قـرار وزاري رقم (342 / 2025) لسنة 2025

بشأن الإطار التنظيمي لآلية تسجيل الأدوية البشرية

وزيـر الصحة:

- بعد الإطلاع على أحكام المرسـومين بقانون ونظام الخدمة المدنية وتعديلاتهما.
- وعلى أحكام القانون رقم 28 لسـنة 1996 في شـأن تنظيم مهنة الصـيدلة وتداول الأدوية والمعدل بالقانون رقم 30 لسـنة 2016 ولائحتهما التنفيذية.
- وعلى القرار الوزاري رقم (341) لسـنة 2025 بشـأن تسـجيل الأدوية البشرية وتداولها.
- وبناءً على مقتضـيات مصـلحة العمل، وما عرضـه علينا السـيد/ وكيل الوزارة.

قـرر

مـادة أولى

يعتمد الإطار التنظيمي لآلية تسجيل الأدوية البشرية المتضمن إجراءات وشروط تسجيل وتقييم الأدوية البشرية والإطار الزمني المحدد للتقييم وفقاً للمسارات التنظيمية المعتمدة الموافق لهذا القرار (Regulatory Framework For Drug Approval).

مـادة ثانيـة

يبلغ هذا القرار من يلزم لتنفيذه، ويعمل به اعتباراً من تاريخ صدور القرار، وينشر في الجريدة الرسمية.

وزيـر الصحـة

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الموافق : 22 ديسمبر 2025م

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REGULATORY FRAMEWORK FOR DRUG APPROVAL

الإطار التنظيمي لآلية تسجيل الأدوية البشرية

ملحق القرار الوزاري رقم (342) لسنة 2025

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recent years towards optimizing its regulatory processes, ensuring timely access to safe, effective, and high-quality medicines while upholding rigorous standards of evaluation. This document serves as a reference for industry stakeholders, regulatory professionals, and healthcare decision-makers engaged in the development, submission, and review of marketing authorization applications in Kuwait.

Scope

This framework outlines the key regulatory pathways and approval mechanisms currently implemented in Kuwait for human medicinal products. It provides comprehensive guidance on both review pathways and approval processes to ensure clarity and consistency in regulatory submissions and evaluations.

Review Pathways

Medicine and Medical Products Registration and Regulatory Administration recognizes multiple types of regulatory submissions, each with defined eligibility criteria and specific documentation requirements. Review pathways determine the timeline and procedural approach used by Kuwait's regulatory authority to assess registration applications. The following provides a detailed classification of the available review pathways:

Standard Pathway

The standard submission pathway involves a comprehensive evaluation of the product based on a complete Common Technical Document (CTD/eCTD). This route requires a full scientific assessment by the authority.

Eligibility Criteria:

This pathway is applicable to all medicines that meet the criteria set forth in the Ministerial Decree for Registration of Pharmaceutical Medicinal Products.

Submission Requirements:

A complete CTD/eCTD submission, including Modules 1–5.

Timelines:

Initial Assessment	90 working days from the date of a valid submission
R1 response assessment	40 working days from the date of receiving the first response
R2 response assessment	40 working days from the date of receiving the second response
R3 response assessment	40 working days from the date of receiving the third response

Clock Stop – A maximum clock stop period of 90 calendar days will be granted to the applicant to respond to the requirement issued by the Medicine and Medical Products Registration and Regulatory Administration.

Fast Track Pathway

The Fast Track review process aims to expedite the registration of new drug products, to ensure fast and timely access to patients with minimal delays. Request for fast track along with supportive documents must be submitted to Medicine and Medical Products Registration and Regulatory Administration by the local agent on behalf of the marketing authorization holder. Upon submission, Medicine and Medical Products Registration and Regulatory Administration will evaluate the request within 10 working days. If approved, the applicant must submit a complete technical dossier for further review.

This review pathway may follow a simplified pathway for

Glossary

Term	Definition
Gulf Health Council (GHC)	The Gulf Health Council (GHC) is a specialized health organization established under the umbrella of the Gulf Cooperation Council (GCC). It operates as a regional regulatory and coordination body for health-related initiatives among member states, which include Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain, and Oman.
Clock Stop	Clock Stop refers to the period during which the regulatory authority halts the review timeline to await additional information or responses from the applicant (i.e., maximum calendar days allowed for the applicant to respond before the clock resumes).
Common Technical Document (CTD)	The CTD is a standardized format developed by the International Council for Harmonization (ICH) for submitting applications for the registration of medicines. It organizes data into five well-defined modules (module 1–5) covering administrative information, quality, non-clinical, and clinical information.
Drug	Any substance or combination of substances intended to be used in the diagnosis, treatment, mitigation or prevention of disease in man or to restore, correct or modify physiological functions
Electronic Common Technical Document (eCTD)	The eCTD is the electronic version of the Common Technical Document. It retains the same modular structure but allows digital submission lifecycle management, and electronic navigation of documents.
Emergency Use Authorization (EUA)	Emergency Use Authorization (EUA) is a regulatory mechanism that allows the use of unapproved medical products or unapproved uses of approved products during a declared public health emergency.
Ministry of Health (MOH) – Kuwait	The Ministry of Health is the central governmental authority responsible for regulating, planning, and overseeing healthcare services in the State of Kuwait.
Response Assessment R(1), (2), (3)	R refers to the assessment of MEDICINE AND MEDICAL DEVICE REGISTRATION AND REGULATORY ADMINISTRATION to responses to requirements or deficiencies issued regarding a product after the first assessment
Stringent Regulatory Authority (SRA)	SRAs include USFDA, EMA, Health Canada, MHRA, PMDA, Swiss medic, TGA and other regulatory authorities that are recognized by the World Health Organization (WHO) as operating at Maturity Level 4 or is a WHO listed Authority (WLA). These authorities typically demonstrate advanced regulatory capacity and are often involved in mutual recognition agreements.

Introduction

This document presents a comprehensive overview of the regulatory framework governing the evaluation, review, and approval of pharmaceutical drug products in the State of Kuwait. It aims to provide clear guidance on the review pathways and approval processes available for product registration. The review pathways include Standard, Fast Track, Priority, Expedited, Biosimilar, Emergency Use, Gulf Health Council pathway and Rolling Pathways, while the approval processes include Standard Approval, Conditional Approval and Emergency Use Authorization (EUA). The document is designed to align with international regulatory best practices and to assist stakeholders in navigating the Kuwait regulatory systems. Medicine and Medical Products Registration and Regulatory Administration has made significant strides in

alternative.

Eligibility Criteria:

1. The product must be authorized by SRA or Gulf Health Council (GHC) prior to submission.
2. Drugs intended for the treatment of serious or life-threatening conditions.
3. Products addressing an unmet medical need with no registered alternatives available in the local market.
4. Product requested by the CMS or included in the CMS drug shortage list.

Submission Requirements:

16. A formal request must be submitted by CMS.
17. Certificate of a Pharmaceutical Product (CPP) from Health Authority in Country of origin.
18. Letter of appointment from the Marketing Authorization Holder stating the local agent in Kuwait.
19. A valid Manufacturing License (ML), Good Manufacturing Practice (GMP) certificate, and Site Master File (SMF) must be submitted (in case the site is not registered).
20. Certificate of Analysis (COA) of the finished product.
21. Finished product specification with method of analysis.
22. Confirmation of the active substance manufacturer, along with a valid Good Manufacturing Practice (GMP) certificate for the respective site.
23. Outer pack, label & Patient Information Leaflet (PIL).
24. Long term stability data conducted in accordance with ICH guidelines for Kuwait's climatic zone (Zone IV).
25. Accelerated stability studies conducted for 6 months in accordance with ICH guidelines.
26. Confirmation regarding primary packaging material, pack size, shelf life and storage condition intended for Kuwait market.
27. Clinical & non-clinical studies for innovator products.
28. Bioequivalence studies for generic products (If applicable) and comparative quality, non-clinical ,and clinical studies for biosimilars.
29. Confirmation regarding the Marketing Authorization Holder (MAH), manufacturer, primary & secondary packager and batch releaser for Kuwait market.
30. Commitment letter to complete all the CTD/eCTD file registration requirements within one year.

Timelines:

Initial Assessment	10 working days from the date of a valid submission
R1 response assessment	10 working days from the date of receiving the first response
R2 response assessment	10 working days from the date of receiving the second response
R3 response assessment	10 working days from the date of receiving the third response

Clock Stop – A maximum clock stop period of 30 calendar days will be granted to the applicant to respond to the requirement issued by Medicine and Medical Products Registration and Regulatory Administration.

Expedited Pathway

This expedited review process is designed to accelerate the evaluation of drugs intended for the treatment of serious or life-threatening conditions, or those that address unmet medical needs where no alternative is currently available in Kuwait market.

Locally based MAH or manufacturers may also utilize this pathway to contribute to the development of the national pharmaceutical products that are approved by a Stringent Regulatory Authority (SRA).

Eligibility Criteria:

To qualify for the Fast Track review pathway, the product must be authorized by SRA and falls under the following categories:

1. Innovative products, which include:

- New Chemical Entity (NCE)
- Biological products
- Novel vaccines, including next-generation vaccines, those developed using innovative platforms, or containing new active substances or technologies.
- New indication or dosage form of already approved innovative products

2. Orphan drug products:

An orphan drug is defined as a medicinal product intended for the diagnosis, prevention, or treatment of a rare disease or condition. According to the World Health Organization (WHO), a disease is considered rare when it affects less than 0.1% of the population. Orphan drugs are often developed for conditions that are life-threatening or chronically debilitating, and their development is supported through regulatory incentives to ensure the availability of treatments for small patient populations.

3. Advanced therapy medicinal products (ATMPs) as:

- Gene Therapy Medicinal Products (GTMPs)
- Somatic Cell Therapy Medicinal Products (sCTMPs)
- Tissue-Engineered Products (TEPs)
- Combined ATMPs

Submission Requirements:

1. A complete CTD/eCTD submission, including Modules 1–5.
2. Orphan designation products may require a less comprehensive data package for registration purposes. Applicants should submit:

- Scientific justification for orphan status.
- Description of the medicinal product, its intended indication, and therapeutic benefits.
- Available clinical and non-clinical data, although less comprehensive data may be accepted during evaluation.
- A plan for continued development of safety, efficacy, and quality data.

Timelines:

Initial Assessment	30 working days from the date of a valid submission
R1 response assessment	30 working days from the date of receiving the first response
R2 response assessment	30 working days from the date of receiving the second response
R3 response assessment	30 working days from the date of receiving the third response

Clock Stop – A maximum clock stop period of 30 calendar days will be granted to the applicant to respond to the requirement issued by Medicine and Medical Products Registration and Regulatory Administration.

Priority Pathway

A priority review may be granted for requests submitted by Central Medical Store (CMS) for Ministry of Health (MOH) Kuwait, for drugs intended for the treatment of serious or life-threatening conditions, or those that address unmet medical needs and without any available registered

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designed to rapidly evaluate and authorize the use of medical products during a declared public health emergency (i.e., pandemic, outbreak, bioterrorism event). It allows the temporary use of such products when no adequate, approved, and available alternatives exist.

Eligibility Criteria:

To qualify for the Emergency Use pathway, the product must have obtained prior approval from a recognized SRA. The following conditions must be met:

1. A declared public health emergency.
2. The product may include vaccines, drugs, biologics, or diagnostics that fall under one of the following:
   - o Unapproved products, or
   - o Approved products being used for unapproved indications
3. There must be an urgent medical need, and the product must meet both of the following:
   - o Addresses a serious or life-threatening condition related to the declared emergency.
   - o No adequate, approved, and available alternatives are currently accessible.
4. There must be preliminary evidence of benefit.
5. The product must meet acceptable quality and GMP standards to ensure safety during emergency use.
6.

Submission Requirements:

The following documents should be included in the submission dossier:

1. Module 1: Complete set of regional administrative and product-specific documents.
2. Proof of approval from the national regulatory authority in the country of origin.
3. Evidence of prior authorization or approval from a recognized SRA.
4. Product fact sheet.
5. Evidence of effectiveness.
6. Preclinical study reports.
7. Detailed and updated clinical study data.
8. Ongoing submission of updated data (i.e., safety and efficacy).
9. Summary of clinical studies, including participating countries and number of volunteers involved in each study.
10. Safety and efficacy reports demonstrating a favorable benefit-risk profile.
11. Information on chemistry, manufacturing, and controls (CMC).
12. List of manufacturers for the active ingredient(s) and finished product.
13. A valid GMP for each manufacturing site.
14. Confirmation regarding the pack size to be registered in Kuwait.
15. Confirmation of container closure system (primary and secondary packaging material) to be registered in Kuwait.
16. Confirmation of shelf life and storage conditions.
17. Long term stability data for three recent production batches, covering the full proposed shelf life, and conducted in accordance with ICH guidelines for Kuwait's climatic zone (Zone III/IV).
18. Accelerated stability studies for the same three batches, conducted for 6 months in accordance with ICH guidelines.

pharmaceutical sector. This expedited designation does not compromise the scientific standards, or the level of evidence required for product approval.

Eligibility Criteria:

1. Drugs intended for the treatment of serious or life-threatening conditions.
2. Products addressing an unmet medical need with no registered alternatives available in the local market.
3. If the application does not meet the criteria outlined in points 1 or 2, only submissions made by locally based MAHs or manufacturers will be accepted to support national pharmaceutical advancement.

Submission Requirements:

1. Applicants must include a justification request outlining the rationale for assigning the product to the expedited review pathway.
2. A complete CTD/eCTD submission, including Modules 1–5.

Timelines:

Initial Assessment	60 working days from the date of a valid submission
R1 response assessment	30 working days from the date of receiving the first response
R2 response assessment	30 working days from the date of receiving the second response
R3 response assessment	30 working days from the date of receiving the third response

Clock Stop – A maximum clock stop period of 30 calendar days will be granted to the applicant to respond to the requirement issued by the Medicine and Medical Products Registration and Regulatory Administration

Biosimilar Pathway

This review pathway is intended for biosimilar products that demonstrate high comparability to a reference (originator) biological product that is already approved by a recognized SRA. The goal is to provide a streamlined evaluation process for biosimilars that meet established international standards.

Eligibility Criteria:

To be eligible for this pathway, the biosimilar must have obtained prior approval from a recognized SRA or GHC. This pathway applies to biosimilars that ensure robust comparability data demonstrating similarity to the reference biological product including quality, non-clinical and clinical data.

Submission Requirements:

1. A complete CTD/eCTD submission, including Modules 1–5.

Timelines:

initial Assessment	60 working days from the date of a valid submission
R1 response assessment	30 working days from the date of receiving the first response
R2 response assessment	30 working days from the date of receiving the second response
R3 response assessment	30 working days from the date of receiving the third response

Clock Stop – A maximum clock stop period of 90 calendar days will be granted to the applicant to respond to the requirement issued by Medicine and Medical Products Registration and Regulatory Administration.

Emergency Use Pathway

The Emergency Use Review is a regulatory pathway

criteria

- Present a submission schedule with planned data delivery dates
- Inform the Medicine and Medical Products Registration and Regulatory Administration whether they have submitted a request for this designation to other regulatory authorities and the outcome of this request

2. Submit data in CTD/eCTD format, including:
- Application form
- Module 2 overview
- Clinical stages of development including clinical trial phase and clinical trial registration number, If any (i.e., EudraCT or ClinicalTrial.gov)
- Complete sections (i.e., full CMC, nonclinical, or clinical modules)

3. Provide a rolling submission plan detailing:
- Data to be submitted in each cycle
- Timelines for future data availability

4. Ensure each review cycle allows for a defined review period (i.e., 90 working days) per module or data set
5. Include the final full dossier submission once sufficient data has been reviewed

Timelines:

Initial Assessment	90 working days from the date of a valid submission
R1 response assessment	90 working days from the date of receiving the first response
R2 response assessment	90 working days from the date of receiving the second response
R3 response assessment	90 working days from the date of receiving the third response

Clock Stop – A maximum clock stop period of 90 calendar days will be granted to the applicant to respond to the requirement issued by Medicine and Medical Products Registration and Regulatory Administration.

GHC-Approved Drug Pathway

This pathway is designated for pharmaceutical products that have already received approval from the Gulf Health Council (GHC) under the centralized registration procedure. It aims to streamline national registration by leveraging the scientific assessment and approval conducted at the GCC level, while ensuring full compliance with local regulatory requirements.

Eligibility Criteria:

To qualify for this pathway, the product must hold a valid GHC approval.

Submission Requirements:

1. A valid GHC registration certificate issued by the GHC.
2. The dossier submitted to the Medicine and Medical Products Registration and Regulatory Administration must be identical to the one submitted to the GHC.
3. A complete CTD/eCTD submission, including Modules 1–5.

Timelines:

Initial Assessment	30 working days from the date of a valid submission
R1 response assessment	30 working days from the date of receiving the first response
R2 response	30 working days from the date of

19. Benefit-risk assessment report.
20. Pharmacovigilance and reporting requirements to be submitted to Kuwait on monthly basis.
21. Detailed risk management plan.
22. Information about quantity of finished product on hand and the surge capabilities of the manufacturing sites.

Timelines:

Initial Assessment	7 working days from the date of a valid submission
R1 response assessment	7 working days from the date of receiving the first response
R2 response assessment	7 working days from the date of receiving the second response
R3 response assessment	7 working days from the date of receiving the third response

Clock Stop – A maximum clock stop period of 15 calendar days will be granted to the applicant to respond to the requirement issued by Medicine and Medical Products Registration and Regulatory Administration.

Rolling Pathway

A rolling review is a regulatory pathway that allows for the submission and evaluation of data in stages (as they become available) instead of waiting for a complete data package at once. This process speeds up the assessment timeline, especially useful in emergencies or for high-priority medicines. The product must be justified as eligible for rolling review based on its designation as a breakthrough therapy or equivalent accelerated development status. Products submitted through this pathway must be under review by SRA.

Eligibility Criteria:

To be eligible for rolling review, a product should meet the following criteria:

1. The product is intended for the treatment of a serious debilitating or life-threatening condition.
2. It addresses an unmet medical need (i.e., no existing treatment is available or current treatments present serious limitations).
3. It is expected to provide a significant therapeutic advantage over currently available treatments.
4. The potential adverse events of the product are considered to be outweighed by the benefits, supporting a reasonable expectation of a favorable benefit-risk balance profile.
5. The product must not be registered with any regulatory authority at the time of submitting the designation request.
6. Sufficient preliminary non-clinical and/or clinical data available to support staged review.
7. There must be robust evidence that pivotal studies are ongoing and sufficiently powered.
8. Manufacturing processes should demonstrate adherence to standards of quality and consistency.
9. The applicant should intend to submit a full Marketing Authorization Application (MAA) once adequate data become available.

Submission Requirements:

To initiate a rolling review, applicants should:

1. Hold a pre-submission meeting with the Kuwait Drug Regulatory Authority to:
   - Discuss the potential of the product to meet the eligibility

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	3. Orphan drugs 4. Advanced therapy medicinal products (ATMPs)
Priority Pathway (Products for MOH)	1. The product must be authorized by SRA or Gulf Health Council (GHC) prior to submission. 2. Drugs intended for the treatment of serious or life-threatening conditions. 3. Products addressing an unmet medical need with no registered alternatives available in the local market. 4. Product requested by the CMS or included in the CMS drug shortage list.

Table 2: Eligibility Criteria by Review Pathway continued

Expedited Pathway	1. Drugs intended for the treatment of serious or life-threatening conditions. 2. Products addressing an unmet medical need with no registered alternatives available in the local market. 3. If the application does not meet the criteria outlined in points 1 or 2, only submissions made by locally based MAHs or manufacturers will be accepted to support national pharmaceutical advancement.
Biosimilar Pathway	To be eligible for this pathway, the biosimilar must have obtained prior approval from a recognized SRA or GHC. This pathway applies to biosimilars that ensure robust comparability data demonstrating similarity to the reference biological product including quality, non-clinical and clinical data.
Emergency Use Pathway	The product must be authorized by SRA prior to submission. 1. A declared public health emergency. 2. The product may include vaccines, drugs, biologics, or diagnostics that fall under one of the following: - Unapproved products, or - Approved products being used for unapproved indications 3. There must be an urgent medical need 4. There must be preliminary evidence of benefit. 5. The product must meet acceptable quality and GMP standards to ensure safety during emergency use.

Table 2: Eligibility Criteria by Review Pathway continued

Rolling Pathway	1. The product is intended for the treatment of a serious debilitating or life-threatening condition. 2. It addresses an unmet medical need (i.e., no existing treatment is available or current treatments present serious limitations). 3. It is expected to provide a significant therapeutic advantage over currently available treatments. 4. The potential adverse events of the product are considered to be outweighed by the benefits, supporting a reasonable expectation of a favorable benefit-risk balance profile. 5. The product must not be registered with any regulatory authority at the time of submitting the designation request. 6. Sufficient preliminary non-clinical and/or clinical data available to support staged review. 7. There must be robust evidence that pivotal studies are ongoing and sufficiently powered. 8. Manufacturing processes should demonstrate adherence to standards of quality and consistency. 9. The applicant should intend to submit a full marketing authorization application (MAA) once adequate data becomes available.
GHC-Approved Drug Pathway	1. The product must hold a valid GHC approval.

Approval Processes

Standard Approval

Standard registration is the primary regulatory pathway for placing a pharmaceutical product on the local market. It applies to products with a complete data package that demonstrates their quality, safety, and efficacy. Registration must be submitted by a licensed local pharmaceutical company (Local Agent or scientific office) acting on behalf of the MAH.

Approval Validity :

Standard registration is valid for five years from the date of approval.

Conditional Approval

Conditional approval is a regulatory mechanism that allows for the early market authorization of promising pharmaceutical products intended to address serious or life-threatening conditions, where comprehensive clinical data are not yet complete (early-phase efficacy data Phase II trials), but there is sufficient evidence to suggest a positive benefit-risk balance.

Approval is granted under the condition that the applicant will complete ongoing or post-authorization studies to confirm the product's efficacy and safety.

Approval Validity:

Conditional approvals are valid for one year

- Full marketing authorization may be granted once comprehensive data confirm the product's safety and efficacy.

Once the Medicine and Medical Products Registration and Regulatory Administration considers that the data package is sufficiently complete, the conditional approval will be granted. The decision to approve is always made by Medicine and Medical Products Registration and Regulatory Administration on the basis that the benefits outweigh the risks. Applicants must fulfill specific post-approval obligations within predefined timelines.

Post-approval obligations:

1. The applicant must submit all the remaining data to complete the dossier within one year from the date of conditional approval.
2. Phase III trials is still ongoing at the time of conditional approval and are typically required as post-authorization commitments.
3. Periodic safety update reports (PSURs) and any new safety or efficacy data must be submitted as they become available.
4. The product's benefit-risk profile will be continuously monitored through post-marketing surveillance.

Failure to fulfill post-approval commitments and complete the full data package within one year will result in automatic cancellation of the conditional approval.

Transition to Standard Registration

Once the applicant successfully completes the full data package, including confirmatory clinical trials, and the updated benefit-risk assessment remains positive, the product may be transitioned to full standard registration. The decision is made based on a comprehensive review of all submitted data, including quality, nonclinical, clinical, and post-market surveillance findings.

Conditional approval may be renewed annually based on assessment by Medicine and Medical Products Registration and Regulatory Administration ensuring that the benefit risk is still favorable and evaluating the progress on the post approval obligations.

Emergency Use Authorization (EUA)

EUA is a regulatory mechanism that allows the temporary approval of pharmaceutical products, including vaccines or treatments, during a declared public health emergency. The EUA pathway enables early access to products that may prevent or treat serious or life-threatening conditions when no adequate, approved alternatives are available.

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assessment	receiving the second response

Clock Stop – A maximum clock stop period of 30 calendar days will be granted to the applicant to respond to the requirement issued by Medicine and Medical Products Registration and Regulatory Administration.

Table 1: Overview of Review Timelines, Clock Stops, and Permitted Response Cycles by Review Pathway





Figure 1: Timeline of review stages for each review type (including Clock Stops). This timeline represents an estimated period in calendar days.

Table 2: Eligibility Criteria by Review Pathway

Review Pathway	Eligibility Criteria
Standard Pathway	This pathway is applicable to all medicines that meet the criteria set forth in the Ministerial Decree for Registration of Pharmaceutical Medicinal Products.
Fast Track Pathway	The product must be authorized by SRA prior to submission. 1. Innovative products including: • New Chemical Entity (NCE) • Biological products • Novel vaccines, including next-generation vaccines, those developed using innovative platforms, or containing new active substances or technologies. 2. New indication or dosage form of already approved innovative products

delivering the documents required for the timely processing of an application.

3. The review timelines, response cycles and timelines outlined in this document apply for standard conditions. Exceptions may be granted on a case-by-case basis, subject to regulatory approval, depending on the product's complexity or urgency or inquiries requested.

4. To maintain market authorization, the Local Agent must submit a renewal application before the end of the 5-year period, in accordance with regulatory requirements and timelines.

5. Failure to submit a renewal application on time may result in suspension or cancellation of the registration.

Renewal

The renewal application in intended to extend the marketing authorization of a registered pharmaceutical product upon expiry of its validity period, typically five years. It ensures continued compliance with current regulatory standards, safety, efficacy, and quality requirements.

Eligibility Criteria:

Products with a valid marketing authorization that is approaching its expiry date are eligible to apply to renewal. The application must be submitted within the timeline specified by the regulatory authority (i.e., 6 months prior to expiry).

Timelines:

Initial Assessment	60 working days from the date of a valid submission
R1 response assessment	30 working days from the date of receiving the first response
R2 response assessment	30 working days from the date of receiving the second response
R3 response assessment	30 working days from the date of receiving the third response

Clock Stop – A maximum clock stop period of 30 calendar days will be granted to the applicant to respond to the requirement issued by the Medicine and Medical Products Registration and Regulatory Administration.

based on preliminary evidence supporting their safety and potential benefit.

Approval Validity:

1. EUA approvals are valid for one year from the date of authorization or till pandemic ends

2. The EUA may be extended or converted to standard registration if sufficient data is submitted and the benefit-risk balance remains positive

3. The Medicine and Medical Products Registration and Regulatory Administration can revoke or cancel this authorization at any time if the emergency declaration ends or new evidence indicates safety concerns or lack of efficacy

Post-approval obligations:

Holders of an EUA must fulfill the following obligations:

1. Submit updated safety and efficacy data from ongoing or new clinical trials as soon as it becomes available.

2. Implement an active pharmacovigilance system, including submission of Periodic safety update reports (PSURs) or expedited adverse event reporting as required by the Medicine and Medical Products Registration and Regulatory Administration .

3. Notify the Medicine and Medical Products Registration and Regulatory Administration immediately of any regulatory actions, safety concerns, or product recalls occurring internationally or locally.

4. Ensure that labeling and product information (i.e., SmPC and PIL) are updated promptly if new information arises that affects the benefit-risk profile.

5. Continue all post-marketing commitments, including finalizing ongoing confirmatory trails and submitting the complete data package to support full registration.

Pricing

The local agent is responsible for following up on the pricing documentation with the Pricing Department of the Kuwait Regulatory Authority. In order for any product to be available in the private sector in Kuwait, it must obtain pricing approval from the Pricing Department.

General considerations

1. The Medicine and Medical Products Registration and Regulatory Administration reserves the right to suspend or revoke the product's registration at any time if new evidence-whether generated locally or internationally-indicates a negative benefit-risk balance, raise safety concerns, or non-compliance with post-authorization obligations.

2. The agent can help expedite the registration procedure by replying promptly to the requirements and by

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