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COMPARATIVE REGULATORY PATHWAYS FOR VACCINE APPROVAL: INSIGHTS FROM THE USA, EUROPE, AND INDIA

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ABSTRACT
Vaccines represent one of the most powerful public health interventions, significantly reducing global morbidity and mortality. Their regulatory approval requires rigorous evaluation to ensure safety, efficacy, and quality before widespread use. This article provides a comparative analysis of vaccine approval pathways in the United States, Europe, and India, focusing on legal frameworks, timelines, and reliance mechanisms. The U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Central Drugs Standard Control Organization (CDSCO) each follow structured processes involving preclinical evaluation, phased clinical trials, regulatory review, and post-marketing surveillance. Despite these shared fundamentals, notable differences exist in submission procedures, review timelines, and emergency pathways, including the FDA's Emergency Use Authorization (EUA), the EMA's Conditional Marketing Authorization (CMA), and India's Restricted Emergency Use provisions. The COVID-19 pandemic demonstrated the critical role of such accelerated pathways in enabling timely vaccine access and highlighted increasing regulatory convergence. The findings underscore the importance of transparency, harmonization, and cross-regional collaboration to streamline vaccine development, strengthen preparedness for future health emergencies, and ensure equitable global access.

KEYWORDS: Vaccine approval, FDA, EMA, CDSCO, regulatory framework, expedited pathways, global harmonization.

1. INTRODUCTION
Vaccines are biological preparations that stimulate the immune system to provide protection against infectious diseases. They have been instrumental in reducing morbidity and mortality worldwide. From the eradication of smallpox to the control of polio, measles, and, more recently, COVID-19, vaccines remain one of the most effective public health interventions.[1] To ensure their safety, efficacy, and quality, vaccines must undergo stringent regulatory review before public use. The regulatory processes vary across regions, influenced by scientific standards, public health priorities, and socio-economic conditions.[2]

Although the scientific principles of vaccine development are universal progressing from preclinical studies through phased clinical trials and post-marketing surveillance, the regulatory frameworks guiding approval differ across regions. In the United States, the Food and Drug Administration (FDA) through the Center for Biologics Evaluation and Research (CBER) regulates vaccines under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.[3,4,5] Approval begins with an Investigational New Drug (IND) application, followed by Phase I–III clinical trials, and culminates in a Biologics License Application (BLA).[6] submitted via FDA Form 356h. The FDA also offers expedited pathways such as Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review. Post-marketing surveillance (Phase IV) ensures long-term monitoring of vaccine safety.[7] In the European Union (EU), the European Medicines Agency (EMA)

centrally coordinates approvals follow a Marketing Authorization Application (MAA) ensuring harmonized access across member states.[8,9,10]

In India, the Central Drugs Standard Control Organization (CDSCO) under the Drugs Controller General of India (DCGI) oversees vaccine evaluation, guided by the Drugs and Cosmetics Act and the New Drugs and Clinical Trials Rules (2019).[11,12,13] Accelerated pathways, including Emergency Use Authorizations (EUA), are available for urgent public health needs. In 2024, the World Health Organization (WHO) confirmed that India's vaccine regulatory framework meets international standards.[14]

These systems share common principles but differ in timelines, reliance mechanisms, and emergency pathways. The COVID-19 pandemic underscored both the adaptability of these frameworks and the urgent need for regulatory convergence. Few studies, however, provide a direct comparative analysis of vaccine approval processes across these three major regions.[15,16]

This article aims to review and compare the regulatory approval pathways for vaccines in the USA, Europe, and India, highlighting similarities, differences, and areas for harmonization. By analyzing legal frameworks, approval timelines, and expedited mechanisms, the study provides insights into how regulatory alignment can accelerate global vaccine access without compromising safety.

1.1 Vaccine Development Stages

Vaccine development is a multi-stage process designed to establish safety, immunogenicity, and efficacy before approval for public use.[17] The standardization process for vaccine approval is an exploratory stage, pre-clinical stage, clinical development, investigating, and acceptance stages as shown in **Figure 1.**

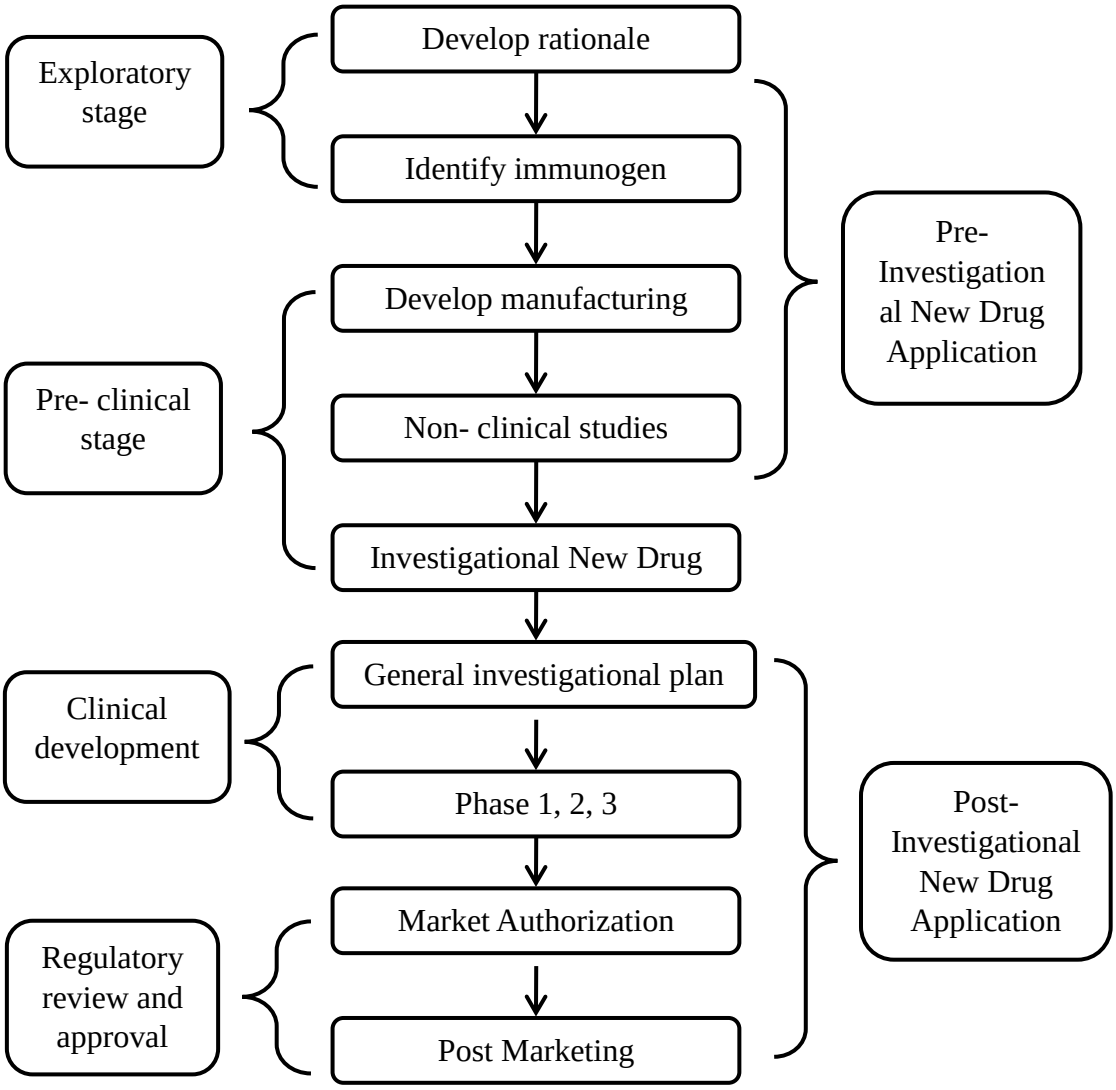

Figure 1. The general phases of a vaccine development cycle.

Exploratory Stage (2–4 years): Early laboratory research identifies potential antigens such as pathogen-derived proteins, attenuated toxins, or virus-like particles.[18]

Preclinical Stage (1–2 years): Candidate vaccines are evaluated in vitro and in animal models to assess immunogenicity, toxicity, and optimal dosing. Data from this stage support transition to human studies.[19]

Clinical Development (6–8 years): Conducted under regulatory oversight[20]

- *Phase I:* 20–80 volunteers; safety and immune response.
- *Phase II:* Several hundred participants; dosing, immunogenicity, and adverse events.
- *Phase III:* Thousands of participants; large-scale safety and efficacy confirmation.

Regulatory Review and Approval: Data are compiled into formal applications-BLA (USA), MAA (EU), or NDA/Biologics Application (India) for comprehensive review.[21]

Post-Marketing Surveillance (Phase IV): Continuous monitoring of adverse events and long-term effectiveness through national pharmacovigilance systems.[22]

2. REGULATORY FRAMEWORK FOR VACCINE APPROVAL AND REVIEW

2.1 Vaccine regulation in USA

In the United States, vaccines are regulated by the Food and Drug Administration (FDA) through the Center for Biologics Evaluation and Research (CBER). The process begins with submission of an Investigational New Drug (IND) application, followed by phased clinical trials (Phase I–III) to evaluate safety, immunogenicity, and efficacy. Successful candidates are submitted through a Biologics License Application (BLA).[6,10] for FDA review, supported by the Vaccines and Related Biological Products Advisory Committee (VRBPAC).[23]

The FDA offers multiple expedited pathways, including Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, and Emergency Use Authorization (EUA). During the COVID-19 pandemic, EUA enabled the rapid deployment of mRNA and vector-based vaccines while maintaining safety oversight. Post-approval, vaccine safety is continuously monitored through the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD).[24] **Figure 2** represents the process of filing and approval of Biologic License Application.

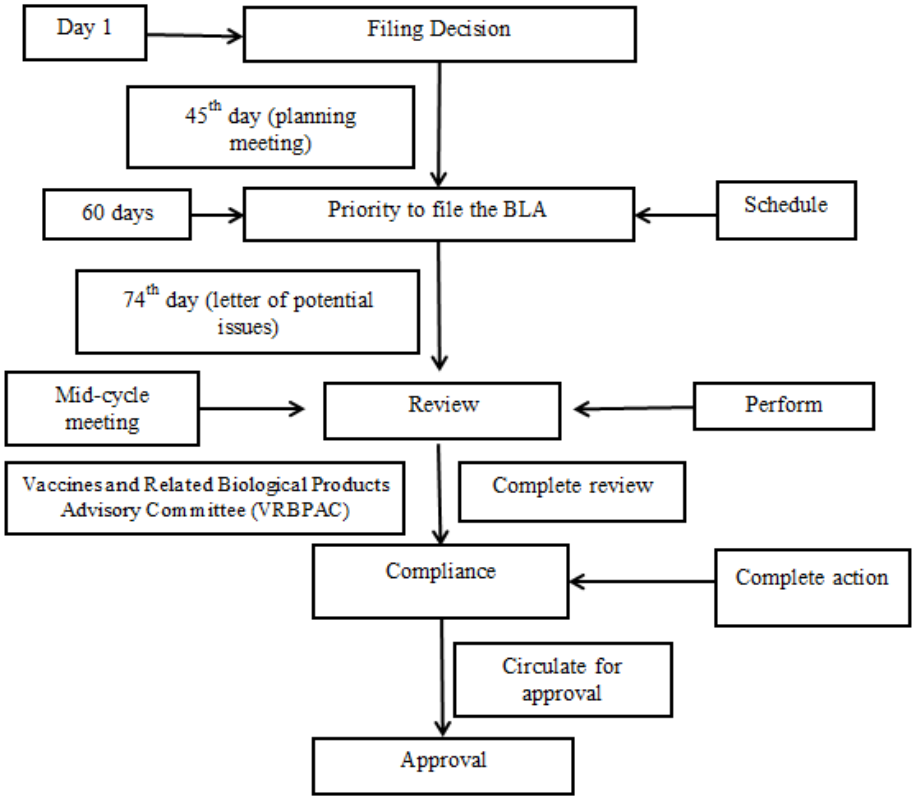

Figure 2. Filing of Biological License Application (BLA).

After the Phase 3 trials, the producer must submit a CBER of USFDA form 356h biologic license application to request permission to manufacture and commercialize the vaccine to a large population. Depending on whether the application is being reviewed as a priority or under a regular review, it could take anywhere from 6 to 12 months to complete. Phase 4, often known as post-marketing surveillance, will start after the approval procedure. Within 15 days of the vaccination administration, any adverse events or effects must be notified to the authority as shown in **Figure 3**.[25]

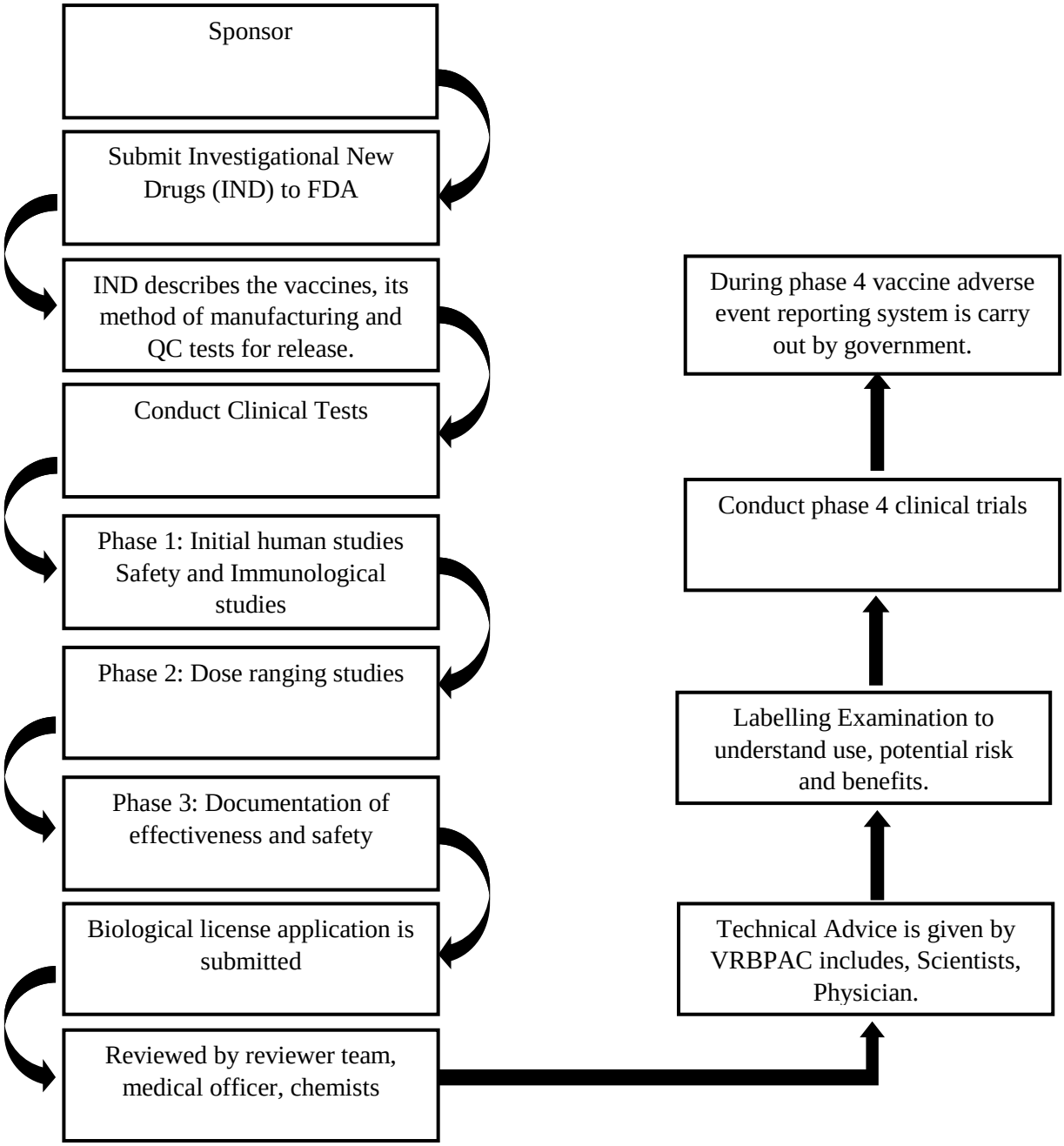

Figure 3. Registration process of vaccines in USA.

2.2 Vaccine regulation in Europe

In the European Union (EU), vaccine approval is centrally regulated by the European Medicines Agency (EMA), with the Committee for Medicinal Products for Human Use (CHMP) serving as the primary scientific advisory body. The National Competent Authorities (NCAs) oversee the clinical trial authorizations and may participate in decentralized/mutual recognition procedures. The framework emphasizes both scientific rigor and EU-wide harmonization to ensure consistent vaccine access across all Member States.[26]

The process of vaccine approval in the European Union is represented schematically in the flowchart (**Figure 4**), which illustrates the sequence from pre-submission activities through CHMP evaluation to the final marketing authorization granted by the European Commission. The flowchart highlights key milestones such as validation of the dossier by EMA, circulation of evaluation reports.[27] CHMP adoption of inspection requests, and the issuance of a final opinion. This visual representation complements the textual description of the centralized MAA pathway, underscoring the structured, time-bound nature of the EU approval process.[28]

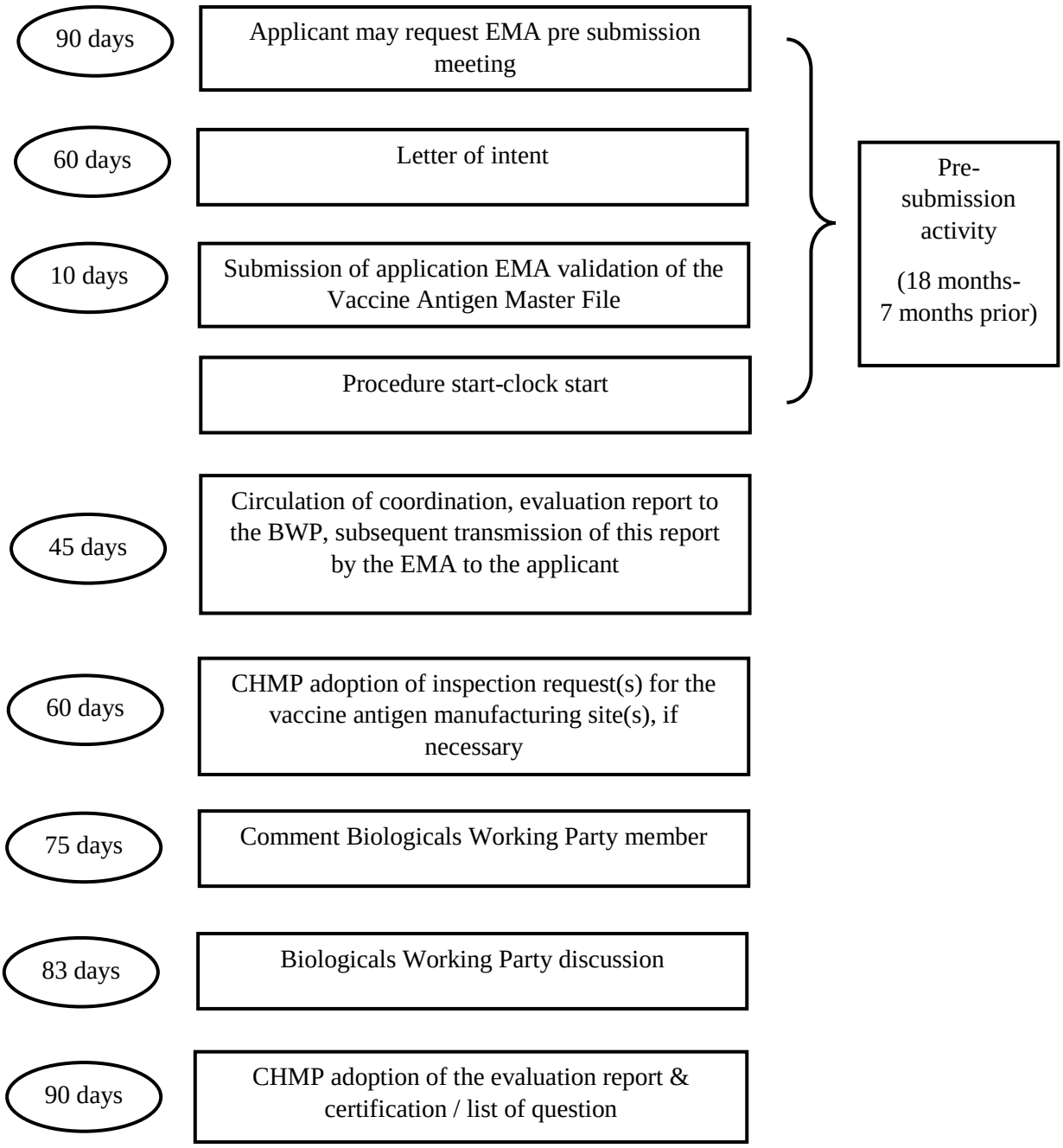

Figure 4. Marketing Authorization Process of Vaccines in the EU.

2.2.1 Registration

In the European Union, vaccines can be approved through four regulatory pathways: centralized, decentralized, mutual recognition, and national procedures.[29] Among these, the centralized procedure is most used, as it allows manufacturers to obtain a single marketing authorization valid across all EU Member States, thereby ensuring broad and consistent access to vaccines for both patients and healthcare systems.The four procedures for vaccine registration in Europe are summarized in **Figure 5.**

Centralised procedure- The centralized procedure enables manufacturers to submit a single marketing authorization application to the European Medicines Agency (EMA). If approved, the authorization is valid across all EU Member States, providing uniform access to vaccines throughout the Union.[30] This pathway is mandatory for most novel vaccines and is generally preferred by manufacturers because it simplifies market entry and ensures consistency in regulatory oversight. The stepwise process for centralized approval, including dossier submission, CHMP evaluation, and final authorization by the European Commission, is illustrated in **Figure 5(a).**

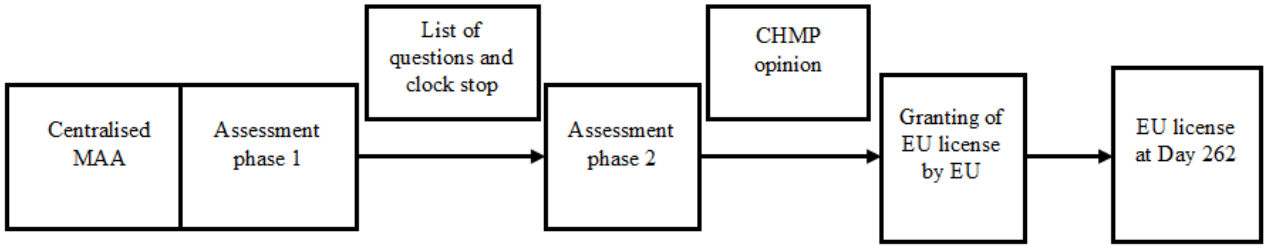

Figure 5(a): Centralised procedure for vaccine approval in Europe.

Decentralised procedure- Under the decentralized procedure, a company may apply for marketing authorization simultaneously in several EU Member States where the product has not yet been authorized.[29] One Member State acts as the "reference country" to coordinate the scientific assessment, while the others act as "concerned countries". This approach facilitates broader access without prior authorization in a single country. The process is outlined in **Figure 5(b).**

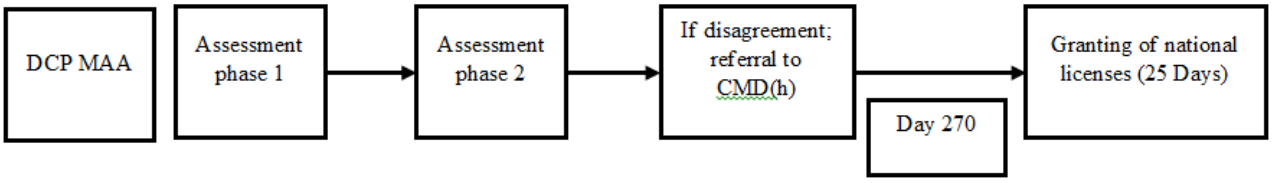

Figure 5(b): Decentralised procedure of vaccine approval in Europe.

Mutual Recognition Procedure (MRP) - In this procedure, a vaccine that has already been authorized in one EU Member State can gain approval in additional Member States by mutual recognition of the original authorization.[29] This pathway avoids duplication of scientific review and expedites market entry into multiple countries. The stepwise approach to MRP is depicted in **Figure 5(c).**

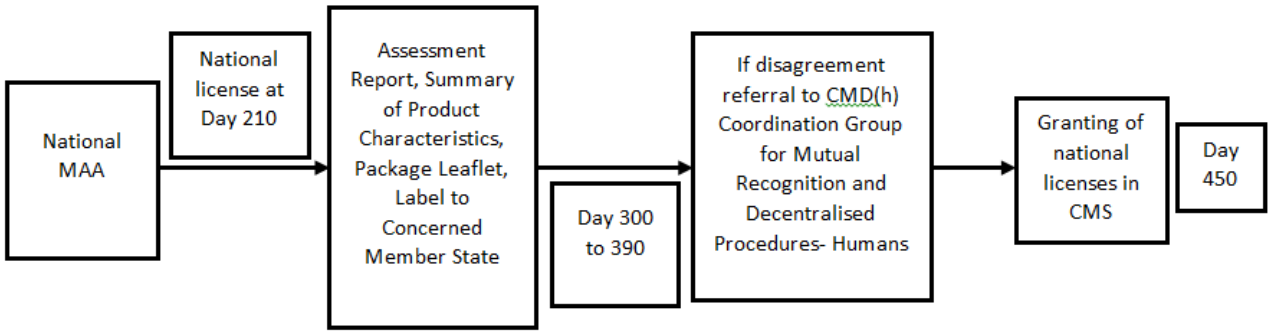

Figure 5(c): Mutual Recognition Procedure of vaccine approval in Europe.

National procedure- Each EU Member State retains the option of approving vaccines solely for its domestic market through its National Competent Authority (NCA). This pathway is generally used for products intended for a specific country only and does not provide EU-wide authorization.[31] The steps for national authorization are illustrated in **Figure 5(d).**

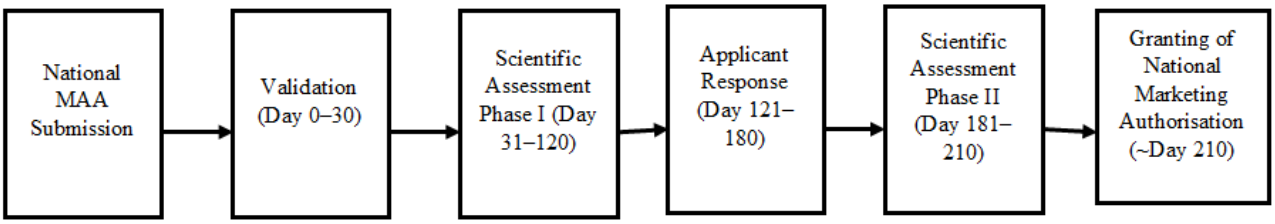

Figure 5(d): National Procedure of vaccine approval in Europe.

Figure 5: Registration procedures of vaccines in EU Before vaccines are released into the market, they undergo stringent batch testing and quality checks. This process is coordinated by the European Directorate for the Quality of Medicines (EDQM),[32] which oversees Official Medicines Control Laboratories (OMCLs).[33]

Following marketing authorization, vaccines are continuously monitored to ensure they maintain their established safety profile. A Risk Management Plan (RMP) is required for all new vaccines, detailing how potential risks will be identified, characterized, and minimized. These activities are coordinated through Eudra Vigilance, the EU's pharmacovigilance database.[34]

2.3 Vaccine regulation in India

Vaccine regulation in India involves several key bodies working under the Ministry of Health and Family Welfare.[38] The Central Drugs Standard Control Organisation (CDSCO), headed by the Drugs Controller General of India (DCGI), is the primary authority responsible for vaccine approval, clinical trial authorization, and licensing.[39] The Central Licensing Approval Authority (CLAA) grants central approvals for vaccines intended for national use. The Drug Technical Advisory Board (DTAB) serves as the highest statutory decision-making body, providing expert recommendations on the introduction of vaccines into immunization programs. In addition, the Indian Council of Medical Research (ICMR) plays an important role in issuing guidelines for the ethical conduct of clinical trials and ensuring that studies adhere to Good Clinical Practices (GCP).[40,41]

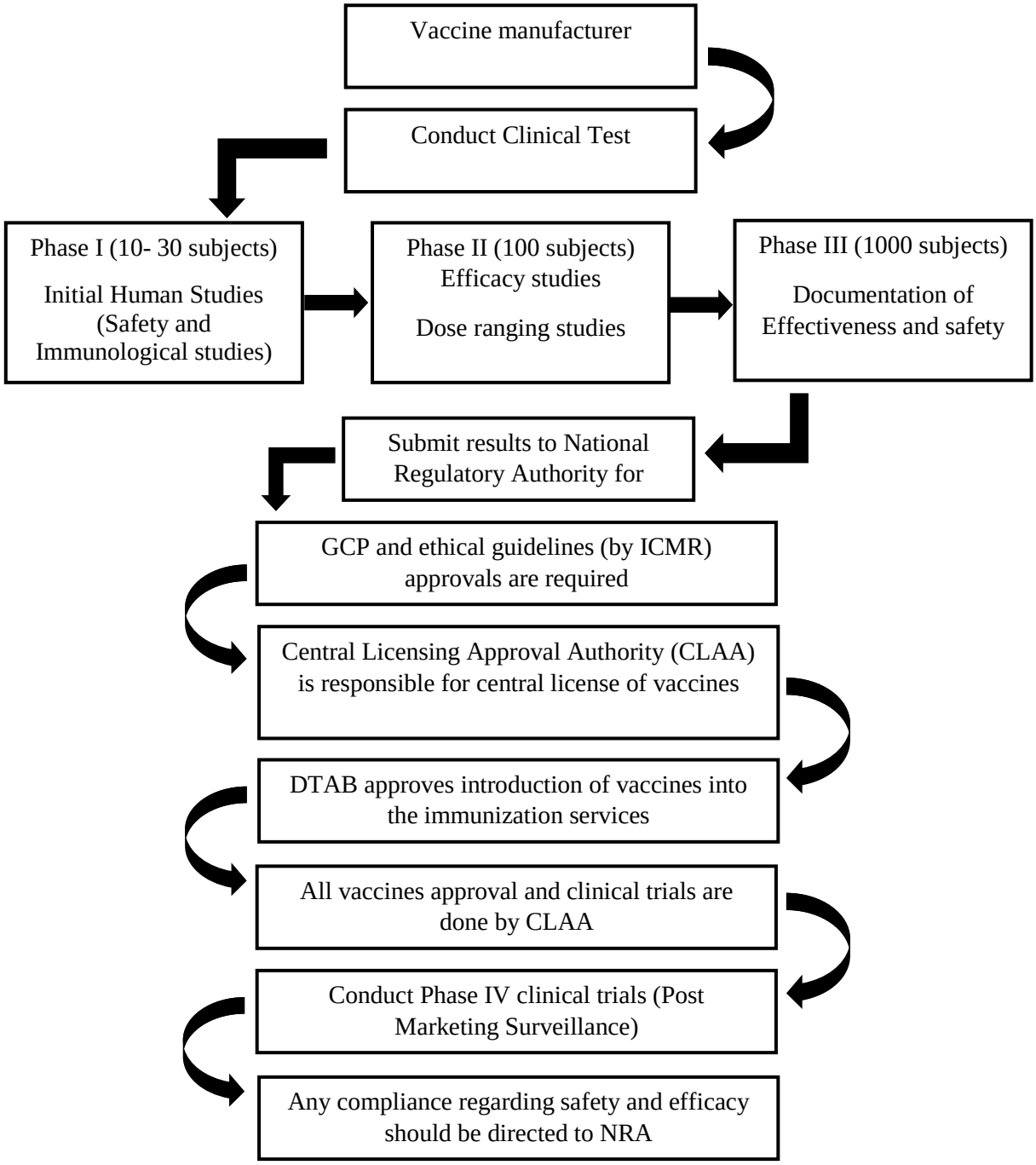

Figure 6. Process for regulatory approval of vaccines in India.

While each region has distinct regulatory structures, all emphasize rigorous clinical evaluation, manufacturing quality, and pharmacovigilance. Timelines vary (6–12 months for FDA, ~210 days for EMA, 12–18 months for CDSCO), but accelerated mechanisms align in principle. The COVID-19 pandemic demonstrated unprecedented regulatory convergence and reliance, underscoring the importance of harmonization and global collaboration to ensure rapid and equitable vaccine access.[42]

2.4 Comparison of Vaccine Approval Regulatory Framework: USA, Europe, and India

The regulatory frameworks for vaccine approval in the United States, European Union, and India share the common objective of ensuring that vaccines are safe, effective, and of high quality. All three regions follow a structured process beginning with preclinical studies, advancing through phased clinical trials, and culminating in regulatory review and post-marketing surveillance. However, important differences exist in legal frameworks, timelines, reliance models, and the use of expedited pathways.[43]

In the United States, the FDA relies on a well-defined pathway from IND submission to Biologics License Application (BLA), supported by advisory committees and extensive post-market surveillance systems such as VAERS and the Vaccine Safety Datalink. The European Union, by contrast, emphasizes harmonization across Member States through the centralized Marketing Authorization Application (MAA) reviewed by EMA's CHMP. While decentralized and mutual recognition routes are available, they are less relevant for vaccines, which typically require EU-wide approval. India's CDSCO, guided by the Drugs and Cosmetics Act and NDCTR 2019, has traditionally longer approval timelines, though its reliance on local trial data ensures vaccine relevance to the Indian population.

A key point of convergence across all three regions is the adoption of expedited pathways during public health emergencies**.** The FDA's Emergency Use Authorization (EUA), EMA's Conditional Marketing Authorization (CMA), and India's Restricted Emergency Use provisions played pivotal roles in the rapid deployment of COVID-19 vaccines. While these mechanisms differ in legal structure, they collectively reflect regulatory flexibility in balancing urgency with safety oversight.The comparative analysis in Table 1 highlights the key similarities and differences in regulatory requirements and approval mechanisms for vaccines across the USA, Europe, and India.[2,5]

Table 1: Comparison of Vaccine Approval Regulatory Framework in USA, Europe and India.

Aspect	USA	Europe (EU)	India
Regulatory Authority	U.S. Food and Drug Administration (FDA) –Center for Biologics Evaluation and Research (CBER)	European Medicines Agency (EMA) – Committee for Medicinal Products for Human Use (CHMP)	Central Drugs Standard Control Organization (CDSCO) under DCGI (Ministry of Health & Family Welfare) handles approvals and clinical trial permissions.
Legal Framework	Public Health Service Act (PHSA), Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 CFR Parts 600–680	Regulation (EC) No 726/2004, Directive 2001/83/EC, EMA guidelines	Drugs and Cosmetics Act & Rules, New Drugs and Clinical Trials Rules (NDCTR) 2019 CDSCO specific vaccine guidance (including COVID-19 emergency guidance).
Preclinical Requirements	Good Laboratory Practices compliant studies on animals for safety, immunogenicity, toxicity	Good Laboratory Practices animal studies per EMA vaccine guidelines	Good Laboratory Practices animal studies per CDSCO/ICMR guidance
Clinical Trial Oversight	IND application and Phases 1, 2, 3 under FDA monitoring	Clinical Trial Application (CTA) Phases 1–3 under EMA/National Agencies	Clinical Trial Application (Form CT-04) Phases 1–3 under CDSCO
Review Pathway	IND to BLA (Biologics License Application)- Advisory Committee on Vaccines and Related Biological Products	CTA to MAA (Marketing Authorization Application) via centralized EMA procedure	CTA to New Drug Application (NDA) / Biologics Application to CDSCO
Timeline for approval	Standard Review (10 months), Priority Review (6 months), Accelerated Approval, EUA (Emergency Use Authorization)	Centralized procedure (mandatory for vaccines) – standard ~210 days; accelerated & conditional approvals possible	Standard Review (approx. 12–18 months), Accelerated Approval, Restricted Emergency Use
Expedited / emergency pathways	Emergency Use Authorization (EUA) for public health emergencies (temporary); FDA may also use accelerated approvals where applicable.	Rolling reviews and Conditional Marketing Authorization (CMA) or accelerated assessment during public health emergencies.	Restricted Emergency Use / Emergency Authorization (CDSCO issued specific guidance for COVID-19 vaccines) Eg. Covaxin EUA (Jan2021)

	Eg. COVID-19 mRNA vaccines: Pfizer-BioNTech EUA (Dec 2020)	Eg. COVID-19 vaccines: BioNTech/Pfizer CMA (Dec 2020)	
Emergency Use Provision	EUA under Section 564 of FD&C Act	Conditional Marketing Authorization (CMA)	Restricted Emergency Use under NDCTR & CDSCO guidance
Quality & GMP Compliance	cGMP per 21 CFR Parts 210–211, 600–680	EU GMP guidelines (EudraLex Volume 4)	Schedule M GMP guidelines
Post-Marketing Surveillance	Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD)	EudraVigilance, Periodic Safety Update Reports (PSURs)	Pharmacovigilance Programme of India (PvPI), Adverse Event Following Immunization (AEFI) surveillance
Examples	Gardasil (HPV vaccine, 2006, Merck) Prevnar 13 (Pneumococcal conjugate vaccine, 2010	Bexsero (Meningococcal B vaccine, 2013, Novartis/GSK) Cervarix (HPV vaccine, 2007, GSK)	Rotavac (Rotavirus vaccine, 2014, Bharat Biotech) Typbar-TCV (Typhoid conjugate vaccine, 2013, Bharat Biotech

The regulation of vaccines in the USA, Europe, and India shows both convergence and regional distinctions. In the United States, the FDA through CBER oversees vaccine approval under the FD&C Act and PHSA, while in Europe, the EMA under CHMP manages approvals through the centralized procedure, and in India, CDSCO under DCGI regulates vaccines guided by the Drugs and Cosmetics Act and NDCTR 2019.[7] Overall, despite structural and legal differences, the three systems share a common goal of ensuring safety, efficacy, and quality, and the COVID-19 experience demonstrated a global shift toward regulatory convergence, reliance, and accelerated access strategies.[44]

CONCLUSION

The comparative analysis of vaccine regulatory frameworks in the USA, Europe, and India demonstrates both convergence in core principles and divergence in procedural details. While all three emphasize rigorous preclinical testing, phased clinical trials, and robust pharmacovigilance to safeguard public health, they differ in legal underpinnings, review timelines, and reliance mechanisms. The availability of expedited pathways EUA in the USA, CMA in Europe, and Restricted Emergency Use in India proved instrumental during the COVID-19 pandemic, underscoring the adaptability of regulatory systems in times of crisis. Moving forward, greater reliance, harmonization, and transparency across regulatory agencies are essential to accelerate vaccine development without compromising safety. Strengthening global cooperation will not only enhance preparedness for emerging infectious threats but also ensure more equitable and timely access to vaccines, reaffirming their role as a cornerstone of public health protection worldwide.

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