

Internal Guidance for IPPF Member Associations MAs Guidance to prepare and access Covid-19 Vaccines

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Background Information¹:

As of January 25 2021, a total of nine vaccine candidates have received authorization (emergency use or regulatory approval) for use in countries across the world. Of these nine, three of the below candidates are the most widely available and for which data on their safety and efficacy are available in the public domain. In addition, it is expected that the below three vaccines (and one additional candidate from India) are the ones likely to be available in volumes across multiple countries to meet the demand. A brief note on each of the three vaccines with external links to additional information and data are provided below.

Pfizer BioNTech vaccine: Also known as “Comirnaty”, a mRNA vaccine developed by Pfizer and BioNTech. The vaccine is given as an intramuscular injection in two doses 21 days apart (in trials, national protocols may vary). Comirnaty generates an immune response against SARS-CoV-2, the virus that causes COVID-19, by encoding a mutated form of the full spike protein of the virus.

This vaccine has also received a WHO emergency use validation², enabling Unicef and PAHO to procure the vaccine and allows for countries that don’t have a regulatory body to speed up approvals based on this emergency use validation. Additional information on the relevance of the WHO Emergency use listing is given under “Related info & news” below. Although 50 million doses were expected to be delivered in 2020, Pfizer has run into challenges and has delayed supplies to many countries, most notably the EU. This is an evolving situation and we will like have updates in the late January/early February 2021.

This was the first approved C-19 vaccine in the world. List of countries where approved (as of Jan 21 2021) are United Kingdom, Bahrain, Canada, Mexico, US, Singapore, Costa Rica, Ecuador, Jordan, Panama, Chile, Oman, Saudi Arabia, Argentina, Switzerland, Kuwait, EU, Philippines, Pakistan, Colombia, Iraq, Israel, Qatar, Singapore, United Arab Emirates, Faroe Islands, Greenland, Iceland, Malaysia, Norway, Serbia.

Related info & news:

- Press release from Pfizer: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine>
- Safety and efficacy data published in NEJM (interim analysis): <https://www.nejm.org/doi/full/10.1056/NEJMoa2034577>
- WHO Interim Guidance on Emergency Use Listing of the Pfizer- BioNTech vaccine against Covid-19: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1

¹ Source of information: <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker>

² Moderna and COVID-19 Vaccine AstraZeneca vaccines are likely to seek WHO Emergency Use Listing in the coming months subject to these manufacturers working with WHO to seek this Emergency Use Validation.

Moderna vaccine: This is also a mRNA based vaccine that generates an immune response by containing a code for the spike protein of the SARS-Co-V-2. Developed by Moderna, BARDA, NIAID (USA), this vaccine is given as two doses 28 days apart as an injection. Similar to the Pfizer-BioNTech vaccine, it is given as two doses four weeks apart as an intramuscular injection. However, it is different from the above in that it does not require an ultracold chain and can be stored at 2–8 °C (shorter expiry). Although a large number of doses have been ordered by many countries (over a billion doses in total) it is unclear as to the timelines for delivery for the different countries given that the vaccine is being manufactured only at two sites currently (One in USA and another in Switzerland).

Related info & news:

- Statement from NIH and BARDA on the Emergency use authorization by FDA: <https://www.nih.gov/news-events/news-releases/statement-nih-barda-fda-emergency-use-authorization-moderna-covid-19-vaccine>
- Safety and efficacy of the Moderna vaccine (interim analysis) published in NEJM: DOI: 10.1056/NEJMoa2035389 (<https://www.nejm.org/doi/full/10.1056/NEJMoa2035389>)

Covid 19 vaccine from Astrazeneca: This is a vaccine that contains a common cold virus that is made to carry the code for the spike protein of the SARS-Co-V-2 virus causing COVID-19. The vaccine is most commonly offered in national schedules as two doses given 4 -12 weeks apart as an injection. Of note, this vaccine safety and efficacy was established through a pooled analysis of data from four trials conducted in the UK, Brazil and South Africa. There is another smaller trial of the vaccine that is currently on-going aimed at providing data on safety and efficacy for HIV positive individuals. This vaccine is being manufactured at a number of sites across the world, with the Serum Institute of India being a key player aimed at producing close to 1 billion doses in total with 400 million doses of this being made available before end of 2021. It is significant to note that this vaccine will likely be shipped to South Africa by April 2021 and will likely be the first Covid-19 vaccine to be made available in Africa.

As of January 21 2021, this vaccine has received authorization/ approval for us in UK, Argentina, El Salvador, Dominican Republic, India, Bangladesh, Mexico, Nepal, Pakistan, Brazil, Saudi Arabia, Iraq, Hungary, Thailand.

Related info & news:

- Safety and efficacy of the Oxford Astrazenaca vaccine published in The Lancet: DOI: [https://doi.org/10.1016/S0140-6736\(20\)32661-1](https://doi.org/10.1016/S0140-6736(20)32661-1)

Other vaccines are developed in China and Russia but are more limited in their global availability. Also to note that most of the vaccines have been tested among individuals aged 18 and 65 predominantly with some trials including persons over 65years. However, data on safety and efficacy for other age groups (<18 years or > 85 years) are limited for the three widely available vaccines. Moderna is currently undertaking a trial of the vaccine among 12 -18 year olds and results are awaited. Similarly, most of the trials did not include pregnant women and hence trial data is limited for this population group as well.

National vaccine roll-out structures:

Within large immunisation programmes there are normally stages to roll out. Prioritisation of vaccines is usually decided based on supply, population at risk, disease specific transmission dynamics, ethics and human values. For Covid-19 vaccines the key issue is supply of the vaccines and the need for two doses within a specified interval. In almost all countries where the vaccine is being deployed, front line health workers are deemed to be at high risk and are prioritised for vaccines. This should be an advantage for MA staff in frontline health worker roles. National programs also prioritize other age groups based on the demographic pyramid of the country (e.g. In UK individuals aged >80years were prioritized in the first phase of vaccination while in India this was set at individuals aged >50years

with any co-morbidity). MAs should identify staff (including those in non-frontline health worker roles) based on the criteria set out in the national vaccination criteria.

Recommendation for IPPF MAs to ensure vaccination of Frontline Healthcare Workers

Aim: Guidance for IPPF MAs to enable and facilitate access to vaccines for willing MA frontline health care workers within the appropriate phases of the national vaccination roll-out.

Step 1: Read what information on vaccines is available in country and any information on national vaccine roll-out to understand the following basic information

- Which of the above vaccines are authorized/approved for use in your country?
- If not, what is the national regulatory process for authorization/approval of vaccines in your country?
- Is there an existing or in-development National Covid-19 Vaccine rollout plan (*WHO related resource - [Covid-19-vaccine-country-readiness-and-delivery](#)*)

Identify and assign a key focal point from the MA senior leadership who can engage in this area (relevant subject matter expertise) and has authority to take quick decisions to engage in country and link up with IPPF Secretariat as necessary. A sample template is provided and should be modified as needed by the MAs

| KEY MESSAGE RELEVANT FOR MA & STAFF | SOURCE OF INFORMATION | VALID AS ON (DD/MM/YY) | VERIFIED BY (MA STAFF) |
|-------------------------------------|-----------------------|------------------------|------------------------|
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Step 2: Identify and map all relevant key stakeholders who will have access to information and or will be part of the national vaccine roll-out and determine how you will partner/engage with them. Identify in particular key partners in the Ministry of Health, WHO, UNICEF at a minimum, as well as other health providing civil society organisations. Often Government (e.g. the armed forces, national disaster management authorities) and NGO partners (e.g. CARE, Save the Children etc) involved in the routine immunization program (for polio, measles and other infectious diseases) are often involved in the design and implementation of national vaccine plans.

Given that many IPPF MAs participate in the national immunization program for other paediatric infectious diseases, discuss within the senior management team to identify if there is interest, opportunity and capacity for the MA to play a role in the Covid-19 vaccine rollout in country (some potential e.g. Can MA Service Delivery Points offer C-19 vaccinations? Can MA staff be trained to offer the vaccine one day a week? Can mobile outreach infrastructure and Community Based Distribution sites of MAs play a role in community mobilization, tracking and or offering the vaccines?). A sample template is provided and should be modified as needed by the MAs.

| STAKEHOLDER | KEY CONTACT AT STAKEHOLDER ORGANISATION | YOUR RELATIONSHIP AND HOW YOU WILL ENGAGE WITH THEM | AIM OF THE PARTNERSHIP AND EXPECTED ASK/SUPPORT |
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Step 3: Engage with staff and share accurate information including specifics that can counter some of the ongoing rumours and fake news around Covid-19 Vaccines and educate staff on the action and expected side-effects of these vaccines. Recognize that vaccine hesitancy/resistance is a real and important problem and always engage respectfully with colleagues and provide accurate scientific data/information where available to respond to their valid concerns. A staff engagement plan is critical to ensure that there is clarity and willingness to consider adopting the Covid-19 vaccines. Ensure you develop one and be prepared to respond to questions in an accurate, scientific and non-judgmental manner. Recognize that a decision to accept or reject a vaccine is a personal choice and support colleagues irrespective of their decision.

A critical output of this engagement plan is to gather data on the names, age, sex, co-morbidities if any (along with other relevant information required by national vaccine plans) of MA staff who are willing to be vaccinated. This data should be stored, handled and managed in line with the IPPF Data Management policy considering the sensitive nature of this information. Engage your IPPF Secretariat office if you are faced with questions or concerns on the vaccine and would require information. A sample information sheet for the MA to consolidate this information is provided below and should be modified as necessary by MAs.

| NAME OF STAFF | AGE (IN YRS) | SEX | REGISTERED HEALTH WORKER (Y/N) | ANY APPLICABLE CO-MORBIDITIES (Y/N) | IN COUNTRY LOCATION | WILLINGNESS INDICATED ON (DD/MM/YY) | CONTACT INFO (PHONE, EMAIL OR OTHER) | 1 ST DOSE VACCINATION DATE | 2 ND DOSE VACCINATION DATE | VACCINATION STATUS (COMPLETE/ DUE FOR SECOND DOSE/ INCOMPLETE) |
|---------------|--------------|-----|--------------------------------|-------------------------------------|---------------------|-------------------------------------|--------------------------------------|---------------------------------------|---------------------------------------|--|
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Step 4: Where still relevant, develop a country specific MA strategy of how the MA will enable and facilitate access to Covid-19 vaccines for MA staff and assign responsibility to key MA staff for specific actions. Implement strategy and review plans every 2 – 4 weeks as appropriate. Please remember that a number of actions need to be completed during the planning stage of the National Covid-19 vaccine rollout plans rather than wait for vaccination to start in country. Do not hesitate to seek guidance and inputs from the IPPF Secretariat advocacy and program delivery colleagues in developing or implementing this strategy as needed. A sample template is provided and should be modified as needed by the MAs.

| TARGET AUDIENCE/STAKEHOLDER | OBJECTIVE | ACTION | KEY MESSAGES | EXPECTED OUTCOME AND TIMELINE | RESPONSIBLE MA STAFF |
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Critical links and background reading:

External links:

Vaccine Tracker (Regulatory affairs): <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker>

WHO page on Covid-19 vaccines: This covers a number of relevant topics providing a range of information for general public, program managers and public health officials
- <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

COVID-19 Vaccine supply forecasts and delivery scheduled (Regional level) -
<https://www.gavi.org/news/media-room/covax-announces-new-agreement-plans-first-deliveries>

COVAX: The COVAX Facility is the global procurement mechanism of COVAX. The COVAX Facility will make investments across a broad portfolio of promising vaccine candidates (including those being supported by [CEPI](#)) to make sure at-risk investment in manufacturing happens now. This means the COVAX Facility, by pooling purchasing power from all countries that participate, will have rapid access to doses of safe and effective vaccines as soon as they receive regulatory approval.

- **GAVI COVAX** - <https://www.gavi.org/covax-facility#what>
- **CEPI COVAX** - <https://cepi.net/covax/>

Internal Links

IPPF - <https://ippf-covid19.org/>