RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR REGISTRATION OF INNOVATIVE HUMAN MEDICAL PRODUCTS

NOVEMBER, 2025

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is the national regulatory authority established by the Law N° 003/2018 of 09/02/2018. One of the core functions of Rwanda FDA is to ensure the quality, safety, and efficacy of pharmaceutical products to protect public health.

In alignment with its legal mandate and in accordance with the applicable technical regulations governing the registration of medicinal products, the Authority issues these *"Guidelines for Registration of Innovative Human Medical Products"*.

These guidelines are intended to address emerging advancements in pharmaceutical research and development. They outline technical and administrative requirements for the submission of registration dossiers for innovative human medical products. These guidelines provide detailed guidance on the structure, content, and format of dossiers, thereby supporting applicants in preparing comprehensive and compliant submissions.

Adherence to these guidelines by all concerned applicants will streamline the assessment process, facilitate efficient regulatory decision-making, and promote timely access to innovative therapeutic options.

The Authority acknowledges all the efforts of stakeholders who participated in the development and validation of these guidelines.

Prof. Emile BIENVENU
Director General

Digitally signed by RWANDA FDA(Director General)
Date: 2025.11.27 18:59:17 +02'00'

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Date of revision	Version number	Changes made and/or reasons for revision
-	1	First issue

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

API	Active Pharmaceutical Ingredient
CTD	Common Technical Document
FDC	Fixed dose combination
FIFO	First-in first-out rule
FPP	Finished Pharmaceutical Product
GMP	Good manufacturing practice
ICH	International conference on harmonisation
iRIMS	Integrated Regulatory Information Management System
LTR	Local technical representative
RMP	Risk management plan
Rwanda FDA	Rwanda Food and Drugs Authority
STED	Summary of Technical Documentation
WHO	World Health Organization

DEFINITIONS

The definitions provided below apply to the terms used in these guidelines. They may have different meanings in other contexts and documents.

Active Pharmaceutical Ingredient (API) or drug substance
A substance used in the FPP, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

Active Pharmaceutical Ingredient (API) Starting Material
A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API starting material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house.

Applicant
An applicant is a person who applies for registration of a human Medical product to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. After the product is registered, the applicant shall be the Marketing Authorization Holder.

Authority
Authority means Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under the article 2 of the Law N°. 003/2018 of 09/02/2018.

Bio batch
The batch used to establish bioequivalence or similarity to the comparator product as determined in bioequivalence or bio waiver studies, respectively.

Final Pharmaceutical Intermediate
The last reaction intermediate in the synthetic pathway that undergoes synthetic transformation to the API or the crude API. Purification is not considered to be a synthetic transformation.

Finished Pharmaceutical Product (FPP)
A finished dosage form of a medical product which has undergone all stages of manufacture including packaging in its final container and labelling.

First in First out (FIFO)
In assessment and registration, the "FIFO rule" refers to a First-In, First-Out system for scheduling applications to be assessed, prioritizing them based on their submission date. Once a product application meets the initial completeness requirements and is accepted for assessment, it is placed in a queue to be processed in the order it was received based on assessment pathway, ensuring fairness and a systematic approach to regulatory review

Innovative product
A medical product not previously registered in Rwanda or abroad that apply for registration in order to add a new therapeutic advantage and fulfilling the eligibility criteria specified in these guidelines.
This includes: breakthrough innovation which is new molecular entity either single or in combination or incremental innovation, a novel modification that is made to already registered products.

Innovator product
The first medicinal product (containing a new chemical entity that has not been previously used in other medications) authorized for marketing, typically as a patented product based on a complete set of documentation demonstrating its quality, safety and efficacy.

In-Process Control
Check performed during manufacture to monitor or to adjust the process in order to ensure that the final product conforms to its specifications.

Local Technical Representative (LTR)
Means any registered company in Rwanda and licensed by Rwanda FDA to deal with regulated products that has received a mandate from the Applicant to act on his/her behalf with regard to matters pertaining to the registration of regulated products.

Manufacturer
A company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of Medical products.

Medical products
Any medicine or similar product intended for human use, which is subject to control under health legislation in the manufacturing and importing state. It includes human and veterinary drugs; human and animal vaccines and other biological products, poisonous substance, herbal medicines, medicated cosmetics, laboratory and household chemicals and pesticides, medical devices, in vitro diagnostics, and pharmaceutical products including any substance capable of preventing, treating human or animal in order to diagnose diseases, restore, correct out modifications of organic or mental functions. It also means products used in disinfecting premises in which food and drugs are manufactured, prepared, or stored, cleaning hospitals, equipments, and farm houses.

Pilot-Scale Batch
A batch of an API or FPP manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch. For example, for solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger, unless otherwise adequately justified.

Production Batch
A batch of an API or FPP manufactured at production scale by using production equipment in a production facility as specified in the application.

Therapeutic advantage

An advantage that is added by the innovative product. It includes any of the following advantages:

1. An innovative product which is more effective.
2. An innovative product which ensures greater safety.
3. An innovative product which has better pharmacokinetics.
4. An innovative product which improves patient's compliance to medication.
5. An innovative product which adds a new therapeutic option.

CHAPTER.I GENERAL INTRODUCTION

I.1 Introduction

Rwanda Food and Drugs Authority (Rwanda FDA) is established by the Law N° 003/2018 of 09/02/2018. Considering the provisions of the Regulations Governing the Registration of Human Pharmaceutical Products which gives the power to issue guidelines, the Authority has issued *Guidelines for Registration of Innovative Human Medical Products*.

The Purpose of issuing this regulatory guideline is to define the concept of the innovative products and to stipulate their registration procedures by Rwanda FDA. In addition, it provides guidance to applicants preparing a Common Technical Document (CTD) for the Registration of Medicines for Human Use.

The Authority recognises the following differences between Innovator and Innovative medical products.

Feature	Innovator	Innovative
Definition	The first authorized version authorized medicines developed with full data of quality, safety and efficacy	A medicinal product that introduces significant novelty such as a new chemical entity, mechanism or therapeutic
Regulatory basis	Approved based on complete (full) registration dossier	May be newly developed or significantly modified/improved compared to existing therapies
Example	The original brand –name drug(eg-Lipitor) by Pfizer	Anew gene therapy or a novel mRNA Vaccine
Patent status	Usually patented or protected	May or may not be Patented-the focus is on therapeutic Novelty
Role in drug life cycle	Serves as the reference for generics or Biosimilar	May later become the Innovator if it is the first in the class

WHO/ICH content	Basis for Generic product comparison	Recognized in the priority review, orphan drug or breakthrough therapy designations

For Innovator product, Rwanda FDA applies either the *Guidelines for Registration of Pharmaceutical Products* or the *Guidelines for Registration of Human Biological Products*, based on the classification and nature of products.

Based on the above outlined differences, it necessitated the development on a separate document of guidelines for registration of innovative medical products.

I.2 Scope

These guidelines shall apply to human medical products that have not previously been registered by Rwanda FDA or abroad which apply for registration in order to add a new therapeutic advantage.
The principles in these guidelines would also apply to chemical combinations and complexes that comprise more than one active ingredient including fixed dose combinations (FDC).

More details on the scientific principles applicable to the assessment of FDC products is stipulated in the *Rwanda FDA guidance on registration of fixed dose combination (FDC) for human pharmaceutical products*

CHAPTER.II ORGANISATION OF REGISTRATION PROCESS

II.1 Eligibility criteria for innovative human medical products registration procedure

Products that meet the following criteria are eligible for the Innovative human medical product registration procedure at Rwanda FDA:

a. The product (Break-through innovation) is not registered by any regulatory authority at the time of submission to Rwanda FDA;
b. The product (Incremental innovation) offers a significant advantage over currently approved products;
c. It should be manufactured in Rwanda. if manufactured abroad, clinical trials should have been conducted in Rwanda.

Note: In case the clinical trials are conducted abroad, such products should have been registered in the country of origin or other reference National Regulatory Authority (NRA) where clinical trials were conducted and, in this case, the guidelines for registration of pharmaceutical products, biological products or for medical devices including IVDs shall apply.

II.2 Registration procedure and designation of innovative human medical products status

II.2.1 Inquiry request

Applicant notifies Rwanda FDA of the intention for registration and submits a cover letter, application form accompanied by the supporting documentation indicated in the Appendix No. (1) via official communication channels (e.g. info@rwandafda.gov.rw).

Rwanda FDA committee for Scientific Evaluation of Innovative Products shall review the request within 15 working days from the date of receiving a complete request and notify the applicant of the status of the submitted request in terms of the acceptance or rejection.

II.2.2 Pre-submission meeting.

Upon acceptance notification, the applicant shall be invited to the pre-submission meeting in the next 15 working days. The Authority shall convene the pre-submission meeting to discuss with applicant the application requirements, and provide additional guidance in line with upcoming application dossier.

II.2.3 Submission of the application dossier

II.2.3.1 Application requirements

The applicant shall be required to submit the scientific data of the innovative product in line with CTD format (with exception of medical devices) and other documentations requested during the pre-submission meeting for evaluation. Submission will be done through IRIMS; Rwanda FDA online portal (https://www.irims.rwandafda.gov.rw/portal).

The following are the application requirements:

a. Application Cover letter;
b. Evidence of appointment of LTR and Qualified person for pharmacovigilance;
c. Proof of payment, made in accordance with regulations related to regulatory services tariffs/ fees and charges;
d. Technical dossier, CTD format in (PDF), QOS and QIS in MS-Word or STED for medical devices;
e. Physical samples of the product packaged in the primary packaging and other needed materials for testing;
f. Risk management plan (RMP);
g. Application for GMP Inspection/Quality audit for sites that have not been inspected by Rwanda FDA.

Note:

1. The languages accepted for the application should be **English, French or Kinyarwanda**. Any document that is in any other language must be accompanied by a certified or notarized translation.
2. The summaries (Quality Information Summary, Quality Overall Summary), should be formatted as a word document following the templates downloadable on Authority's website.
3. All other documents shall be in, selectable and searchable PDF

4. All pages of the application should be numbered in the style: ***page x of y***.
5. A separate application is required for each product
6. The application must contain a complete index to the various appendices.

II.2.3.2 Officially Recognized References

The official recognized pharmacopoeias by the Authority are British Pharmacopoeia (BP), European Pharmacopoeia (Ph.Eur.), The International Pharmacopoeia (Ph.Int), Japanese Pharmacopoeia (JP) and United States Pharmacopeia (USP). References should be cited in accordance with the current edition of compendia.

When reference is made to specifications, quality control procedures and test methods in official recognized compendia or scientific publications, full references and copies of relevant pages shall be enclosed.

II.3 REVIEW OF SUBMITTED DOSSIER AND COMMUNICATION TO THE APPLICANT

II.3.1 Screening of applications for Innovative products

The application for registration of Innovative Medical Products submitted to the Authority are not considered valid until they have been screened for completeness. All applications shall undergo screening phase before the full assessment (first and second) are conducted. The application shall then be screened for completeness and compliance with the regulatory requirements **within thirty (30) working days** from the submission date.
In case the applicant has provided incomplete information after screening, the Authority communicates through the system and requests the missing regulatory requirements.

The applicant submits missing requirements through the system, within **fifteen (15) working days** unless she/he request for extension before the deadline. An incomplete application will be subjected to resubmission.

II.3.2 Review of Application

The application is thoroughly reviewed to ensure transparency and quality assurance.

The review process follows the first-in, first-out (FIFO) principle, except for applications submitted in response to public health emergencies such as disease outbreaks, which are given priority.

The application shall be assessed to ensure safety, efficacy, and quality of innovative medical products as per the relevant standard operating Procedures (SOPs). After the review, Rwanda FDA committee for Scientific Evaluation of Innovative Products will be convened to review the outcome of evaluations.

II.3.2.1 Timelines for review

The routine review of new innovative medical products application does not exceed 24 months. For emergency use, accelerated (intensive work) assessment will be done within 8 months.

These timelines shall not include the time taken by the applicant to respond to any request for additional information or clarification from the Authority. A stop-clock mechanism shall thus apply each time the Authority requests for additional information. This will help to monitor timelines for each application from the date of application to the final approval.

The response to queries or clarifications from the applicant shall not exceed ninety (90) working days unless she/he requests for extension in writing before deadline.

II.3.2.2 Types of review

The Authority shall conduct comprehensive review (full assessment) of all modules of the CTD to establish quality, safety and efficacy of submitted, including risk management plan, GMP and clinical trials. During the process, it may hire/invite the external reviewers following the internal procedures depending on the complexity of innovative medical applications that require special expertise. The experts will sign a confidentiality agreement with the Authority to ensure the protection of information, in accordance with relevant procedures.

a. Routine Reviews

The routine review process is a pathway following first in first out (FIFO) principle. The review of all modules of the CTD to establish quality, safety and efficacy of submitted, including risk management plan, GMP and clinical trials.

b. Non-routine reviews

The non-routine review process is a pathway for accelerating the review and approval of innovative medical products application decision-making under certain circumstances (e.g., public health emergencies).

c. Joint reviews

The joint reviews of Applications are carried out jointly by the Authority with other relevant regulatory bodies at regional or international level. The applications are reviewed by experts from each participating regulatory body and the coordination is done by a designated regulatory authority. Therefore, a regulatory decision will be taken at national level once all the requirements are fulfilled.

II.3.2.3 Review of additional data

Rwanda FDA reviews the query responses/clarifications provided and if the information is satisfactory marketing authorisation certificate is issued. In case the applicant provides non satisfactory query responses for three consecutive times, the application shall be rejected.

II.3.2.4 Presentation of the report to the Technical Scientific Committee

The division in charge of registration shall present the registration report of the product to the Technical Scientific Committee, in order to take the appropriate decision (Approval/additional information /Rejection) within 20 working days.

II.3.2.5 Post Approval changes

The validity of marketing authorisation, Emergency use authorisation, Renewal, variations, publications, Cancellation or Suspension will follow applicable relevant guidelines.

The post-marketing surveillance and adverse effects reports shall be submitted to the Authority annually, for evaluation and determination of risk benefit profile of the registered products every year. Failure to submit the reports shall render the registration of the medicinal product suspended.

ENDORSEMENT OF THE GUIDELINES

	Prepared by	**Checked by**		**Approved by**
Title	**Division Manager for Human Medicines and Devices Registration**	**Head of Drugs Department**	**Division Manager for Quality Management System**	**Director General**
Names	Dr. Steven NKUSI	Dr.Vedaste HABYALIMANA	Ms. Marie Ange UWASE	Prof. Emile BIENVENU
Date & Signature	Digitally signed by Dr. Steven NKUSI Date: 2025.11.17 13:09:00 +02'00'	Digitally signed by RWANDA FDA(Head of Drugs Department) Date: 2025.11.17 13:39:45 +02'00'	Digitally signed by Marie Ange UWASE Date: 2025.11.21 14:15:14 +02'00'	Digitally signed by RWANDA FDA(Director General) Date: 2025.11.27 18:58:47 +02'00'

APPENDICES

Appendix (1): Request inquiry for registration of innovative product.

General Notes

Note I: Font to use" Times New Roman size 12"
Note II: A medical product not previously registered in Rwanda or abroad that apply for registration in order to add a new therapeutic advantage and fulfilling the eligibility criteria specified in these guidelines.
Note III: The innovative product could be either a new molecule or novel modification of existing drug.

Section 1: "Product description"

1	Name of the Applicant	
2	Marketing Authorization Holder (MAH)	
3	Type of the product	
4	Active ingredients (or drug substance) with concentrations ** clarify salts of your active ingredients & their equivalence	
5	Proposed dosage form	
6	Proposed route of administration	
7	Proposed pack in details (Describe the package, package material, package size & if it contains any additional accessories).	
8	Manufacturer of the active substance/ drug substance	
9	Manufacturer of the finished product (Clarify primary packager, secondary packager, solvent manufacturer if present)	
10	Proposed indication(s)	
11	Proposed dose, dose regimen & method of administration	
12	Does any active ingredient have a narrow therapeutic index?	**Yes** ☐ **NO** ☐
13	Are active ingredient(s) approved for intended indication in treatment guidelines?	**Yes** ☐ **NO** ☐

Section 2: "Preliminary Evaluation"

□□Which of the following categories can the submitted product be classified?		
1	New molecular entity	
2	New indication	
3	Novel technology in manufacturing	
4	New route of administration of the already existing drug	
5	Novel formulation	
6	New Fixed dose combination	
7	New Stereoisomer	
8	Others (kindly mention)	
What is the added therapeutic value(s) for the submitted product?		
1	Superior efficacy	
2	Better safety profile	
3	Better pharmacokinetic profile	
4	Improvement of patient compliance	
5	New treatment option	
6	Others (Kindly mention)	
□□In case of new molecular entity, did the company apply for a patency?		**YES OR NO**
1	Does the manufacturer have the ability to manufacture the submitted product upon approval?	
2	Is the submitted product new and not registered or under registration in local or global market?	
3	Is there any supportive evidence from credible literature that support the safety and efficacy of the submitted product	
4	Is there any market need for this product?	
5	Is there any safety concern on the active ingredient(s)?	
6	Does the company have the ability to perform clinical trials when needed?	
7	Does the company have a strong PV system?	

Applicant name, address signature and stamp
Mobile number and email

Appendix (2): Template for scientific evaluation of innovative product

General Notes

Note I: Font to use" Times New Roman size 12"
Note II: If any information isn't available, write NA "Not available"
Note III: After acceptance of your file, send the soft data of this completed evaluation form along with full application dossier as specified in the guidelines to (info@rwandafda.gov.rw)
Note IV: A medical product not previously registered in Rwanda or abroad that apply for registration in order to add a new therapeutic advantage and fulfilling the eligibility criteria specified in these guidelines.
Note V: The innovative product could be either a new molecule or novel modification of an existing drug.

Section 1: Product Description

1	Name of the Applicant	
2	Type of license	
3	Type of the product (Pharmaceutical, biological or medical devices)	
4	Active ingredients (or drug substance) with concentrations ** clarify salts of your active ingredients & their equivalence	
5	Proposed dosage form	
6	Proposed route of administration	
7	Proposed pack in details (Describe the package, package material, package size & if it contains any additional accessories).	
8	Manufacturer of the active substance/ drug substance	
9	Manufacturer of the finished product (Clarify primary packager, secondary packager, solvent manufacturer if present)	
10	Category of innovation	
11	Added therapeutic value	
12	Proposed indications	
13	Proposed dose, dose regimen & method of administration	YES ☐ NO ☐
14	Does any active ingredient have narrow therapeutic index?	YES ☐ NO ☐

Section 2: Proposed summary of products characteristics

Attach a proposed summary of product characteristics (SmPC) for the submitted product.

Section 3: Regulatory status of reference countries

A. List the nearest registered product(s) to the submitted innovative product that registered in different reference countries.

B. In case of fixed dose combination, add to the previous list the reference products for each active ingredient (if available). **(Please fulfil each item in table 1).**

Note I: Links for product search sites in reference countries in the last page.
Note II: The original SmPC for the mentioned reference product(s) should be attached and in case of non-English language, the translated English version should be also attached.

Table (1):

Reference country	Trade name	Composition and strength	Dosage form	Marketing status	SmPc "Link if available"

Section 4: Clinical safety data and safety concern

A. Mention any available clinical safety data for the submitted innovative product or for the nearest ones.

B. Mention any safety concerns available for active ingredient(s) contained within the submitted innovative product (either single or in combination**).**

Note: References for the above mentioned data should be attached.

Section 5: For Products containing more than one active ingredient

A: Drug-Drug Interactions:

If your product contains more than one active ingredient, please clarify if there is a drug-drug interaction between its active ingredients. (Please fulfil each item in table 2).

Note

I. Links for Drug-drug interactions search sites in the last page; you can use any of them;
II. Using of other drug- drug interaction search sites is also accepted.

Table (2):

Drug-Drug Interaction	**Possible side effect**	**Recommendation/Management**

B: Dosing interval and dose timing:

If your product contains more than one active ingredient, please clarify if they have the same dosing interval and dose timing (Please fulfil each item in table 3)

Table (3):

Active ingredient	Same dosing interval	Same dosing timing	Management if different dosing interval or dose timings

Section 6: Proposed composition, incompatibilities and proposed Pack

A. Attach a composition sheet for the submitted product and certificates of analysis for the product**;**
B. Clarify if there are any physical and chemical incompatibilities. Clarify if there are any physical or chemical incompatibilities between ingredients of the submitted products. (Please fulfil each item in table 4).

Table (4):

Active ingredients	Physical incompatibilities	Chemical incompatibilities	Management

C. Clarify the reasons for choosing the proposed materials, package size & additional accessories (if present).

Section 7: Guidelines

Show the guidelines for treatment of targeted disease (please fulfil each item in table 5)

Table (5)

Guidelines Title	Guidelines association	Line of treatment(1st line 2rd line,3rd line…) & level of evidence	Year

Section 8: Scientific rationale for the development of innovative product

-Attach a summary for innovative product characteristics that explains clearly the need and the impact of the claimed innovation.

-This summary must show the scientific evidence (supported by credible literature as a reference) that explains clearly the added therapeutic value of the submitted innovative product over the registered products either in local or global market (Maximum four pages).

Scientific Evidence Criteria:

I-Credible literature includes guidelines of treatment and other supportive studies
(systematic reviews & meta-analysis, systematic reviews, clinical efficacy studies, clinical safety studies) that are performed on the submitted product or similar ones (exact active ingredients, composition & dosage form).

** If the available credible literature is insufficient for the submitted product or similar products, other credible literature for the nearest product(s) could be submitted.
** Comparative studies are preferred.

II – Pharmacokinetics data such as: absorption, distribution, metabolism, excretion could be submitted (if available) especially for products with new dosage form or new route of administration or novel formulation or new fixed dose combination.

III- Animal pharmacological data could be submitted for new molecules (if available). IV- Animal toxicology data (systemic toxicity studies, reproductive studies, local toxicity, genotoxicity, carcinotoxicity) could be submitted for new molecules (if available).
**Local Toxicity data as dermal toxicity, topical ocular toxicity, inhalation toxicity, vaginal toxicity, photo allergy, rectal tolerance test; could be submitted for innovative local products (if available).

Section 9: Supportive studies

Provide a full text article for studies demonstrating the scientific evidence mentioned in section 8. Please, fulfil each item in table 6 and then attach the full study)

Table (6)

N0	**Literature Type**	**Title**	**Publication year**	**Main findings**	**Link**
1	Systematic reviews & meta analysis				
2	Systematic Reviews				
3	Clinical efficacy studies				
4	Clinical safety studies				
5	Pharmacokinetics studies				
6	Animal pharmacological data				
7	Animal toxicology data				
8	Others				

Applicant name, address signature and stamp
Mobile number and email

Assessor
Name, title and signature

Links for products search sites in Reference countries

Name of regulatory authority	**Home page**	**Online product database**
EMEA	http://www.ema.europa.eu	https://www.ema.europa.eu/en/medicines
FDA	www.fda.gov	https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm
TGA (Australia)	www.tga.gov.au	https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuMedicines?OpenView
MHRA (UK)	www.mhra.gov.uk	https://products.mhra.gov.uk/
EMC(Electronic Medicines Compendium)	http://www.medicines.org.uk/emc/	https://www.medicines.org.uk/emc#gref
France	https://ansm.sante.fr/documents/reference/repertoire-desmedicaments	http://agenceprd.ansm.sante.fr/php/ecodex/index. php
Health Canada	https://www.canada.ca/en.html	https://health-products.canada.ca/dpd-bdpp/indexeng.jsp
Japan	http://www.pmda.go.jp/english/index.html	http://www.info.pmda.go.jp/psearch/html/menu_tenpu_base.html
IMB (Ireland)	https://www.hpra.ie/homepage/about-us	https://www.hpra.ie/
Italy	http://www.agenziafarmaco.it/en	https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/
Germany	http://www.pharmnethttp://www.pharmnet-bund.de/dynamic/en/am-info-system/index.htmlbund.de/dynamic/en/am-infohttp://www.pharmnet-bund.de/dynamic/en/am-info-system/index.htmlsystem/index.html	http://www.pharmnethttp://www.pharmnet-bund.de/dynamic/en/am-info-system/index.htmlbund.de/dynamic/en/am-infohttp://www.pharmnet-bund.de/dynamic/en/am-info-system/index.htmlsystem/index.html
EMEA	http://www.ema.europa.eu	https://www.ema.europa.eu/en/medicines
FDA	www.fda.gov	https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm
TGA (Australia)	www.tga.gov.au	https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuMedicines?OpenView
MHRA (UK)	www.mhra.gov.uk	https://products.mhra.gov.uk/
EMC(Electronic Medicines Compendium)	http://www.medicines.org.uk/emc/	https://www.medicines.org.uk/emc#gref

Swiss medic (Switzerland)	http://www.swissmedic.ch/index.html?lang=en	https://www.swissmedicinfo.ch/?Lang=EN
Spain	http://www.aemps.es/	https://www.aemps.gob.es/cima/fichasTecnicas.do?metodo=detalleForm
Sweden	http://www.lakemedelsverket.se/english/	http://www.lakemedelsverket.se/Sok-efter-lakemedel-och-mediciner-i-Lakemedelsfakta/
Belgium	http://www.faggafmps.be/en/human_use/medicines/herbal_medicinal_products/pharmacovigilance/	http://bijsluiters.faggafmps.be/?localeValue=nl
Austria	http://www.ages.at/	https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx?_afrLoop=50195861171580298&_afrWindowMode=0&_adf.ctrlstate=16yka9pwvp_4
Denmark	https://laegemiddelstyrelsen.dk/en/	http://produktresume.dk/AppBuilder/search
Finland	http://www.fimea.fi/	http://www.fimea.fi/web/en/databases_and_registeries/fimeaweb
Iceland	http://www.lyfjastofnun.is/	http://serlyfjaskra.is/
Netherlands	http://www.cbg-meb.nl/cbg/nl	https://www.geneesmiddeleninformatiebank.nl/nl
Luxembourg	https://sante.public.lu/fr.html	https://cns.public.lu/en/legislations/textes-coordonnes/liste-medcomm.html
New Zealand	http://www.medsafe.govt.nz/	http://www.medsafe.govt.nz/regulatory/DbSearch.asp
Norway	http://www.legemiddelverket.no/	https://www.legemiddelsok.no/
Portugal	http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH	https://extranet.infarmed.pt/INFOMED-fo/

Drug-Drug Interaction sites

https://www.drugs.com/drug_interactions.html
https://reference.medscape.com/drug-interactionchecker
https://www.webmd.com/interaction-checker/default.htm