The Role of Regulatory Entities in Global Vaccine Availability

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BACKGROUND

Patient access to new vaccines depends on several interrelated factors, including public health infrastructure, funding availability, and political stability. While some countries integrate newly approved vaccines into their national immunization schedules almost immediately, others experience significant delays due to limited resources, logistical challenges, or legal and regulatory barriers. Government regulatory authorities and multilateral organizations play key roles in shaping vaccine access by granting market authorization, issuing reimbursement and procurement recommendations, and supporting funding and distribution. Because vaccines are administered to healthy individuals, often across entire populations, they require coordinated oversight to ensure safety, effectiveness, and equitable access. Regulatory decisions are also influenced by public health needs, particularly during infectious disease outbreaks that heighten the urgency of vaccine deployment. Recommendations for vaccine use are determined through formal, evidence-based review processes led by national or regional expert advisory bodies. In most countries, these functions are carried out by an in-country or national immunization recommendation committee, such as the U.S. Advisory Committee on Immunization Practices or the U.K. Joint Committee on Vaccination and Immunisation, which evaluate evidence on disease burden, vaccine efficacy, cost-effectiveness, and implementation feasibility before issuing national guidance. In countries without established public health infrastructure, National Immunization Technical Advisory Groups (NITAGs) perform this role. Supported by the World Health Organization (WHO) and regional partners, NITAGs provide independent, evidence-based recommendations to ministries of health to guide vaccine introduction, prioritize target populations, and align national policies with global best practices. Vaccine recommendations generally fall into two categories. Routine recommendations apply to vaccines advised for all individuals within specific age groups or for the general population—for example, the measles vaccine for all children. Risk-based recommendations, by contrast, target individuals with specific exposure or health risks, such as the Mpox vaccine for certain adult populations or the Japanese encephalitis vaccine for those living in or traveling to endemic regions.

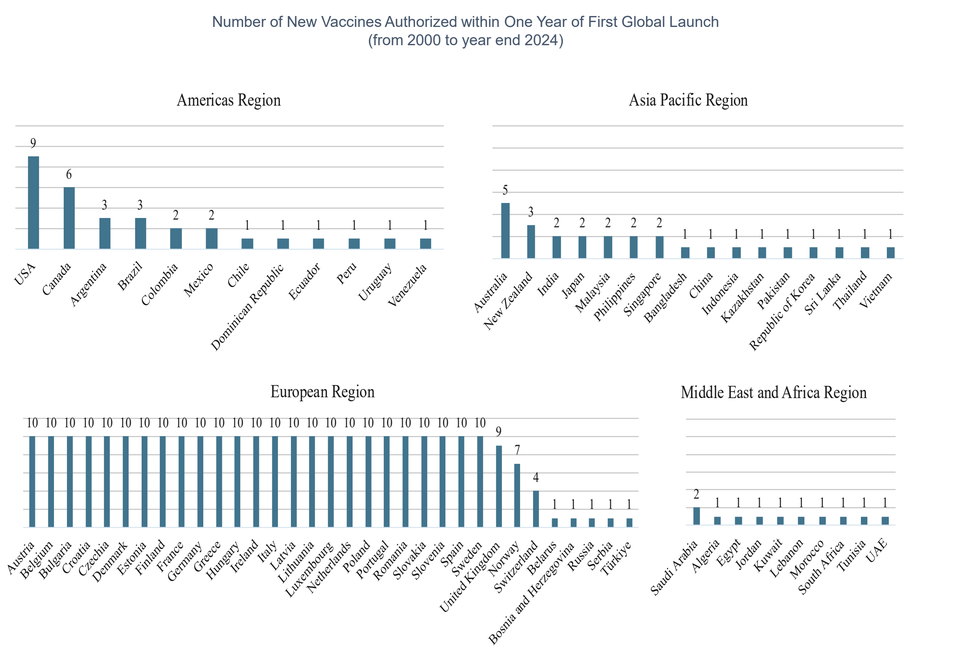
RESEARCH OBJECTIVES

This study examines how government regulatory bodies, global procurement institutions and NITAGs contribute to vaccine availability by examining authorization, recommendation, and reimbursement of vaccines introduced since 2000 across 71 high-, middle-, and low-income countries.

METHODS

- New vaccines were identified as new active substances approved by the European Medicines Agency, U.S. Food and Drug Administration, or Japan's Pharmaceuticals and Medical Devices Agency, including those under an Emergency Use Authorization since 2000.
- New vaccines were designated into two categories: routine immunization and outbreak response immunization. Vaccines under analysis included the first product developed per antigen since 2000 and authorized in any of the 71 countries in scope.
- The following routine immunizations were included: herpes zoster (HZ) vaccine; human papillomavirus (HPV) vaccine; meningococcal group B (MenB) vaccine; meningococcal group A, C, W, and Y (MenACWY) vaccine; pneumococcal conjugate 7-valent (PCV7) vaccine; respiratory syncytial virus (RSV) vaccine, and RSV monoclonal antibody (RSVmab). The following outbreak-response immunizations were included: chikungunya vaccine, COVID-19 vaccine, dengue vaccine, Ebola vaccine, and mpox vaccine.
- Vaccines introduced since 2000 only in countries outside the scope of this analysis, such as hepatitis E (HepE) vaccine, malaria vaccine, meningococcal A (MenA) vaccine, and typhoid vaccine, were excluded.
- Vaccine introduction date was determined by reviewing each country's routine immunization program, as recommended by the WHO as standard routine immunizations all countries should offer: Bacillus Calmette–Guérin (BCG) vaccines, Hepatitis B (HepB) vaccines, polio vaccines, diphtheria-tetanus-pertussis (DTP) containing vaccines, Haemophilus influenzae type b (Hib) vaccines, pneumococcal conjugate (PCV) vaccines, rotavirus vaccines, measles-containing vaccines, rubella-containing vaccines, and HPV vaccines.
- Vaccine recommendation date was determined by reviewing individual country NITAGs or national advisory bodies. A vaccine was deemed recommended if it had a formal recommendation by either a NITAG or national advisory body.
- Vaccine reimbursement date was determined by reviewing all publicly available reimbursement listings, including global procurement institutions and NITAGs, in each country. A new vaccine's reimbursement status was deemed reimbursed if it was covered by public insurance, national health programs, or other government funding.
- When primary sources were unavailable or lacked sufficient detail, secondary sources were used, including global vaccine tracking databases (e.g. European Centre for Disease Prevention and Control Vaccine Schedule, View-Hub by International Vaccine Access Center, Pan American Health Organization), peer-reviewed journal articles, news reports, and grey literature.
- Date data were recorded in day/month/year format. In the event of missing data, June 15th standardized reference points for missing month and day, respectively

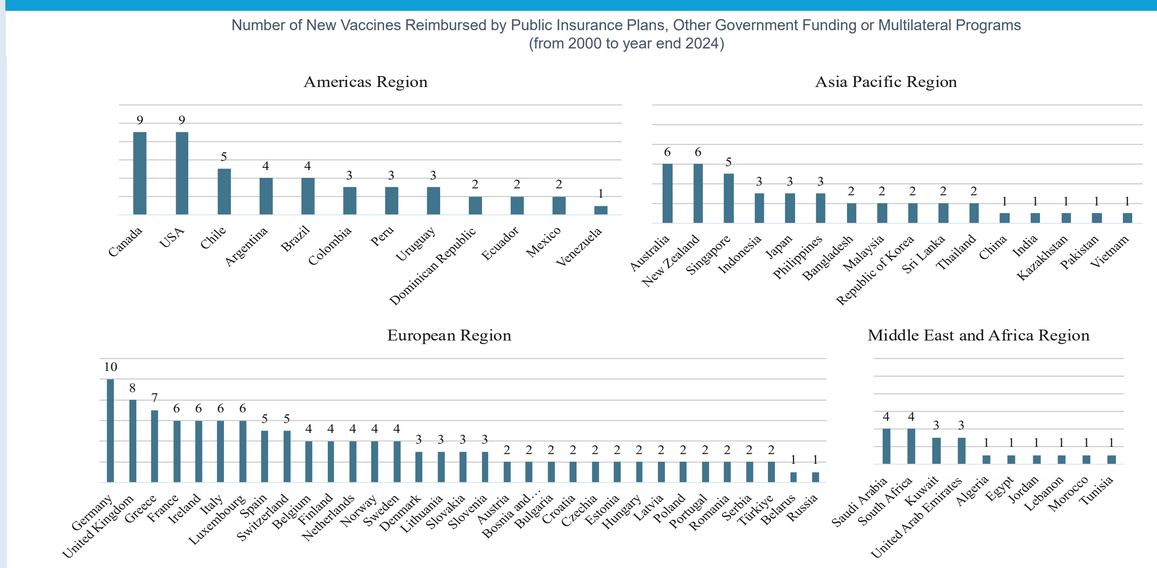
Vaccines Are Authorized First and Fastest in High-Income Countries



RESULTS

Access to new vaccines remains concentrated in high-income countries, particularly in Europe and the Americas. While most vaccines are authorized and recommended in these regions, far fewer are publicly reimbursed. The United States is the only country to have introduced all 12 vaccines, and EU countries show broad, but uneven, adoption. In contrast, many countries in Asia Pacific, the Middle East and Africa, and Latin America have introduced or authorized only a limited number, often due to regulatory delays and resource constraints. Authorization typically occurred within one year of global approval in the U.S. and EU but took significantly longer elsewhere, except for COVID-19 vaccines, which achieved rapid worldwide authorization. Fewer vaccines were formally recommended or reimbursed, with the U.S., Canada, Germany, France, and the U.K. leading in both categories. Most OECD and G20 countries reimburse fewer than half of new vaccines despite existing recommendations.

Vaccine Reimbursement is Greater in Upper- and Upper-Middle-Income Countries



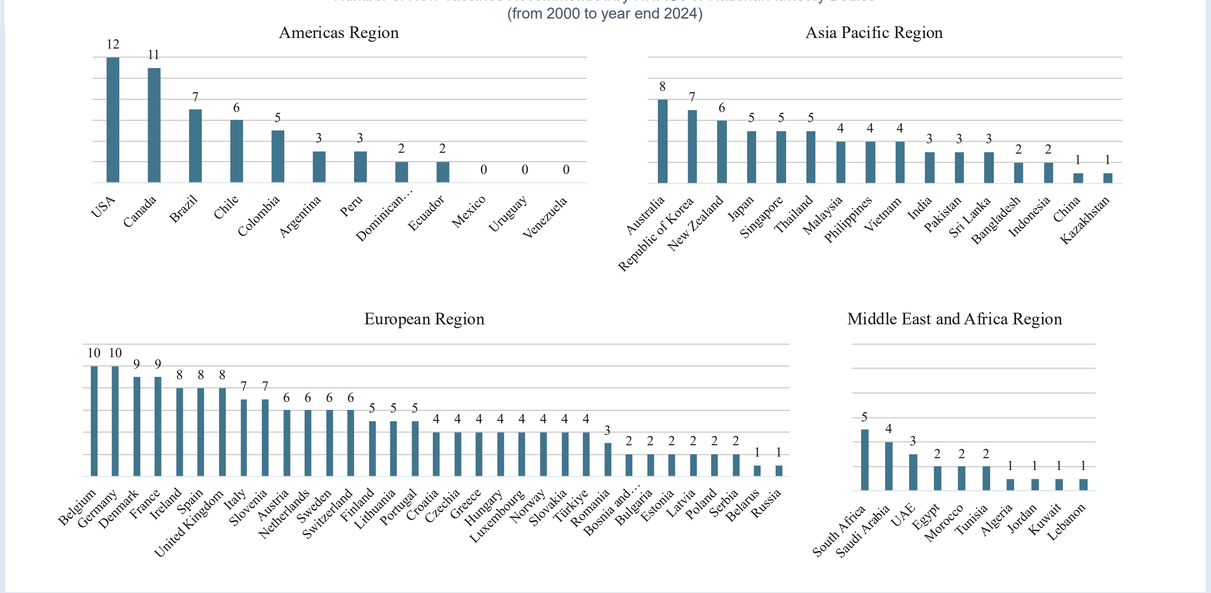
FINANCING AND REIMBURSEMENT

Unlike most medicines, which are typically covered through public or private health insurance, vaccine financing relies on a mix of government programs, employer initiatives, and international partnerships. Immunization program funding directly influences access, with models varying widely across income levels. In high-income countries, vaccines are generally financed through public budgets and provided free of charge under national immunization schedules. The United Kingdom, for example, centrally procures vaccines through the National Health Service, ensuring no cost-sharing for eligible groups. In Germany, vaccines recommended by the Standing Committee on Vaccination are fully reimbursed under statutory health insurance, while non-recommended or travel vaccines require private payment. Procurement typically occurs through formal tendering processes in which governments negotiate directly with manufacturers. In low- and middle-income countries, mixed financing models are common, combining domestic budgets, health insurance schemes, and external support from partners such as Gavi and UNICEF. Bangladesh, for instance, provides routine childhood vaccines free through its Expanded Programme on Immunization, co-financed by government and donor funds. Jordan offers free vaccines under its National Immunization Program but relies on private providers and non-governmental organizations for other vaccines, particularly for adults. Vaccine budgets and procurement systems are often managed separately from those for other medicines, leading to variable coverage, especially for adult or risk-based vaccines, where reimbursement depends on financing source, care setting, or national priorities.

LIMITATIONS

Our analysis faced several limitations that affected the consistency and completeness of vaccine access data. First, data collection included only the initial introduction of each vaccine in a country. Later transitions to updated formulations were not captured, though initial introduction typically represents the main regulatory and policy hurdle, with subsequent versions following established pathways. Second, data availability varied by vaccine type. Information for routine immunizations was generally comprehensive due to established reporting mechanisms, while data for outbreak-response vaccines were more limited given their reliance on emergency authorizations, temporary funding, and rapidly evolving policies. Researchers cross-verified available data through regulatory filings, procurement records, and reports from international health agencies. Finally, public reporting of historical vaccine policies and reimbursement structures was inconsistent. Many countries lacked routine publication of immunization updates or phased rollout details, leading to potential gaps. Where official sources were unavailable, secondary data from government statements and academic literature were used, though some omissions may remain.

Europe and the Americas Recommend Far More New Vaccines Than Other Regions



CONCLUSION

These findings demonstrate that global access to new vaccines remains highly uneven and vaccine dependent. Outbreak-response vaccines, such as those for Ebola, are often deployed reactively during epidemics rather than integrated into routine national immunization schedules, even in endemic regions. In contrast, newer products such as RSV and RSVmAb have achieved rapid uptake in the United States and Europe but, as of late 2024, had not been authorized or recommended in most other countries, underscoring persistent disparities in regulatory timelines, review capacity, and policy prioritization. The World Health Organization's recent prequalification of the maternal RSV vaccine and its updated position statement on RSV immunization represent important steps toward expanding global authorization and recommendation. As novel vaccines and technologies continue to emerge, access will increasingly depend on the strength and coordination of national regulatory authorities and immunization recommendation bodies. These institutions serve as critical gatekeepers, assessing evidence, guiding national policy, and determining which populations benefit first. Strengthening their technical capacity, transparency, and collaboration with international partners will be essential to accelerating global vaccine availability, particularly across low- and middle-income countries.

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*Joint first authorship