Comparative analysis of regulatory policy on drug pricing in USA, Japan, and European Union

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree

of Master of Business Administration (MBA)

in

Pharmaceutical Management

by

Rishabh Parashar

Under the Supervision and Guidance of

Ashok peepliwal
Associate professor, School of Pharmaceutical management
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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Comparative analysis of regulatory policy on drug pricing in USA, Japan, and European Union** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name of the student- Rishabh Parashar

Date- 05/07/2022

CERTIFICATE

This is to certify that Rishabh Parashar in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed his internship at IIHMR University during March 22, 2022 to June 19, 2022.

Place:
Date:

Preceptor/Head of the Organization
IIHMR University

CERTIFICATE

This is to certify that dissertation titled Comparative analysis of regulatory policy on drug pricing in USA, Japan, and European Union is a record of the research work undertaken by Rishabh Parashar in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

Ashok Peepliwal
IIHMR University, Jaipur

Date 05/07/2022

Dr. Saurabh Banerjee
IIHMR University, Jaipur

Date-05/07/22

Content

Research & Methodology

- **Study Duration** -3 Months
- **Study Design**- intellectual document Study article
- **Sample size** – 3 countries' regulatory policy article

2) Data collection through intellectual Documents and Research articles and journals.

3) Data collection through various online platforms.

Like PubMed,PMDA USFDA EU

INTRODUCTION

Executive Summary

Every country in the world has a national health policy, which is clearly expressed in the form of ambiguous policy documents and government measures. Little research has been done to compare national drug policies and try to understand which policies have been successful in achieving their availability, accessibility, quality, and appropriate drug use goals, and why. not.

In most EU member states, it is directly controlled by the producer's price state. In some EU countries (Cyprus-Denmark, Finland, Latvia, Netherlands, Poland, Sweden, UK for imported medicines), producer prices are indirectly controlled. H. Regulate the interests of UK companies at higher prices approved by the Nordic authorities or the Pharmaceutical Price Control Scheme (PPRS)

European Union

European Union Regulatory Requirements -

• The Political Union also known as the European Union

IT was established in 1993 with the goal of achieving political and economic integration.

• The EU includes 28 member states of Europe.

• The total population of the EU is estimated at 500 million

• In the EU there are two regulatory measures when a drug is approved in the market

1. Application for clinical examination (accredited member state)

2. Market authorization (authorized by both member states and intermediate level)

Regulation in the Industry

The pharmaceutical enterprise is regulated certainly business legal guidelines imposed to provide powerful and secure pharmaceutical products. It takes extra than eight to fifteen years to construct a brand-new drug product and price extra than $ 800 million.

When did the law arrive?

During the 20th century, there were no laws or regulations to protect the public from the harmful effects of drugs.

Tragedy, disaster, and catastrophe have caused much progress in drug control There are some examples of diaster that lead to the formation of rules in the industry.

1. Thalidomide Disaster (1962)

2. Elixer sulfanilamide (1937) (taste of death)

EU drug regulatory system

The European Medicines Control System is based on a network of about 50 regulatory authorities from 31 EEA countries, the European Commission and the EMA.

This network is what makes the EU regulatory system different.

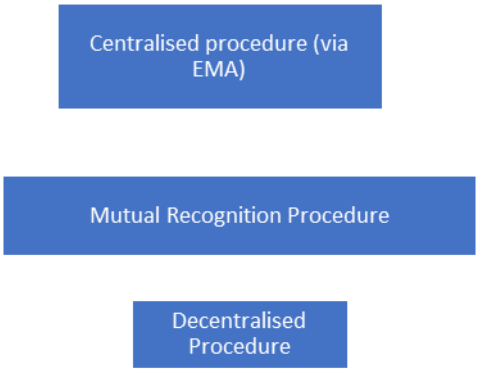
The network is backed by a group of thousands of experts from across Europe, which allows them to acquire the best scientific technology for drug management in the EU and to provide the highest quality scientific advice.

28 European Union Member Countries

Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia , Slovenia, Spain and Sweden

Registration in Europe post nov 2005:

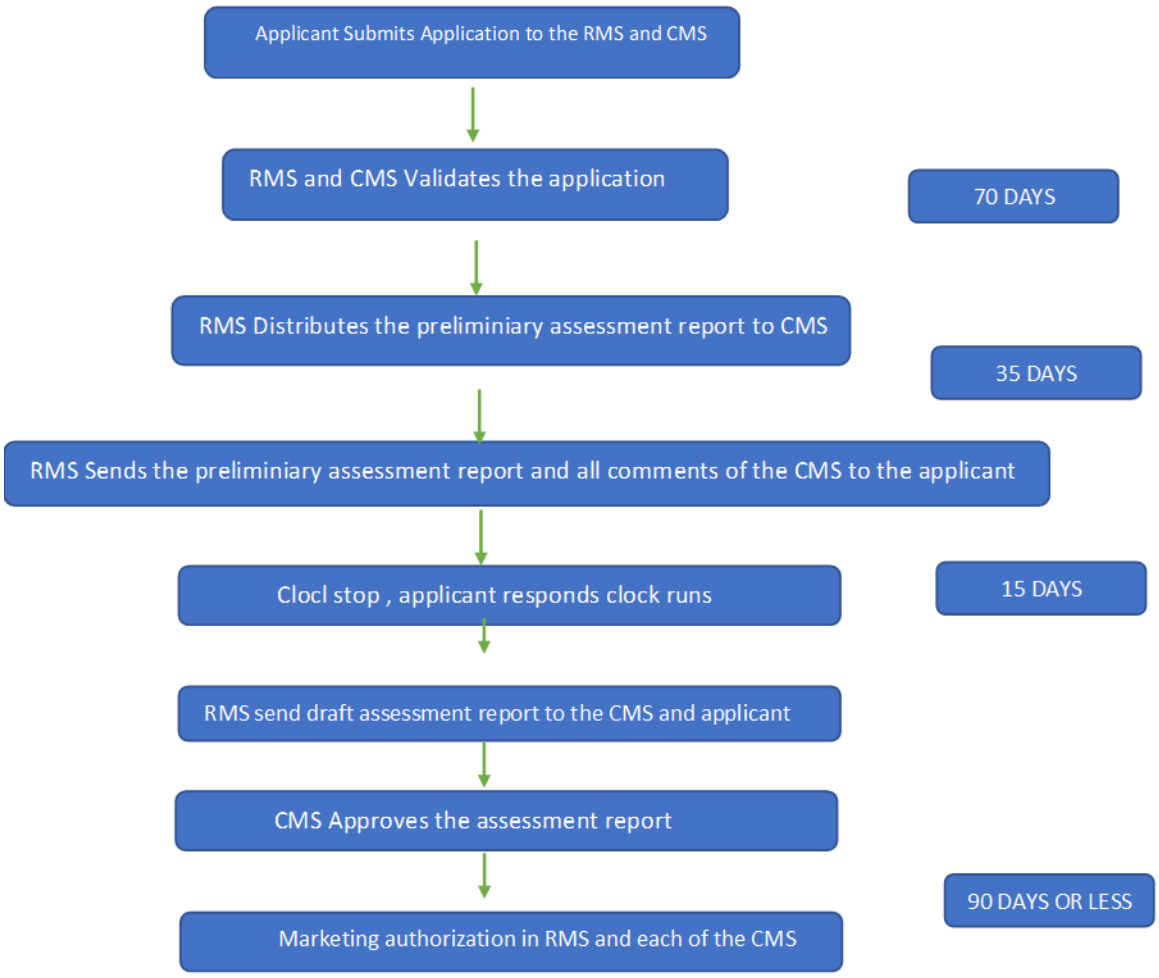
- Three european system



Marketing authorization

- To guard public fitness and make sure the provision of excessive quality, secure and powerful drug treatments for European Citizens, all drug treatments have to be authorised earlier than being located available in the marketplace withinside the EU. The European machine gives extraordinary approaches for such authorization
- Central Procedure: Allows a drug to be advertised on the idea of a unmarried EU-huge evaluation and advertising and marketing authorization legitimate at some point of the EU.
- Pharmaceutical businesses follow for a unmarried authorization to EMA.
- Rules and necessities making use of to capsules withinside the EU are the equal irrespective of the manner a drug is legal.

DCP FLOW CHART



Pricing and Reimbursement

If an advertising and marketing authorization has been taken by authority

choices concerning fee and repayment are made at the extent of every person considering the capability position and use of the drug withinside the context of that country's country wide fitness system.

Role

- Grants or rejects, changes or suspends marketing authorization for drugs offered by central procedure, based on scientific evaluations made by EMA.
- The can take action on other drug regulation:
- Right of initiative

- Application
- Global reach

The Role of EMA –

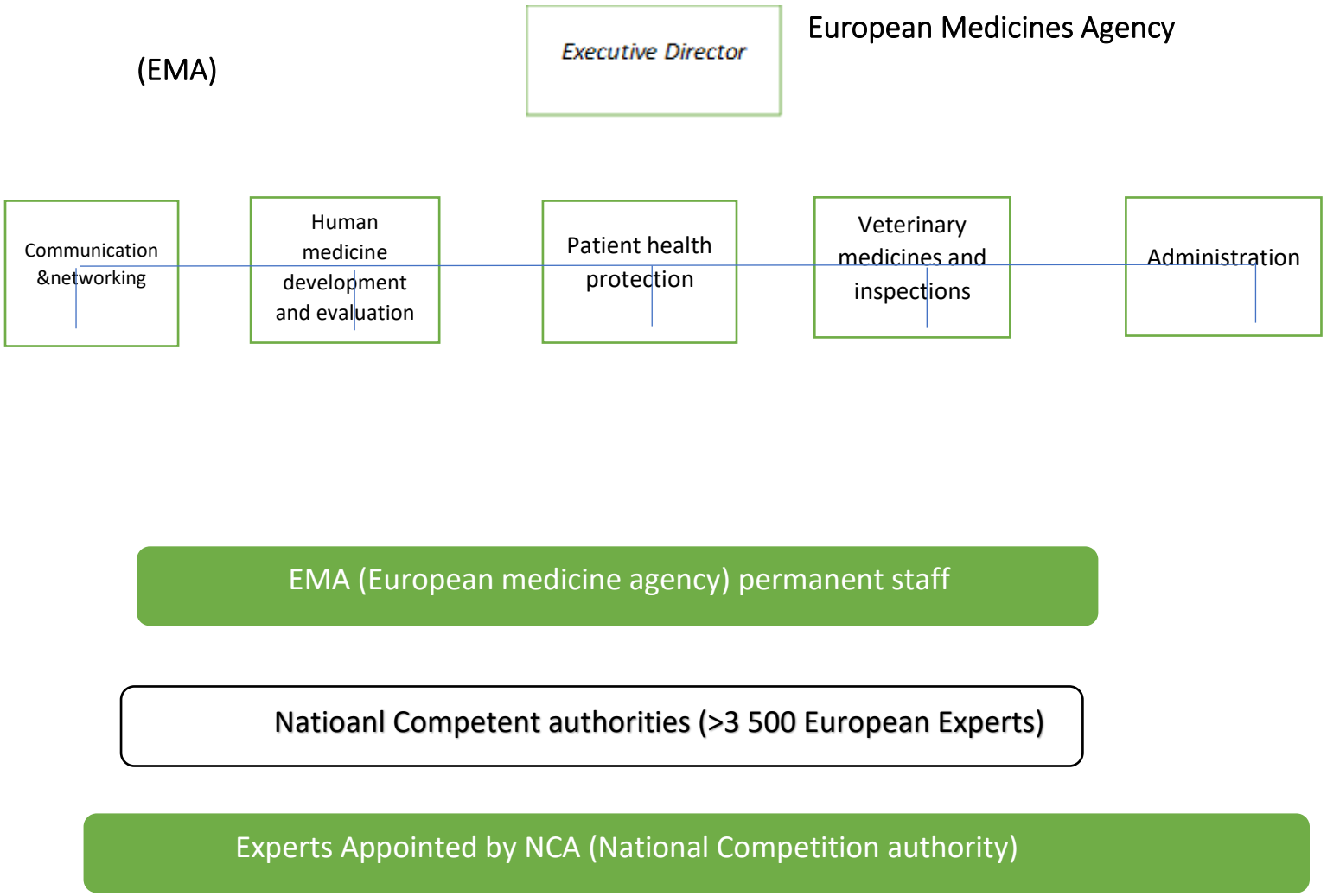
EMA is liable to clinical assessment of revolutionary and hightech capsules advanced with the aid of using pharmaceutical companies, mostly to be used withinside the EU.

EMA turned into mounted in 1995 to make the high-quality use of clinical assets throughout Europe for the assessment.

Experts take part withinside the EMA as contributors of its clinical committees, running groups, clinical advisory groups, or countrywide assessment groups that compare capsules.

Experts are decided on primarily based totally on their clinical expertise, and lots of are submitted to the EMA with the aid of using NCAs in member countries.

Patients and healthcare experts are more and more more worried withinside the paintings of the institution, along with the assessment of medications



National Competition authorities

The National Competition authorities (NCA),

to blame for the regulation of human and veterinary medication

The heads of NCAs work with the EMA and the European Commission to maximise the sharing work and make sure the economical functioning of the eu drug regulative network.

Advice

- EMA develops clinical recommendations in collaboration with specialists from its clinical committees and running groups.
- These recommendations replicate the first-rate considering improvement in biomedical science.
- This is an vital device to assist make and enhance excessive excellent correctly and efficiently.
- Safe capsules for the gain of patents.
- Scientific recommendation also can accept via way of means of NCAs

Saftey monitering of medicines

The European regulatory gadget for drugs video display units the protection of all drugs to be had at the European marketplace at some stage in their lifetime.

If there's a protection difficulty with a drug certified in a couple of Member State, the identical regulatory movement is taken and the identical steerage is supplied for sufferers and healthcare specialists throughout the EU and in all Member States.

Food and Drug Administration

(FDA or USFDA)

- The U.S. Food and Drug Administration (USFDA) is an enterprise of the united states Department of Health and Human Services
- is for regulating and the safety of food, dietary supplements, drugs, vaccines, and biological medicinal products.

The FDA is mounted in Rockville and is supported with the useful resource of the use of 13 laboratories located withinside the United States.
FDA is accountable for Protecting the general public fitness with the aid of using assuring that meals are secure, nutritional dietary supplements are secure and nicely labeled Regulating tobacco merchandise Advancing
the general public fitness with the aid of using supporting to hurry product improvements

organized into the subsequent major subdivisions,

Office of the Commissioner (OC)
Center for Drug Evaluation and Research (CDER)
Center for Biomedical Research and Research (CBER)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Devices and Radiological Health (CDRH)
Veterinary Center (CVM)
National Center for Toxicological Research (NCTR
Office of Administrative Affairs (ORA)

It works with Federal agencies

as well as the authority, the Department of Agriculture,

- First, from the attitude of US consumers, pharmaceuticals account for 12% of overall US healthcare spending (2008) or kind of 2% of GDP.

- Second, from the attitude of all consumers, america money owed for about 40% of the sector pharmaceutical market

Background:
Legislation and Historical Developments

- At that time, health care solely enclosed pharmaceuticals taken by hospitalized patients under half A and prescribed drugs (typically injections) underneath half B.
- half D of medicine, that covers patient medicine, was later enacted in 2006.

Pricing

- Prices not regulated
- Price tends to be high than in more regulated market
- Actual market prices are
    1. Discounts and rebates
    2. Drugs patent status
    3. Market status
    4. Prompt payment

Pricing benchmarks

- Existing benchmarks
- New benchmarks

Existing benchmarks

Wholesale cost of purchasing (WAC): Manufacturers selling drugs to wholesalers at a list price WAC

Average wholesale price (Awp): An estimate of the average price posted by pricing agencies as a list price, called AWP, by wholesalers sold to pharmacies

For example, the payer can set the pharmacy reimbursement to AWP-18%, where the discount from the AWP is negotiated between the payer and the pharmacy chain.

WAC+ 20% = AWP

Average many-manufacturer price: The average price a manufacturer charges for a drug sold for distribution to retail pharmacies.

AWP is used to calculate the discount; manufacturer, mediciad pays for drugs dispensed to the patient

Best price: The lowest ex-factory price for any PMO, HMO, or other private wholesaler or distribution network.

Average selling price: The average ex-factory price excluding any discounts and discounts for all purchases in the US, including wholesalers, retailers, HMO, Hospitals, and governments.

Average Cost of Acquisition (AAC): Calculated based on survey actual average prices paid for prescriptions by state retail pharmacies.

New Bench marks

National average cost of acquiring drugs (NADAC)

It was created through a voluntary monthly survey on pharmacy purchase prices.

Off-bill discounts and discounts are not taken into account

NADAC never exceeds equal AWP.

National average retail price (NARP)

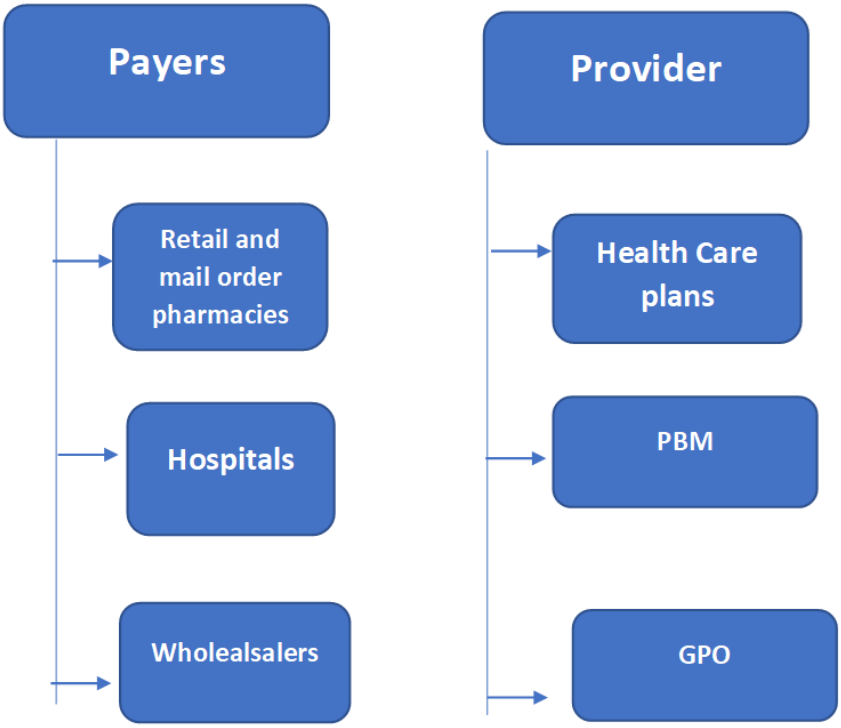
To reflect actual prices paid by retail pharmacies for prescription drugs (cost of ingredients + any applicable patient co-payments + pharmacy dispensing fees).

Pricing of Generic Drugs

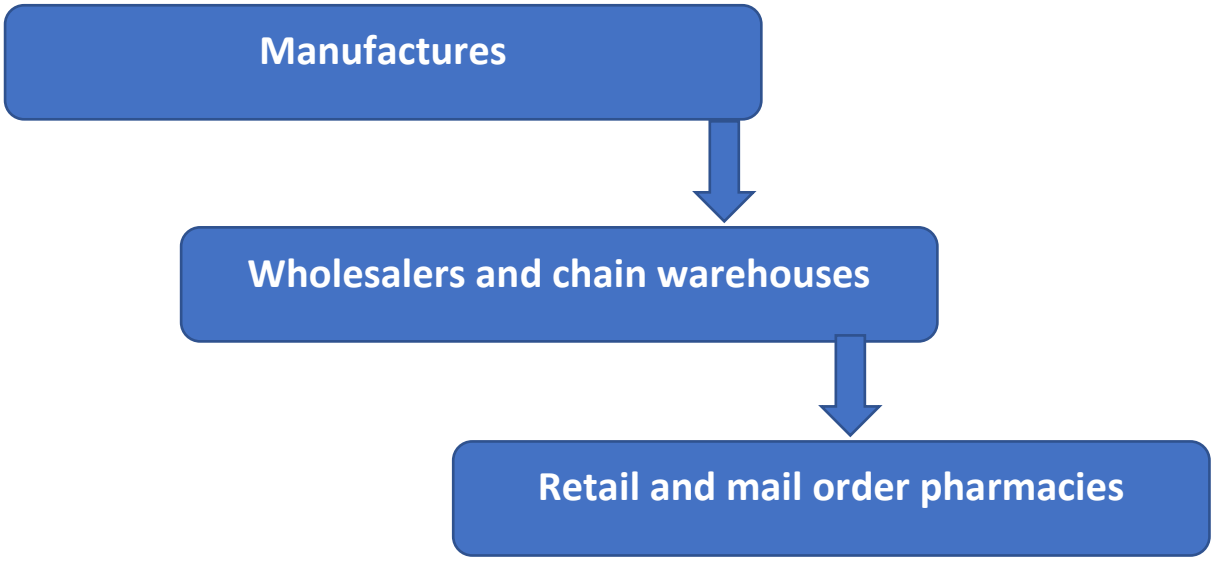
The traditional microeconomic theory toolkit is often sufficient for analyzing generic drug pricing.

The number of generic entrants increases with the size of the branded molecule market (measured in dollars) before patient protection is lost.

Payers and providers



Distribution Channel logistics and pricing



Pharmaceutical Benefit Managers

PBM services embrace profit style for third-party payers (insurers, employers, government) and catching with makers.

Pharmacy network formation period prescription help compliance certification and claim process Formula management and discount negotiations.

Regulatory req. approval procedure of drugs in JAPAN

PMDA (pharmaceuticals and medical devices agency)

PMDA (prescribed drugs and scientific tool organization) is a Japanese regulatory organization that works with the ministry of fitness and hard work welfare (MHLW).

The PMDA become hooked up in April 2004 to offer offerings withinside the area of drug and scientific tool opinions, post-advertising and marketing protection measures, and remedy offerings for damaging fitness effects.

Our responsibility is to guard public fitness via way of means of making sure the protection and pleasant of drugs and scientific devices.

The PMDA's function is to offer consultations on medical trials of latest pills and scientific devices, and to behavior validation opinions and surveys at the reliability of exercise data.

Function of PMDA

Drug and Medical Device Testing Scientific review of market approval practices based on the Japanese Drug Law. Advice on the preparation of dossiers for clinical studies or approval procedures (New Drug Application (NDA)

Mission

To provide

. safer and more effective medicines and medical device

GCP, GLP and Good practice system and program examination and conformity assessment

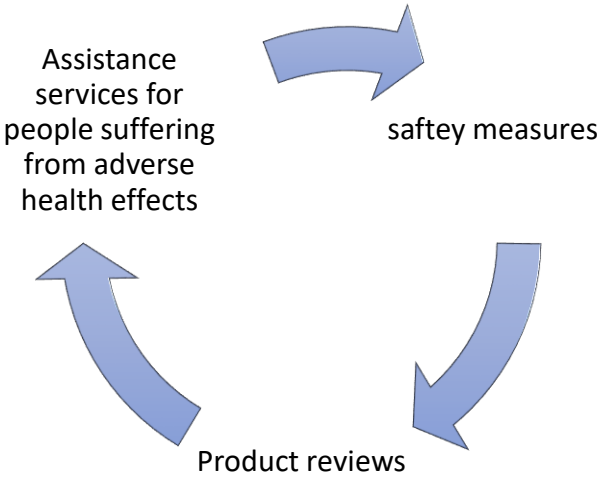
Organization Of PMDA

PMDA Organization

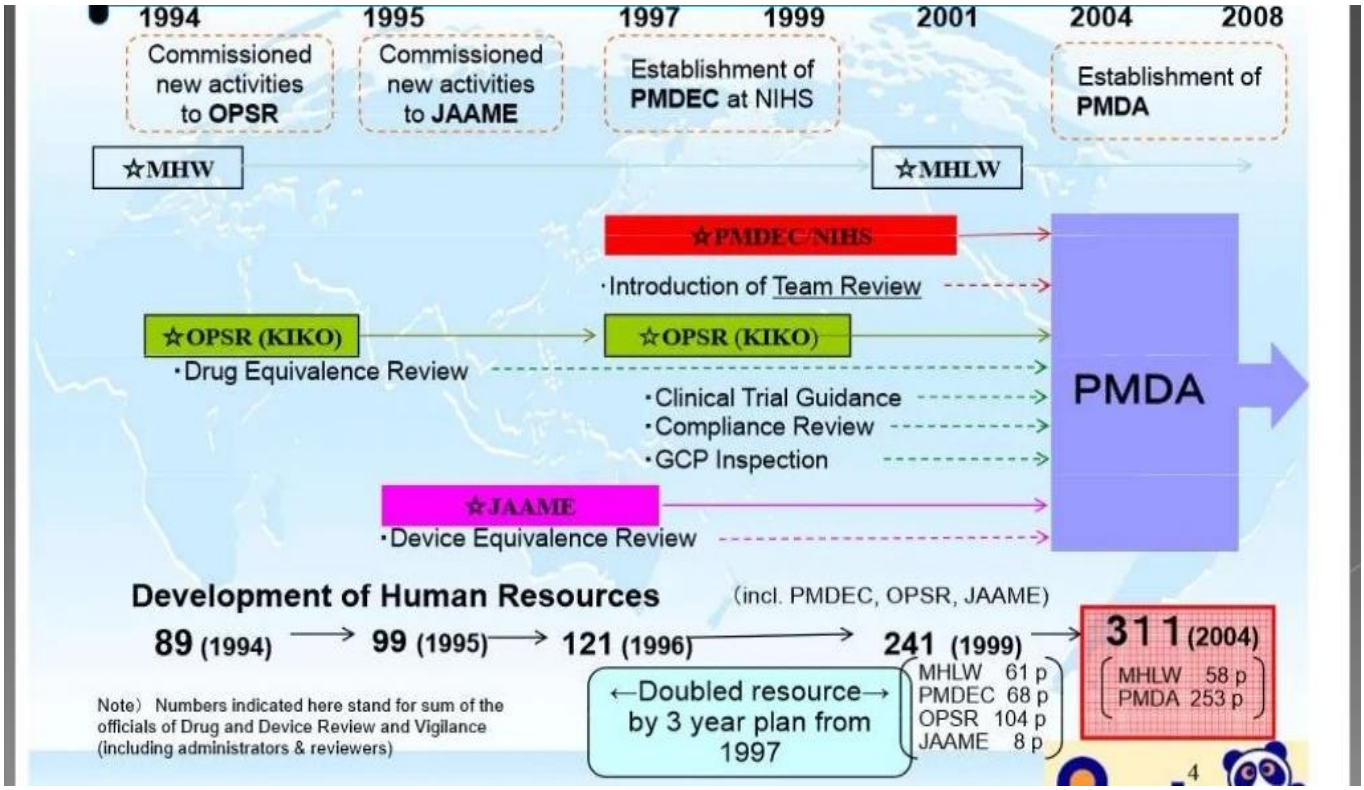
The Ministry consists of appropriate, affiliated institution councils, Near area branch and outside of the organizations,

PMDA -JAPAN is run by CEO Tatsuya Konodo.

PMDA works on 3 core services, a safe education system.



History of drug Review System in japan



To reduce Medication Delivery Delay

1. Promoting Global Clinical Research

• Development of Guidelines

• MRCT Workshop is Held

2. Consultation

• Pharmaceutical Business Consultancy on R&D Strategy

• Preliminary Evaluation Consultancy on Drugs

3. Efforts in Regulatory Sciences

• Cooperation with the Academy

• Establishment of the Scientific Committee

• MHLW/PMDA/Akademia Collaboration Study

S no.	Country	USA	JAPAN	EU
1	**REGULATORY AGENCIES**	**USFDA**	**MHLW**	**EMA**

Japan Regulatory body also PMDA and MHLW

CONCLUSION

In this Document, we have established the relationship between the policies between the various countries and have established the relationship of the various regulatory bodies and how they work in their respective countries, to conclude I have clarified the significance of the comparison between the various Regulatory bodies a how they operate in their respective countries.

Reference

https://apps.who.int/iris/handle/10665/63513

https://www.researchgate.net/publication/276072878_Regulation_of_Generic_Drugs_in_Japan_the_Current_Situation_and_Future_Prospects

External Reference Pricing. Europe Economics, London

pharma Price Information (PPI) service. Further information available from: www.goeg.at/en/PPI. Gesundheit Österreich GmbH