

CONSOLIDATED REGIONAL AND GLOBAL INFORMATION ON ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) AGAINST COVID-19 AND OTHER UPDATES

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CANADA

- As of 4 June 2021, 25,387,552 doses of COVID-19 vaccines had been administered: Pfizer-BioNTech (72%), Moderna (18.6%), and AstraZeneca and Covishield (AstraZeneca produced by the Serum Institute of India) (9.4%).
- A total of 6,864 individual reports of one or more adverse events (0.027% of doses administered) were received. Of these, 1,391 were considered serious events (0.005% of doses administered), with anaphylaxis being the most frequently reported.
- Of total reports, there were 2,867 reports of non-serious events and 896 of serious events associated with the Pfizer-BioNTech vaccine. For the Moderna vaccine, there were 1,975 reports of non-serious events and 176 of serious events, while for Covishield/AstraZeneca there were 614 reports of non-serious events and 260 of serious events.
- A total of 19,591 adverse events following immunization (AEFI) were reported, including 6,864 reports of one or more events, of which the majority were for non-serious events, such as injection-site reactions, paresthesia, pruritus, hives, headache, hypoesthesia, and nausea. A total of 72 cases of anaphylaxis were reported (60 for the Pfizer-BioNTech vaccine and 12 for the Moderna vaccine).
- As of 4 June, 53% of vaccine doses had been administered to women and 47% to men. The majority of reported adverse events were in women (81.0% of total doses administered).
- As of 4 June, there were 50 reports of thrombosis with thrombocytopenia syndrome (TTS), of which 46 cases occurred following vaccination with the Covishield/AstraZeneca vaccine, three with the Pfizer-BioNTech vaccine, and one following vaccination with the Moderna vaccine. Symptoms occurred between one and 52 days after vaccination; 18 were in women (ages 44 to 88), 31 were in men (ages 34 to 81), and in one case the sex of the person was not specified.
- A total of 104 reported cases of adverse events resulted in post-vaccination deaths.
 Following a medical review, it was determined that 40 of these deaths were not linked to





administration of the COVID-19 vaccine, while 43 are still under investigation. Six deaths (cases of TTS) were potentially attributable to vaccination, and in 15 cases, the cause of death could not be classified due to insufficient information.

As of 4 June, 35 cases of myocarditis/pericarditis had been reported; 25 of these cases followed vaccination with the Pfizer-BioNTech vaccine, 6 with the Moderna vaccine, 3 with the Covishield/AstraZeneca vaccine, and in one case the vaccine was not identified. Nineteen of these cases occurred in women (ages 20 to 78) and 16 in men (ages 29 to 70). Twenty-two of the reported cases occurred after the first dose, 11 after the second dose, and in two cases there was no indication whether the occurrence followed the first or second dose. Onset of symptoms occurred between 5 hours and 94 days after administration of the vaccine. No clear association between myocarditis/pericarditis and COVID-19 vaccines has yet been established.

Source: https://health-infobase.canada.ca/covid-19/vaccine-safety/

SPAIN

- As of 30 May 2021, 26,227,825 doses of COVID-19 vaccines had been administered in Spain. Comirnaty accounted for 70% of doses administered, Vaxzevria for 19%, Moderna for 9%, and Janssen for 2%.
- As of 30 May, there were 24,491 reports of adverse events, of which the most frequently reported were general disorders (fever and injection-site pain), and symptoms related to the nervous system (headache and dizziness) and the musculoskeletal system (myalgia and arthralgia).
- Of total adverse events reported, 4,659 were considered serious, of which 2,432 were associated with the Comirnaty vaccine, 1,815 with the Vaxzevria vaccine, 374 with the Moderna vaccine, and 20 with the Janssen vaccine, while 18 reports of adverse events did not specify the vaccine.

Source: <u>https://www.aemps.gob.es/informa/boletines-aemps/boletin-fv/2021-boletin-fv/6o-informe-de-farmacovigilancia-sobre-vacunas-covid-19/#acontecimientosadversos</u>



SWITZERLAND

- In Switzerland, as of 18 April 2021, 2.1 million doses of mRNA vaccines had been administered, with approximately 769,000 people fully vaccinated.
- As of 20 April 2021, Swissmedic, in collaboration with Switzerland's regional pharmacovigilance centers, had evaluated 1,485 reports of AEFI with COVID-19 vaccines in the country. The rate of reported adverse events was approximately one per 1,000 doses administered.
- Of these, 706 reported AEFI were associated with Pfizer/BioNTech's Comirnaty vaccine, while 761 were associated with the Moderna vaccine. The majority of reports 948 (63.8%) were classified as non-serious, while 537 (36.2%) were classified as serious.
- The majority of reports involved more than one event (1,485 reports involving 3,851 events), an average of 2.6 events per report. Among the most frequently reported events in cases classified as serious were shortness of breath (39), headaches/migraine (37), reactivation of shingles (34), hypersensitivity (27), anaphylactic reactions (13), and elevated blood pressure (25).
- A total of 61 cases of shingles (herpes zoster) were reported, caused by a reactivation of the varicella-zoster virus (VZV). Risk factors for shingles include immunosuppressive treatments, diabetes mellitus, female gender, psychological stress, and mechanical trauma. The incidence of shingles increases with age, ranging from 3 per 1,000 cases in people aged 40-50, to 10 per 1,000 in people over age 80. In the reported cases, the average age of those affected was 72. Given the frequency of shingles in the age groups with the highest rates of vaccination, from a statistical standpoint a certain number of shingles cases associated with receiving a COVID-19 vaccination are expected over time. The possibility of a causal connection between the vaccinations and the onset of shingles is currently under investigation.
- Of the 64 serious cases that resulted in death, deaths occurred at different intervals of time after administration of the vaccine. The average age of those who died was 82; most were suffering from serious pre-existing conditions, and there was no concrete evidence that vaccination was the cause of death.

Source: <u>https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-</u>19/nebenwirkungen-covid-19-impfungen-update-4.html



In the weekly epidemiological COVID-19 update, issue 43, of 8 June 2021, WHO included an update on emerging evidence of the phenotypic impact of SARS-CoV-2 variants of concern (VOC) on transmissibility, disease severity, risk of reinfection, and impact on diagnosis and vaccination. Table 1 shows an adaptation of the table included in the above-referenced weekly report.

	Alpha	Beta	Gamma	Delta
Transmissibility	Increased transmissibility and secondary attack rate	Increased transmissibility	Increased transmissibility	Increased transmissibili ty and secondary attack rate
Disease severity	Not confirmed, possible increased risk of hospitalization, severity, and mortality	Not confirmed, possible increased risk of hospital mortality	Not confirmed, possible increased risk of hospitalization	Not confirmed, possible increased risk of hospitalizatio n
Risk of reinfection	Neutralizing activity retained, risk of reinfection remains similar	Reported reduction in neutralizing activity; T cell response elicited by the D614G virus remains effective	Reported moderate reduction in neutralizing activity	Reported reduction in neutralizing activity
Impact on diagnostics	Limited impact: S- gene target failure (SGTF); no impact on the overall result from multi-target RT- PCR; no impact was observed on Ag RDTs	No impact has been observed on RT- PCR or Ag RDTs	None reported to date	None reported to date
Impacts on vaccine efficacy/effectivene ss	Protection against disease is retained • Severe illness: No/minimal loss: Pfizer BioNTech- Comirnaty	Reduced protection against the disease; limited evidence • Severe disease: No/minimal loss:	Protection likely against the disease; very limited evidence, on	Protection likely against the disease; very limited evidence on

Table 1: Summary of the phenotypic impact* of WHO variants of concern (VOC)





	 Symptomatic 	Pfizer BioNTech-	only one	only two
	disease: No/minimal	Comirnaty	vaccine	vaccines
	loss: AstraZeneca-	 Mild-moderate 	 Symptomatic 	•
	Vaxzevria, Novavax-	disease: No/minimal	disease:	Symptomatic
	Covavax, Pfizer	loss: Janssen-Ad26.	No/minimal	disease:
	BioNTech-Comirnaty	COV 2.5.	loss: Sinovac-	No/minimal
	 Infection: 	 Moderate loss: 	CoronaVac	loss: Pfizer
	No/minimal loss:	Novavax-Covavax.	 Infection: 	BioNTech-
	Pfizer BioNTech-	Inconclusive/substan	No/minimal	Comirnaty,
	Comirnaty	tial loss, limited	loss: Sinovac-	AstraZeneca
	 Asymptomatic 	sample size:	CoronaVac	- Vaxzevria
	infection: No/minimal	AstraZeneca-		• Minimal/
	loss: Pfizer	Vaxzevria		modest loss:
	BioNTech-Comirnaty.	 Infection: Moderate 		single dose
	 Inconclusive/modera 	loss: Pfizer		of Pfizer
	te-substantial loss,	BioNTech-Comirnaty		BioNTech-
	limited sample size:	 Asymptomatic 		Comirnaty,
	AstraZeneca-	infection: no		AstraZeneca
	Vaxzevria	evidence		-Vaxzevria
Impact on	No/minimal loss:	Minimal/moderate	• No/minimal	• Modest/
neutralizing	Bharat-Covaxin,	loss: Beijing CNBG-	loss:	moderate
antibodies	Gamaleya-Sputnik V,	BBIBP-CorV,	AstraZeneca-	loss: Pfizer
following	Moderna-mRNA,	Sinovac-CoronaVac,	Vaxzevria,	BioNiech
vaccination	Novavax-Covavax,	Annui ZL-	Sinovac-	Comirnaty,
	Pfizer-Bioin Lech-	Recombinant	Coronavac	Bharat-
	Comirnaty, Beijing	Minimal to	•	Covaxin
	CNBG-BBIBP-CorV,	substantial loss:	Minimai/modera	(NOTE:
	Sinovac-Coronavac	Moderna-mRNA-	te loss:	sublineage
	• Iviinimai/moderate	1273, Pilzer Dia NTaah, Camimatu	Moderna-	OT B.1.017
	Ioss: Astrazeneca-	Bioin Tech-Comimaty	MRNA-1273, Dfizor	not specilied
	vaxzevna		Plizer BioNTooh	III Dharat-
		Substantiar loss.	Comirpoty	covaxin etudu)
		Aslidzeneud- Vavzovria	Commandy	• Substantial
		Gamaleva- Sputnik		loss single
		V Janssen-		dose of
		Ad26 COV 2 5		AstraZeneca
		Novavax-Covavax		-Vaxzevria
		2.5		

* Generalized findings compared to previous/co-circulating variants. Based on emerging evidence, including nonpeer-reviewed preprinted articles and reports, all subject to investigation and ongoing review.

Source: <u>https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---</u> 8-june-2021

> World Health Organization

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Results of clinical studies of the Novavax vaccine show that it is safe and prevents COVID-19

The results of a Phase 3 clinical trial (PREVENT-19) enrolling 29,960 adult volunteers in the United States and Mexico show that Novavax's investigational vaccine known as NVX-CoV2373 demonstrated 90.4% efficacy in preventing symptomatic COVID-19 disease. It also demonstrated 100% protection against moderate and severe disease. In people at high risk of developing complications from COVID-19 (people 65 years of age or older, and people under age 65 with certain comorbidities or with likely regular exposure to COVID-19), the vaccine showed 91.0% efficacy in preventing symptomatic COVID-19 disease.

Safety data indicate that the investigational vaccine was generally well tolerated. Mild to moderate pain and tenderness at the injection site were the most common local symptoms among participants. The most common systemic symptoms were fatigue, headache, and muscle pain, and lasted an average of less than two days.

The PREVENT-19 trial began in late December 2020, and participants were randomly assigned to receive two injections, 21 days apart, of the investigational vaccine or a placebo.

NVX-CoV2373 is a subunit vaccine made from a stabilized form of the coronavirus spike protein, using recombinant protein nanoparticle technology. The vaccine also contains a patented adjuvant, MatrixM[™]. NVX-CoV2373 comes in liquid form and can be stored and distributed at temperatures between 2°C and 8°C (36°F and 46°F).

In May 2021, the PREVENT-19 trial was expanded to evaluate the safety, efficacy, and immunogenicity of NVX-CoV2373 in adolescents ages 12 to 17; the recruitment of 2,248 participants has recently been completed.

Source: <u>https://www.nih.gov/news-events/news-releases/us-clinical-trial-results-show-novavax-vaccine-safe-prevents-covid-19</u>

Progress in clinical trials of COVID-19 vaccines in Cuba

As of 8 June, Cuba reported having administered 3,016,266 doses of Cuban candidate vaccines (Soberana 1, Soberana 2, Soberana Plus, and Abdala). A total of 1,833,775 people have received at least one dose of one of these vaccines; 969,119 people have already received a second dose, and 213,372 people have received a third dose. This number includes, beside the



Phase III clinical trials, a health intervention involving at-risk groups and territories, authorized by the Minister of Public Health based on the epidemiological situation and availability of vaccine candidates which have provided evidence of safety and immunogenicity in Phases I and II clinical trials.

A sequential, open, adaptive, and multicenter Phase I/II clinical trial, recently approved by the Center for State Control of Medicines and Medical Equipment and Devices (CECMED), has been designed to evaluate the safety, reactogenicity, and immunogenicity of SARS-CoV-2 vaccine candidates in population under 18 years old The proposed regimen for Cuban children and adolescents is heterologous, with two doses (0-28 days apart) of the vaccine candidate FINLAY-FR-2 (Soberana 02), and a third dose with the vaccine candidate FINLAY-FR-1 (Soberana Plus) on day 56. The trial will include 350 healthy subjects ages 3 to 18. As of the end of the first day of June, children and adolescents diagnosed with COVID-19 accounted for 12.1% of all individuals in the country infected with the disease.

Source: Cuban scientists offer details of the first clinical trial in the pediatric population with vaccine candidate Sovereign 02. Cuba debates. 11 June 2021

ANVISA authorizes exceptional import of Sputnik V to Brazilian states

Brazil's National Health Surveillance Agency ANVISA authorized the importation of 928,000 doses of the Sputnik V vaccine to 13 of the country's 27 Federative Units. The authorization was issued with the following conditions:

- The vaccine will be used in a study, approved by ANVISA and conducted in accordance with best clinical practices, to assess the effectiveness of the vaccine in healthy adults.
- All vaccine lots imported will be evaluated by the National Institute for Quality Control in Health (INCQS) prior to their use.
- People will be informed that the quality, efficacy, and safety of the vaccine have not yet been determined by ANVISA.
- ANVISA may, at any time, suspend the import, distribution, and use of imported doses of this vaccine.

Source: Brazil gives Russian COVID-19 vaccine a chance, approving the import of limited doses. Science. 9 June 2021.





Updated SAGE/WHO recommendations for use of the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines

On 15 June 2021, WHO's Strategic Advisory Group of Experts on Immunization (SAGE) reported that the interim recommendations for use of COVID-19 vaccines from Pfizer-BioNTech, Moderna, and Janssen had been updated, based on the latest relevant evidence. The main findings were as follows:

- Pfizer-BioNTech:
 - Indication: Indication for use was extended to individuals ages 12 and older. WHO
 recommends that countries consider vaccinating children ages 12 to 15 only when there
 is high vaccination coverage in high-priority groups.
 - Considerations for postponing the second dose in settings with a limited supply of vaccines: Post-vaccination studies in countries that have implemented a longer interval between doses, along with additional immunological data, suggest that delaying the second dose of vaccine for up to 12 weeks in countries with a high incidence of COVID-19 combined with severe vaccine shortages could be considered in order to achieve higher first-dose coverage in high-priority populations.
 - Interchangeability of vaccines: Preliminary results from heterologous vaccine administration studies, in which the Pfizer-BioNTech vaccine was administered as a second dose, following an initial dose of the AstraZeneca vaccine, showed slightly increased, but acceptable levels of reactogenicity, with similar or higher immunogenicity, thus supporting use of a heterologous vaccine regimen.
 - Precautions: A possible causal association of the vaccine with very rare cases of myocarditis in young men (ages 16 to 24) is being investigated.
 - Pregnancy: Completed studies of reproductive toxicity and development in animals showed no harmful effects of the vaccine on pregnancy. Data from small studies have shown that mRNA COVID-19 vaccines are immunogenic in pregnant women, and that vaccine-elicited antibodies are transported into umbilical-cord blood and breast milk, suggesting possible neonatal as well as maternal protection. As data become available from additional studies currently being conducted, these recommendations will be updated.





- SARS-CoV-2 variants: Preliminary results indicate that after 2 doses of the Pfizer-BioNTech vaccine, effectiveness against symptomatic SARS-CoV-2 infection with the Beta variant (B.1,351) is 75.0% (95% CI 70.5%-78.9%); for the Delta variant (B.1,617.2), effectiveness was estimated to be 88% (95% CI 78.2%-93.2%), with 93% effectiveness (95% CI 90.4%-95.5%) against the Alpha variant (B.1.1.7).
- Storage temperature: The length of time that the undiluted vaccine can be kept between 2°C and 8°C was extended from the initially authorized five days to up to one month (31 days).
- Safety surveillance and monitoring: The Group of Experts recommends monitoring the following serious adverse events: myocarditis, thromboembolic events, thrombosis with thrombocytopenia syndrome (TTS), anaphylaxis and other severe allergic reactions, Bell's palsy, transverse myelitis, cases of multisystem inflammatory syndrome following vaccination, and cases of COVID-19 following vaccination that result in hospitalization or death.

Updated recommendations for the Pfizer-BioNTech vaccine are available at:

https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE recommendation-BNT162b2-2021.1

Moderna:

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- Considerations for postponing the second dose in settings with a limited supply of vaccines: Post-vaccination studies in countries that have implemented a longer interval between doses, along with additional immunological data, suggest that delaying the second dose of vaccine for up to 12 weeks in countries with a high incidence of COVID-12 combined with severe vaccine shortages could be considered in order to achieve higher first-dose coverage in high-priority populations.
- Precautions: A possible causal association of the vaccine with very rare cases of myocarditis in young men (ages 16 to 24) is being investigated.
- Pregnant and nursing women: The text was updated and harmonized with Pfizer-BioNTech's recommendations for the mRNA vaccine.
- SARS-CoV-2 variants: Preliminary results indicate some reduction in the neutralizing activity conferred by the vaccine against the Beta variant of concern (B.1.351), and a less marked reduction for the variants of interest -- Gamma (P1), Alpha (B.1.1.7), and

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Epsilon (B.1.429) (16). Effectiveness against the Delta variant (B.1.617.2) is still unknown.

 Safety surveillance and monitoring: The Group of Experts recommends monitoring the following serious adverse events: myocarditis, thromboembolic events, thrombosis with thrombocytopenia syndrome (TTS), anaphylaxis and other severe allergic reactions, Bell's palsy, transverse myelitis, cases of multisystem inflammatory syndrome following vaccination, and cases of COVID-19 following vaccination that result in hospitalization or death.

Updated SAGE recommendations for the Moderna vaccine are available at: <u>https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-</u> <u>1273-vaccine-against-covid-19</u>

- Janssen:
 - General characteristics of the vaccine: Results on the efficacy of the vaccine were incorporated in figures for hospitalizations after 28 days following administration of the vaccine. There are reports of deaths in the placebo group, with no reported deaths in the vaccinated group. There are also reports that vaccine efficacy is maintained in settings where the P2 and B1.351 variants are responsible for the majority of cases.
 - Precautions: Information related to thrombosis with thrombocytopenia syndrome (TTS) and its possible association with the vaccine has been included. Recommendations are given on the importance of early identification of TTS, in order to initiate appropriate treatments. It should still be emphasized that the benefit of vaccination in protecting against COVID-19 outweighs the risks.
 - Pregnant women: Women during pregnancy may have a higher incidence of thrombosis, thrombocytopenia, and bleeding, and although it is not known whether there is an increased risk of thrombosis with thrombocytopenia syndrome (TTS), WHO recommends the use of this vaccine in pregnant women only if the benefit of vaccination outweighs the potential risks.
 - Safety surveillance and monitoring: The Group of Experts recommends monitoring the following serious adverse events: myocarditis, thrombosis with thrombocytopenia syndrome (TTS), anaphylaxis and other severe allergic reactions; cases of multisystem



inflammatory syndrome following vaccination; cases of COVID-19 following vaccination that result in hospitalization or death; AEFI baseline rate (including thromboembolic events, cerebral venous sinus thrombosis, and TTS); maternal and neonatal outcomes; mortality in groups prioritized for vaccination; and incidence of TTS by WHO region, age, and sex.

Updated recommendations for the Janssen vaccine are available at: <u>https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-2021.1</u>

The European Medicines Agency (EMA) includes capillary leak syndrome as a contraindication for the Vaxzevria vaccine

The EMA's safety committee, PRAC (the Pharmacovigilance Risk Assessment Committee), conducted an assessment of six cases of capillary leak syndrome in people who had received the Vaxzevria COVID-19 vaccine, formerly the AstraZeneca vaccine, and concluded that people in whom capillary leak syndrome had previously occurred should not be vaccinated with the Vaxzevria vaccine. The committee indicated that the product information will be updated to include a contraindication in people with a history of capillary leak syndrome, and this will also be included as a side effect of this vaccine; the frequency of this event is unknown.

As of 27 May 2021, more than 78 million doses of the Vaxzevria vaccine had been administered in the European Union and the United Kingdom. Most cases of capillary leak syndrome occurred in women, within four days after vaccination. Of the six cases evaluated, three occurred in individuals with a history of capillary leak syndrome, one of whom subsequently died.

Capillary leak syndrome is a serious, very rare condition that can be fatal if untreated. It causes fluid leakage from the capillaries, resulting in edema affecting primarily the extremities, causing hypotension, hemoconcentration and hypoalbuminemia. People who have been vaccinated with the Vaxzevria vaccine should seek immediate medical care if they experience swelling of the arms and legs or sudden weight gain in the days following vaccination. These symptoms are often associated with feeling faint, due to low blood pressure.

Source: <u>https://www.ema.europa.eu/en/news/vaxzevria-ema-advises-against-use-people-history-</u> capillary-leak-syndrome





FDA authorizes an extension of the shelf-life of Pfizer-BioNTech COVID-19 vaccine under refrigeration

The U.S. Food and Drug Administration (FDA) reported that, after a review of new stability data submitted by Janssen, it was authorizing an extension of the shelf life of Janssen's COVID-19 vaccine from 3 months to 4.5 months, when stored at between 2°C and 8°C.

Source: https://www.fda.gov/media/150064/download

Chile's Institute of Public Health authorizes an update to the refrigerator storage period

for the Pfizer-BioNTech vaccine

The Institute of Public Health of Chile (ISP) reported on 7 June 2021 that it had evaluated the updated stability data for the Pfizer-BioNTech vaccine submitted by the company and was authorizing an extension of the shelf life of the undiluted thawed product, under storage conditions of between 2°C and 8°C for 30 days.

Source: <u>https://www.ispch.cl/noticia/isp-evalua-conforme-nuevos-antecedentes-sobre-la-condicion-de-almacenamiento-y-traslado-de-la-vacuna-pfizer-biontech/</u>

Chile's Institute of Public Health Authorizes Emergency Use of Janssen's COVID-19 Vaccine through the COVAX Mechanism

Chile's Institute of Public Health (ISP) reported on 10 June 2021 that it was authorizing emergency use of Janssen's COVID-19 vaccine, which is included in the emergency use listing (EUL) of the World Health Organization (WHO) and indicated that Chile will receive it through the COVAX Facility. This vaccine requires only a single dose and is licensed for use in people 18 years of age and older.

Source: <u>https://www.ispch.cl/noticia/isp-valida-uso-de-emergencia-de-la-vacuna-janssen-de-johnson-a-traves-de-mecanismo-covax/</u>

Strategies and plans for the implementation of COVID-19 vaccination in the European Union and the European Economic Area

Overview

 As of 11 June 2021, 333,678,903 COVID-19 vaccine doses had been distributed to countries of the European Union/European Economic Area (EU/EEA). The Pfizer-BioNTech's Comirnaty vaccine accounts for 67.3% of all doses distributed to EU/EEA countries through the European Commission's vaccine strategy, followed by AstraZeneca's Vaxzevria vaccine, accounting for 19.5%, the Moderna COVID-19 vaccine, accounting for 9.6%, and the Janssen COVID-19 vaccine for 3.3%.

 A total of 284,124,689 doses of vaccines have been administered in the EU/EEA, representing 85% of the doses distributed in the EU/EEA since rollout began, according to data available from 29 countries.

Vaccination strategies and policies during implementation

- Sixteen countries have extended the timing between vaccine doses in order to provide the first dose to as many people in the priority groups as possible. The timing between the first and second dose varies by country and vaccine product.
- For individuals previously infected with SARS-CoV-2, eleven countries currently recommend only one dose (for vaccines with a two-dose schedule).
- Seventeen countries recommend specific COVID-19 vaccines for specific population groups.
- Most countries have adapted their vaccination guidelines, following the report of rare cases of thrombosis with thrombocytopenia syndrome (TTS) after vaccination with the Vaxzevria and Janssen COVID-19 vaccines. These adaptations are based mainly on agespecific recommendations for administration of the Vaxzevria and Janssen vaccines.
- A minority of countries (n=4) reported that they have adapted their COVID-19 vaccination strategy due to the circulation of new variants of concern. Adjustments included providing more doses of vaccines to areas with a high incidence of variants of concern, or redefining priority groups based on the epidemiological situation.
- Five countries are planning to expand vaccination to all adolescents, and 14 countries are currently discussing vaccinating children under the age of 12. Decisions will be made once the European Medicines Agency authorizes any COVID-19 vaccine for use in that age group.

Source: <u>https://www.ecdc.europa.eu/sites/default/files/documents/Overview-of-the-</u> implementation-of-COVID-19-vaccination-strategies-and-deployment-plans-14-June-2021.pdf

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