



GUIDANCE ON REGISTRATION PATHWAYS FOR PHARMACEUTICAL AND BIOLOGICAL DRUGS FOR HUMAN USE

Document No: PE&R/GL/RP/010
Document History: First Edition
Effective Date: 17-09-2026

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www.dra.gov.pk

July 2026



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1. HISTORY

This is the first edition of this guidance document.

2. APPLICATION (Industry)

The guidelines provided in this document are applicable to all manufacturers and importers seeking approval and grant of registration/marketing authorization of pharmaceutical and biological drug products for human use through the registration pathways established by the Drug Regulatory Authority of Pakistan (DRAP). These guidelines shall be read in conjunction with the DRAP Act, 2012, the Drugs Act, 1976, and the rules framed thereunder. Additional requirements may apply to specific pathways as notified by the Authority or the Registration Board from time to time.

3. PURPOSE

This guidance document is intended to facilitate the submission of complete and accurate applications by defining the applicable requirements and procedural expectations for each registration pathway. It further aims to promote consistency, transparency, predictability, and efficiency in the regulatory review process for the grant of registrations in Pakistan to support timely access to quality-assured drug products by adopting and implementing internationally recognized regulatory principles and practices, including risk-based and reliance approaches. This document also provides a better understanding of the reliance approach and the mechanism adopted by DRAP to consider and accept the work of other regulatory authorities in relation to the quality, safety, and efficacy of drugs.

4. INTRODUCTION

The registration of pharmaceutical and biological drug products is a critical regulatory function aimed at ensuring access to quality-assured, safe, and efficacious drugs. As the pharmaceutical and biotechnology sectors continue to advance, the increasing diversity of drug products, emergence of innovative therapies, expansion of global regulatory reliance practices, and growing demand for timely patient access have highlighted the need for a more structured and risk-proportionate regulatory approach. Furthermore, the emergence of innovative therapeutic modalities, growing international convergence of regulatory standards, and wider implementation of regulatory reliance and recognition practices have underscored the need for registration processes that are proportionate to the level of product risk, scientific complexity, and available regulatory evidence. Consequently, it has become essential to distinguish



between products based on their characteristics, development pathways, benefit-risk profiles, and the extent of prior scientific assessment and regulatory oversight conducted by recognized Reference Regulatory Authorities (RRAs). In consideration of these evolving regulatory and scientific paradigms, and in alignment with internationally accepted best practices, this Guideline establishes a structured pathway-based framework for the registration of pharmaceutical and biological drug products intended for human use. The framework introduces distinct regulatory pathways based on product characteristics, available evidence, and the extent of prior evaluation by recognized Reference Regulatory Authorities (RRAs). This approach is intended to enhance regulatory predictability, improve transparency, facilitate timely access to essential and innovative medicines, and strengthen the overall effectiveness of the drug registration framework.

5. LEGAL FRAMEWORK

Drugs are registered in Pakistan under the provisions of the Drug Regulatory Authority of Pakistan Act, 2012 (DRAP Act, 2012), the Drugs Act, 1976, and the Drugs (Licensing, Registering and Advertising) Rules, 1976. Within the Drug Regulatory Authority of Pakistan (DRAP), the Pharmaceutical Evaluation and Registration (PE&R), Division and the Biological Evaluation and Registration (BE&R) Division are responsible for the scientific assessment, evaluation, and processing of applications relating to pharmaceutical and biological drug products in accordance with Section 4 of DRAP Act, 2012, respectively. The grant, renewal, variation, suspension, and cancellation of registrations are undertaken by the Registration Board (RB), constituted under Section 7 of the DRAP Act, 2012, in accordance with the applicable statutory and regulatory requirements.

The registration framework is based on the criteria of internationally accepted principles of quality, safety, and efficacy. The Drugs (Licensing, Registering and Advertising) Rules, 1976 empower the Registration Board to assess available scientific evidence and apply risk-based regulatory approaches, including consideration of prior evaluations conducted by recognized foreign regulatory authorities. Rules 29 and 30 provide the legal basis for utilizing quality, safety, efficacy, and clinical information generated through established regulatory systems, while ensuring continued oversight of safety-related regulatory actions and emerging pharmacovigilance data. For biological products, the DRAP Act, 2012 recognizes products released under quality assurance and lot-release systems operating in accordance with World



Health Organization (WHO) requirements, thereby supporting reliance on internationally recognized regulatory oversight mechanisms.

Pursuant to these provisions, DRAP has adopted a reliance framework based on designated Reference Regulatory Authorities (RRAs), as listed in Appendix-I, to facilitate assessment of applications submitted through facilitated registration pathways, as well as post-approval variations and renewals, while maintaining appropriate standards of quality, safety, and efficacy.

6. DEFINITIONS

- | | |
|--|---|
| 6.1 Collaborative Registration Procedure (CRP) for drug products prequalified by WHO | Procedure for collaboration between the World Health Organization (WHO) Prequalification Team (WHO/PQT) and interested national regulatory authorities (NRAs) in the assessment and accelerated national registration of WHO prequalified pharmaceutical products and vaccines. |
| 6.2 Collaborative Registration Procedure (CRP) for drug products approved by Stringent Regulatory Authorities (SRA) | Registration procedure in which assessment and national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (reference SRAs) is facilitated and accelerated by sharing of detailed assessment and inspection outcomes generated by a reference SRA. |
| 6.3 WHO Listed Authority (WLA) | A WHO Listed Authority (WLA) is a regulatory authority (RA) that is available in the WLA list of World Health Organization within scope as defined by WHO. |
| 6.4 Stringent Regulatory Authority (SRA) | a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour |



and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015)); or

- b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
- c) a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

6.5 Sameness

Compared to the reference authority, the submitted product application shall have identical essential characteristics. All relevant aspects of the product, including those related to the quality of the product and its components, should be considered to confirm that the product is the same or sufficiently similar (e.g., same qualitative and quantitative composition, strength, pharmaceutical form, intended use, manufacturing process, suppliers of active pharmaceutical ingredients, quality of all excipients). Additionally, the results of supporting studies of safety, efficacy, quality, indications, and conditions of use should be the same.

6.6 Verification

For the purpose of this document, verification means confirmation that the relevant reference Authority has approved and the drug product has been marketed in any of the reference country.

6.7 Emergency Use Authorization (EUA)

An authorization to allow use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk to public health, subject to the applicable decision of the Registration Board.

6.8 Reference Regulatory Authorities (RRA)

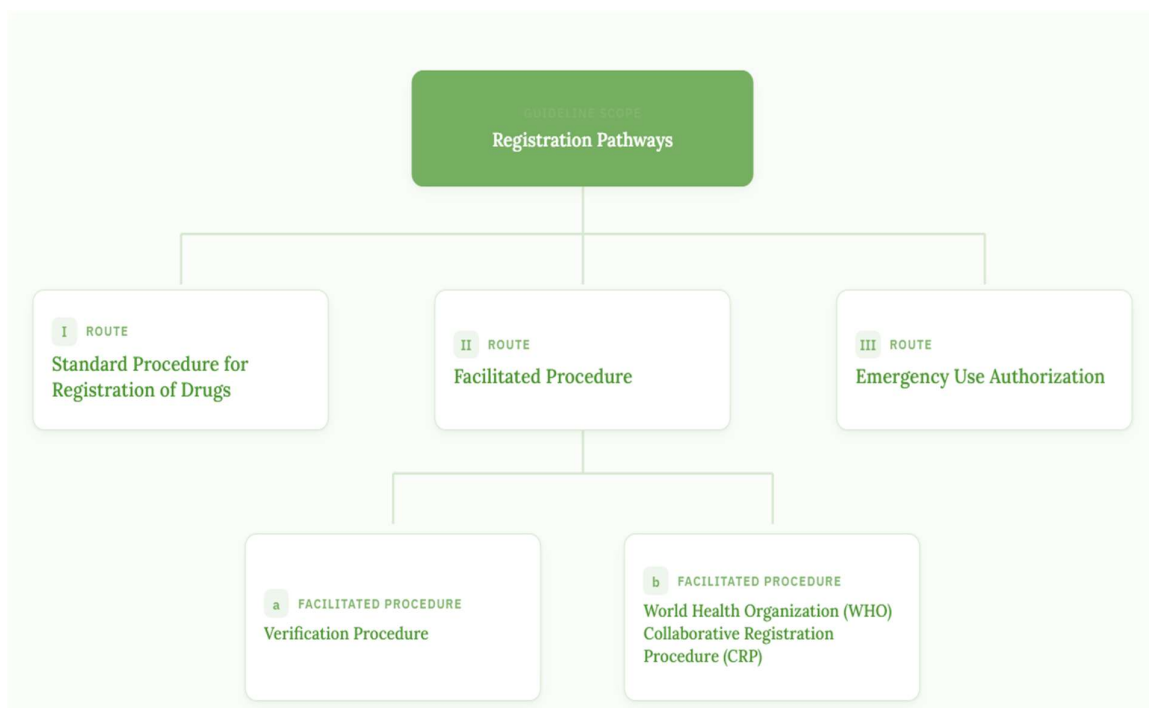
RRA's include regulatory authorities present in WLA's and ICH as mentioned above.



7. REGISTRATION PATHWAYS

The following registration pathways for pharmaceutical and biological drugs for human use are applicable:

- I. Standard Procedure for Registration of Drugs
- II. Facilitated Procedure
 - a. Verification Procedure
 - b. World Health Organization (WHO) Collaborative Registration Procedure (CRP)
- III. Emergency Use Authorization



These pathways are applicable to:

- a. Pharmaceutical Drugs for human use.
- b. Biological Drugs including vaccines for human use.

7.1 PATHWAY SELECTION

The appropriate registration pathway shall be selected on the basis of the eligibility criteria and regulatory evidence applicable to the product. The Standard Registration Procedure



remains the default pathway unless the product qualifies for a facilitated or emergency pathway.

7.2 STANDARD PROCEDURE FOR REGISTRATION OF DRUGS

The Standard Registration Procedure applies to drug products that are not eligible for a facilitated or emergency registration pathway. Applications submitted under this pathway shall undergo a complete scientific, technical, and regulatory assessment before the grant of registration or marketing authorization.

7.2.1 ELIGIBILITY CRITERIA

An application shall be eligible for review under the Standard Registration Procedure where the applicant satisfies all of the following conditions:

- i. Product containing same active pharmaceutical ingredient or biological entity in particular strength and dosage form shall be available in any of the reference regulatory authorities as defined above.
- ii. In case of non-availability of the Product containing same active pharmaceutical ingredient or biological entity in particular strength and dosage, same pathways will be used with the additional conditions as prescribed by the Registration Board, on case-to-case basis.
- iii. The applicant is a licensed manufacturer or authorized importer holding a valid Drug Manufacturing Licence (DML) or Drug Sale Licence (DSL), as applicable under the applicable laws of Pakistan.
- iv. The application is submitted in the prescribed regulatory format using Form 5-F (Common Technical Document) for pharmaceutical and biological products intended for human use.
- v. The product falls within the regulatory jurisdiction of DRAP and requires registration prior to manufacture, import, distribution, or marketing in Pakistan.
- vi. The product is not being submitted under any alternative registration pathway.
- vii. The product complies with applicable pharmacopoeia standards, Good Manufacturing Practices (GMP), quality requirements, and other regulatory requirements prescribed by DRAP.
- viii. The application contains complete quality, safety and efficacy data appropriate to the product category and complies with the applicable CTD requirements.



- ix. Where required, bioequivalence, interchangeability, stability, non-clinical and clinical studies have been conducted in accordance with internationally accepted scientific standards and applicable DRAP guidelines.
- x. The proposed manufacturing sites possess valid GMP certification or equivalent evidence acceptable to DRAP.
- xi. The clinical trials and bioequivalence protocols shall be approved by the Pharmacy Services Division of DRAP in accordance with Bio-Study Rules, 2017.

7.2.2 SUBMISSION REQUIREMENTS

Applications shall be submitted electronically and/or in the manner prescribed by DRAP, together with all applicable administrative documents, technical data, and prescribed fees. Complete data for all applicable modules of Form 5-F (Common Technical Document) shall be submitted.

7.3 FACILITATED PATHWAYS

Under the following registration routes, the applicant does not undergo the full assessment process that would normally be required under the Standard Registration Procedure. Instead, DRAP facilitates or streamlines its regulatory assessment by making use of work, evidence, or regulatory conclusions already generated by another recognized regulatory body or mechanism.

7.3.1 VERIFICATION PATHWAY

The submission of application shall be in accordance with Form-5F (Common Technical Document) and data requirements in respective Guidance Document for Submission of Applications on Form-5F (CTD) for Registration of Pharmaceutical & Biological Drugs for Human Use.

In Module 1, applicants must add the following:

- i. In the cover letter: mention the request for consideration of application by verification pathway under Facilitated Registration Procedure.
- ii. Date of approval of the drug product by the WHO Listed Authority (WLA).
- iii. A declaration letter/ Undertaking by the applicant stating that all aspects of the drug product's quality, including but not limited to, the formulation, manufacturing site(s), release and shelf-life specifications, primary packaging and active pharmaceutical ingredient(s) source are identical to that currently approved by WLA at the time of



submission. However, a different type of container closure system (e.g. Alu/Alu blister vs. HDPE bottle) may be proposed subject to fulfilling the criteria of stability.

- iv. A complete assessment report and other relevant supporting documents from the WLA, as applicable, including the following:
 - a) Complete clinical and quality assessment report along with if applicable assessment on the Question & Answer documents between the Sponsor/manufacturer and WLA and all annexes.
 - b) Assessment reports and/or documents pertaining to post-approval variations (if applicable).
 - c) The submitted assessment reports should be unredacted or unedited, when possible, and should include details of imposed licensing conditions, final product labelling, chemistry and clinical review, and other information concerning the product's approval. Redacted or edited reports might be acceptable if not related to the quality, safety or efficacy of the product. Trade secrets, confidential commercial and financial information, can be excluded from the submission.
 - d) Assessment reports obtained solely from the public domain are not acceptable as a substitute for the reports required from the WLA.
- v. For inspection requirements:
 - a) Valid GMP certificates from the local authority and other international authorities.
 - b) A copy of the Site Master File (SMF).
 - c) A list of all products manufactured at the site and supplied to Pakistan.
 - d) The latest inspection report, in English, from the local authority.
 - e) If available, the latest inspection report, in English, from other international authorities.

DRAP may request additional documentation not specifically outlined in this guideline where necessary to adequately assess the quality, safety, and efficacy of a drug product.

7.3.2 COLLABORATIVE REGISTRATION PROCEDURE (CRP)

Applicants intending to register their products under the Facilitated Registration Procedure, using the WHO Collaborative Registration Procedure for prequalified products or products approved by Stringent Regulatory Authorities, must adhere to the principles, mechanisms, and steps outlined by WHO in the relevant Technical Report Series:



- i. Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (WHO TRS 1010, 2018)
- ii. Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines (WHO TRS 996, 2016)

7.4 EMERGENCY USE AUTHORIZATION (EUA)

Emergency Use Authorization (EUA) is an exceptional pathway for the authorization of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk to public health. The Registration Board may consider an EUA for countermeasures intended to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by the emergency agent where adequate, approved, and available alternatives are not available.

7.4.1 GENERAL CONDITIONS

EUA may be considered where the benefit to public health from immediate availability is greater than the risk associated with the extent of available evidence. The type and amount of information required may vary according to the nature of the declared emergency and the candidate product.

7.4.2 APPLICANT'S REQUEST FOR DETERMINATION OF SUITABILITY

The applicant shall first submit a request for determination of suitability for EUA before lodging the application dossier. The request should be no more than 10 pages and should address the following:

- i. Justification for addressing the general conditions applicable to the expedited pathway in the emergency situation.
- ii. Justification for fulfilling the eligibility criteria for Emergency Use Authorization/Registration.
- iii. Regulatory status of the product with reference regulatory authorities, where available.

Where multiple drug products contain the same pharmaceutical ingredient/drug substance, they may be combined in one application. Separate applications shall be submitted



for multiple products otherwise. The request for determination of suitability shall be addressed to the Secretary, Registration Board.

7.4.3 EUA APPLICATION PROCESS

Applicants are advised to engage in early dialogue with DRAP to discuss the product development plan and the proposed evidence package before submission of the application. After submission, the application shall be evaluated by DRAP, and the evaluation report shall be presented to the Registration Board. The Board shall decide on the application taking into consideration the risk-benefit profile and the nature of the emergency.

7.4.4 EUA DATA AND SUPPORTING REQUIREMENTS

The exact type and amount of data required to support an EUA shall be determined according to the nature of the declared emergency and the candidate product. The Registration Board may issue additional requirements for emergency use registration. In determining the data requirements, consideration may be given to:

- i. The seriousness of the clinical condition.
- ii. The incidence of the clinical condition.
- iii. The likelihood that the product may be effective in treating the condition.
- iv. The effect that use of the product may have in ensuring national security.
- v. Whether the product could be used by a large population or is limited to specific subpopulation(s).
- vi. The extent to which the product would serve a significant unmet medical need in a special population.
- vii. The availability and, where known, the safety and effectiveness of other countermeasures.
- viii. The urgency of treatment, including the available window of opportunity for treatment.
- ix. The adequacy of available non-clinical and clinical information.
- x. The quantity of product required.
- xi. The availability of alternative brands of the same formulation.
- xii. The availability of a functional Pharmacovigilance system of the applicant

DRAP shall determine the application form to be submitted for emergency use registration, as applicable.



7.4.5 TERMINATION OF EUA

Upon termination of the emergency, the use and disposition of an unapproved product, or of labeling and product information for an unapproved use, shall be managed as directed by DRAP. The registration holder shall intimate the relevant Division of DRAP in writing. A manufacturer/importer may choose to have an unapproved product returned after termination. Notwithstanding termination, the authorization may continue to support the continued use of the product in a patient who began treatment before termination to the extent considered necessary by the attending physician.

7.4.6 REVOCATION OF EUA

The Registration Board may periodically review the circumstances and appropriateness of an EUA and may revoke the authorization where warranted. Circumstances may include significant inspectional findings affecting product purity, potency, or safety; adverse events linked to or suspected to be caused by the product; product failure; new evidence undermining the conclusion that the product may be effective; or availability of a preferred product.

7.5 POST-REGISTRATION VARIATION

Applicants are required to follow the Post-Registration Variation Guidelines for Pharmaceutical and Biological Products available at DRAP's website for all the products registered under any of the regulatory pathways. The following additional guidance complements the above-mentioned guidelines.

7.5.1 VERIFICATION PATHWAY

The application submission requirements are similar as laid down in the Post Registration Variation Guidelines for Pharmaceutical and Biological Products. The following additional documents shall also be submitted.

- i. Approval letter from the reference agency.
- ii. A signed declaration of sameness of the product, including justification for any potential differences.
- iii. A complete assessment report, unredacted and unedited, for the approved variation(s) by the reference agency.
- iv. Report that includes all questions and answers between the applicant and reference agency, including all annexes (unredacted/unedited), if applicable



7.5.2 COLLABORATIVE REGISTRATION PROCEDURE (CRP)

Applicants intending to submit applications of post registration variation under the Facilitated Registration Procedure, using the WHO Collaborative Registration Procedure for prequalified products or products approved by Stringent Regulatory Authorities, must adhere to the principles, mechanisms, and steps outlined by WHO in the relevant Technical Report Series:

- i. Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (WHO TRS 1010, 2018)
- ii. Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines (WHO TRS 996, 2016)

8. PROCEDURE FOR SUBMISSION OF APPLICATION

The applicant shall submit the application through the DRAP online e-Application System after payment of the prescribed fee. Where an application is found not eligible for the selected pathway, it may be transferred to the applicable routine/standard procedure. The user manual for fees submission and Registration Module on the e-APP is accessible on DRAP's website

- User Manual for Submission of Fees: (<https://www.dra.gov.pk/wp-content/uploads/2025/07/Fee-Chalan-Software-manual-Autosaved.pdf>).
- User Manual for Registration Module for submission of registration applications: (<https://www.dra.gov.pk/wp-content/uploads/2025/07/eApp-Manual.pdf>).

Note: Registration fees are non-refundable.

9. PERFORMANCE TARGETS

The performance targets start when the application receives formally in e-Application System after screening:



Pathway	Performance Target (Overall time from DRAP*)
Standard Pathway	365 Working Days
Verification Pathway	90 Working Days
WHO Collaborative Registration Procedure (CRP)	90 Working Days
Emergency Use Authorization	30 Working Days

**This excludes the time taken by the applicant to respond to shortcomings and other queries from DRAP.*

10. Selection of Brand Name for Registered Drugs

The prime responsibility of the Drug Regulatory Authority of Pakistan (DRAP) while granting registration of therapeutic goods is to ensure that the safety, efficacy and quality/conformance of registered products under the provision of the Drugs Act, 1976, DRAP Act, 2012 and rules framed thereunder.

The brand names of products are assigned to choice of applicants on a first-come-first-served basis. However, if the assigned brand name resembles an existing/earlier brand name to cause confusion, the subsequent registration holder/ applicant shall be required to submit alternate brand names and change the brand name to remove similarity.

1. An applicant may submit:
 - (i) At least three proposed brand names in order of priority at the time of submission of Registration Dossier or
 - (ii) After approval and uploading of minutes on DRAP's website, an applicant shall be responsible to submit at least three proposed names through General Request Tab for its approved product or
 - (iii) Upload the Registration Letter of the product in General Request Tab, if brand name is already registered for other strength or dosage form.
2. Proposed brand names shall be submitted keeping in view that they do not:
 - (i) suggest greater safety or efficacy;
 - (ii) imply a therapeutic use.



- (iii) imply superiority over other similar products.
 - (iv) imply the presence of substance which is not present in the product.
 - (v) cause visual, phonetic or conceptual confusion with another registered product's name.
3. An applicant can avail maximum of 03 attempts for submission of alternate brand names (i.e., 03 brand names at a time). After failure of 03 attempts, generic name shall be assigned to the product.
4. Brand name which appears visually or phonetically similar to the innovator's/ reference product will not be given even if the innovator's/ reference product is not registered in Pakistan. In this context, originator in Pakistan shall declare the brand name of innovator's product at the time of registration. Furthermore, if a registered brand name i.e., visually or phonetically similar to the innovator's/ reference product is identified at any later stage, it shall be changed.
5. One brand name will be assigned for one molecule / Drug Substance in all dosage forms for an applicant. It is the responsibility of applicant to declare that he has no other brand name for same molecule / Drug Substance.
6. Different brand names will be granted for same formulation with different strength if indications are different.
7. Brand names implying therapeutic indication of the product shall not be permitted in any case.
8. Same brand name, either alone or along-with any suffix or prefix, will not be permitted for formulations having different Drug Substances.
9. In case of fixed dose combinations, a suffix or prefix can be added with the registered brand name to identify addition.
10. Except multivitamins and minerals, brand name once granted for pharmaceutical preparations (drugs and biologicals), irrespective of their status, will not be permitted to any other product enlisted as alternative medicine and health & OTC (non-drug) products and *vice versa*.



11. Brand name once assigned for any active ingredient (e.g., Paracetamol) will not be allowed to any other pharmaceutical preparations having different active ingredients (e.g., Ibuprofen), in any case even if NOC has been issued by previous MA holder.
12. In case a formulation is withdrawn for safety reasons, its brand name shall not be allowed for another formulation.
13. Brand name of any reported un-registered product (excluding any innovator's or RRA approved product) shall not be assigned to any other product. In this context, a list/ database of all already reported un-registered products will be made available on the official website of DRAP.
14. Brand name registered exclusively for export purposes will not be assigned for local marketing if it is resembling with already registered brand name or has been granted to any other company for local marketing.
15. For export purposes, an applicant can acquire brand name of any local registered drug/enlisted product based on NOC of registration/enlistment holders for local market.
16. For all those dosage forms, in which manufacturers / importer provide diluent (WFI or lignocaine for IV or IM administration respectively); IM or IV will be written in a very conspicuous manner along with brand name to avoid any potential life-threatening matter.
17. DRAP encourages manufacturers to rely on their corporate name and the International Nonproprietary Names (INNs), rather than on trademarks, to promote and market multi-source products.
18. If similar brand names are granted to the two or more companies having similar active ingredients, company having an issue can avail change of brand name under similarity clause, however, DRAP will not ask any brand holder to change its brand name until and unless any legal direction from any competent forum is received e.g., IPT.
19. Any previous decision regarding issuance/ change of brand name shall stand null and void.



10. REFERENCES

1. Drug Regulatory Authority of Pakistan Act, 2012.
2. Drugs Act, 1976.
3. Drugs (Licensing, Registering and Advertising) Rules, 1976.
4. Reliance Mechanism in Regulatory Processes (Edition 02), QMSC/GL/RM/005.
5. Guidance Document for Submission of Applications on Form-5F (CTD) for Registration of Pharmaceutical and Biological Drugs for Human Use.
6. Post Registration Variation Guidelines for Pharmaceutical and Biological Products.
7. Priority Review and Accelerated Approval of Registration/Market Authorization (Edition 01), PE&R/GL/PR/006, Effective Date: 13-03-2024.
8. WHO Collaborative Registration Procedure: WHO Technical Report Series 996 (2016) and WHO Technical Report Series 1010 (2018).
9. WHO Emergency Use Assessment and Listing Procedure (EUAL) for candidate medicines for use in the context of a public health emergency.

**APPENDIX-I: LIST OF REFERENCE REGULATORY AUTHORITIES**

The following Reference Regulatory Authorities and international/regional organization are listed in the DRAP Reliance Mechanism in Regulatory Processes (Edition 02). This list includes 19 Regulatory Authorities and 02 Organizations. Their use under a particular registration pathway shall remain subject to the applicable DRAP requirements.

Sr. No.	Country/Region	Reference Regulatory Authority
1	USA	Food and Drug Administration (FDA)
2	Canada	Health Canada
3	Australia	Therapeutic Goods Administration (TGA)
4	Japan	Pharmaceuticals and Medical Devices Agency (PMDA)
5	UK	Medicines and Healthcare products Regulatory Agency (MHRA)
6	France	National Agency for the Safety of Medicine and Health Products (ANSM)
7	Germany	Federal Institute for Drugs and Medical Devices
8	Netherlands	Medicines Evaluation Board
9	Switzerland	Swissmedic
10	Austria	Austrian Agency for Health and Food Safety
11	Denmark	Danish Medicines Agency
12	Sweden	Medical Products Agency
13	Norway	Norwegian Medicines Agency
14	Belgium	Federal Agency for Medicines and Health Products
15	Finland	Finnish Medicine Agency
16	Italy	Italian Medicine Agency (AIFA)
17	Ireland	Health Products Regulatory Authority (HPRA)
18	Iceland	Icelandic Medicine Agency
19	Spain	Spanish Agency for Medicines and Health Products
20	Europe	European Medicines Agency (EMA)
21	WHO	World Health Organization

**APPENDIX-II: COMPARISON TABLE FOR REGISTRATION PATHWAYS**

Pathway	Regulatory Basis	Salient Eligibility Criteria	Key Submission Requirements	Distinguishing Features
Standard Procedure 7.2 – default pathway	Applies where a product does not qualify for any facilitated or emergency pathway.	a. Licensed manufacturer/authorized importer holding valid DML/DSL b. Form 5-F (CTD) submission for human pharmaceutical/biological products c. Product within DRAP's jurisdiction; not filed under any alternative pathway d. Complies with pharmacopoeia, GMP, and DRAP quality requirements e. Complete QSE data per applicable CTD modules f. BE/stability/non-clinical/clinical studies per DRAP guidelines, where required g. Manufacturing site(s) hold valid GMP certification h. BE and clinical trial protocols approved by Pharmacy Services Division under Bio-Study Rules, 2017	i. Electronic/prescribed-manner submission with administrative documents, technical data and fees ii. Complete data for all applicable Form 5-F (CTD) modules	• Full, independent scientific, technical and regulatory assessment • No reliance on prior approval from RRAs
Verification Pathway 7.3.1 – Facilitated Procedure	Reliance route for products already approved by a WHO Listed Authority (WLA).	a. Product currently approved and marketed by a WLA b. Drug product identical ("sameness") to the WLA-approved version i.e. formulation, site(s), specifications, packaging and Drug Substance source c. A different container-closure system may be proposed if stability is demonstrated	i. Form-5F (CTD) per the Form-5F Guidance Document ii. Cover letter requesting the Verification Pathway iii. WLA approval date; signed sameness declaration/undertaking iv. Complete, unredacted WLA clinical & quality assessment report, Q&A record and annexes; post-approval variation reports, if any v. Inspection package: valid GMP certificates, Site Master File, product list supplied to Pakistan, latest local and (if available) international inspection reports in English	• Reports sourced only from the public domain are not acceptable in place of WLA reports • DRAP may request further documentation beyond this list



Pathway	Regulatory Basis	Salient Eligibility Criteria	Key Submission Requirements	Distinguishing Features
Collaborative Registration Procedure (CRP) 7.3.2 – <i>Facilitated Procedure</i>	Reliance route for WHO-prequalified products or products approved by a Stringent Regulatory Authority (SRA).	a. Product is WHO-prequalified, or approved by a recognized SRA b. Applicant adheres to the WHO collaborative procedure for the relevant category	i. Compliance with WHO TRS 1010 (2018) ii. SRA-approved products and vaccines iii. Compliance with WHO TRS 996 (2016) iv. WHO-prequalified products and vaccines	Through WHO designated SOPs
Emergency Use Authorization (EUA) 7.4 – <i>exceptional pathway</i>	Declared public-health emergency; an unapproved product, or an unapproved use of an approved product, with no adequate approved alternative available.	a. Benefit of immediate public-health availability outweighs the risk from the available evidence b. Data expectations vary with the nature of the emergency and the candidate product c. Assessed against specific considerations, e.g. seriousness/incidence of the condition, likely effectiveness, urgency, population size and unmet need, adequacy of non-clinical/clinical data, alternatives available	i. Pre-application "determination of suitability" request (≤ 10 pages) addressed to the Secretary, Registration Board, justifying the general conditions and eligibility criteria and stating regulatory status with reference authorities, if available ii. Same-ingredient products may be combined in one request; otherwise separate applications required iii. Early dialogue with DRAP before dossier submission; DRAP evaluation report presented to the Registration Board for decision	- Time-limited and conditional subject to termination when the emergency ends - Subject to periodic Board review and revocation (e.g. adverse inspection findings, safety signals, product failure, ineffectiveness, or a preferred product becoming available) - Authorization may continue for a patient already under treatment, at the attending physician's discretion