

CONSOLIDATED REGIONAL AND GLOBAL INFORMATION ON EVENTS SUPPOSEDLY ATTRIBUTABLE TO VACCINATION OR IMMUNIZATION (ESAVI) AND OTHER UPDATES

Fifty-third report

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Mpox Vaccine

Brazil

Between 15 March 2023 and 31 December 2024, a total of 32,221 doses of the Mpox vaccine were administered in Brazil, of which 19,212 (59.6%) were first doses and 13,009 (40.4%) were second doses. During this period, 198 reports were registered in the *e-SUS Notifica* system, equivalent to 6.1 reports per 1,000 doses administered.

Of the reports, 51 (25.8%; 1.6 per 1000 doses administered) were classified as events supposedly attributable to vaccination or immunization (ESAVIs), of which 49 (96.1%) were non-serious and 2 (3.9%) were classified as serious. The most frequently reported non-serious events were edema (9.8%), fever (8.9%), pain (8.1%), headache (6.5%), and diarrhea (4.1%). Other reported events included erythema, pruritus, hyperemia, cutaneous nodules, myalgia, and local reactions such as warmth, hardening, and redness, which together indicate a predominance of mild, self-limiting manifestations with a transient impact on the health of those vaccinated.

Of the two serious ESAVIs, both occurred after the first dose. One case, in a person living with HIV, presented a seizure 48 hours after vaccination and was classified with indeterminate causality (B2) due to the lack of investigation of differential diagnoses. The second case involved vomiting, abdominal pain, and renal failure, requiring hospitalization with a favorable outcome; causality was classified as coincidental (C).

Report rates varied across states, with the highest rates observed in Pará (11.1 per 1,000 doses administered), Rio de Janeiro (7.0 per 1,000 doses administered), and Paraná (3.7 per 1,000 doses administered). Among women, the rate was 5.2 per 1,000 doses administered, compared to 1.1 per 1,000 doses administered in men. By age group, the 30- to 39-year-old group stood out with a rate of 1.9 per 1,000 doses administered.

Source: Department of the National Immunization Program, Secretariat for Health and Environmental Surveillance, Ministry of Health. Report: Monitoring the Safety of the Mpox Vaccine, Epidemiological Week 6 of 2023 to Epidemiological Week 1 of 2025, Brazil. Updated 31 December 2024. Available from: https://www.gov.br/saude/pt-br/vacinacao/esavi/monitoramento-dos-eventos/2025.

Yellow Fever Vaccine

Brazil

Between July 2024 and March 2025, 66 human cases of yellow fever were reported in the country, with a case fatality rate of 42.4%, in addition to transmission in non-human primates in various states.

Technical Note No. 18/2025 describes the main serious events associated with the yellow fever vaccine (attenuated) (YFV), highlighting:

- **Yellow fever vaccine-associated neurotropic disease (YFV-AND):** including encephalitis, meningitis, Guillain-Barré syndrome, and acute disseminated encephalomyelitis, with onset generally between one and four weeks after vaccination;

- **Yellow fever vaccine-associated viscerotropic disease (YFV-AVD):** a severe multisystem dysfunction with a case fatality rate of approximately 50%, clinically resembling wild-type yellow fever.

Historical data (2015–2021) indicate low occurrence rates: YFV-AND (0.16 cases per 100 000 doses administered) and YFV-AVD (0.03 cases per 100 000 doses administered).

The document details the diagnostic criteria, laboratory investigation, causality classification, and surveillance actions for the detection, immediate reporting (within 24 hours), and appropriate management of serious ESAVIs.

Source: Ministry of Health, Secretariat for Health and Environmental Surveillance, Department of the National Immunization Program. Technical Note No. 18/2025-CGFAM/DPNI/SVSA/MS. Published on 25 March 2025. Available from: https://www.gov.br/saude/pt-br/vacinacao/esavi/notas-tecnicas/nota-tecnica-no-18-2025-cgfam-dpni-svsa-ms.

COVID-19 and Influenza Vaccines

Immunogenicity and safety of influenza and COVID-19 multicomponent vaccine in adults 50 years and older: a randomized clinical trial

Published on May 7, 2025, a phase 3, randomized, observer-blinded, noninferiority clinical trial was conducted across 146 sites in the United States to evaluate the immunogenicity and safety of the investigational mRNA-1083 vaccine against seasonal influenza and SARS-CoV-2 in adults aged 50 years and older. Between October 19 and November 21, 2023, a total of 8,015 participants were enrolled, including 4,017 individuals aged 65 and above and 3,998 aged 50 to 64 years, with median ages of 70 and 58 years, respectively. Participants were randomly assigned to receive either mRNA-1083 plus placebo or the coadministration of licensed comparator vaccines: high-dose quadrivalent inactivated influenza vaccine (HD-IIV4) for those 65 and older, standard-dose IIV4 (SD-IIV4) for those aged 50–64, and mRNA-1273 for COVID-19 in all age groups.

The primary objective was to demonstrate noninferiority of the humoral immune response induced by mRNA-1083 compared to the licensed vaccines against matched strains at day 29, as well as to assess reactogenicity and safety. Secondary objectives included demonstrating the superiority of mRNA-1083's immune response over the comparators. The results showed that mRNA-1083 met noninferiority criteria for all matched influenza and SARS-CoV-2 strains. Moreover, it elicited stronger immune responses than SD-IIV4 in the 50–64 age group for all four influenza strains and surpassed HD-IIV4 in the ≥65 age group for three strains (A/H1N1, A/H3N2, B/Victoria), as well as against SARS-CoV-2 across all ages.

Solicited adverse reactions were more frequent and somewhat more severe in the mRNA-1083 groups compared to the comparator groups in both age cohorts (83.5% vs. 78.1% in ≥65 years; 85.2% vs. 81.8% in 50–64 years), though most were mild to moderate and transient. No safety concerns were identified.

Based on these findings, the authors suggested that mRNA-1083 could meet the criteria for a viable alternative to current seasonal influenza and COVID-19 vaccines, potentially offering enhanced immunogenicity with an acceptable safety profile. It could therefore represent a promising option for combined seasonal vaccination in older adults.

Source: Rudman Spergel AK, Wu I, Deng W, Cardona J, Johnson K, Espinosa-Fernandez I, et al. Immunogenicity and safety of influenza and COVID-19 multicomponent vaccine in adults ≥50 years: a randomized clinical trial. *JAMA*. 2025 May 7. doi:10.1001/jama.2025.5646.

Respiratory Syncytial Virus (RSV) Vaccine

Real-world effectiveness of RSVpreF vaccination during pregnancy against RSV-associated lower respiratory tract disease leading to hospitalization in infants during the 2024 RSV season in Argentina (BERNI study): a multicenter, retrospective, test-negative, case–control study

Published on May 5, 2025, this retrospective, test-negative, case-control study (BERNI) was conducted to evaluate the effectiveness of maternal RSVpreF vaccination in preventing RSV-associated lower respiratory tract disease (LRTD) and severe LRTD leading to hospitalization among infants during their first respiratory syncytial virus (RSV) season following vaccine implementation.

The study was carried out in 12 hospitals across Argentina during the 2024 RSV season. It included infants aged 6 months or younger who were hospitalized with LRTD between April 1 and September 30, 2024, and who were tested for RSV using PCR or indirect immunofluorescence. Infants with a positive RSV test were considered cases, while those with a negative PCR result served as controls. Maternal vaccination with RSVpreF was defined as receipt of the vaccine between 32⁰⁄₇ and 36⁶⁄₇ weeks of gestation and at least 14 days prior to delivery. Vaccine effectiveness (VE) was estimated using multilevel logistic regression models adjusted for potential confounders.

Among 633 hospitalized infants, 505 met full eligibility criteria for the primary VE analysis, including 286 cases and 219 controls. Of these, 51 (18%) cases and 109 (50%) controls were born to individuals vaccinated with RSVpreF during pregnancy. VE against RSV-associated LRTD leading to hospitalization was estimated at 78.6% (95% CI: 62.1–87.9) from birth to 3 months of age, and 71.3% (95% CI: 53.3–82.3) from birth to 6 months. VE against RSV-associated *severe* LRTD requiring hospitalization was 76.9% (95% CI: 45.0–90.3) from birth to 6 months. Notably, all three RSV-associated in-hospital deaths occurred in infants whose mothers had not received the vaccine.

Based on these findings, the authors suggested that maternal RSVpreF vaccination could provide high protection against RSV-associated LRTD and severe disease requiring hospitalization in young infants, particularly during the first three months of life, with protective effects potentially sustained through six months. These results may support the real-world impact of maternal immunization strategies in reducing RSV-related morbidity and mortality in early infancy.

Source: Pérez Marc G, Vizzotti C, Fell DB, Di Nunzio L, Olszevicki S, Mankiewicz SW, et al. Real-world effectiveness of RSVpreF vaccination during pregnancy against RSV-associated lower respiratory tract disease leading to hospitalization in infants during the 2024 RSV season in Argentina (BERNI study): a multicentre, retrospective, test-negative, case–control study. *Lancet Infect Dis*. 2025 May 5. doi:10.1016/S1473-3099(25)00156-2.

Mpox Vaccine

Safety and effectiveness of MVA BN vaccination against Mpox in at-risk individuals in Germany: (SEMVAc and TEMVAc): a combined prospective and retrospective cohort study

Published on March 18, 2025. This study was conducted in Germany between July 7, 2022, and December 31, 2023. It combined two complementary approaches: a prospective, multicenter, observational cohort study (SEMVAc) and a retrospective, emulated target trial (TEMVAc) based on data from a historical cohort. The goal was to evaluate the safety, reactogenicity, and effectiveness of the third-generation smallpox vaccine MVA-BN (Modified Vaccinia Ankara–Bavarian Nordic) against mpox, particularly in at-risk populations. The study population included men who have sex with men and transgender individuals aged 18 years or older with changing sexual partners, enrolled from 31 specialized outpatient clinics for HIV and infectious diseases. Participants were excluded if they had prior mpox infection or had received MVA-BN as post-exposure prophylaxis.

A total of 6459 participants were enrolled in the prospective SEMVAc study, and 4788 were included in the safety cohort. Adverse reactions were infrequent, occurring in 0.35% of participants after the first vaccine dose and 0.14% after the second dose. The most common reactions were local injection site pain, more frequent after the first dose than the second, and systemic symptoms such as fatigue, headache, and myalgia. No cases of myocarditis, pericarditis, or encephalitis were reported. Reactogenicity was generally mild to moderate in severity.

To assess vaccine effectiveness, 9354 individuals were enrolled in the TEMVAc study, of whom 3027 vaccinated participants were matched 1:1 with 3027 unvaccinated controls. During a median follow-up of 55 days, 16 cases of mpox occurred in the vaccinated group versus 32 cases in the unvaccinated group. The estimated effectiveness of the vaccine at 14 days or more after the first dose was 57.8% (95% CI 11.8 to 83.0). Subgroup analysis showed higher effectiveness in people without HIV (84.1%) and in those receiving PrEP (80.8%), but lower effectiveness in people living with HIV (34.9%). Among those with childhood smallpox vaccination, effectiveness was 68.1%.

Breakthrough infections among vaccinated individuals were associated with milder symptoms, fewer lesions, shorter duration of illness, and no hospitalizations, compared with unvaccinated individuals. Systemic symptoms such as fever were less frequent, and the median healing time for skin lesions was notably shorter in the vaccinated group (10 days) compared to the unvaccinated group (18 days). Among breakthrough infections, 70.8% occurred in people living with HIV.

The authors conclude that MVA-BN vaccination could be safe and well tolerated, including among people living with HIV, those taking PrEP, and individuals previously vaccinated against smallpox. Although one dose could provide protection, particularly in HIV-negative individuals, the findings support the need for completing the recommended two-dose regimen, especially for people living with HIV.

Source: Hillus D, Le NH, Tober-Lau P, Fietz AK, Hoffmann C, Stegherr R, et al. Safety and effectiveness of MVA-BN vaccination against mpox in at-risk individuals in Germany (SEMVAc and TEMVAc): a combined prospective and retrospective cohort study. *Lancet Infect Dis*. 2025 Mar 18. doi:10.1016/S1473-3099(25)00018-0.

Chikungunya Vaccine

Chikungunya virus virus-like particle vaccine safety and immunogenicity in adolescents and adults in the USA: a phase 3, randomized, double-blind, placebo-controlled trial

Published on March 27, 2025, data from a pivotal phase 3 clinical trial conducted at 47 sites in the United States provide insight into the safety, tolerability, immunogenicity, and lot-to-lot consistency of the investigational Chikungunya virus-like particle vaccine, Vimkunya, in healthy adolescents and adults aged 12 to 64 years.

Participants were stratified by age (12–17, 18–45, and 46–64 years) and randomized to receive one of three consecutively manufactured lots of Vimkunya or a placebo (identical formulation without antigen or adjuvant). A total of 3,258 individuals were enrolled between September 2021 and September 2022, with 2,790 receiving Vimkunya and 464 receiving placebo. The primary endpoints focused on seroresponse rates, geometric mean titres (GMT) of Chikungunya virus neutralizing antibodies at day 22, and consistency in GMT responses across the three vaccine lots in adults aged 18–45.

Immunogenicity results at day 22 showed that 97.8% of those receiving Vimkunya developed a seroresponse, compared to only 1.2% in the placebo group. The difference in seroresponse rates was 96.6% (95% CI 95.0–97.5; $p<0.0001$), and the GMT in the vaccine group was substantially higher (1618 vs. 7.9; $p<0.0001$). Lot-to-lot comparisons demonstrated consistency, with GMT ratios between lots A, B, and C ranging from 0.95 to 0.98. Regarding safety, the vaccine was well tolerated. Most adverse events were mild or moderate in severity and self-limiting. The most frequent were injection site pain, fatigue, headache, and myalgia.

Based on these findings, the authors suggested that Vimkunya could induce a rapid and robust immune response and may offer protection against Chikungunya virus disease in individuals aged 12 to 64 years. The consistent immunogenicity across vaccine lots and the favorable safety profile further support its potential suitability for broad use in this age group.

Source: Richardson JS, Anderson DM, Mendy J, Tindale LC, Muhammad S, Loreth T, et al. Chikungunya virus virus-like particle vaccine safety and immunogenicity in adolescents and adults in the USA: a phase 3, randomized, double-blind, placebo-controlled trial. *Lancet*. 2025 Mar 27. doi:10.1016/S0140-6736(25)00345-9.

Chikungunya Vaccine

The Brazilian Health Regulatory Agency Approves First Chikungunya Vaccine

On 14 April, the Brazilian Health Regulatory Agency (ANVISA) announced the approval of the marketing authorization for the IXCHIQ vaccine from the Butantan Institute. The vaccine was developed by the Austrian pharmaceutical company Valneva and is manufactured in Germany by IDT Biologika GmbH. The Butantan Institute in Brazil plans to produce the vaccine domestically in the future.

The IXCHIQ vaccine was approved as a single-dose vaccine for the prevention of the disease in individuals aged 18 and older who are at increased risk of exposure to the chikungunya virus. It is contraindicated for pregnant individuals and those who are immunodeficient or immunosuppressed.

To evaluate the vaccine, ANVISA's team reviewed production data, quality information, and clinical studies, which included assessments in adults in the United States and adolescents in Brazil. In addition, ANVISA participated in the European Medicines Agency (EMA)'s evaluation of the IXCHIQ vaccine, as part of the OPEN (Opening Procedures at EMA to Non-EU Authorities) initiative, which allows different regulatory agencies to simultaneously assess vaccines and medicines of public health interest.

To grant marketing authorization, ANVISA established an agreement with the Butantan Institute that includes a commitment to conduct effectiveness and safety studies, as well as active pharmacovigilance activities, to expand knowledge about the vaccine's efficacy and safety profile.

Additional information is available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/anvisa-aprova-primeira-vacina-para-chikungunya

The European Medicines Agency's Risk Assessment Committee Begins Review of the IXCHIQ Chikungunya Vaccine

On 7 May, the EMA announced that the Pharmacovigilance Risk Assessment Committee (PRAC) has initiated a review of the IXCHIQ chikungunya vaccine following reports of serious adverse events in elderly individuals.

The agency indicated that, to date, 17 serious adverse events have been reported worldwide, including two deaths, in people aged 62 to 89 who received the vaccine.

Since the clinical studies of IXCHIQ were conducted primarily in individuals under 65 years of age, and the vast majority of serious cases occurred in people aged 65 and older, the PRAC has temporarily recommended restricting the use of the vaccine in adults over 65. Additionally, health care professionals are reminded that IXCHIQ should not be administered to individuals with weakened immune systems due to illness or medical treatment.

The EMA states that IXCHIQ was authorized on 28 June 2024. Approximately 43 400 doses have been used worldwide. Within the European Union, the vaccine is available in Austria, Belgium, Denmark, Finland, France, Germany, Luxembourg, the Netherlands, Norway, and Sweden.

The PRAC indicated that it will review all available data to assess the benefits and risks of the vaccine and will issue a recommendation on whether to modify the terms of its marketing authorization, if necessary.

More information is available at https://www.ema.europa.eu/en/news/ema-starts-review-ixchiq-live-attenuated-chikungunya-vaccine

Canada Recommends Against the Use of the Live Attenuated Chikungunya Vaccine (IXCHIQ) in Persons Aged 65 Years or Older

On 19 May, the Committee to Advise on Tropical Medicine and Travel (CATMAT), in coordination with Health Canada, issued recommendations advising against the use of the live attenuated IXCHIQ chikungunya vaccine in individuals over 65 years of age, despite considering the certainty of the evidence to be very low.

This recommendation is based on actions taken by the U.S. Food and Drug Administration (FDA) and the EMA. Health Canada is monitoring the safety of IXCHIQ and will take appropriate action if new safety information arises that could affect the benefit-risk profile of IXCHIQ in a specific patient population.

More information is available at: https://www.canada.ca/en/public-health/services/catmat/guidance-use-live-attenuated-chikungunya-vaccine-ixchiq-persons-65-years-older.html

COVID-19 Vaccine

WHO Statement on the Antigen Composition of COVID-19 Vaccines

On 15 May, the World Health Organization (WHO) published recommendations from the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC), summarized as follows:

- The monovalent vaccines based on the JN.1 or KP.2 lineages remain appropriate vaccine antigens, and the monovalent LP.8.1 vaccine is an acceptable alternative.

- In accordance with the policy of the WHO's Strategic Advisory Group of Experts on Immunization (SAGE), vaccination should not be delayed in anticipation of access to vaccines with an updated composition.

TAG-CO-VAC will continue to monitor the genetic and antigenic evolution of SARS-CoV-2 variants, immune responses to SARS-CoV-2 infection and COVID-19 vaccination, and the performance of COVID-19 vaccines against circulating variants.

More information is available at: https://www.who.int/news/item/15-05-2025-statement-on-the-antigen-composition-of-covid-19-vaccines

European Medicines Agency Emergency Task Force Recommends Updating COVID-19 Vaccines

On 16 May, the EMA's Emergency Task Force (ETF) recommended updating COVID-19 vaccines for the 2025/2026 vaccination campaign to target the new SARS-CoV-2 variant LP.8.1, which is currently the most widely circulating variant worldwide.

The ETF noted that vaccines targeting the JN.1 or KP.2 strains could still be considered for the 2025 vaccination campaigns until the updated LP.8.1 vaccines become available.

Additional information is available at: https://www.ema.europa.eu/en/news/etf-recommends-updating-covid-19-vaccines-target-new-lp81-variant

Influenza Vaccine

EMA Issues Recommendations on Seasonal Influenza Virus Strains for Fall 2025

On 8 April, EMA published recommendations on the seasonal influenza virus strains for the 2025/2026 season, summarized as follows:

- **Live attenuated or egg-based trivalent** vaccines should include the following three strains:
    - an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
    - an A/Croatia/10136RV/2023 (H3N2)-like virus;
    - a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

- **Cell-based trivalent vaccines** should include the following three strains:
    - an A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
    - an A/District of Columbia/27/2023 (H3N2)-like virus;
    - a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

The EMA notes that, since the B/Yamagata strain has not been detected in circulation since March 2020, the ETF has recommended transitioning from quadrivalent to trivalent vaccines for the 2025/2026 season, excluding the B/Yamagata strain. If necessary to avoid disrupting the vaccination campaign, manufacturers of inactivated vaccines can consider producing a quadrivalent vaccine containing two influenza B virus strains for the 2025/2026 season. In that case a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus in addition to the strains mentioned above is considered appropriate.

Additional information is available at: https://www.ema.europa.eu/en/news/eu-recommendations-2025-2026-seasonal-flu-vaccine-composition

ANVISA Approves Regulation on the Composition of Seasonal Influenza Vaccines to Be Used in Brazil

On 17 April, ANVISA announced the approval of a regulation establishing the composition of seasonal influenza vaccines to be used in Brazil.

ANVISA notes that, in accordance with WHO recommendations, the influenza vaccine composition for the 2025 season is the same for both the Northern and Southern Hemispheres, and the recommended compositions are as follows:

- **For trivalent vaccines:**
  - an A/Victoria/4897/2022 (H1N1) pdm09-like virus;
  - an A/Croatia/10136RV/2023 (H3N2)-like virus; and
  - a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.
- **For tetravalent vaccines**, which contain two types of influenza B virus strains, the following is added:
  - a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

They also indicate that influenza vaccines must be labeled with the following wording:

> "2025 SOUTHERN HEMISPHERE STRAINS" or "2025-2026 NORTHERN HEMISPHERE STRAINS."

Additional information is available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/aprovada-norma-sobre-a-composicao-das-vacinas-influenza-sazonais-a-serem-usadas-no-brasil

Zoonotic Influenza Vaccine

EMA Approves Modification of Marketing Authorization for the Seqirus Zoonotic Influenza Vaccine

On 25 April, the EMA announced that the Committee for Medicinal Products for Human Use (CHMP) recommended a modification to the marketing authorization of the Seqirus H5N8 zoonotic influenza vaccine, expanding its indication to include active immunization of children from 6 months of age.

The Seqirus vaccine had previously been authorized for active immunization against influenza A viruses of the H5 subtype in adults aged 18 and older.

Additional information is available at:
https://www.ema.europa.eu/en/medicines/human/variation/zoonotic-influenza-vaccine-seqirus

ANVISA Streamlines Evaluation Process for Pre-Pandemic Vaccine Candidate

On 12 June, ANVISA announced that it is currently evaluating the inactivated split adjuvanted monovalent type A (H5N8) influenza vaccine candidate developed by the Butantan Institute. This pre-pandemic vaccine is being developed to help prepare Brazil's health system for a potential need to vaccinate against avian influenza.

ANVISA stated that the review of documentation for the vaccine candidate was initiated as a priority, using a rolling submission process with the aim of accelerating the evaluation. This procedure is applied in exceptional situations of high relevance and need, such as in the case of vaccines.

Following the analysis of the documentation submitted, ANVISA identified additional information needed to complete the evaluation and is currently awaiting its submission by the Butantan Institute.

Additional information is available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/vacina-para-gripe-aviaria-anvisa-atualiza-andamento-da-analise

Varicella Vaccine

EMA's Risk Assessment Committee Reviews Risk of Encephalitis Linked to Varicella Vaccines

On 6 June, the EMA reported that the PRAC reviewed the risk of encephalitis associated with two varicella vaccines, VARILRIX and VARIVAX, which are authorized for use in adults and children from 12 months of age, and in certain populations from 9 months.

The PRAC initiated this review following a report from Poland involving a child who developed encephalitis a few days after receiving the VARILRIX vaccine and later died as a result of the illness. As a precautionary measure, the Polish medicines agency suspended distribution of the batch involved.

VARILRIX and VARIVAX vaccines are widely used throughout the European Union, and encephalitis is listed in the product information as an uncommon side effect reported during post-marketing surveillance.

The PRAC will assess all available evidence to better understand the risk of encephalitis and determine whether any regulatory action is necessary. They note that while the EMA investigates the issue, the vaccines can continue to be used in line with the approved product information.

Additional information is available at: https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-2-5-june-2025

Vaccine Safety

Vaccine Safety Surveillance in Chile

On 1 April, Chile's Public Health Institute (ISP) published information regarding vaccine safety surveillance in the country. They stated that the vaccines currently used by the Ministry of Health's National Immunization Program do not contain heavy metals or derivatives thereof.

They note that, in some exceptional cases, traces of metals have been detected in hepatitis B, diphtheria, and tetanus vaccines. This results from thimerosal, which is used to prevent microbial contamination during the manufacturing process. Thimerosal was formerly used as a preservative, and numerous studies have widely demonstrated that the very low doses administered did not cause harm and are safe for the population.

Additional information is available at: https://www.ispch.cl/noticia/seguridad-de-las-vacunas-del-programa-nacional-de-inmunizaciones-de-chile/

Protocol on Estimation of Guillain-Barré Syndrome Background Rates in the General Population of Low- and Middle-Income Countries

On 28 May, the WHO published the protocol for estimating background rates of Guillain-Barré syndrome (GBS) in the general population of low- and middle-income countries. This is a master protocol approved by the WHO Ethics Review Committee (ERC), designed to be used by study sites submitting a protocol to their national ethics committee.

Background rates of possible adverse events are crucial to monitoring vaccine safety as they help separate potential safety signals following vaccination from events that are temporally associated with but not caused by vaccination. The association between GBS and vaccination is of interest in vaccine safety studies because GBS has been identified as a rare adverse event of special interest (AESI) associated with certain vaccine products.

Additional information is available at:
https://iris.who.int/bitstream/handle/10665/381527/9789240108240-eng.pdf?sequence=1

Ordinance Updates Information on Brazil's Interinstitutional Committee for Pharmacovigilance of Vaccines and Other Immunobiologicals

On 11 June, ANVISA reported that the Ministry of Health published Ordinance GM/MS 6,931, dated 4 June 2025, which establishes provisions regarding the Interinstitutional Committee for Pharmacovigilance of Vaccines and Other Immunobiologicals (CIFAVI) in Brazil.

CIFAVI was established in 2008 and evaluates the technical and scientific aspects of the most complex adverse events, including serious, rare, or unexpected events resulting from vaccine use, while respecting the authority of public bodies responsible for pharmacovigilance activities. It is composed of representatives from the Ministry of Health, ANVISA, and the National Institute for Quality Control in Health (INCQS/Fiocruz).

The new ordinance includes ANVISA as co-coordinator of CIFAVI alongside the Ministry of Health. It also assigns new responsibilities to the committee, such as recommending immunization and surveillance actions following causality assessments of ESAVIs, and providing technical support to the State Committees for Pharmacovigilance of Vaccines and Other Immunobiologicals (CEFAVIS) upon request, with the aim of strengthening pharmacovigilance at the state level. Additionally, it guarantees ANVISA's participation in all CIFAVI meetings, including extraordinary emergency sessions, thereby enhancing information exchange and active coordination.

ANVISA notes that by facilitating collaboration between the Ministry of Health and ANVISA, it contributes to strengthening pharmacovigilance of vaccines used in Brazil. Additionally, it fulfills the evaluation requirements set by the WHO for national regulatory authorities regarding the need for coordination mechanisms among stakeholders involved in vaccine safety.

Additional information is available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/portaria-atualiza-informacoes-de-comite-que-acompanha-seguranca-de-vacinas

COVID-19 Vaccine

WHO Prequalifies Two COVID-19 Vaccine

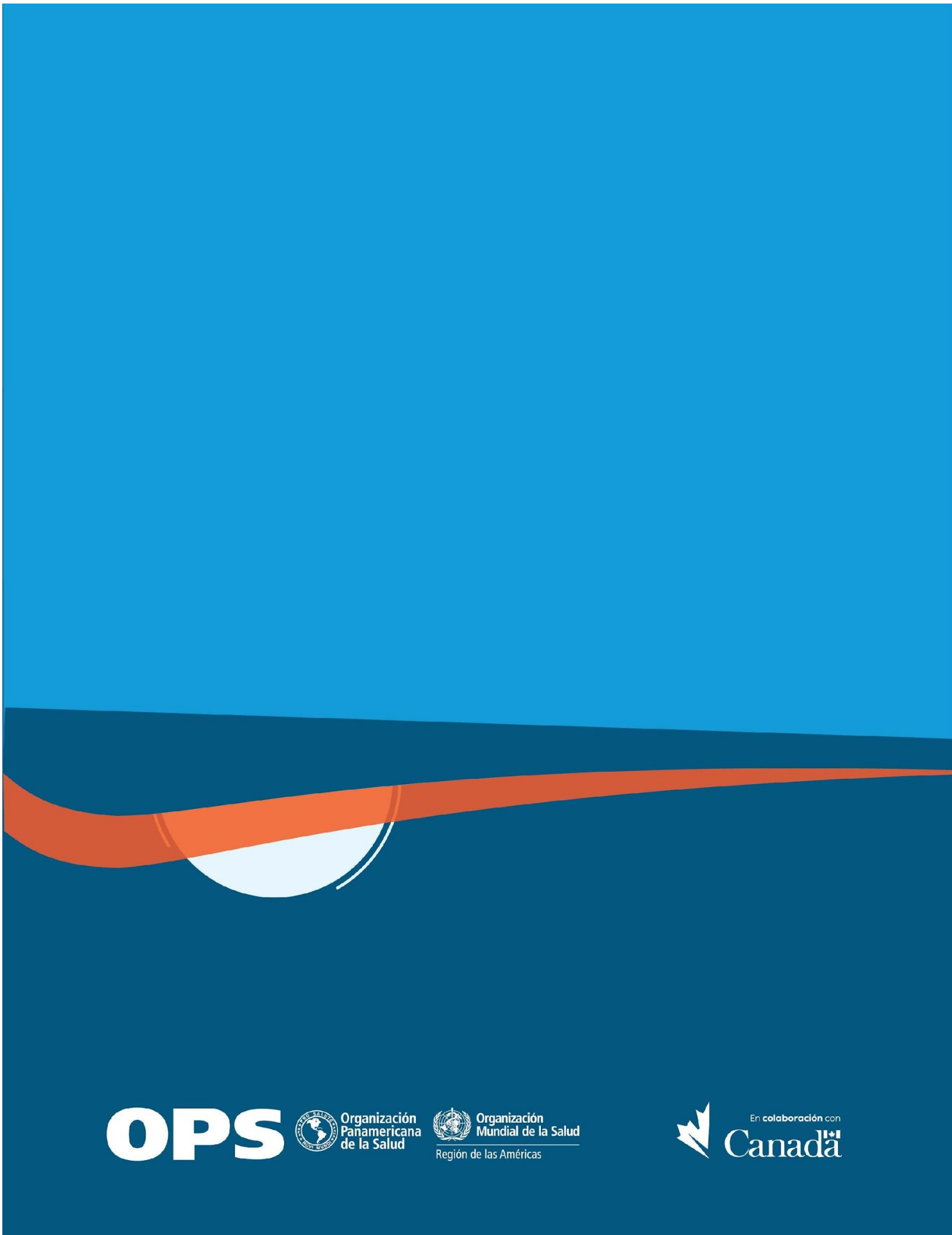
On 13 and 26 June, respectively, the WHO announced the prequalification of the COVID-19 vaccines COVOVAX™ and NUVAXOVID; both vaccines are indicated for people aged 12 years and older. Below are more details about these vaccines.

Vaccine	Manufacturer	Regulatory Authority	Pharmaceutical Form	Presentation/ Storage
COVOVAX™ COVID-19 vaccine (Omicron XBB.1.5) (recombinant, Matrix-M adjuvant)	Serum Institute of India Pvt. Ltd.	Central Drugs Standard Control Organization, India	Injection dispersion	Single-dose vial 2-8 °C, protected from light Shelf life: 9 months
NUVAXOVID COVID-19 vaccine (Omicron JN.1) (recombinant, Matrix-M adjuvant)	NOVAVAX CZ a.s.	European Medicines Agency	Injection dispersion	Single-dose vial 2-8 °C, protected from light Shelf life: 9 months

In 2023, the WHO prequalified the COVID-19 vaccine BIMERVAX, manufactured by Hipra Human Health, S.L.U., and in 2024, the COVID-19 vaccine COMIRNATY, manufactured by BioNTech Manufacturing GmbH.

Additional information is available at: https://extranet.who.int/prequal/vaccines/p/covovaxtm
https://extranet.who.int/prequal/sites/default/files/vwa_vaccine/FVP-P-478_Covovax_1dose_SIIPL_XBB.1.5_PI-2025_0.pdf
https://extranet.who.int/prequal/vaccines/p/nuvaxovid
https://extranet.who.int/prequal/sites/default/files/vwa_vaccine/FVP-P-481_C-19_1dose_NOVAVAX_WHOPAR_V1.pdf

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