RESEARCH PAPER

Understanding International Vaccine Regulatory Frameworks: A Cross-Country Analysis

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ABSTRACT
Vaccination is one of the most successful and cost-effective global public health projects, preventing an estimated 2.5 million deaths annually. This study compares the vaccination trends and regulatory frameworks of five high-income regions: the USA, Europe, Japan, Canada, and Australia. The paper summarizes vaccination policies, development paths, and public health outcomes to understand how different nations approach immunization-based viral illness prevention. It highlights the variations in regulatory approval processes between the US FDA (CBER), EMA (CHMP), PMDA (Japan), Health Canada (NACI), and Australia's TGA. It also outlines the stages of vaccine development, from preclinical and exploratory research to phased clinical trials and post-marketing surveillance. Comparative analysis reveals that despite the fact that all countries have strong immunization programs, sociopolitical pressures, accessibility problems, and reluctance continue to generate disparities in vaccine uptake. The study emphasizes how policy integration, digital health registries, and public engagement strategies could boost vaccination rates. Additionally, the COVID-19 pandemic spurred global innovation in vaccination technology and infrastructure, emphasizing the need for fair distribution mechanisms and international collaboration. The study concludes that strengthening surveillance, increasing vaccine knowledge, and harmonizing international regulatory requirements are necessary to ensure global health equity and preserve preparedness against emerging viral threats.

Keywords: Vaccine regulation, CBER, EMA, Covid-19, Health Canada, Pharmacovigilance
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1. INTRODUCTION

Vaccination remains one of the most cost-effective and impactful public health measures, preventing approximately 2.5 million deaths each year [1,2]. By reducing morbidity and mortality associated with infectious diseases, vaccines have significantly extended life expectancy and improved quality of life. Among vulnerable populations—particularly the elderly—immunization plays a critical preventive role, as infectious diseases account for nearly one-third of deaths in adults aged 65 and older [3,4]. Despite these successes, vaccination adherence has plateaued in recent years, influenced by factors such as

the COVID-19 pandemic, misinformation, accessibility barriers, and inadequate public education [5-7]. To strengthen global immunization efforts, it is essential to analyse how different countries design and implement vaccination strategies. This comparative review examines viral vaccination landscapes across five high-income regions—the USA, Europe, Japan, Canada, and Australia—focusing on their regulatory mechanisms, immunization policies, and coverage for key viral infections, including influenza, hepatitis B, HPV, and COVID-19. These regions were selected for their advanced healthcare systems, robust regulatory structures, and substantial contributions to vaccine innovation [8]. The study also explores challenges such as vaccine hesitancy, public perception, and equitable access, alongside the integration of new technologies and policy frameworks [9]. By identifying best practices and shared challenges, this comparative analysis aims to inform global health strategies, promote standardization of vaccination guidelines, and enhance preparedness for future viral outbreaks.

1.1 VACCINE DEVELOPMENT STAGES

It includes the exploratory phase, preclinical phase, clinical development study and approval phase. Figure 1 represents the General phase of vaccine development.

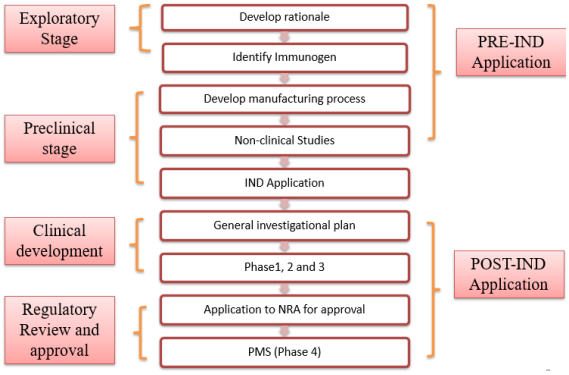

Fig. 1: General phases of vaccine development

Exploratory stage

Researchers from scholastics, industry and government recognizes natural or engineered antigen which will have capability to prevent infection or treat them [10]. These antigens may incorporate microscopic substances i.e. bacteria, virus-like particles, inactivated bacterial toxins, or weakened viruses, inferred from irresistible infections pathogens. An objective of this stage is to inquire about and produce such a product which is secure as well as immunogenic and meets appropriate rules of regulatory organizations.

Preclinical stage

After a vaccine is developed, preclinical studies investigate immunogenicity, or efficacy and safety of inducing immune res ponses using cell culture and animal metho ds experiments [11]. The studies give researchers an idea of the biological responses expecting in humans and suggest a safe starting dose for later studies. Animals can also be used in exposure experiments where animals are immunized before trying to expose them to the target pathogen [12].

Clinical Testing stage

Once preclinical studies on a product have been conducted (Usually in animal models) and clinical trials in humans are being considered, an application for the IND is presented. The clinical research plan must be approved by the IND representing the organization conducting the clinical study [13, 14]. The application must be approved by the respective regulatory agency in 30 days. The vaccine must be tested in three stages after the IND application is approved. With IND approval, the clinical development phase begins. All the clinical

trials must be conducted after the approval from institutional review. The final stage of clinical development can take up to 7-8 years. Fig 4 shows the Clinical Stages for development of vaccine.

Clinical Trials-Phase I

Phase I trials are the initial stage involving human participants. These studies typically involve small groups of 10 to 50 individuals who are closely monitored throughout the trial. Researchers carefully observe vaccine safety, tolerability, and any local or systemic side effects [15]. Once the results are gathered, they evaluate if the vaccine triggers the intended immune response. At this point, both the researchers and participants are aware of whether they are getting the real vaccine or a placebo, a scenario referred to as an open-label or non-blinded state. Participants are carefully observed, and conditions are meticulously controlled [16]. Phase I trials usually take at least one year to complete. Not all vaccine candidates that pass Phase I trials proceed to Phase II. Researchers only advance to Phase II if Phase I results show a success rate of 70% or higher [17].

Clinical Trials-Phase II

Phase II trials involve numerous hundred people from the vaccine's target population, including those at high risk of acquiring the disease. Phase II studies evaluate the vaccine's ability to provoke an immune response and provide initial estimates of common side effects. These studies are randomized and typically double-blind with a placebo control group [18]. For pathogens that can be treated, trials may be carried out in vulnerable adults within controlled environments to assess the vaccine's protective efficacy against experimental challenges. This phase lasts at least two years to collect data. The vaccine can advance to the next phase only if Phase II trials demonstrate an achievement rate of at least 33% [19]. During this phase, multiple trials are conducted to assess the vaccine's effectiveness across different age groups and formulations. Furthermore, suggested dosages, immunization timelines, and distribution techniques are established. The findings of these preliminary studies provide the essential data to advance to Phase III trials. Sponsors are advised to consult with the CBER upon completing Phase II testing to review the progress of the research [20].

Clinical Trials-Phase III

Phase III clinical trials are extensive and generally include anywhere from a few hundred to several thousand participants. This study may span 1 to 4 years. In Phase III trials, the investigational vaccine is tested against a placebo in a randomized, double-blind manner [21]. Vaccines in this phase have a low success rate of only 25% to 30%. Phase III trials contrast the unvaccinated group with vaccinated participants to evaluate safety, effectiveness, and dosage. This phase assesses the vaccine's balance of benefits and risks, which is crucial for its approval. As the final clinical trial stage, Phase III also addresses manufacturing reproducibility by evaluating lot consistency and ensuring process validation [22]. The potential effects of co-administering other vaccines are also considered. These trials are expensive, necessitate a sophisticated healthcare infrastructure, and involve extensive participant groups, sometimes conducted internationally. They also require skilled personnel and adequate laboratory capabilities for monitoring. Extra expenses are incurred if live attenuated or recombinant vaccines need quarantine facilities for Phase I and II trials [23].

Clinical Trials-Phase IV

After a vaccine receives licensure and approval, the developer might choose to undertake further studies called Phase IV trials, which are continuous investigations. During this phase, the manufacturer keeps tracking the vaccine's effectiveness and safety in the market [24]. These Phase IV trials, also referred to as post-marketing surveillance studies, evaluate the vaccine's optimal use, safety, and efficacy. Drug safety programs evaluate negative reactions associated with the vaccine, and documentation is kept throughout this continuous study. Clinical stages for development of vaccines is depicted in Figure 2.

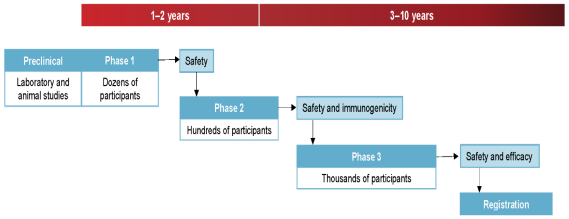

Figure 2: Clinical Stages for development of vaccine

2. MERITS, CHALLENGES, AND CURRENT PERSPECTIVE OF VACCINATION

Vaccination not only prevents infectious diseases but also enhances productivity, well-being, and cognitive growth, contributing to both individual and societal advancement. By reducing medical expenses—including consultation fees, drug costs, and hospitalization—vaccination lessens the economic burden, especially in developing countries like India, where millions live below the poverty line and struggle to afford healthcare [25-28]. Routine immunization thus promotes socioeconomic and health equity by breaking the cycle of poverty, illness, and low income. When children are protected through proper nutrition, hygiene, and vaccination, communities experience better health outcomes and economic stability [29].

Unlike medicines, which treat existing illnesses, vaccines prevent infections by training the immune system to recognize pathogens, offering long-term or even lifelong protection[30]. Vaccines benefit entire populations by creating herd immunity, although 100% efficacy is rare and may vary depending on health status and vaccine type. Minor adverse effects such as swelling, fever, or allergic reactions can occur, while severe complications remain exceedingly rare [30-34]. The COVID-19 pandemic underscored vaccines' vital role in global disease prevention, demonstrating their superiority over therapeutics for outbreak control.

Despite these benefits, vaccine development faces high production costs, the need for advanced laboratories, and skilled manpower. India, historically limited in infrastructure and funding, has recently expanded its vaccine production capabilities, becoming a global leader during COVID-19 [35-38]. Maintaining vaccine stability is another major challenge, as most require strict temperature control. Innovations like intranasal vaccines aim to overcome such limitations [39]. Regulatory frameworks also vary across nations, ensuring vaccine safety and efficacy while adapting to evolving global health needs. Overall, vaccination remains a cornerstone of preventive healthcare, demanding continued investment, infrastructure, and international collaboration [40].

3. REGULATORY REVIEW AND APPROVAL

The regulatory review and approval process starts after the completion of Phase 1, Phase 2, and Phase 3 clinical trials. At this stage,

post-marketing surveillance is conducted following the acquisition of market authorization for vaccines before they are sold.

Vaccine Regulation in US:

The Center for Biologics Evaluation and Research (CBER), the Vaccines and Related Biological Products Advisory Committee (VRBPAC), and the Biologics License Application (BLA) are some of the regulatory organizations in the US that are involved in vaccine registration [41]. The US vaccine registration procedure is shown in Figure 3. Before a vaccine is approved, the CBER, which works under the U.S. Food and Drug Administration (FDA), is in charge of its scientific examination, safety, and effectiveness. To guarantee that regulatory decisions are clear and supported by science, the VRBPAC offers impartial expert assistance. Manufacturers submit a Biologics License Application (BLA) to the FDA for assessment when a vaccine has successfully finished clinical testing [42, 43]. Comprehensive information on clinical results, quality assurance, and manufacturing procedures is included in this application. Long-term safety and performance are guaranteed by ongoing monitoring following approval via programs like the Vaccine Safety Datalink (VSD) and the Vaccine Adverse Event Reporting System (VAERS). Only vaccines that satisfy strict safety and efficacy standards are made available to the general population thanks to the severe multi-tiered evaluation procedure [44].

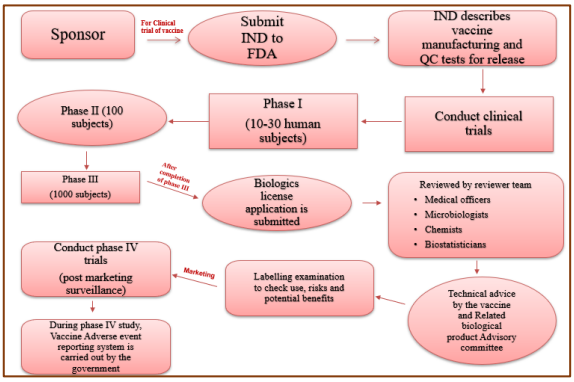

Figure 3: Registration process of vaccines in US

Vaccine Regulation in Europe:

The Committee for Medicinal Products for Human Use (CHMP), the Marketing Authorization Application (MAA) procedure, and the Vaccine Antigen Master File (VAMF) application are some of the regulatory agencies in the EU that are involved in vaccine registration [45]. The EU's vaccine registration procedure is displayed in Figure 4. The European Medicines Agency (EMA) oversees the CHMP, which is in charge of conducting a scientific assessment of the efficacy, safety, and quality of vaccines that are submitted for approval [46]. Through a single, centralized process, manufacturers can apply for authorization to commercialize a vaccine in every EU member state thanks to the MAA process. By allowing data on vaccines with the same antigen to be used repeatedly, the VAMF system simplifies documentation and speeds up subsequent submissions [47]. Following approval, vaccinations are granted a marketing authorization that is valid across the European Economic Area. The EudraVigilance database, which monitors and evaluates vaccination-related adverse events, is used for post-marketing surveillance. Additionally, to guarantee continued vaccine efficacy and risk-benefit balance throughout Europe, the Pharmacovigilance Risk Assessment

Committee (PRAC) continually checks safety signals [48].

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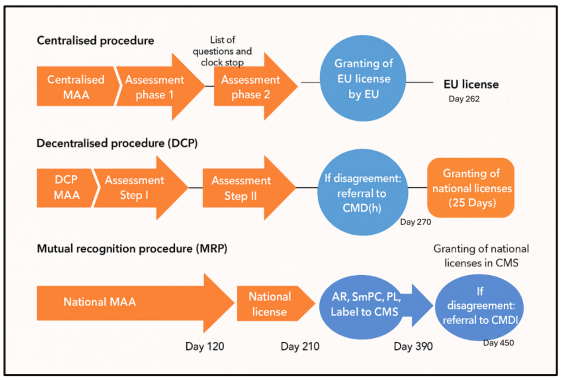

Figure 4: Registration process of vaccines in EU

Vaccine Regulation in Japan:

The Ministry of Health, Labour, and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA), and the Advisory Committee on Vaccines and Immunization are important regulatory organizations in Japan that oversee vaccine registration [49]. The Japanese vaccine registration procedure is shown in Fig. 5. Before approving a vaccine, the PMDA thoroughly examines preclinical and clinical data to guarantee its efficacy, safety, and quality. Based on the PMDA's assessment and public health requirements, the MHLW, as the central health authority, ultimately decides whether to grant marketing license [50]. The Advisory Committee offers professional advice on vaccination regulations and the National Immunization Program's (NIP) vaccine inclusion. In order to confirm production uniformity and quality control standards, Good Manufacturing Practices (GMP) inspections are a key component of Japan's approval procedure [51-54]. Vaccines are continuously monitored after approval using programs like the Pharmaceutical and Medical Device Safety Information Reporting Program. Japan's regulatory structure places a high priority on public safety, openness, and upholding public confidence through risk disclosure and evidence-based decision-making [55]. The Japanese vaccine registration procedure is illustrated in Figure 5.

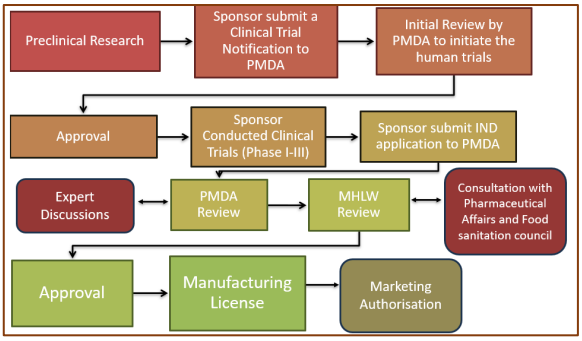

Figure 5: Registration process of vaccines in Japan

Vaccine Regulation in Canada:

The Public Health Agency of Canada (PHAC), the National Advisory Committee on Immunization (NACI), and Health Canada—more especially, the Biologic and Radiopharmaceutical Drugs Directorate (BRDD)—are important regulatory organizations in Canada that are involved in vaccine registration [56]. The Canadian vaccine registration procedure is shown in Figure 6. Health Canada's BRDD is in charge of doing a thorough analysis of preclinical and clinical trial data in order to assess the efficacy, safety, and quality of vaccines. Health Canada issues a Notice of Compliance (NOC) and a Drug Identification Number (DIN) to vaccines that satisfy all regulatory requirements, allowing them to be marketed and distributed [57-59]. In order to provide prompt reactions to new health risks, the PHAC supervises national vaccination programs and surveillance of vaccine-preventable diseases. NACI offers unbiased, fact-based advice on booster regimens, priority populations, and vaccination schedules [60]. The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), which

tracks and reports adverse effects, is used to continue post-marketing surveillance. To maintain high vaccination standards, Canada's regulatory framework places a strong emphasis on scientific integrity, public transparency, and cooperation between federal, provincial, and territorial health authorities [61].

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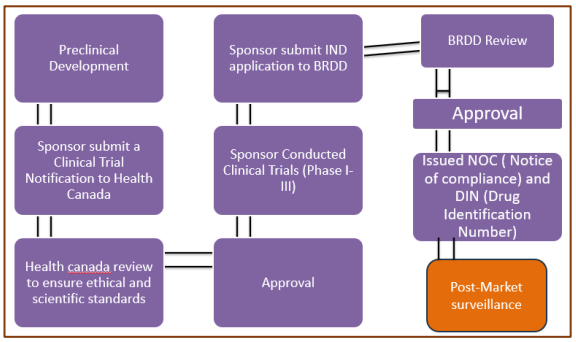

Figure 6: Registration process of vaccines in Canada

Vaccine Regulation in Australia:

The Advisory Committee on Vaccines (ACV), the Department of Health and Aged Care, and the Therapeutic Goods Administration (TGA) are important regulatory organizations in Australia (Figure 7) that oversee vaccine registration [62]. Before vaccinations are authorized for public use, the TGA is the main body in charge of evaluating their efficacy, safety, and quality. Clinical data, manufacturing standards, and adherence to Good Manufacturing Practices (GMP) are all thoroughly assessed during the approval process [63, 64]. Vaccines can be legally supplied within Australia once they are licensed and listed on the Australian Register of Therapeutic Goods (ARTG). Regarding immunization schedules, priority groups, and new disease dangers, the ACV offers professional scientific guidance [65, 66]. The Adverse Event surveillance System, which gathers information of possible adverse effects to guarantee continued vaccine safety, is used for post-market surveillance. Furthermore, the Department of Health and Aged Care's National Immunisation Programme (NIP) guarantees fair access to necessary vaccinations for all age groups and geographical areas, demonstrating Australia's dedication to robust public health regulation [67-70].

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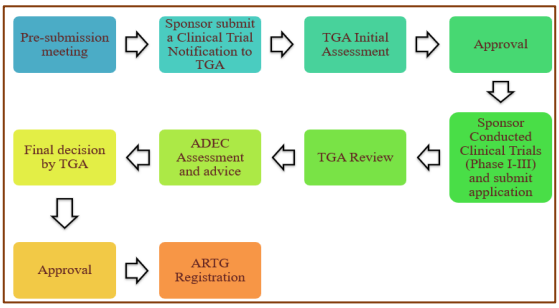

Figure 7: Registration process of vaccines in Australia

Vaccine Regulation in India:

The Central Drug Standard Control Organization (CDSCO), India's national regulatory organization, is led by the Director General of the Drug Controller. The Drug Controller General of India and the Ministry of Health and Family Welfare (MoHFW) oversee this organization's operations [71, 72]. It is headquartered in New Delhi and is in charge of regulating medicines, cosmetics, and medical devices nationwide. Simplifying clinical trials and guaranteeing the supply of safe and efficient medications in the Indian market are its main objectives. In India, the DCGI is responsible for approving, overseeing, and managing clinical studies [73]. The goal of CDSCO is to improve public health by guaranteeing the quality, safety, and effectiveness of medications, cosmetics, and medical equipment. Furthermore, the DCGI oversees the licensing, approval, and GMP monitoring of vaccines in India [74] (Figure 8). For scientific assessment and policy development, the Indian vaccine

regulatory framework also collaborates with organizations like the Department of Biotechnology (DBT) and the Indian Council of Medical Research (ICMR) [75]. Before receiving marketing permission, all vaccine candidates go through a thorough evaluation process for preclinical and clinical evidence. To guarantee long-term safety, vaccinations are regularly examined after approval through the Adverse Events Following Immunization (AEFI) surveillance program [76].

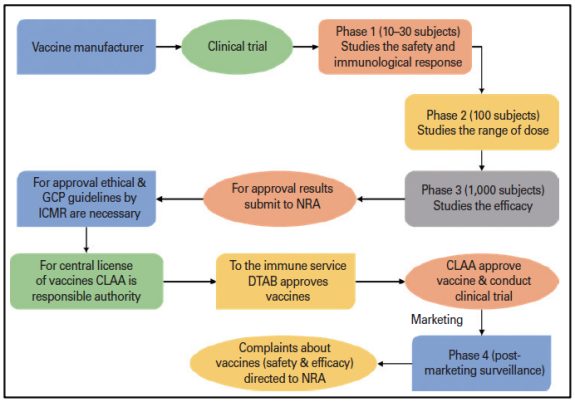

Figure 8: Vaccine registration process in India

Before vaccination batches are released, the National Institute of Biologicals (NIB) does additional quality testing [77]. With expedited review processes like "accelerated approval" and "restricted emergency use authorization," India's regulatory framework has seen substantial change, especially since the COVID-19 epidemic. By ensuring that both domestic vaccination requirements and foreign supply commitments are effectively fulfilled, these actions have improved India's standing as a worldwide vaccine hub [78-80].

4. COMPARATIVE INSIGHTS AND ANALYSIS

An analysis comparing viral immunization initiatives in the United States, Europe, Japan, Canada, and Australia showed that while these regions follow several common approaches, each also exhibits distinct national practices shaped by their policies, health systems, and vaccination behaviors. Although all five demonstrate a strong, evidence-driven commitment to vaccination supported by regulatory oversight, the organization and delivery of these programs vary considerably [81]. For instance, while the USA operates through a centralized federal advisory system (ACIP under CDC), Europe exhibits a more fragmented model where individual nations implement national programs under the broader coordination of the European Centre for Disease Prevention and Control (ECDC) [82]. Japan and Canada follow hybrid models, where national frameworks guide immunization strategies, but regional or prefectural authorities handle implementation. Australia operates a centrally coordinated National Immunization Program, characterized by strong federal governance and the seamless incorporation of school-based vaccination initiatives [83].

Although vaccination prices are quite high in these nations, there are still differences, especially among marginalized and rural communities. Australia's initiatives to target rural areas and Canada's emphasis on immunizing indigenous communities stand out as proactive steps to reduce equity gaps [84]. While on the other hand, vaccination hesitancy has been a major problem in the USA due to political divisiveness and false information. As demonstrated in Japan, where past vaccine issues have resulted in more cautious public attitudes despite strict safety monitoring, public faith in government and health officials is crucial. While Australia's usage of centralized registries and marketing efforts offers as an example of successful public engagement, Europe's heterogeneous geography presents

variety in uptake and digital record integration [85]

Managing disinformation, guaranteeing fair access, and preparing for future pandemics with flexible vaccine development and delivery systems are major issues in every region. Innovations like digital health surveillance and mRNA vaccines are being incorporated to differing degrees; the USA and Europe are at the forefront of research and development, while other countries are modifying these technologies according to local capabilities [86]. In order to improve immunization outcomes globally, the comparative analysis (**Table1**) ultimately emphasizes the significance of customizing vaccination regimens to cultural, political, and infrastructural situations while encouraging international cooperation and knowledge-sharing [87].

Table 1: Comparative overview of vaccine regulatory frameworks across six major regions (USA, Europe, Japan, Canada, Australia, and India).

Parameter	**USA**	**Europe (EU)**	**Japan**	**Canada**	**Australia**	**India**	**Reference**
Regulatory Authority	FDA – Center for Biologics Evaluation and Research (CBER)	EMA – Committee for Medicinal Products for Human Use (CHMP)	PMDA under MHLW	Health Canada – Biologic and Radiopharmaceutical Drugs Directorate (BRDD)	TGA – Therapeutic Goods Administration	CDSCO under Ministry of Health & Family Welfare (MoHFW)	[88]
Registration / Approval Process	Investigational New Drug (IND) → Biologics License Application (BLA) → FDA & VRBPAC review	Centralized procedure via MAA → CHMP evaluation → European Commission authorization	Pre-application → Clinical Trial Notification → PMDA review → MHLW approval	New Drug Submission (NDS) → BRDD review → Notice of Compliance (NOC) & DIN	Pre-submission → TGA scientific evaluation → ACV review → Market authorization	Pre-clinical → Clinical Trial Approval by DCGI → Review by Subject Expert Committee (SEC) → CDSCO/ DCGI	[89]

						final approval	

Parameter	USA	Europe (EU)	Japan	Canada	Australia	India	Reference
Approximate Dossier Review Timeline	10–12 months (priority review <6 months)	12–18 months (accelerated route 6–9 months)	12–15 months (fast-track <9 months)	~12 months (priority review ~6 months)	9–12 months (provisional or priority 6 months)	12–18 months (accelerated/emergency authorization <6 months)	[90]
Approvers / Advisory Committees	CBER, VRBPAC, FDA Commissioner	EMA-CHMP, PRAC, European Commission	PMDA, MHLW, Advisory Committee on Vaccines	BRDD, NACI, PHAC	TGA, ACV, Department of Health	DCGI, CDSCO, SEC, ICMR, DBT	[91]
National Immunization Program	CDC's VFC and ACIP guidelines	Coordinated by ECDC across member states	National Immunization Program (NIP)	NACI and PHAC	National Immunisation Program (NIP)	Universal Immunization Programme (UIP) under MoHFW	[92]
Post-Marketing Surveillance	VAERS, Vaccine Safety Datalink (VSD), FDA Sentinel	EudraVigilance, PRAC monitoring	PMDA post-marketing re-examination, MHLW database	CAEFISS, Vaccine Vigilance Program	AusVax Safety, Adverse Event Monitoring System, ARTG review	Adverse Events Following Immunization (AEFI) program, PvPI, and CDSCO monitoring	[93]
Adverse Reaction Reporting System	VAERS (mandatory manufacturer & provider reporting)	EudraVigilance (central EU database)	PMDA/ MHLW safety reporting	PHAC coordinated AEFI system	TGA online national AEFI database	AEFI Surveillance Portal integrated with CDSCO & ICMR	[94]

Key Vaccines Used	mRNA (Pfizer, Moderna), J&J, Novavax	Pfizer, Moderna, AstraZeneca, Novavax	Pfizer, Moderna, Shionogi, Takeda	Pfizer, Moderna, AstraZeneca, Novavax	Pfizer, Moderna, AstraZeneca, Novavax	Covishield (AstraZeneca), Covaxin (BBIL), Corbevax, Sputnik V	[95]
COVID-19 Vaccination Coverage	~80% (≥1 dose)	75–90% (varies by nation)	~80%	~85%	~85%	~90% (adult population, national data 2023)	[96]
Influenza Vaccination Rate	~50% (varies by age)	45–60% (elderly-focused)	50–60%	40–70% (high in elderly)	40–60%	~35–45% (urban-focused, limited rural uptake)	[97]
HPV Vaccination Strategy	Routine for adolescents (ages 11–12)	School-based programs widely adopted	Expanded adolescent program	Routine, school-based	School-based, high coverage	Introduced in UIP (2023) for girls aged 9–14 years	[98]
Public Health Campaigns	Strong federal/state coordination	EU-level & national campaigns	Centralized messaging via MHLW	Evidence-based outreach, rural inclusion	Public messaging for remote access	Mission Indradhanush, Har Ghar Dastak, COVAXIN awareness	[99]
Challenges	Vaccine hesitancy, misinformation	Unequal access across member states	Historical vaccine mistrust	Indigenous & rural access	Indigenous outreach, anti-vaccine sentiment	Funding gaps, cold-chain logistics, rural coverage disparities	[100]
Innovations in Vaccines	mRNA, nasal vaccines in trial	mRNA & viral vector combination vaccines	Cell-based & adjuvanted flu vaccines	Pediatric mRNA dosing research	Intranasal & combination vaccine	DNA vaccines, mRNA-based R&D, indigenous	[101]

					development	production scaling	
Global Contribution	Major R&D and manufacturing hub	EMA sets global regulatory standards	Innovation in adjuvants and formulations	Supports WHO, GAVI, COVAX	Key COVAX contributor in Asia-Pacific	One of world's largest vaccine producers; global supplier via COVAX & UNICEF	[102]

CONCLUSION AND FUTURE PERSPECTIVES

The comparative review of vaccine regulation and immunization practices across major global regions depicts that while all countries maintain strong scientific oversight, their regulatory pathways, approval timelines and implementation strategies markedly different. These variations directly influence how widely vaccines are accepted, public confidence, and the efficiency of national immunization systems. Despite the presence of sophisticated digital platforms, streamlined regulatory procedures, and robust post-marketing surveillance, gaps in public trust, access and equitable coverage still influence programs performance.

For India, the analysis highlights both significant progress and areas needing reinforcement. The country has made rapid strides in vaccine development and manufacturing capacity, yet regulatory delays, uneven digital infrastructure, and cold-chain limitations continue to hinder efficiencies. To elevate India's global standing, regulatory agencies could benefit from adopting harmonized review pathways, expanding scientific staffing, and integrating real-time digital platforms for monitoring and evaluation. Closer partnerships between CDSCO, academic institutions, and industry would also help to accelerate dossier evaluation and improve transparency in decision making. Additionally, investing in advanced regulatory science, strengthening pharmacovigilance networks, and modernizing data-sharing platforms will enable faster, more evidence-driven regulatory actions. By focusing on these improvements, India can reinforce its role as a leading global vaccine hub while ensuring consistent, high-quality regulatory oversight for national and international public health.

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ABBREVIATIONS

FDA: Food and Drug Administration; **CBER**: Center for Biologics Evaluation and Research; **EMA**: European Medicines Agency; **CHMP**: Committee for Medicinal Products for Human Use; **PMDA**: Pharmaceuticals and Medical Devices Agency; **MHLW**: Ministry of Health, Labour and Welfare; **TGA**: Therapeutic Goods Administration; **BRDD**: Biologics and Radiopharmaceutical Drugs Directorate; **NACI**: National Advisory Committee on Immunization; **PHAC**: Public Health Agency of Canada; **CDSCO**: Central Drugs Standard Control Organization; **DCGI**: Drug Controller General of India; **MoHFW**: Ministry of Health and Family Welfare; **IND**: Investigational New Drug; **BLA**: Biologics License Application; **MAA**: Marketing Authorisation Application; **VAMF**: Vaccine Antigen Master File; **GMP**: Good Manufacturing Practices; **ARTG**: Australian Register of Therapeutic Goods; **NOC**: Notice of Compliance; **DIN**: Drug Identification Number; **AEFI**: Adverse Events Following Immunization; **VAERS**: Vaccine Adverse Event Reporting System; **VSD**: Vaccine Safety Datalink; **CAEFISS**: Canadian Adverse Events Following Immunization Surveillance System; **ACV**: Advisory Committee on Vaccines; **NIP**: National Immunization Program; **WHO**: World Health Organization.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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