



**World Health
Organization**

COVID-19 vaccination: WHO perspective

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COVID-19 vaccinations and patients with cancer: Vaccinate. Monitor. Educate. - An ESMO Call to Action

Friday January 8, 2021

Objectives of this presentation (10mn)

1. Provide an update **on the state of Covid-19 vaccination**
2. Present the **roadmap towards prioritization of target populations**
3. **Share WHO interim recommendation for the use of mRNA BNT162b2 (Pfizer-BioNTech)**
4. Provide an **update on Regulatory Review of COVID-19 Vaccines/Products**
5. Zoom on **COVAX**

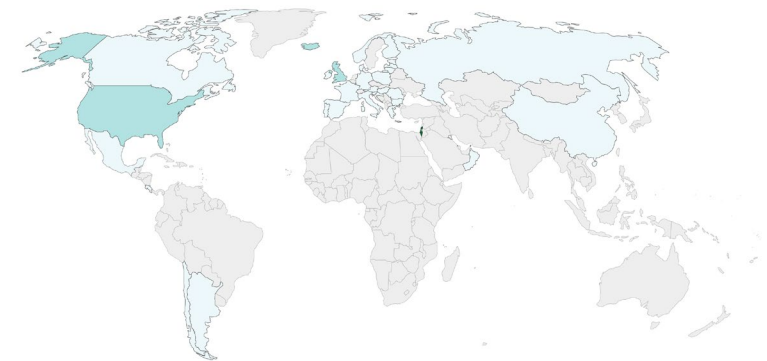
1. State of vaccination (as of January 6)

State of Vaccines: key numbers (data as of 6 January 2021)

- The 1st vaccination programme started exactly **1 month ago**¹
- So far, **16 million of vaccine doses** have been administered
 - Top 3 countries in terms of # of doses administered are USA, China and Israel
 - At least 6 types of vaccines have been administered²
- Campaigns **have started in 43 countries**
 - 36 HICs
 - 7 UMICs
 - 0 LICs/LMICs

COVID-19 vaccination doses administered per 100 people, Jan 4, 2021
Total number of vaccination doses administered per 100 people in the total population. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).

Our World
in Data













Source: Official data collated by Our World in Data. Dates refer to when the data was reported. OurWorldInData.org/covid-vaccinations • CC BY

1. Dec. 8, 2020 in the UK (Pfizer); Dec. 5, 2020 in Russia (Gamaleya)
2. Pfizer, Moderna, AZ, Gamaleya, Sinovac, Sinopharm

State of Vaccines: 16 million vaccine doses have been administered (data as of 6 January 2021)

Total number of vaccination doses administered¹
Million of doses (% of doses administered worldwide)

			% of pop. vaccinated	Vaccines²	Last updated
 USA	5.5 (34%)	1.7%	Pfizer, Moderna	Jan. 6	
 China	4.5 (28%)	0.3%	Sinopharm, Sinovac	Dec. 31	
 Israel	1.5 (9%)	16.5%	Pfizer	Jan. 6	
 UK	1.3 (8%)	2.0%	Pfizer, AZ	Jan. 5	
 UAE	0.8 (5%)	7.7%	Pfizer, Sinopharm	Jan. 5	
 Russia	0.8 (5%)	0.6%	Gamaleya	Jan. 2	
 Germany	0.4 (2%)	0.4%	Pfizer	Jan. 6	
 Italy	0.3 (2%)	0.4%	Pfizer	Jan. 6	
 Canada	0.2 (1%)	0.5%	Pfizer, Moderna	Jan. 6	
 Spain	0.1 (1%)	0.3%	Pfizer	Jan. 6	
Other countries	0.7 (4%)	-	-	Jan. 6	
Total	16.0	<0.1%	-	Jan. 6	


1. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).

2. Non exhaustive

State of Vaccines: campaigns have started in 42 countries incl. 36 HICs

(data as of 6 January 2021)

Legend

 Ongoing vaccination campaign

Country classification by income level ¹	# of countries per income group	# of countries where vaccination has started	% of countries where vaccination has started	List of countries where vaccination has started
HIC	83	36	43%	Austria, Bahrain, Belgium, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kuwait, Latvia, Lithuania, Luxembourg, Malta, Norway, Oman, Poland, Portugal, Romania, Saudi Arabia, Slovakia, Slovenia, Spain, South Africa, UAE, UK, US
UMIC	56	7	11%	Argentina, Bulgaria, China, Costa Rica, Mexico, Russia
LMIC	50	0	0%	-
LIC	29	0	0%	-
Total	198	42	21%	-

1. World Bank classification (2021)

Source: World Bank; Our World in data

2. Prioritization of target populations

Roadmap towards prioritization of target populations

To support country planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability in different epidemiologic settings

Key assumptions:

- Vaccines are licensed and meet all minimum criteria of WHO TPP;
- Vaccines have at least minimal level efficacy in older age groups; idem for other subpopulations;
- NPI continue to be used;
- Vaccine effect on transmission less relevant for early scenarios, but information becomes available at some point;
- No account has been taken of seroprevalence and the possible degree of population protection already established.

	Community transmission	Cluster of cases/ sporadic transmission	No cases, risk of importation
Very limited supply (1-10%)			
Limited supply (11-20%)			
Moderate supply (21-50%)			

Contextualized and targeted public health strategies

Roadmap towards prioritization of target populations: example for community transmission

Community Transmission

Strategy: Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions.

Stage I (1-10%)	Stage II (11-20%)	Stage III (21-50%)
<p>Stage Ia (initial launch)</p> <ul style="list-style-type: none">- Health workers at <i>high to very high risk</i> of acquiring and transmitting infection <p>Stage Ib</p> <ul style="list-style-type: none">- Older adults defined by age-based risk specific to country/region	<ul style="list-style-type: none">- Older adults not covered in Stage I- Individuals with comorbidities or health states determined to be at <i>significantly higher risk</i> of severe disease or death- Sociodemographic groups at <i>significantly higher risk</i> of severe disease or death- Health workers engaged in immunization delivery- High priority teachers and school staff	<ul style="list-style-type: none">- Remaining teachers and school staff- Other essential workers outside health and education sectors- Pregnant Women- Health workers at <i>low to moderate risk</i> of acquiring and transmitting infection- Personnel needed for vaccine production and other high-risk lab staff- Social/employment groups at <i>elevated risk</i> of acquiring and transmitting infection because they are unable to effectively physically distance

3. WHO interim recommendation for the use of mRNA BNT162b2 (Pfizer-BioNTech)

Announced on Jan. 5th

Publication of interim recommendations Jan 8th

https://apps.who.int/iris/bitstream/handle/10665/338484/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1-eng.pdf?sequence=1&isAllowed=y

WHO interim recommendation for the use of mRNA BNT162b2 (Pfizer-BioNTech) (1/2)

- BNT162b2 has been shown to have an **efficacy** of 95% against symptomatic SARS-CoV-2 infection.
- No data are available related to **impact on transmission** or viral shedding.
- Vaccination is recommended for persons aged 16 years and above.
- The **recommended schedule** is two doses given intramuscularly with an interval of 21–28 days between the doses.
- The need for **flexibility** in the schedule was acknowledged and current data support an extension up to 42 days.
- The same product should be used for both doses. There are no studies on **interchangeability** with other vaccines against COVID-19 .

WHO interim recommendation for the use of mRNA BNT162b2 (Pfizer-BioNTech) (2/2): Vaccination of specific populations

- BNT162b2 is not a live vaccine, the mRNA does not enter the nucleus and is rapidly degraded. Animal studies show no toxicity to the fetus, but no data on safety in pregnant women exist.
- SAGE recommends not to use BNT162b2 in **pregnancy** until more data are available, except in circumstances where the benefit of vaccinating a pregnant woman outweighs the risks, such as in health workers at high risk of exposure or women with significant comorbidities.
- Vaccination can be offered to **breastfeeding women** if part of risk group, and WHO does not recommend discontinuation of breastfeeding after vaccination.
- Vaccination can be offered to **people living with HIV** in accordance to the prioritization roadmap

4. Regulatory Review of COVID-19 Vaccines/Products

Priority: expediting regulatory review of key products (data as of Jan. 7)

Stringent Regulatory Authority & WHO approvals

- Pfizer multiple SRAs & WHO (30 Dec)
- Moderna US, CAN; EMA (week of 4 Jan); WHO (TBD)
- AZ/Oxford UK; (EMA, FDA, WHO decision Feb/Mar)

National Regulatory Authority (NRA) approvals

- SII/AZ India (WHO decision Jan/Feb)
- Bharat Biotech India ('clinical trial use')
- Sputnik Russia, Argentina; (WHO in discussion)
- Sinopharm China, UAE, Bahrain; (WHO inspection Jan/Feb)
- Sinovac TBD; (WHO site inspection Jan/Feb)



WHO PQ/EUL Updates for COVID-19 Vaccines

PQ/EUL update on COVID-19 vaccines

Status of applications/assessments

https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_Dec2020.pdf

List of SRAs from which approval will be acceptable, under exceptional circumstances, for product eligibility under the COVAX Facility

https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

EUL Pfizer report

<https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-mrna-vaccine-nucleoside-modified-comirnaty%C2%AE>

PQ/EUL update on Immunization Equipment

- Two brands of 0.3 ml AD syringes were PQed 31 December 2020
- ultra-low shipment supplement to WHO shipping guidelines to be published in Q1 2021
- WHO specifications for ULT freezers and associated power requirements, end January 2021

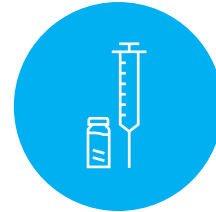
4. Zoom on COVAX

Context - Objectives of COVAX

To end the acute phase of the pandemic by end 2021



To deliver 2 billion doses by end 2021



To guarantee fair and equitable access to COVID19 vaccines for all participants



To support the largest actively managed portfolio of vaccine candidates globally

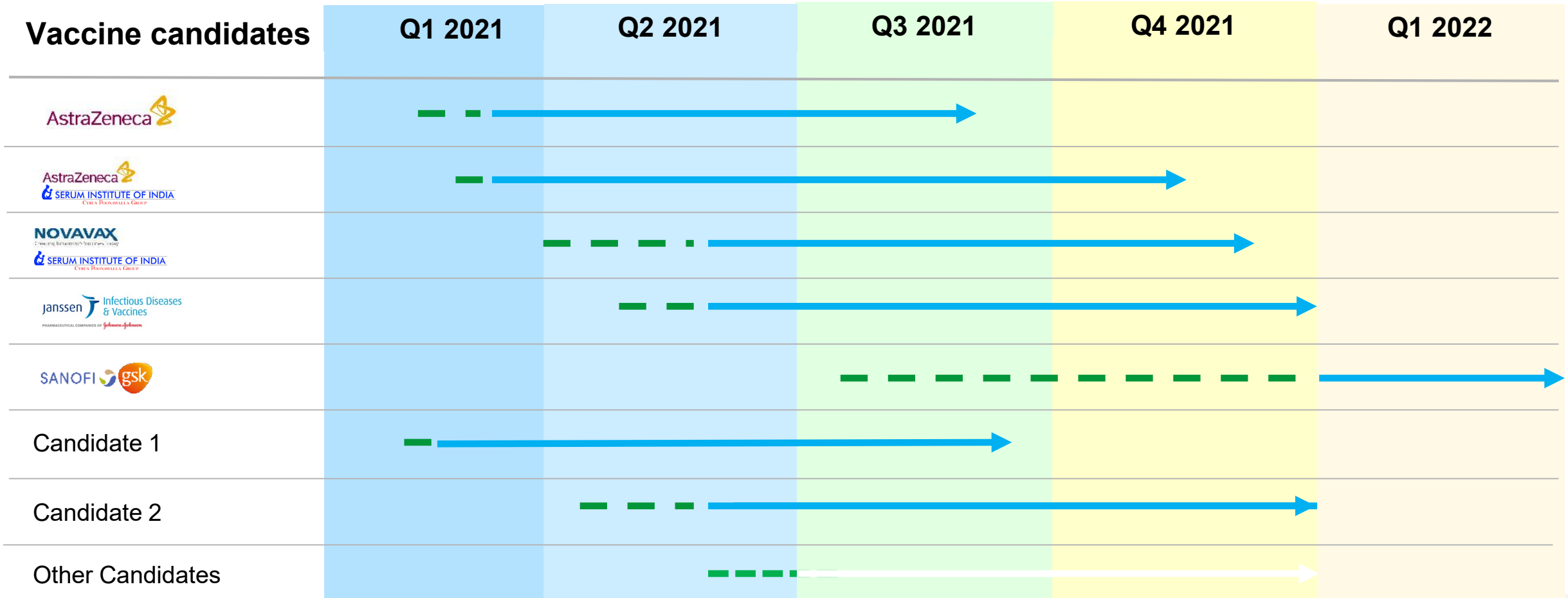


To offer a compelling return on investment by delivering COVID19 vaccines as quickly as possible



COVAX Facility Portfolio – Expected regulatory & supply timelines

- - - - - Expected regulatory & WHO PQ timeframe
—————> Expected supply timeframe



Many Thanks!

<https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials>

<https://www.who.int/teams/blueprint/covid-19>

<https://www.who.int/teams/regulation-prequalification/eul/covid-19>