Fifty-sixth report

# Consolidated regional and global information on events supposedly attributable to vaccination or immunization (ESAVI) and other updates

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# 01

# Official reports from pharmacovigilance programs

# Respiratory syncitial virus (RSV) vaccine

## Brazil

In May 2026, Brazil's Ministry of Health published a report presenting the results of safety surveillance for the respiratory syncitial virus (RSV) vaccine between epidemiological weeks 13/2024 and 10/2026.

During the period covered by the report, 928 975 doses of RSV vaccine were administered in Brazil, of which 816 420 (87.9%) were of the RSV types A and B (recombinant) vaccine, which was incorporated into the Brazilian Unified Health System in 2025. A total of 504 reports were recorded in the e-SUS Notifica system, which corresponds to 54.7 reports per 100 000 doses administered. Of these reports, 274 (54.4%) were classified as ESAVIs. Of the reported ESAVIs, 34 (12.4%) were serious but nonfatal and 26 (9.5%) were serious and fatal.

Of the 60 serious events assessed, 1 case (1.7%) was deemed consistent with vaccination following a causality assessment. This was a hypersensitivity reaction consistent with anaphylaxis, which occurred approximately 25 minutes after administration of the vaccine and was characterized by paresthesia and progressive swelling of the lower lip, with a potential risk of upper airway obstruction. None of the fatal serious ESAVIs were deemed causally consistent with the RSV vaccine.

A total of 43 adverse events of special interest (AESI) related to pregnancy, fetal, and neonatal outcomes were identified, which corresponds to a rate of 5.3 AESIs per 100 000 doses administered. The most frequently reported events were stillbirths (19 cases; 2.3 per 100 000 doses administered) and preterm birth (13 cases; 1.6 per 100 000 doses administered). Most events were classified as coincidental, with no evidence of a causal association with vaccination, and all observed frequencies were lower than the expected rates in the general population.

The report concludes that no safety signals were identified that would indicate a consistent causal association between the RSV vaccine and the monitored events, reinforcing both the favorable safety profile of this vaccine and the importance of ongoing surveillance.

Source: Ministry of Health. Health and Environmental Surveillance Secretariat (SVSA). Department of the National Immunization Program (DPNI). General Coordination of Pharmacovigilance (CGFAM). Safety Monitoring of the Respiratory Syncytial Virus (RSV) Vaccine (Recombinant): Epidemiological Weeks 13/2024 to 10/2026, Brazil. May 2026. Available at: https://www.gov.br/saude/pt-br/vacinacao/esavi/monitoramento-dos-eventos/2026/informe-monitoramento-da-seguranca-da-vacina-vsr-maio-2026.pdf/view. Data reproduced by PAHO/WHO.

## Chile

In May 2026, Chile's Institute of Public Health published an analysis of ESAVIs reported following administration of nirsevimab during the 2024 and 2025 nationwide RSV immunization campaigns.

During both campaigns, 301 096 doses of nirsevimab were administered overall. Throughout this period, 30 reports of ESAVIs were received, which corresponds to a rate of 0.99 reports per 10 000 doses administered. Of the reports received, 7 (23.3%) were classified as serious, corresponding to 0.23 reports per 10 000 doses administered. The serious events all involved patients who required hospitalization and consisted of one case of myositis; one episode of tonic-clonic seizures with cyanosis, a staring spell, and febrile seizures; one hypotonic-hyporesponsive episode with inconsolable crying and cyanosis; one case of myoclonus; one case of febrile seizure; one case of neonatal seizure; and one case of lack of effectiveness.

The causality assessment conducted by the Expert Committee on Vaccine Pharmacovigilance determined that only one case was considered consistent with the administration of nirsevimab: a nodule at the injection site, initially reported as myositis. Two cases were classified as inconsistent and four as indeterminate, primarily due to the concurrent administration of other vaccines which could also explain the observed events.

The report concludes that safety monitoring conducted during the 2024 and 2025 campaigns confirms that nirsevimab continues to have a favorable risk-benefit ratio.

Source: Institute of Public Health of Chile. Subdepartamento Farmacovigilancia y Estudios Clínicos. Boletín de Farmacovigilancia N.° 27. Mayo de 2026. Available from:https://www.ispch.cl/wp-content/uploads/2026/05/BoletinFV27V01-11052026C-vf2.pdf. Data reproduced by PAHO/WHO.

# Dengue vaccine

## Brazil: Safety signal associated with the Butantan-DV vaccine

In June 2026, the Brazilian Ministry of Health published a Technical Note containing guidance to health services and the National ESAVI Surveillance System regarding a safety signal under review associated with the dengue vaccine manufactured by the Butantan Institute.

This vaccine, which contains live attenuated virus, can cause transient vaccine-induced viremia, peaking around the ninth day post-vaccination and lasting up to 21 days. As part of post-marketing surveillance, events resembling dengue with warning signs and cases consistent with severe dengue – which were not observed during clinical trials – were identified. Preliminary analysis deemed this a priority signal due to the timing of the cases, their biological plausibility, clinical consistency, analogy with the naturally occurring illness, laboratory confirmation of the presence of vaccine virus in some cases, and potential impact on public trust.

As of May 30, 2026, 501 044 doses of the vaccine had been administered, with 42 cases of dengue with warning signs and 3 cases of severe dengue reported. Among several hypotheses being investigated is the possibility of an association with transient replication of the vaccine virus or with a heightened immune response in susceptible individuals. However, the Ministry of Health stresses that the investigation is still ongoing, and that the available data do not yet allow for the establishment of any causal relationship.

In light of the precautionary principle and the need to conduct a more thorough risk-benefit assessment, the Ministry of Health ordered a temporary suspension of the vaccination strategy which employs the Butantan Institute dengue vaccine, while also mandating enhanced surveillance, laboratory testing, and active monitoring of all individuals who received the vaccine for 21 days following administration.

Source: Ministry of Health of Brazil. Department of Health Surveillance and the Environment. Departamento do Programa Nacional de Imunizações (DPNI). Nota Técnica nº 58/2026-DPNI/SVSA/MS: Orientações sobre sinal de segurança relacionado à vacina dengue produzida pelo Instituto Butantan. 8 de junho de 2026. Available from: https://www.gov.br/saude/pt-br/centrais-de-conteudo/publicacoes/notas-tecnicas/2026/nota-tecnica-no-58-2026-dpni-svsa-ms.pdf/view. Data reproduced by PAHO/WHO.

SECTION

# 02

## Publications on potential safety signals

# Respiratory syncytial virus (RSV) vaccine

## The impact of maternal respiratory syncytial virus vaccination on infant and perinatal outcomes: A systematic review and meta-analysis of randomized controlled trials

This systematic review and meta-analysis aimed to evaluate the efficacy and safety of maternal RSV vaccination during pregnancy in preventing RSV disease in infants and assessing perinatal outcomes. The analysis included six randomized, placebo-controlled clinical trials involving 18,011 pregnant women and 17,769 infants from multiple regions worldwide, including high-, middle-, and low-income countries.

The maternal age across all studies ranged from approximately 26 to 29 years, and vaccination was generally administered between 24 and 36 weeks of pregnancy. Three RSV vaccine platforms were evaluated, including nanoparticle RSV F-protein vaccines and prefusion F-protein vaccines, both adjuvanted and non-adjuvanted formulations. Infant follow-up ranged from 6 to 24 months after birth.

The primary objectives were to assess the effect of maternal RSV vaccination on infant RSV-associated lower respiratory tract infection (LRTI), severe RSV-LRTI, RSV-related hospitalization within the first 180 days of life, and key perinatal safety outcomes, including preterm birth, congenital malformations, low birth weight, developmental delay, and other neonatal outcomes.

Results demonstrated that maternal RSV vaccination significantly reduced severe RSV-associated LRTI in infants by 65% (RR 0.35; 95% CI 0.15–0.87) and RSV-related hospitalization by 47% (RR 0.53; 95% CI 0.37–0.76) during the first 180 days of life. A reduction in medically attended RSV-LRTI was also observed (RR 0.47; 95% CI 0.18–1.21), although the estimate did not reach statistical significance. Protection appeared particularly pronounced in low- and middle-income countries, where the baseline burden of RSV disease was higher.

Regarding safety, maternal RSV vaccination was not associated with a statistically significant increase in preterm birth (RR 1.15; 95% CI 0.95–1.38), low birth weight (RR 0.98; 95% CI 0.78–1.23), congenital malformations (RR 0.92; 95% CI 0.58–1.45), stillbirth (RR 0.98; 95% CI 0.58–1.64), preeclampsia (RR 0.99; 95% CI 0.73–1.35), or small-for-gestational-age infants (RR 0.88; 95% CI 0.68–1.13). No consistent safety concerns were identified across the evaluated vaccine platforms. Although exploratory analyses suggested a possible imbalance in preterm births with one discontinued adjuvanted vaccine candidate (RSVPreF3), this signal was not observed with the currently licensed non-adjuvanted RSVpreF vaccine.

The authors concluded that maternal RSV vaccination could provide clinically meaningful protection against severe RSV disease and RSV-related hospitalization during early infancy while maintaining an overall reassuring perinatal safety profile. These findings may support the incorporation of maternal RSV immunization into routine prenatal care programs and reinforce the importance of continued post-marketing pharmacovigilance, particularly in high-risk obstetric populations.

Source: Lopes JR, Esteves IM, Dias SO, da Silva FMTFG, da Silva GCDM, Libonati NB, Gasparetti RM, Nau AL. The impact of maternal respiratory syncytial virus vaccination on infant and perinatal outcomes: a systematic review and meta-analysis of randomized controlled trials. Journal of Perinatology. 2026;46:739–747. DOI: 10.1038/s41372-026-02675-0.

## Efficacy, immunogenicity, and safety of an investigational maternal respiratory syncytial virus prefusion F protein–based vaccine

This phase 3 randomized clinical trial evaluated the efficacy, immunogenicity, and safety of a maternal RSV prefusion F protein-based vaccine (RSVPreF3-Mat). A total of 5,345 pregnant women (24–34 weeks' gestation) and 5,235 infants were enrolled across 24 countries, with follow-up through 6 months postpartum for mothers and 12 months for infants.

The primary objectives were to assess the efficacy of maternal immunization against any and severe medically assessed RSV-associated lower respiratory tract disease (MA-RSV-LRTD) in infants until 6 months of life, as well as to evaluate safety in infants until 12 months of age. Secondary objectives included the evaluation of immunogenicity through maternal neutralizing antibody titers and the transplacental transfer ratio.

Maternal vaccination significantly reduced the risk of RSV-associated lower respiratory tract disease (RSV-LRTD) in infants during the first 6 months of life, with efficacy of 69.0% against severe disease and 65.5% against any RSV-LRTD. Protection against RSV-related hospitalization was more modest (50.1%) and appeared lower in low- and middle-income settings compared to high-income countries. Robust maternal immune responses were observed, with efficient transplacental antibody transfer, although clinical protection waned beyond 6 months (cumulative efficacy at 12 months: 23.0%).

Overall, the safety profiles were broadly comparable between the vaccine and placebo groups for serious adverse events. However, an important safety signal was identified, preterm birth occurred more frequently in the vaccine group than in the placebo group. Preterm birth was reported in 6.8% of infants in the vaccine group, compared with 4.9% in the placebo group. The relative risk of preterm birth was 1.37 (95% CI, 1.08–1.75) for the vaccine group versus the placebo group. This imbalance was particularly evident in low- and middle-income countries and was associated with a higher number of neonatal deaths, likely secondary to prematurity. The biological mechanism underlying this finding remains unclear.

The trial was limited by early termination and a reduced sample size, resulting in descriptive rather than confirmatory efficacy analyses. Immunogenicity data were incomplete for some participants, and unblinding may have introduced bias in outcome assessment. Additionally, overlap with the COVID-19 pandemic likely altered RSV epidemiology, contributing to fewer observed RSV-LRTD cases than expected.

In summary, although RSVPreF3-Mat demonstrated clinically meaningful protection and effective antibody transfer in early infancy, its development was discontinued due to safety concerns related to preterm birth. These findings support the feasibility of prefusion F–based maternal vaccines while emphasizing the critical importance of safety evaluation in this population.

Source: Banooni P, Gonik B, Epalza C, Reyes O, Madhi SA, Gomez-Go GD, Zaman K, Llapur CJ, López-Medina E, Stanley T, Kantele A, Huang LM, Mussi-Pinhata MM, Dewulf J, Langley JM, Seidl C, Ota M, Kirabo M, Anspach B, Dieussaert I, Henry O, Kim JH, Picciolato M; investigational RSV mAternal vacCinE (GRACE) Study Group. Efficacy, Immunogenicity, and Safety of an Investigational Maternal Respiratory Syncytial Virus Prefusion F Protein-Based Vaccine. Clinical Infectious Diseases. 2026;82(1):e146–e155. DOI: 10.1093/cid/ciaf033. (Referenced from the file ciaf033_2.pdf)

## Real-world evidence on RSV vaccine uptake, effectiveness, and safety in older adults: a systematic review and meta-analysis

This systematic review and meta-analysis evaluated real-world uptake, effectiveness, and safety of RSV vaccines in older adults following their recent introduction. A total of 36 studies including over 121.8 million individuals across nine countries were analyzed, covering data from the 2023/24 and 2024/25 RSV seasons. The included population comprised adults aged ≥60 years, with vaccination programs differing by country. Uptake data were primarily derived from the United States, United Kingdom, and Canada, while effectiveness and safety outcomes were assessed across multiple healthcare settings and populations, including high-risk and immunocompromised individuals.

Overall RSV vaccine uptake was low, with a pooled estimate of 18.0% (95% CI: 12.2–25.7) among adults ≥60 years in the United States during the 2023/24 season. Uptake was higher in older age groups (≥75 years), individuals with comorbidities, and immunocompromised populations, but significantly lower among Black, Hispanic, and other non-White populations, highlighting marked sociodemographic disparities.

Pooled vaccine effectiveness estimates demonstrated consistent and high protection across outcomes: 75.3% against laboratory-confirmed RSV infection, 76.4% against RSV-related emergency or urgent care visits, 74.8% against RSV-associated hospitalizations, and 79.8% against severe disease. Effectiveness was generally similar across age groups, although slightly reduced in immunocompromised individuals, particularly transplant recipients. Population-level analyses from the UK showed a reduction in RSV-related hospitalizations following vaccine implementation, with decreases of 30–62% depending on coverage levels.

Regarding safety, RSV vaccines demonstrated a favourable profile. Local (42.0%) and systemic (31.7%) adverse reactions were common but generally mild. A potential safety signal for Guillain–Barré syndrome was identified, with attributable risks ranging from 5.2–6.5 cases per million doses for the GSK vaccine and 9.0–18.2 cases per million doses for the Pfizer vaccine. No increased risk of atrial fibrillation was observed.

The authors conclude that RSV vaccines in older adults show high real-world effectiveness and an overall acceptable safety profile, supporting their public health value. However, low uptake and persistent disparities represent key challenges, and continued surveillance is needed to better characterize rare adverse events and long-term effectiveness in diverse populations.

Source: Trusinska D, Lee B, Ferdous S, Lansbury L, Burden C, Anand A, Stowe J, Mensah A, LIM W, Marsh K, Gibbons Ch, Shi T. (2026) Real-world evidence on RSV vaccine uptake, effectiveness, and safety in older adults: a systematic review and meta-analysis. The Lancet Regional Health – Europe 2026;64: 101623; https://doi.org/10.1016/j.lanepe.2026.101623

# COVID-19 vaccine

## Quality and methodological heterogeneity of COVID-19 vaccine safety studies focusing on the myocarditis safety signal: A systematic review, meta-analysis and meta-regression

This systematic review and meta-analysis evaluated the methodological characteristics and sources of heterogeneity among observational studies investigating the association between COVID-19 vaccination and myocarditis. The review aimed to understand how differences in study design, risk window definitions, outcome ascertainment, and handling of COVID-19 infection may influence effect estimates and contribute to variability in reported myocarditis risks following vaccination.

A total of 30 observational studies were included, representing predominantly population-based investigations conducted across Western Europe (47%), North America (23%), Asia (17%), and Israel (13%). Most studies used existing healthcare databases and vaccination registries. The majority evaluated multiple COVID-19 vaccines and multiple vaccine doses. Risk of bias (RoB) was assessed using the ROBINS-I tool. Meta-analyses and multivariable meta-regression were performed for studies addressing comparable population–intervention–comparator–outcome (PICO) frameworks

Considerable heterogeneity was identified in key design features, including risk window duration (7–288 days), definition of reference periods (three distinct approaches), and strategies to account for COVID-19 infection (five approaches). Thirteen analyses (37%) were judged to have serious or critical overall RoB. The greatest heterogeneity was observed in studies of the general population evaluating the second dose of BNT162b2 and mRNA-1273 compared with unvaccinated individuals or reference periods ($I^2$ = 96%, prediction interval [PI] 0.40–20.20; $I^2$ = 92%, PI 1.23–88.63, respectively). Meta-regression for the former PICO indicated that studies using a 28-day risk window reported effect estimates 0.56 times lower (95% CI 0.43–0.72) than those using a 7-day risk window; however, this difference was not statistically significant overall.

The authors conclude that substantial methodological heterogeneity exists in observational studies evaluating myocarditis following COVID-19 vaccination, particularly regarding risk-window selection, reference-period definitions, and management of COVID-19 infection. These design choices may contribute significantly to variability in reported myocarditis risk estimates. Future vaccine safety studies should incorporate sensitivity analyses to assess the impact of methodological decisions on study outcomes.

Source: Trang TPH, Bazelier MT, Klungel OH, Bots SH. Quality and methodological heterogeneity of COVID-19 vaccine safety studies focusing on the myocarditis safety signal: A systematic review, meta-analysis and meta-regression. Vaccine. 2026 Jul 11;85:128722. doi: 10.1016/j.vaccine.2026.128722.

SECTION

# 03

## Decisions of regional and international regulatory authorities

# Chikungunya vaccine

## The European Medicines Agency has updated safety information for the Ixchiq chikungunya vaccine

On June 12, the European Medicines Agency (EMA) reported that its Pharmacovigilance Risk Assessment Committee (PRAC) had updated the safety information for health care professionals regarding the Ixchiq chikungunya vaccine to include a recommendation that its use be restricted to individuals aged 12 years and older who are at high risk of chikungunya infection and only after careful consideration of the potential benefits and risks. This vaccine is contraindicated in patients whose immune system is weakened due to illness or medical treatment and it should not be co-administered with other vaccines.

The PRAC also endorsed a direct health care professional communication (DHPC) to inform these professionals of the updated recommendations.

The EMA reported that this restriction on the indication follows a review of the impact of serious adverse events reported with the vaccine (including aseptic meningitis) and of the risk-benefit balance of its use.

Additional information available from https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-8-11-june-2026.

# COVID-19 vaccine

## WHO recommendations on the composition of COVID-19 vaccines

On May 16, the WHO published the following recommendations from the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC):

- Monovalent vaccine: the recommended strain is LP.8.1 (Nextstrain: 25A; GenBank: PV074550.1; GISAID: EPI_ISL_19467828).

They do note that other antigens, such as XFG or NB.1.8.1, or other approaches that demonstrate broad and robust neutralizing antibody responses or efficacy against currently circulating SARS-CoV-2 variants could also be used.

Additional information available from https://www.who.int/news/item/16-05-2026-statement-on-the-antigen-composition-of-covid-19-vaccines.

## The EMA recommends updating COVID-19 vaccines to include the XFG variant

On May 29, EMA's Emergency Task Force (ETF) recommended updating COVID-19 vaccines to target the new SARS-CoV-2 variant XFG for the 2026–2027 vaccination campaign.

The XFG variant is part of the JN.1 family of Omicron subvariants; its circulation has increased worldwide and, by October 2025, it had peaked at 74% of infections genetically sequenced globally.

The ETF noted that the evidence suggests that XFG-targeted vaccines would provide the best protection against COVID-19 caused by JN.1 Omicron subvariants, as well as against BA.3.2. They further noted that vaccines targeting the LP.8.1 strain could still be considered for the 2026 vaccination campaigns, and that these recommendations may need to be updated if the epidemiological situation changes substantially, given the growing circulation of BA.3.2 and its potential for evolution and immune evasion.

Additional information available from https://www.ema.europa.eu/en/news/etf-recommends-updating-covid-19-vaccines-target-xfg-variant.

# Influenza vaccine

## WHO recommendations for influenza vaccine composition for the 2026–2027 Northern Hemisphere influenza season

On 27 February, WHO announced its recommendations for the composition of influenza vaccines for the 2026–2027 influenza season in the northern hemisphere.

- **Egg-based vaccines:**
  - an A/Missouri/11/2025 (H1N1)pdm09-like strain;
  - an A/Darwin/1454/2025 (H3N2)-like strain; and
  - a B/Tokyo/EIS13-175/2025 (B/Victoria lineage)-like strain.

- **Cell culture-, recombinant protein- or nucleic acid-based vaccines**
  - an A/Missouri/11/2025 (H1N1)pdm09-like strain;
  - an A/Darwin/1415/2025 (H3N2)-like strain; and
  - a B/Pennsylvania/14/2025 (B/Victoria lineage)-like strain.

This analysis is based on data from the Global Influenza Surveillance and Response System (GISRS) and WHO Collaborating Centers, which indicated that influenza A viruses were predominantly circulating, particularly the A(H3N2) and A(H1N1) variants, as well as low levels of influenza B viruses

of the B/Victoria lineage. Since March 2020, there have been no reported infections caused by the B/Yamagata lineage.

Additional information available from https://www.who.int/news/item/27-02-2026-recommendations-for-influenza-vaccine-composition-for-the-2026-2027-northern-hemisphere-season.

## EMA recommendations for influenza vaccine composition for the 2026–2027 season

On March 30, the EMA issued guidelines on the composition of seasonal influenza vaccines, based on the WHO recommendations.

- **Live-attenuated vaccines or egg-based vaccines:**
  - an A/Missouri/11/2025 (H1N1)pdm09-like virus;
  - an A/Darwin/1454/2025 (H3N2)-like virus;
  - a B/Tokyo/EIS13-175/2025 (B/Victoria lineage)-like virus.
- **Cell-based vaccines:**
  - an A/Missouri/11/2025 (H1N1)pdm09-like virus;
  - an A/Darwin/1415/2025 (H3N2)-like virus;
  - a B/Pennsylvania/14/2025 (B/Victoria lineage)-like virus.

Since B/Yamagata has not been detected in circulation since March 2020, its use in seasonal influenza vaccines for the 2026–2027 season is not recommended, which is in line with the WHO recommendation regarding the composition of vaccines for that season.

If quadrivalent vaccines are still required, manufacturers of inactivated vaccines may consider producing a vaccine containing two influenza B virus strains for the 2026–2027 season; the EMA proposes they follow WHO recommendations from previous years by including a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

Marketing authorization holders must submit applications to modify the composition of centrally authorized seasonal influenza vaccines by June 15, 2026.

Additional information available from https://www.ema.europa.eu/en/news/eu-recommendations-2026-2027-seasonal-flu-vaccine-composition

# Dengue vaccine

## ANVISA will convene a panel of experts for a more in-depth epidemiological investigation of the Butantan-DV dengue vaccine

On June 12, the Brazilian Health Regulatory Agency (ANVISA) announced the establishment of a panel of experts, composed of representatives from academia and the scientific community, to further the epidemiological investigation on the Butantan-DV dengue vaccine, developed by the Butantan Institute.

This decision was announced following a press conference held by Brazil's Ministry of Health, during which it was reported that the vaccination strategy which employs the Butantan-DV vaccine had been temporarily suspended as a precautionary measure following identification of rare, unexpected adverse events that require a more in-depth assessment.

The panel of experts will assist in reviewing the vaccine's safety profile and risk-benefit ratio. As part of this process, ANVISA requested additional information from the Butantan Institute, which will be evaluated jointly with the Ministry of Health's National Immunization Program. The agency noted that this type of review is part of standard regulatory procedures whenever new evidence emerges that could modify the risk-benefit assessment of a vaccine.

Additional information available from https://www.gov.br/anvisa/en/updates/anvisa-will-establish-a-panel-of-experts-to-deepen-the-epidemiological-investigation-about-the-butantan-dv-vaccine

SECTION

# 04

## Other related updates

# Pharmacovigilance

## The World Health Assembly adopts a resolution to strengthen pharmacovigilance

On May 22, during the 79th World Health Assembly, a resolution was adopted calling on Member States to strengthen and integrate surveillance systems for monitoring the safety of medicines, vaccines, and other health technologies, while improving regulatory capacity and workforce development.

The resolution encourages the use of digital tools and real-world data to enhance surveillance, and highlights the importance of timely detection of safety signals, effective risk communication, and efforts to counter disinformation and misinformation.

Additional information available from https://www.who.int/news/item/24-05-2026-79th-world-health-assembly-adopts-resolution-to-strengthen-pharmacovigilance

## ANVISA conducts public consultation on the creation of the National Pharmacovigilance System

On May 27, ANVISA decided to open a 45-day public comment period on a Proposed Resolution of its Collegiate Board (RDC) for the creation of a National Pharmacovigilance System (SINAF), which will operate as a subsystem integrated into Brazil's National Health Surveillance System (SNVS). The main objective of this initiative is to improve the management of risks associated with the use of medications, thereby strengthening health security and contributing to the safeguarding of public health, in accordance with the constitutional principles of cooperative federalism.

Additional information available from https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2026/anvisa-fara-consulta-publica-para-criacao-do-sistema-nacional-de-farmacovigilancia

### ANVISA publishes Instruction Manual for Reporting in the VigiMed System for health care facilities

On June 9, ANVISA announced the publication of its Instruction Manual for Reporting in the VigiMed System—known internationally as VigiFlow®—for health care facilities. The document provides detailed guidelines for reporting of adverse drug reactions, with the aim of improving and standardizing these reports.

The publication of this manual is part of broader ANVISA strategies to encourage health professionals to report adverse reactions; standardize completeness of reports in VigiMed, thereby promoting higher data quality and traceability; and support health care providers and facilities in fulfilling their pharmacovigilance duties.

The VigiMed Manual for Healthcare Facilities is available from: https://www.gov.br/anvisa/pt-br/assuntos/fiscalizacao-e-monitoramento/notificacoes/vigimed/vigimed-servicos-de-saude-1

Additional information available from https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2026/anvisa-lanca-manual-de-instrucoes-do-vigimed-para-profissionais-dos-servicos-de-saude

## Chikungunya vaccine

### ANVISA authorizes domestic manufacturing of the IXCHIQ vaccine

On May 4, ANVISA authorized local manufacturing of the Butantan Institute's IXCHIQ recombinant attenuated chikungunya vaccine. The Brazilian-manufactured version of this vaccine was developed by the Butantan Institute in collaboration with Franco-Austrian pharmaceutical company Valneva and approved by ANVISA in April 2025. It is indicated for the prevention of chikungunya in people aged 18 to 59 who are at increased risk of exposure to the chikungunya virus, and is contraindicated in pregnant women and immunocompromised individuals.

With this decision, the Butantan Institute has been officially designated as a manufacturing center and may carry out part of the production process (formulation and packaging) at its facilities, maintaining the same standards of quality, safety, and efficacy.

Additional information available from https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2026/anvisa-autoriza-producao-nacional-da-vacina-contra-a-chikungunya.

# Prequalified vaccines

## Vaccines recently prequalified by WHO

The following table lists the main characteristics of those vaccines prequalified by WHO during the first semester of this year.

| Vaccine | Manufacturer | NRA of record | Indication | Pharmaceutical form | Presentation / storage |
|---|---|---|---|---|---|
| **Live-attenuated measles vaccine** | Biological E. Limited (BioE), India | Central Drugs Standard Control Organization, India | Children aged 9-12 months. | Lyophilized<br><br>Diluent: 0.9% sodium chloride | 5- and 10-dose vials.<br><br>Shelf life:<br>24 months when stored at a temperature between 2 and 8 °C. |
| **Novel oral polio vaccine type 2 (nOPV2)** | Biological E. Limited (BioE), India | Central Drugs Standard Control Organization, India | Emergency use in response to outbreaks caused by type 2 poliovirus in all age groups. | Liquid, ready to use. | 20- and 50-dose vials.<br><br>Shelf life:<br>24 months when stored at a temperature below -20 °C and 6 months when stored at 2 to 8 °C. |
| **Tetravalent meningococcal group A, C, W-135, and Y conjugate vaccine**<br><br>Commercial name: Menveo | GlaxoSmithKline Vaccines S.r.l. | European Medicines Agency | Children 2 years of age and older, adolescents, and adults. | Liquid, ready to use. | 1-dose vial.<br><br>Shelf life:<br>24 months when stored at a temperature between 2 and 8 °C. |

Additional information available from https://extranet.who.int/prequal/vaccines/p/measles-vaccine-live
https://extranet.who.int/prequal/vaccines/p/measles-vaccine-live-0
https://www.who.int/news/item/13-02-2026-who-prequalifies-additional-novel-oral-polio-vaccine
https://extranet.who.int/prequal/vaccines/p/menveo-liq

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