer may consult a designated expert, an external committee specialist engaged to provide advanced knowledge in specific areas. For highly complex or exceptional cases, an advisory higher committee may be convened to provide broader scientific and regulatory perspectives.

Post-approval, regulatory oversight continues through monitoring activities, including the assessment of variations, pharmacovigilance signals, and any post-marketing safety or quality concerns. These ongoing evaluations ensure that approved products remain compliant and continue to meet the required standards of safety, efficacy, and quality throughout their lifecycle. Further guidance on post-approval changes is published by JFDA.

The designated internal reviewer or assessor is responsible for conducting the scientific assessment and preparing the assessment report, including the review conclusions and recommendations.

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Where additional specialized expertise is needed, JFDA may seek external expert input. External experts provide advisory input only and shall not replace the responsibilities of the designated internal reviewer or assessor. Their engagement shall be managed in accordance with applicable JFDA procedures, including confidentiality and conflict of interest requirements.

Committee members and external experts shall have distinct roles. Committee members participate in committee deliberation and recommendation or decision-making within the committee’s mandate, while external experts provide specialized scientific advice where needed. Committee members shall not be treated as external reviewers in a way that blurs accountability or bypasses the structured assessment pathway.

Final decision-making accountability shall remain with the legally and/or administratively designated body.

8. Transparency and Documentation

Transparency and Documentation in Regulatory Review

Transparency and comprehensive documentation are fundamental principles of the JFDA's regulatory review framework. All activities conducted throughout the review lifecycle—including validation, scientific assessment, internal consultations, and decision-making—must be systematically and accurately documented in a traceable and auditable manner.

Each regulatory decision must be backed by a clear, evidence-based rationale. In particular, decisions to reject, suspend, or conditionally approve an application must be fully justified, with explicit references to identified deficiencies, applicable regulatory requirements, and scientific considerations. These rationales should be clearly articulated in formal assessment reports and communicated to applicants promptly and in an organized manner to ensure clarity and facilitate any necessary corrective actions.

To uphold procedural fairness and accountability, an appeals and reconsideration mechanism for rejection decisions will be available to applicants. This mechanism allows applicants to formally challenge regulatory decisions by submitting additional data, clarifications, or justifications within defined timelines. Appeals are reviewed by a qualified committee who are independent of the original assessment to ensure objectivity and impartiality.

9. Continuous Improvement

The JFDA is dedicated to the continuous enhancement of its regulatory review system to ensure efficiency, scientific rigor, and alignment with evolving international standards. Continuous improvement is achieved through a structured, data-driven approach that includes the following key components:

- Performance Monitoring and Evaluation: The JFDA conducts regular performance assessments, including annual reviews against predefined key performance indicators (KPIs) such as review timelines, workload distribution, consistency of decisions. These evaluations support informed decision-making and resource optimization.
- Stakeholder Feedback Mechanisms: Systematic collection and analysis of feedback from applicants and healthcare stakeholders are essential for identifying areas for

improvement. Feedback is used to refine guidelines, enhance communication practices, and improve the overall applicant experience.

- International Benchmarking: The JFDA regularly benchmarks its review processes, decision-making frameworks, and performance outcomes against those of leading international regulatory authorities. This comparative analysis supports the adoption of best practices and promotes regulatory convergence.
- Post-Approval Impact Assessment: The impact of regulatory decisions is monitored through post-marketing surveillance, pharmacovigilance data, and lifecycle management activities. Lessons learned from post-approval monitoring inform future regulatory decisions and contribute to the continuous refinement of the system.

Through these measures, the JFDA ensures that its regulatory framework remains adaptive, transparent, and responsive to scientific advancements and public health priorities.

10. References

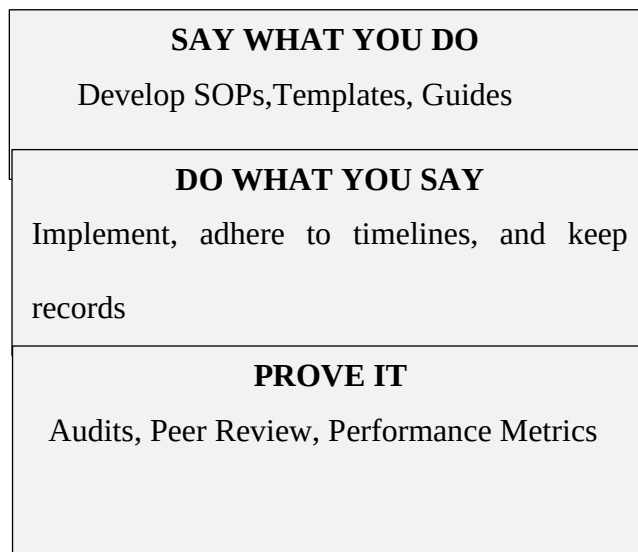
1. World Health Organization (WHO). Technical Report Series, No. 992, Annex 9: Guidelines on Good Review Practices.
2. United States Food and Drug Administration (US FDA). Manual of Policies and Procedures (MAPP) 6030.9.

11. Related guidelines

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

- Guidelines for new submission requirements.
- Data Requirements for Chemical entities evaluation
- JFDA GOOD RELIANCE PRACTICE (GReIP) GUIDELINE
- Transparency and information dissemination policy
- JFDA competency framework

Appendix A: JFDA GRevP Quality Cycle



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Document Title : (JFDA) Comprehensive Guideline on Good Review Practices (GRevP)	

IMPROVE IT

Update tools, learn from experience, and train staff

Appendix B: Template for a Review Strategy Plan

- Application ID:
- Product Name:
- Therapeutic Area:
- Public Health Priority: [High/Medium/Standard]
- Proposed Review Timeline:
- Review Team Members & Roles:
- Summary of other RA actions: [e.g., Approved in EMA/FDA, Key concerns]
- Major Identified Scientific Questions:
- Plan for External Consultation: [Yes/No - If yes, details]
- Communication Plan with Applicant: [Planned meetings, etc.]