IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 6, November 2025
Impact Factor: 7.67

Comparative Regulatory Landscape of Relugolix: A Novel GnRH Antagonist for the Treatment of Prostate Cancer, Endometriosis and Uterine Fibroids

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Abstract: *Relugolix serves as an orally active gonadotropin releasing hormone antagonist. Reserchers developed it to handle hormone dependent conditions. These include prostate cancer, endometriosis, and uterine fibroids. This paper looks at a comparative analysis of its regulatory setup. It covers major agencies around the world. Those are the U.S. FDA, EMA, PMDA, MHRA, Health Canada, and TGA. The review involved regulatory documents. It also included key clinical trials like HERO, LIBERTY, and SPIRIT. Health technology assessment reports got a close look too. All this helped evaluate approval timelines. It covered therapeutic indications, labeling needs, and post marketing commitments. Regulators approved Relugolix as Orgovyx for prostate cancer.Everyone accepted the efficacy data pretty much the same way. Still, regions showed differences in treatment length. They varied on contraindications, heart related warnings, and monitoring rules. The path to approval for Relugolix shows more global agreement on its benefits. This gives useful info for doctors, regulators, and people in the industry. [1].*

Keywords: Relugolix, GnRH antagonist, prostate cancer, endometriosis, uterine fibroids, regulatory landscape

I. INTRODUCTION

In this current era, Hormone dependent disorders for, endometriosis, prostate cancer and uterine fibroids is a seriousglobal health issues and it causes clinical, social and economicburdens. In men worldwide prostate cancer is the 2nd most common diagnosed malignancy. Specially, endometriosis is also critical issue it affect more than 10% women in whole world. also, it causes infertility, pelvic pain, and bad quality of life and create complications [2] , while uterine fibroids is the gynaecological tumors, often associated with anaemia, menorrhagia and reproductive complications.[3] Pharmacological treatments and surgical are available but in case of relugolix, it provides a well therapeutic approach that provide sustained efficacy, improved tolerability, and grater patient convenience.

Relugolix is the drug first in class, consume daily and it is a non peptide GnRH antagonist, was introduced to solve these type of symptoms caused by severe disease conditions. Moreover, it rapidly reduce the circulating the level of testosterone in men and estradiol in women, and also it offers novel therapeutic alternatives across multiple indication.

This review aims to provide a comparative international perspective on the regulatory landscape of relugolix, analysing key clinical evidence, approval timelines, and regional differences. By highlighting harmonized and divergent regulatory decisions, the paper seeks to inform clinicians, policy makers, and industry stakeholders on the global positioning of relugolix and its implications for patient access, safety monitoring, and future drug development.. And also shows a hug r regulatory gap among different agencies The U.S. Food and Drug Administration (FDA) has approved relugolix for the treatment of advanced prostate cancer and uterine fibroids. [4] In contrast, the European Medicines Agency (EMA) has been more cautious, raising concerns about long term safety, particularly the risk of

ISSN 2581-9429 IJARSCT

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bone mineral density loss in women. Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has authorized relugolix for several indications, reflecting a broader acceptance. Meanwhile, in countries such as India, Australia, and Canada, regulatory reviews are still underway. These differences highlight how global agencies vary in their assessment of benefits and risks, the strength of evidence they require, and the types of pharmacovigilance measures they emphasize.

This paper thus aims to provides a comprehensive international comparison of the regulatory landscape of Relugolix across major global agencies, including the FDA, EMA, PMDA, MHRA, and CDSCO. The novelty of this study lies in its integrated evaluation of approval timelines, labeling variations, and post-marketing obligations, highlighting regulatory harmonization as well as regional divergences. By bridging these global insights, the paper offers an original perspective on how varying regulatory frameworks influence patient access, safety monitoring, and policy development for first-in-class oral GnRH antagonists.

II. DISCUSSION

Aim

To analyze and compare the regulatory requirements, approval status, and post-marketing considerations of Relugolix across different global regulatory agencies.

2.1 Objectives

1. To study the mechanism of action and therapeutic indications of Relugolix.
2. To review the approval process and regulatory requirements of Relugolix in the U.S. FDA, EMA, PMDA (Japan), and one emerging market (e.g., CDSCO–India).
3. To compare labeling information, safety concerns, and risk–benefit assessments across these agencies.
4. To identify similarities, differences, and gaps in regulatory approaches.
5. To provide insights on future perspectives for global harmonization of regulatory pathways for novel GnRH antagonists.

2.2 Methodology

This review was conducted using narrative regulatory analysis approach to evaluate international approvals and regulatory decisions related to relugolix drug.

2.2.1 Data sources

2.2.2 Regulatory agencies websites

Official document werecollected from US FDA, PMDA, EMA, MHRA, Health Canada as well as TGA. Furthermore, this websites contains whole regulatory information related to the pathways and drug details.

2.2.3 Clinical Trial Databases:

ClinicalTrials.gov, EU Clinical Trials Register, and Japan Registry of Clinical Trials were searched for pivotal trials (HERO, LIBERTY, and SPIRIT programs) supporting regulatory submissions.

2.2.4 Scientific Literature:

PubMed, Scopus, and Embase databases were searched using keywords such as Relugolix, GnRH antagonist, prostate cancer, uterine fibroids.

2.2.5 Search strategy and time frame

By, Searching method it provides accurate method about its approval time frame. And also to capture the most relevant and updated information following the initial FDA approval.

Regulatory approval documents, publication of pivotal clinical trail and peer reviewed article related to Relugolix. Preclinical studies, non peer reviewed commentaries, and sources not directly related to regulatory or clinical approval aspects.

2.2.6 Data Extraction and Analysis:-

Extracted variables included such as approval dates, brand names approved indications, treatment duration limits, safety warnings, contra indication and also a plan of Risk Management.

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III. DISEASE PROFILE

1. Endometriosis

A gynecologic condition that is chronic and in which tissue that looks like the lining of the uterus (endometrium) grows outside the cavity of the uterus, most often on the ovaries, fallopian tubes, and pelvic peritoneum. It is the cause of pelvic pain, menstrual abnormalities, inflammation, scarring, and infertility. [5]

2. Prostate cancer

A type of cancer tumor that occurs in the prostate gland, a male reproductive gland that lies below the bladder and in front of the rectum. It may be slow-growing or aggressive and may cause difficulty urinating, hematuria, or bone pain if advanced. [6]

3. Uterine Fibroids

Uterine Fibroids Benign (noncancerous) tumors in the uterine muscular tissue (myometrium) made up of smooth muscle cells and fibrous connective tissue. They may range in size and result in heavy menstrual bleeding, pelvic pressure, pain, or reproductive difficulties. [7]

Endometriosis, prostate cancer, and uterine fibroids are significant reproductive health disorders that can severely impact quality of life. These conditions often lead to chronic pain, abnormal bleeding, and infertility in affected individuals. If untreated, they may progress to complications such as severe pelvic inflammation, organ damage, or cancer metastasis. Early diagnosis and appropriate medical or surgical management are crucial to prevent long-term consequences.

IV. DRUG PROFILE

1. Drug name: Relugolix
2. Drug class: Non peptide, orally active gonadotropin releasing hormone (GnRH) receptor antagonist.
3. Molecular formula: $C_{29}H_{27}F_2N_9O_3$
4. Molecular weight: 623.6 g/mol
5. Route of administration: Oral (once daily tablet)
6. Approved brand names: Orgovyx® (monotherapy, prostate cancer), Myfembree® (fixed dose combination, USA), Ryeqo® (fixed dose combination, EU/UK), Japanese brands vary by indication.
7. IUPACname:-1-[4-[1-[(2,6-difluorophenyl)methyl]-5-[(dimethylamino)methyl]-3-(6-methoxypyridazin-3-yl)-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-d]pyrimidin-6-yl]phenyl]-3-methoxyurea. [8]

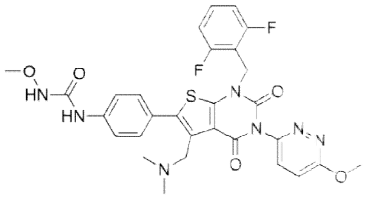

Fig 1- Drug structure

V. PRECLINICAL AND CLINICAL DATA

5.1 Preclinical overview

Pharmacology :- in preclinical animal models such as rodents, dog, non human primates, Relugolix showed dose dependent suppression of pituitary gonadotrophin and sex hormones consistent with competitive Gnrh antagonism. [9]

Toxicology:- When relugolix gave an animals many times, they noticed phospholipids building up inside the cells of organs such as liver, kidney, lungs etc. This build ups called phospholipidosis. But in a 39 week study on animals like monkeys , even with heavy doses- like 50 times higher than what human take in this case there were no human effects on the male reproductive organs.[10]

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5.2 Clinical overview

The clinical summary provides a summary of significant studies assessing the safety and efficacy of Relugolix in multiple therapeutic areas. In Table-1, studies ranging from Phase 1 to Phase 3 have been presented and consist of trials conducted in healthy volunteers and in men with prostate cancer and in women with uterine fibroids and endometriosis. When considered together, the body of evidence obtained from these studies documents that Relugolix is an effective oral GnRH antagonist that exhibits a favorable safety profile.

VI. REGULATORY OVERVIEW

Regulatory Affairs is a recently established profession that emerged from government initiatives to safeguard public health by overseeing the safety and effectiveness of products in sectors such as pharmaceuticals, veterinary drugs, medical devices, pesticides, agrochemicals, cosmetics, and alternative medicines. The firms producing and promoting these items must guarantee that they provide quality products to the public for their well-being and health. Currently, many companies employ specialized teams of Regulatory Affairs professionals

This department is primarily engaged in the registration of pharmaceutical products in their respective countries before they are marketed.

1. Regulatory Affairs in the country of origin (DRA)
2. International Regulatory Affairs (IRA)

Aside from the country of origin, Regulatory Affairs engages with one of the Centers, such as the Center for Drug Evaluation and Research (CDER) at FDA headquarters, MHRA, or the Ministry of Health (MOH) in various countries; Regulatory Affairs is a relatively recent profession established by governments to safeguard public health by overseeing the safety and effectiveness of products. [16]

Without regulatory pharma sector is incomplete because everywhere in case of healthcare it plays vital role to start to end in each and every process documentation is required for its completion.

Global Regulatory Affairs (GRA) is a critical discipline within the pharmaceutical, biotechnology, and medical device industries. It ensures that products are developed, manufactured, and marketed in compliance with regulatory requirements worldwide. The goal is to secure approvals from health authorities and maintain compliance throughout the product's lifecycle.

- Strategic Development

Accelerated Pathways

- Regulatory Agency Interactions
- Preparation & Submission
- Regulatory Compliance
- Medical Device & Diagnostics
- Combination Products

Role of regulatory affairs

I. Drafting and filing regulatory documents.

II. Preparing submissions for clinical trials and marketing authorizations.

III. Maintaining labeling and promotional materials in compliance with regulation. Tracking and responding to new legislation and guidelines.

IV. Interfacing with governmental agencies like the FDA, EMA, and others.

6.1 Overview of global regulatory Authorities

Governmental bodies known as regulatory agencies are in charge of ensuring the quality, safety, and effectiveness of pharmaceuticals, biologics, and medical equipment (Table 2). These organizations evaluate both clinical and non clinical data, approve clinical trials and marketing authorization, and keep an eye on the products over time. [17]

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Sr No.	Study name	Phase	Population	Design& Dosage	Key endpoints	Results
1	Phase I [11]	1	Healthy Men	Oral relugolix, escalating dosses: single and multiple dosing	Safety, pk, testosterone suppression	Dose dependent hormone suppression, well tolerated
2	Phase II [12]	2	Women with endometriosis associated pain	Oral relugolix, various regimens once daily	Change from baseline in mean visual analog scale score for pelvic pain over the 28 days before end of treatment	Well tolerated and also reduced endometriosis related pain
3	HERO TRAIL(NCT030 8509) [13]	3	Advanced prostate cancer	Relugolix vs Leuprolide: 48 weeks: LD 360 mg- 120 mg daily	Sustained testeosterone suppression, CV safety	96.7% suppression vs 88.8% with leuprolide: 54% lower risk of major cv events
4	LIBERT Y 1&2 [14]	3	Women with uterine fibroids & heavy bleeding	Relugolix+ Estradiol+Noreth isteroe vs placebo	Reduction in heavy menstrual bleeding	Significant bleeding reduction. Improved quality of life
5	SPIRIT 1&2 [15]	3	Women with endometriosis pain	Relugolix combination therapy vs placebo	Pain reduction, bone density safety	Effective pain control: maintained bone mineral density

Sr No	Country	Regulatory Authority
1.	United States	FDA (Food and Drug Administration)
2.	Canada	Health Canada (HC)
3.	European Union (EU)	EMA (European Medicines Agency)
4.	United Kingdom	MHRA (Medicines and Healthcare products Regulatory Agency)
5.	France	ANSM (National Agency for Medicines and Health Products Safety)
6.	Japan	PMDA (Pharmaceuticals and Medical Devices Agency)
7.	China	NMPA (National Medical Products Administration)
8.	Australia	TGA (Therapeutic Goods Administration)
9.	Singapore	HSA (Health Sciences Authority)
10.	Saudi Arabia	SFDA (Saudi Food and Drug Authority)
11.	Brazil	ANVISA (Brazilian Health Regulatory Agency)
12.	South Africa	SAHPRA (South African Health Products Regulatory Authority)
13.	India	CDSCO (Central Drugs Standard Control Organization)

6.2 Approval Pathway of drugs of different countries

1. United States (FDA – CDER, CBER)

• United States (FDA – CDER, CBER)
• IND (Investigational New Drug) application
• Clinical Trials -Phase I, II, III
• NDA (New Drug Application) or BLA (Biologics License Application) submission

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• FDA Review
• Approval for marketing
• Special pathways: Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review

2. European Union (EMA + European Commission)
• Preclinical studies
• Clinical Trials in compliance with EU regulations
• MAA (Marketing Authorization Application) via:.
• Centralized Procedure (mandatory for biotech/orphan/oncology)
• Decentralized Procedure (DCP) or Mutual Recognition Procedure (MRP)
• National Procedure (single country only)
• EMA scientific review → European Commission decision
• EU-wide marketing authorization
• Special pathways: PRIME, Accelerated Assessment, Conditional Approval

3. Japan (PMDA + MHLW)
• Preclinical studies
• Clinical Trial Notification (CTN) submission before human studies
• Clinical Trials Phase I–III
• NDA submission to PMDA
• PMDA scientific review -MHLW final approval
• Special pathways: SAKIGAKE Designation, Conditional Early Approval

4. Canada (Health Canada – HPFB)
• Preclinical studies
• CTA (Clinical Trial Application) for clinical studies
• Clinical Trials Phase I–III
• NDS (New Drug Submission) to Health Canada
• Review - Notice of Compliance (NOC) + Drug Identification Number (DIN)
• Special pathways: Priority Review, NOC/c (Notice of Compliance with conditions)

5. India (CDSCO – DCGI)
• Preclinical studies
• CTA for clinical trials
• Clinical Trials Phase I–III
• NDA submission to CDSCO
• CDSCO review -Marketing Authorization approval
• Special pathways: Accelerated Approval for unmet medical needs.

6. Australia (TGA)
• Preclinical studies
• CTA before clinical trials
• Clinical Trials Phase I–III
• Application for listing on ARTG (Australian Register of Therapeutic Goods)
• TGA Review -Approval
• Special pathways: Priority Review, Provisional Approval.

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7. China (NMPA)

• Preclinical studies
• IND submission before clinical trials
• Clinical Trials Phase I–III
• NDA submission to NMPA
• NMPA review - Approval for marketing
• Special pathways: Priority Review, Conditional Approval, Breakthrough Therapy

8. UK (MHRA)

• Preclinical studies
• Clinical Trials Phase I–III
• MAA (Marketing Authorization Application) submission to MHRA
• MHRA review - Marketing Authorization approval
• Special pathways: ILAP (Innovative Licensing and Access Pathway), Conditional & Accelerated Approval. [18].

6.3 Common Technical Document (CTD) Structure

A common technical document is a standardized format for preparing and submitting applications to regulatory authorities for the registration of pharmaceuticals. It is developed by international council.

It was designed to provide a common format between Europe, USA< and Japan for technical documentation. CTD is majorly divided by five main module. Module 1 to Module 5. [19].

Here it is key benefits

• It is a single dossier, used in multiple regions.
• Standardized format and facilitated international cooperation.
• Also speed up review timelines.
• Supports electronic submission
• Helps in lifecycle management, save time & cost.
• It supports strategic planning.
• Supports regulatory harmonization process. [20]

Milestones in CTD Development

• 1990 – Establishment of ICH.
• 1997–1999 – Development of CTD guidelines.
• 2000 – Official adoption of the CTD format by
• ICH.
• 2003 – Mandatory use of CTD in ICH regions
• for new drug applications.
• 2008–present – Transition to the electronic
• Common Technical Document (eCTD)

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The Common Technical Document (CTD) Triangle

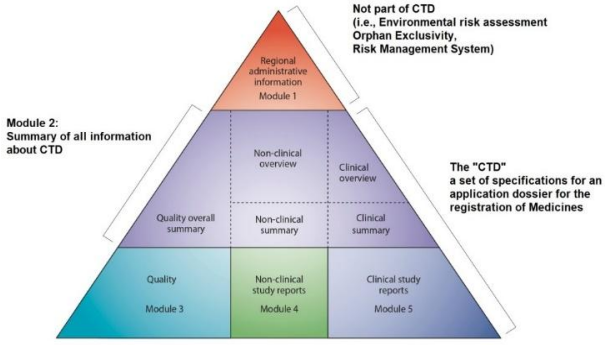

Fig-2- CTD triangle

Module 1: Administrative and Product Information
(Region-specific – not harmonized)
Application form
Cover letter
Administrative information
Prescribing information / labeling
Product information (SPC, PIL, package labeling)
Patent information (if applicable)
Regional guidance-specific requirements

Module 2: Common Technical Document Summaries
2.1 CTD Table of Contents
2.2 Introduction (brief product description, pharmacological class, proposed indication)
2.3 Quality Overall Summary (QOS)
2.4 Nonclinical Overview
2.5 Clinical Overview
2.6 Nonclinical Summaries (Pharmacology, Pharmacokinetics, Toxicology)
2.7 Clinical Summaries (Biopharmaceutics, Clinical pharmacology, Efficacy, Safety)

Module 3: Quality (CMC – Chemistry, Manufacturing, and Controls)
3.1 Table of Contents
3.2 Body of Data
3.2.S Drug Substance
General information, manufacture, characterization, control, reference standards, stability
3.2.P Drug Product Description, composition, manufacturing process, control of excipients & product, container closure, stability
3.3 Literature References

Module 4: Nonclinical Study Reports
Pharmacology studies (primary, secondary, safety)
Pharmacokinetics (ADME, drug interaction studies)
Toxicology(singledose, repeatdose, genotoxicity, carcinogenicity, reproductive, local tolerance, other special studies)

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Module 5: Clinical Study Reports
5.1 Table of contents
5.2 Study reports
Biopharmaceutics
Clinical pharmacology
Efficacy studies
Safety studies
5.3 Case report forms & data listings
5.4 Literature references
Nowadays, major countries use eCTD structure because it is effective, standardized and easily editable. [21]
ASEAN common technical document is a standardized format for preparation and applications to register pharmaceutical across ASEAN) association of southeast Asian nations) member countries.Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

ACTD contents
Part I: Table of Content Administrative Information and Prescribing Information
Section A: Introduction
Section B: Overall ASEAN Common Technical Dossier Table of Contents
Section C: Documents required for registration (for example, application forms, labelling, Product Data Sheet, prescribing information)

Part II: Quality Document
Section A: Table of Contents
Section B: Quality Overall Summary
Section C: Body of Data

Part III: Nonclinical Document
Section A: Table of Contents
Section B: Nonclinical Overview
Section C: Nonclinical Written and Tabulated Summaries

1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology
Section D: Nonclinical Study Reports
1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology
Section D: Tabular Listing of All Clinical Studies
Section E: Clinical Study Reports
Section F: List of Key Literature References. [22]

7. Relugolix approval status in different countries

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Table III. Relugolix approval status in different countries

Sr No	Region	Month of approval	Year of approval	indication	Approval authority	Additional info
1.	USA	Dec	2020	Advanced prostate, Cancer [23]	FDA	First oral GnRH antagonist
		Aug	2022	Endometriosis associated pain	FDA	Relugolix+ Estradiol+ Norethindrone combination. Known as brand Myfembree
2.	EU	April	2022	Advance hormone, sensitive prostate cancer	European commission	Approved brand name Orgovyx and Ryeqo
		July	2021	endometriosis [24].	European commission	Approved brand name Ryeqo
3.	UK	Aug	2022	Uterine fibroids [25]	MHRA	Available in uk brand name Ryeqo
4.	Canada	Oct	2023	Advanced prostate cancer [26], [27]	Health Canada	Approved based on phase 3 Hero study
5.	Japan	Jan	2019	Uterine fibroids [28]	PMDA	Approved as relumine for Uterine fibroids
5.	India	Jan	2024	Advanced prostate cancer	CDSCO	Approved as Rexigo

8. Analysis of labelling and post marketing requirements

Labelling is a important part for every pharmaceutical product and it vary based on local regulations, languages and approval authorities.

Labelling differences country wise

1) united states: (FDA)

• Type of label format:- prescribing information (PI) with highlights & Full product information
• Language:- English
• Guide: 21 CFR part 201.56 &201.57
• Key document: Structured product labelling (SPL). [29]

2) EU (EMA)

• Type of label :- Summary of product Characteristics (Smpc), package leaflet.
• Language :- All EU official languages required for outer packaging & leaflet.
• Guideline: Directive 2001/83/EC. [30]

3) Japan (PMDA)

• Type of label format:- package insert (PI) with approval number, dosage, precautions.
• Language:- Japanese is mandatory requirement.
• Special note:- must include risk info like contraindications and warnings prominently. [31]

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4) India (CDSCO).
• Type of label format:- Package insert, outer label, patient info leaflet.
• Language:- English required, local language for patient leaflets.
• Guidelines:- Drug and cosmetic act & Labelling Rules 1945. [32]

5). Canada (Health Canada).
• Type of label format:- Product monograph+ Outer& Inner label, patient info leaflet
• Language:- English and also a French
• Special note:- Patient medication information (PMI) required. [33]

6) UK (MHRA)
• Type of label format:- Smpc +PIL+ Packaging
• Language:- English
• Special Notes:- Follows EU format but under MHRA guidance post Brexit.

7). China (NMPA)
• Type of label format- Drug instruction (PI) + Packaging.
• Language:- Only Chinese is mandatory [34]

8). Australia (TGA).
• Type of Label format:- PI+ Customer Medicine information (CMI).
• Language:- English is mandatory
• Special notes:- Standards for the uniform scheduling of medicines and poisons (SUSMP) applies. [35]

General Requirements for Labeling
Must provide accurate, clear, and updated information for safe and effective drug use.
Typical contents include:
1. Product identification (name, dosage form, strength)
2. Indications & usage
3. Dosage & administration
4. Warnings & precautions
5. Contraindications
6. Adverse reactions
7. Storage & handling instruction
• Language should be simple and understandable for patients; technical parts for healthcare professionals.
• Labeling must comply with Good Manufacturing Practices (GMP) and national regulatory standards. [36]

Post Marketing requirement
It is an important requirement for every pharmaceutical product. It ensures ongoing safety and efficacy monitoring after a drug approval. There are some elements which is important part of pharmacovigilance system such as periodic safety update reports, risk management plans signal detection process, post marketing clinical studies, labelling updates. These measures help regulatory bodies to continuously evaluation of the risk benefit profile of a drug during overall life cycle.
Purpose :-
• Safety monitoring: find long term or uncommon side effects that clinical trails were unable to detect.
• Evaluation of efficacy:- Examination of how well a medication works in real population.
• Risk management:- Put policies in place to reduce hazards such as US' Risk evaluation and mitigation strategies or REMS. Assure uniformity in manufacturing and adherence to good Manufacturing practices through quality assurance.

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Geneal observation

It aim is that to monitor safety and efficacy of the product after its approvalKey elements is also crucial part as I mentioned earlier.

Differences across countries

• US FDA :- REMS, MedWatch reporting, phase 4 trails, PSURs.

• EU (EMA): RMP, PSURs, post authorization safety studies (PASS)

• Japan (PMDA): re examination period, phase 4 studies

Other countries (Australia, China, UK, Canada): In these countries framework is similar but minor differences in frequency, report formats, and local systems.

Components

1. Pharmacovigilance
2. Post marketing studies:- phase 4 clinical trails, observational studies
3. Risk evaluation and mitigation strategies
4. Manufacturing and quality
5. Labelling update

Interpretation :-

Post marketing requirements are similar globally like risk benefit monitoring but report formats, specific processes may be differ minor. Companies conducting global drug launches must align PV systems and reporting formats with local authorities. [37] [38].

Here it is key benefits of post marketing Requirements

• It enhanced patient safety

• Support for regulatory decision making

• Better risk benefit assessments

• Encourages innovation ibn monitoring tools

• Improved understanding of drug effectiveness

Fig/ Diagram:6- Drug safety life cycle

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9. Benefit Risk assessment- Relugolix

Table IV. Benefit Risk Assessment:-Relugolix

Sr. no	Aspect	Benefit	Risk
1.	Efficacy(Prostate Cancer)	~96.7% medical castration rate (testosterone suppressed < 50 ng/dL) from day 29 through 48 weeks. Faster suppression vs leuprolide; lower risk of major cardiovascular events (~54% lower) in HERO trial.	Hot flushes, musculoskeletal pain, fatigue, diarrhea, constipation etc. Laboratory abnormals: increased glucose, triglycerides, transaminases; decreased hemoglobin
2.	Efficacy (Women health:- pain, bleeding, fibroids)	MYFEMBREE (combination: relugolix + estradiol + norethindrone acetate) — heavy menstrual bleeding associated with uterine fibroids, and later for pain associated with fibroids. Once daily oral treatment; combination therapy designed to reduce hypoestrogenic side effects via add-back therapy (estradiol + progestin)	Estrogen/progestin related risks: thromboembolic disorders, vascular events. Hot flashes, uterine bleeding changes, decreased libido, alopecia etc. Bone mineral density loss with long-term suppression of ovarian hormones.

10. Market Analysis and future aspects

The Relugolix API Market was valued at USD 150 Million in 2024 and is projected to expand at a CAGR of 15.3% between 2026 and 2033, reaching USD 450 Million by 2033.

The Relugolix API market is a quickly changing segment within the pharmaceutical sector, mainly concentrating on the creation and distribution of the active pharmaceutical ingredient (API) utilized in Relugolix, an oral drug that functions as a gonadotropin releasing hormone (GnRH) receptor antagonist. This drug is mainly prescribed for managing advanced prostate cancer and uterine fibroids, along with other ailments. The worldwide market for Relugolix is expected to grow considerably, fueled by a rise in hormone sensitive condition cases and the growing understanding of targeted therapies, which are usually more effective and have fewer adverse effects than conventional treatments.

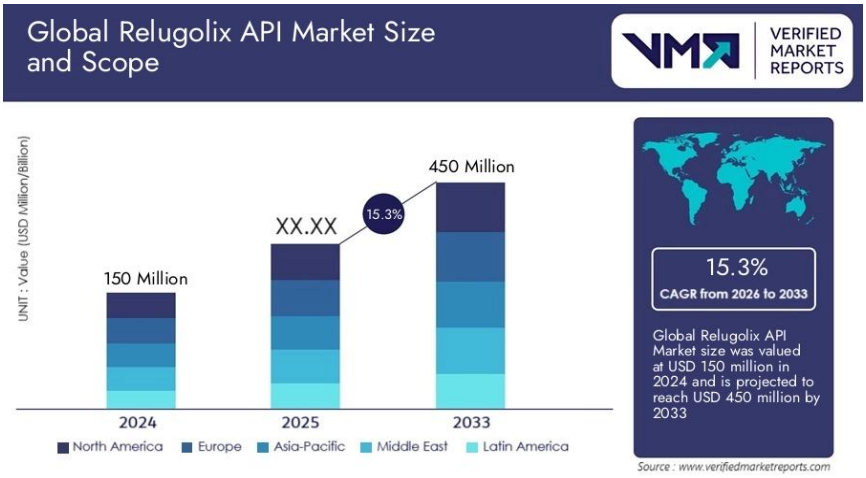
As of 2023, the worldwide market for prostate cancer treatments, including Relugolix, is projected to be worth roughly $30 billion, with a compound annual growth rate (CAGR) of about 7.5% in the next five years, based on information from several health organizations. This increase is linked to the aging demographic and progress in medical research that allows for earlier diagnosis and improved treatment alternatives. Governments are allocating funds to cancer research, as the NationalCancer Institute (NCI) documented a funding rise exceeding $5 billion in 2022 to improve the understanding and treatment of cancer, particularly hormone-related types.

A notable feature of the Relugolix API market is its prospective inclusion within the wider range of hormone therapy medications. Hormone therapy is essential in the treatment of several hormone-sensitive disorders, such as breast cancer and endometriosis. The growing use of these therapies has led to a rise in the need for efficient APIs. As per Verified Market Reports, the worldwide hormone therapy market is expected to attain around $33 billion by 2026, increasing at a CAGR of 8.3%. This creates a hopeful scenario for the Relugolix API as both healthcare practitioners and patients search for viable alternatives to conventional therapies, highlighting the need for innovation in this field. Additional information is available regarding the hormone therapy market.

Relugolix is utilized across various sectors, mainly in oncology and gynaecology, yet its adaptability indicates possible applications in additional therapeutic fields. In oncology, it is used alongside other therapies to improve effectiveness and reduce adverse effects. Gynaecological uses involve addressing symptoms related to uterine fibroids. Moreover, as the pharmaceutical sector transitions to personalized medicine, the Relugolix API could be utilized in customized treatment strategies for different conditions, thus broadening its market presence. With healthcare systems placing more

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 6, November 2025
Impact Factor: 7.67

emphasis on patient centred care, the need for innovative APIs such as Relugolix is expected to rise, underscoring the market's dynamic nature.



STUDY PERIOD	2023-2033
BASE YEAR	2024
FORECAST PERIOD	2026-2033
HISTORICAL PERIOD	2023
UNIT	VALUE
KEY COMPANIES PROFILED	Med Koo Biosciences, Toronto Research Chemicals, AbMole Bioscience, TargetMol Chemicals, Clearsynth, Taiclone, Cayman Chemical, Teva API, Metrochem API Private Limited, Veranova, Dr. Reddys Laboratories, Lee Pharma, Lupin, Moehs Iberica, Medichem S.A, Inno Pharmchem, Changzhou Pharmaceutical Factory
SEGMENTS COVERED	By Drug Type - Oral Tablets, Injectables, Combination Therapies By Therapeutic Area - Oncology, Urology, Gynecology, Endocrinology By Patient Population - Adult Patients, Pediatric Patients, Geriatric Patients, Patients with Co-morbidities By Route of Administration - Oral Administration, Intravenous Administration, Subcutaneous Administration, Intramuscular Administration By Distribution Channel - Hospital Pharmacies, Retail Pharmacies, Online Pharmacies, Specialty Pharmacies By Geography - North America, Europe, APAC, Middle East Asia & Rest of World. [39]

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XII. CONCLUSION

Relugolix is a versatile, effective, and generally safe oral therapy for hormone dependent conditions. It work as rapid and sustained hormone suppression without flare, improving clinical outcomes in prostate cancer. Convenient oral administration, enhancing patient adherence. Combination therapy in women effectively reduces hypoestrogenic side effects while managing symptoms of uterine fibroids and endometriosis. It has great safety profile, particularly regarding cardiovascular risks in men and manageable adverse effects in women. Global regulatory acceptance, supporting its use across diverse patient populations. Its market will boom in future and will approved in other regions.

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