Guidelines for Covid-19 Vaccine

COMIRNATY : Covid 19 mRNA Vaccine (Nucleoside modified)

(05/07/2021)

"COMIRNATY" is the "Pfizer-BioNTech COVID-19 Vaccine" (BNT162b2) for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older as recommended by the manufacturer .(https://www.comirnatyglobal.com/- select country as Sri Lanka).

(Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2-WHO, under Emergency Use Listing updated on 15 June 2021: Age intended to use updated as persons aged 12 years and above) https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1

Important information:

- "COMIRNATY" is a messenger RNA (mRNA) based vaccine against coronavirus disease 2019 (COVID-19). The mRNA instructs the cell to produce proteins of the S antigen (a piece of the spike protein unique to SARS-CoV-2) to stimulate an immune response.
- Efficacy shown in clinical trials in participants with or without evidence of prior infection with SARS-CoV-2 and who received the full series of vaccine (2 doses) was approximately 95% based on a median follow-up of two months.
- "COMIRNATY" is a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles), which needs to be dissolved using 0.9% normal saline.
- The vaccine can be given 16 years of age and older. The safety and efficacy of COMIRNATY in children and adolescents aged less than 16 years of age have not yet been established though limited data are available to date. (However, WHO interim recommendations updated in June 2021, recommend to use 12 years and above)
- It is currently recommended that the same product should be used for both doses if start the vaccination with COMIRNATY-Pfizer-BioNTech vaccine. (Heterologous (mix-and-match) studies are ongoing with regards to the interchangeability of this vaccine with other COVID-19 vaccines.)
- Preliminary results from a heterologous priming schedule where BNT162b2 (COMIRNATY) was given as the second dose following a first dose of ChAdOx1- S [recombinant] vaccine showed a slightly increased but acceptable reactogenicity with superior or similar immunogenicity results.
- WHO interim guidelines recommend the use of Pfizer –BioNTech COVID-19 vaccine as the 2nd dose for those who have received the 1st dose (priming dose) from COVISHIELD vaccine (ChAdOx1-S [recombinant] vaccine) in settings where the second dose for the ChAdOx1-S [recombinant] vaccine is not available due to vaccine supply constraints.
- COMIRNATY vaccine vials (received on 05/07/2021) is a muti-dose vial, after dissolved using the diluent, the vial contains 2.25 mL from which advised to withdraw 6 doses of 0.3 mL, using a low dead volume needle and syringes.

    - *The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.*
- The vaccine is a frozen component required to be dissolved using the diluent 0.9% (9 mg/mL) sodium chloride
- Normal saline (preservative free) - 5 ml normal saline diluent vial can be used only 2 withdrawals to be used to dissolve 2 vaccine vials at one time, under strict aseptic conditions, to prepare 12 doses in 2 vials at one time. (This will minimize the wastage). However, normal saline 5 ml vial can be used for one vial preparation once 2 vials are not required to be dissolved.
    - Other normal saline containers are not advised to use for multiple withdraws for the dilution of the vaccine vials at one time.
- Same vaccine needs to be given as 0.3 mL, 2 doses, keeping 3-4 weeks interval between 2 doses (when the COMIRNATY is been given as the 1st dose).
- Advise to vaccinate intramuscularly preferably to the upper part of the deltoid muscle on the left side.
- There are no data available to date on the interchangeability of COMIRNATY with other COVID-19 vaccines to complete the vaccination course. Individuals who have received 1 dose of COMIRNATY is advised to receive a second dose of COMIRNATY to complete the vaccination course.
- One dose of 0.3 mL contains 30 micrograms of COVID-19 mRNA Vaccine, embedded in lipid nanoparticles and contain following excipients;
    - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
    - Cholesterol
    - Potassium chloride
    - Potassium dihydrogen phosphate
    - Sodium chloride
    - Disodium hydrogen phosphate dihydrate
    - Sucrose
    - Water for injections
- The “COMIRNATY” vaccine vials are stored at ultra-cold temperature of minus 90 °C to minus 60 °C (-90 °C to -60 °C) for 6 months.
- If unopened, not exposed to direct sunlight and handled carefully without exposing to thawing temperature, the vaccine is stable for 6 months (6 months shelf life).
- Vaccines stored at -90 °C to -60 °C, can be transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C to re-store.
- The frozen multidose vial must be thawed prior to dilution.
- Frozen vials should be transferred to an environment of +2 °C to +8 °C to thaw; a 195 vial pack may take 3 hours to thaw before use.
- Alternatively, frozen vials may also be thawed for 30 minutes at room temperatures up to 30 °C for immediate use.
- The unopened vial can be stored for up to 1 month at +2 °C to +8 °C,

- Within the 1-month shelf-life at +2 °C to +8 °C, up to 12 hours may be used for transportation if need.
- The chemical and physical in-use stability has been demonstrated 6 hours at +2 °C to +30 °C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. In fact, diluted vial is not recommend to use after 6 hours.

Additional information : https://www.comirnatyglobal.com/ (select the country as Sri Lanka)

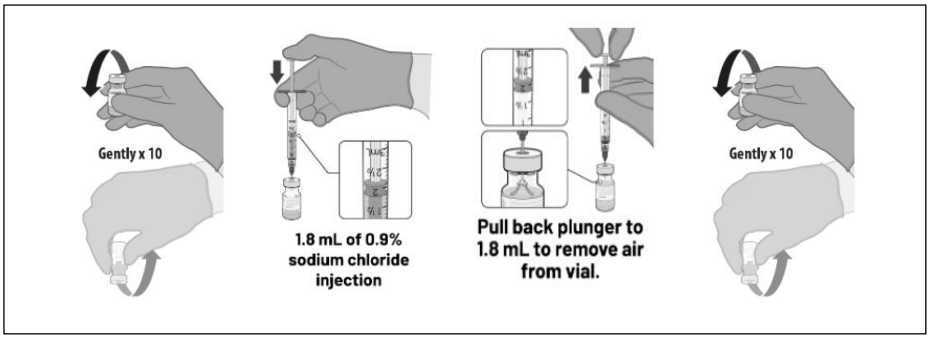
Product presentation:

Vaccine vial : Frozen, sterile, preservative-free, multi-dose concentrate for dilution before administration.

Diluent : 9% normal saline (preservative free)-5 ml vial presentation

Preparation of the vaccine vial for use: Vaccine vial dilution should be done by well-trained health care staff under the supervision of healthcare professional using aseptic technique to ensure the sterility and to ensure the correct composition of the prepared dispersion.

- The vaccine vial needs to be diluted with 0.9% normal saline before use.
- Before dilution, the thawed vaccine vial needs to be inverted gently 10 times, do not shake.
- Diluent syringe (mixing syringe) -recommend 2-3 ml syringe with a needle: 1.8 mL of diluent (0.9% normal saline), needs to draw into the mixing syringe.
- Add this amount of 1.8 mL of diluent (0.9% normal saline) into the vaccine vial; level and need to equalize the pressure in the vial before removing the needle by withdrawing 1.8 mL of air into the empty diluent syringe (mixing syringe).
- Discard diluent syringe in to the safety box (do not reuse)
- Same diluent normal saline 5 ml vial can be carefully used at the same time for a 2nd vial dilution (using a fresh needle and syringe) under careful aseptic conditions. Recommend to discard diluent vial after one time use for a single or 2 vial dilutions.
- Gently invert the vial with diluted vaccine 10 times to mix; do not shake.



- Inspect to make sure that the vaccine is an off-white uniform suspension; do not use if discoloured or if containing particles.
- Record, date and time of dilution on the vaccine vial label and it can be used for the maximum time of 6 hours after dilution.

- Vaccination syringe: 1 ml low dead volume syringe (and a needle) : Recommend to use 1 ml syringe with calibrations to draw 0.3 ml, using a 23 G needle with 24 mm in length.
- From a single vial, manufacturer recommend that 6 doses can be easily withdrawn by using low dead volume syringes and needles for vaccination.
- Draw up the vaccine dose at the time of administration, pre-loading of vaccines in syringes are not recommended.
- Use all vaccine doses in the diluted vaccine vial within 6 hours after dilution.
- After final dose withdrawal from the diluted vaccine vial, if any remaining vaccine solution of less than 0.3 ml in the vial, is not recommended to pool with other remaining doses from other vials for further vaccinations.

Target group:

1. Target groups to be vaccinated will be informed by the Ministry of Health as with the vaccine supply and considering the epidemiological assessment for the best impact for prevention of transmission and prevention of the mortality.
   This product can be used for people aged 16 years of age and above as with the manufacturer guidelines (WHO updated in June 2021 as 12 years and above), but the vaccination category and the age will be informed by the Epidemiology Unit, Ministry of Health after the final decision by the higher authorities of the Ministry of Health.

2. Recommend to use of Pfizer –BioNTech COVID-19 vaccine as the 2nd dose for those who have received the 1st dose (priming dose) from COVISHIELD vaccine (ChAdOx1-S [recombinant] vaccine) and missed the 2nd dose of ChAdOx1-S [recombinant] vaccine due to unavailability as with vaccine supply constraints.

   It is recommend to provide the 2nd dose from Pfizer–BioNTech COVID-19 vaccine at the first opportunity on completion of 8 weeks after the 1st dose or at any time without considering the default time duration in vaccine supply constraint situation.

   This provision of 2nd dose from Pfizer–BioNTech COVID-19 vaccine is recommended only in COVISHILD/ASTRAZENECA/ChAdOx1-S [recombinant] vaccine supply constraint situations.

Vaccine stock requirement:

Number of vaccine doses in a single vial, after accurate dilution and by using low dead volume syringes and needles, is informed as 6 doses (by the Manufacturer).

Method of Administration: The recommended administration is through intramuscular route (IM), preferably to the upper part of the left arm.

Active composition: excipients of the vaccine are given above.

Dosage schedule: recommend to vaccinate each of 0.3 ml per dose into the deltoid muscle (preferably left side), at 3 -4 weeks interval for the 2nd dose.
(as with the information to date : https://www.comirnatyglobal.com , COMIRNATY® (Tozinameran), COVID-19 mRNA vaccine (nucleoside modified) WHO updated information as of 10th May 2021).

Please note: 0.3 ml AD syringes are not available in the country at the moment and advised to use 1 ml low dead volume syringes and needle combination for intramuscular injection. The needle recommended is 23G x 24 mm in length. (Advise all precautions to be taken to minimize the contamination and vaccine wastage during handling of dilution and vaccination)

Storage

- Vaccine vials can be stored at +2^{0}C to +8^{0}C for a period of 1 month
    - After dilution with sodium chloride 9 mg/mL (0.9%) solution for injection (once opened the vial), it can be used only for 6 hours.
    - If vials are kept un opened and kept at +2^{0}C to +8^{0}C and not exposed to room temperature, it can be re-store at ILR. But, strongly advise to take only required amount vaccines from the ILR during the vaccination session and should not expose unopen vials to room temperature.
- Advised to store vaccines preferably in Ice Lined Refrigerators with close monitoring of temperature using fridge tags (24 X 7). Careful temperature monitoring and early intervention is strongly advised.
- The frozen multidose vial must be thawed prior to dilution.
- Frozen vials should be transferred to an environment of +2 °C to +8 °C to thaw; a 195 vial pack may take 3 hours to thaw before use.
- Alternatively, frozen vials may also be thawed for 30 minutes at room temperatures up to 30 °C for immediate use.

Discard any unused vaccine 6 hours after dilution, or at the end of the immunization session, whichever comes first. Take maximum measures to optimally use the vaccine vial diluted to vaccinate 6 person at a time and advise to minimize vaccine wastage.

Indication to use: it can be given to adults over the age of 16 years (12 years as with updated June 2021 WHO recommendations).

The geographic areas and population category selection should be based on the decision taken by the Ministry of Health authorities and informed by the National Immunization Programme, Epidemiology Unit, Ministry of Health.

Indicated to use as the 2nd dose for those who have received COVISHILD/ASTRAZENECA/ChAdOx1-S [recombinant] vaccine as the 1st dose.

Contra indications

- Known history of a severe allergic reaction (e.g. anaphylaxis) to any component of COMIRNATY vaccine (components are mentioned above).

- In particular, COMIRNATY should not be administered to individuals with a known history of severe allergic reaction to polyethylene glycol (PEG) or related molecules.
- Persons with an immediate allergic reaction (e.g. anaphylaxis, urticaria, angioedema, respiratory distress) to the first dose of COMIRNATY should not receive additional doses.
- Immediate or delayed onset anaphylactic or severe allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc (unless proper risk benefit assessment done by an emergency care physicians or similar experts)

Special precautions: following conditions to be considered before intramuscular injection

- Should take caution in persons with a history of any bleeding or coagulation disorders (e.g. clotting factor deficiency, coagulopathy, platelet disorders). Need to get specialized opinion of the disease or understanding of the medical condition before vaccination.
- Chronic liver and kidney diseases, endocrine disorders (apparent thyroid function abnormalities and diabetes mellitus in decompensation stage), serious diseases of the hematopoietic system, epilepsy and other CNS diseases, acute coronary syndrome and acute cerebrovascular event, myocarditis, endocarditis, pericarditis (can be given with caution only if the treating clinician or a Consultant Physician/ emergency care Physician assessed the individual and recommended vaccinating under his/her care).
- Due to lack of data not indicated for persons with:
    - autoimmune diseases (stimulation of the immune system can lead to an exacerbation of the disease, special caution should be exercised with patients with an autoimmune disorder that tend to lead to severe and life-threatening conditions)
    - malignant neoplasms

  (decision to vaccinate for any person not indicated for vaccination or special precautions should be based on the proper risk-benefit assessment by the treating physician or by the recommendations of an expert from the relevant speciality under his/her guidance).

Temporary postponement of vaccination: following conditions are required temporary postponement of the vaccination (vaccination should be postponed for 4-8 weeks)

- Any signs and symptoms suggestive of acute SARS-CoV 2 infection or suffering from any other acute illness who are not fit for the vaccination.
- Already diagnosed SARS-CoV 2 patient who have received anti-CoV 2 monoclonal antibodies or convalescent plasma as a treatment option.

Following conditions are not contraindications for vaccination

- Persons with a past history of SARS-CoV 2 infection (by patient history, RT PCR positive report or sero positivity) : vaccination should be done irrespective of the

previous COVID-19 disease conditions (COVID-19 confirmed cases can be vaccinated 2 weeks after the recovery)

- Co-morbidities such as hypertension; diabetes; asthma; and pulmonary, liver and kidney disease; as well as chronic (stable and controlled) infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV) and hepatitis B virus (HBV) are not contra indications and need to be vaccinated for better protection. However, immune response may be less in these patient categories.
- Lactation (at any time including post-partum period) : stop or delaying of breast feeding before or after vaccination is not required.
- The use of BNT162b2 vaccination in pregnant women has shown benefits outweighing the potential risks (as with updated WHO recommendations).
- In fact, to help pregnant women to get adequate benefits of the vaccination, it should be provided to get the likely benefits of vaccination during 2^{nd} or 3^{rd} trimester after 35 years or at any age for those who are with comorbidities during the 2^{nd} or 3^{rd} trimester.
- Take all precautions in contact with Consultant obstetricians, for any further decisions in identifying eligibility of pregnant women are needed.

Adverse events

- Mild local : tenderness or swelling in your arm at the injection site
- Short term general : feeling tired, headache, muscle pain, joint pain, diarrhoea, fever
- Rare: Itchiness in general, rash, swelling of the lymph nodes, sleeplessness, Bell's palsy (1 in 10,000)
- Serious allergic reactions and anaphylaxis can occur for any pharmaceutical product and need to take maximum precautions

Vaccine safety surveillance suggest close monitoring of ;

- Serious adverse events including myocarditis
- thromboembolic events, thrombosis with thrombocytopenia syndrome (TTS),
- anaphylaxis and other serious allergic reactions,
- Bell`s palsy, and transverse myelitis
- maternal and neonatal outcomes, and mortality in groups prioritized for vaccination

Advise to notify all events with possible association to vaccines and vaccination through the AEFI notification system, over the phone, email and fax to the Epidemiology Unit.

Other logistic requirements

- 1 ml syringes with needles (23 G needle with 24 mm in length) to vaccinate as the number equal to number of doses estimated to vaccinate and 3 ml syringes with needs to dilute as the number equal to vaccine vials required to be diluted.
- Adequate cotton swabs
- Sharp disposal safety boxes (1 standard box =10 L, can hold 100 syringes with needles)
    - Estimated number of AD syringes /100 = required number of safety boxes

- Emergency tray and portable oxygen cylinders with essential items in the emergency tray (to attend immediate Adverse Events Following Immunization (AEFI) as with National guidelines should be available in all immunization clinic centres).

Implementation of the vaccination and Immunization clinic functioning

- The campaign mode vaccination for 1st round and 2nd round of vaccination as with the identified categories and dates informed by the Epidemiology Unit, Ministry of Health as with the evolving requirement of the country for the best impact.
- Vaccinate as one dose campaign for the 2nd dose for those who have received the 1st dose of Covishield and not received the 2nd dose due to supply constraints.
- The vaccination data should be updated on the same day to the National Immunization Programme, Epidemiology Unit, Ministry of Health.
- Vaccine stock request from the RMSD needs to be done by using the Monthly Stock Return of Vaccine and Injection Safety Devices (Annexure 1)
- Vaccine stocks received to the institution are required to be entered into the existing Vaccine/drugs stock ledger in the institution and into the existing MOH office-Vaccine Movement Register (Blue colour book) (format: Annexure 2)
- Vaccine stock request to the clinic, should be based on the existing Clinic-Vaccine Movement Register (Yellow colour book) (format :Annexure 3)
- At the end of the clinic session, if any remaining vials (freeze, unthawed) returned from the clinic, needs to be stored separately in the recommended freezing temperature. (vaccines will be sent in freezer trucks and required return to the same truck to return to freezer rooms)
- At the end of the clinic session, Vaccine Movement Registers need to be balanced, and Immunization Clinic Returns need to be completed and sent to the Regional Epidemiologist (Annexure 8)
- After the 2nd dose of the campaign the Monthly Stock Return of Vaccine and Injection Safety Devices Vaccine Stock Return need to be completed to request required stocks (Annexure 1)
- Vaccine stocks should not keep in any of the institutional refrigerators after the campaign and should return to the freezer truck to store at freezer rooms.

- All clinic centres vaccinating is advised to ready in attending AEFI emergencies and be ready with "emergency tray" to attend any AEFI emergencies.
- Conducting immunization clinics can be done adhering to National guidelines of vaccination under the guidance and supervision by the immunization supervisory health teams from the RDHS/PDHS/ Epidemiology Unit / teams from the Ministry of Health.
- Vaccination clinics should function with adequate human resource to ensure smooth functioning of the clinic.
- Volunteer support can be obtained for services outside the clinic for crowd control, guiding for information and targeted advices for the vaccination in improving the campaign efficiency.
- Take measures to prevent unnecessary gatherings of the crowd in and around the vaccination clinic.

- All precautionary measures need to be taken by the vaccination teams and supporting individuals to the clinic during the clinic sessions in prevention of possible COVID-19 transmission.
- Clinic setting should arrange as 1) waiting area 2) eligibility screening with consent to vaccinate 3) registration and issuing the vaccination card 4) marking of a tally sheet, vaccination and next appointment date 5) AEFI observation area
- Clinic station arrangement should be organized in a way that minimum time wasting at different stations to get the maximum efficiency in the clinic
- Immunization Clinic registration format (Annexure 4) is provided and photocopied sheets of the format can be used for the registration or the printed register provided to identify eligible population can be used for the registration of the vaccination during the session.
- In addition to this, ensure proper registration data is entered into the Electronic web-based person information registration system developed by the Ministry of Health.
- All registration formats / Vaccination Registers should be duly filed in the institution for future review requirements, next dose reminders and if any other official requirements.
- The same Register / Register format used can be utilized for the 2nd dose vaccination or a fresh Register format can be used for the 2nd dose for the convenience. But, ask about the initial dose (1st dose) from the history (H) or check from the "Vaccination card" (C) to ensure completeness of the vaccination.
    - Mark a tick at the appropriate column for the 1st dose, if information is gathered from the Immunization card as "✓ / C" or if information is gathered from the history as "✓ / H".
- It is not advisable to interchange vaccination with different COVID-19 vaccine types (as with existing evidence so far).
    - Take measures to follow up the 2nd dose of the vaccination using the same vaccine product (component II).
- Consent form given in 3 languages should be signed at the most comfortable language for the consent to vaccination (Annexure 5)
- Previous COVID-19 positive and recovered patients should be vaccinated irrespective of the previous COVID-19 disease condition and can vaccinate 2 weeks after the recovery.
- In any doubtful cases for the eligibility, should contact a Consultant/Medical Officer in the hospital/ MOH in the area/ Regional Epidemiologist/Medical Officers-MCH/Provincial or District CCP/ Epidemiology Unit for an advice.
- Tally sheet developed for age group should be used (Annexure 6), in that age category, sex and health status should be properly completed and the summary should enter into the "e-NIP" for national administrative data and should be provided to the Epidemiology Unit/Regional Epidemiologist at the end of the day with the clinic return as required.
- After registering the person (electronic web based system-Immunization tracker- and paper based - Annexure 4) and take measures to issue a "COVID-19 vaccination card" – Annexure 7 (important to mention the name of the vaccine)

- Advice to write the vaccination card in English language in case if required for international use.
- The correct name of the vaccine needs to be entered correctly as 1st or the 2nd dose at appropriate cage. (mention as “Sputnik V”).
- Advise to use 0.5ml AD syringes at all possible instances and carefully withdraw all solution in the single dose ampule.
- The vaccine dose of 0.5 ml IM to be given to the upper arm preferably on left side.
- After vaccination, they should be observed for a minimum of 20 minutes in the clinic for immediate AEFI.
- All vaccination procedure and vaccine management in general should be in accordance with the National guidelines given in the Immunization Handbook (3rd Edition), Epidemiology Unit, Ministry of Health.
- Vaccine safety in Immunization clinics should be maintained and managed according to the circular “Initial Management of Anaphylaxis at Field level” (circular number 01-20/2001, dated 23/08/2011) and National guidelines given in the Immunization Handbook (3rd Edition), Epidemiology Unit, Ministry of Health.
- Any reported AEFI identified at the clinic need to be entered in the Clinic / Hospital AEFI Register and inform to the Epidemiology Unit, Regional Epidemiologist and MOH in the area using AEFI form I (available as carbonated 3 copies in a book: format - Annexure 9). If any significant AEFI needs to be informed to the Regional Epidemiologist and to the Epidemiology Unit immediately over the phone.
- At the end of the clinic, compile all the vaccination data and
    - complete the Immunization clinic return (Annexure 8) in two copies and send one copy to the Regional Epidemiologist and keep one copy at the institution.
    - Tally sheet summary should enter into the “eNIP” web based electronic National Immunization Programme database, together with the target number expected to be vaccinated at the end of the clinic.
- Disposal of sharps in safety boxes and waste bins should be done preferably as incineration and according to the standard accepted practices applied in the routine Immunization clinics.
- All used vaccine vials should be incinerated.
- All vaccine stocks related data, vaccine wastage information and vaccination related data should submit to the Regional Epidemiologist in the provided Immunization clinic return (Annexure 8).

MONTHLY STOCK RETURN OF VACCINE & INJECTION SAFETY DEVICES

Institution : ..... D.P.D.H.S. Division : ..... No. 05910

Month : ..... Year : .....

	BCG doses	DPT doses	OPV doses	HBV Doses		Measles Doses		TT doses	MR doses	DT doses	Rubella doses	ATD doses	JE doses	0.05 ml BCG AD syringes	2 ml disposable syringes	0.5 ml AD syringes	5 ml disposable syringes	Safety boxes	Others	
				2 Dose Vials	10 Dose Vials	5 Dose Vials	10 Dose Vials													
1. Stock in hand at the beginning of the month																				
2. Stocks received during the month																				
3. Stocks distributed or used during the month																				
4. Balance stocks in hand at end of the month																				
5. Stocks now requested																				

Annexure 2

Page No.

Name of the item - ....

Date DD/MM/YYYY (A)	No. of doses / items in hand (B)	Place of distribution (Clinic/ School) (C)	No. of doses / items issued (D)	Batch No. (E)	No. of vaccinations performed (F)	No. of doses / items used (G)	No. of doses / items Returned (H)	Balance in hand (I)

Clinic Vaccine Movement Register Format

Date : .....

Type of vaccine/item	No. of doses /items issued to the clinic	Batch number	No. of vaccinations performed	No. of doses /items used	No. of doses /items returned	No. of doses /items required for the next clinic	Remarks
BCG							
PVV							
OPV							
LJEV							
MMR							
DPT							
DT							
TT							
aTd							
BCG diluents							
LJEV diluents							
MMR diluents							
0.05 ml syringes							
0.5 ml syringes							
2ml syringes							
5 ml syringes							
Safety boxes							

Signature of assigned person at MOH office..... Signature of assigned PHM at clinic.....

Date : .....

Type of vaccine/item	No. of doses /items issued to the clinic	Batch number	No. of vaccinations performed	No. of doses /items used	No. of doses /items returned	No. of doses /items required for the next clinic	Remarks
BCG							
PVV							
OPV							
LJEV							
MMR							
DPT							
DT							
TT							
aTd							
BCG diluents							
LJEV diluents							
MMR diluents							
0.05 ml syringes							
0.5 ml syringes							
2ml syringes							
5 ml syringes							
Safety boxes							

Signature of assigned person at MOH office..... Signature of assigned PHM at clinic.....

උපන් වර්ෂය
பிறந்த ஆண்டு
Year of Birth

පිටු අංකය
பக்க இலக்கம்
Page Number

ලේඛන අංකය பதிவிலக்கம் Reg. Number	නම සහ ජා. හැ .ප. අංකය பெயர் மற்றும் தே.அ.அ இலக்கம் Name & NIC Number	වයස வயது / Age	ස්ත්‍රී/පුරුෂ භාවය பாலினம் / Sex	ලිපිනය முகவரி Address	දුරකථන අංකය தொடர்பிலக்கம் Contact number	එන්නත ලබා දුන් දිනය கொவிட்-19 தடுப்புமருந்தேற்றிய திகதி Date of Covid 19 Vaccination				වෙනත් කරුණු குறிப்புகள் Remarks
						1 වන මාත්‍රාව முதலாவது தடவை 1st Dose	2 වන මාත්‍රාව இரண்டாவது தடவை 2nd Dose			
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
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						YYYY	YYYY	YYYY	YYYY	
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						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
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Institution	Immunization centre name	Serial No :
		NIC / Passport No :

COVID-19 vaccination

කැමැත්ත ප්‍රකාශ කිරීමේ පත්‍රය / சம்மதப் படிவம் / Consent form

..... වන මට අද දින ලබාදෙන COVID-19 එන්නත පිලිබඳව අවශ්‍ය තොරතුරු ලබා ගැනීමටත්, ඒ පිළිබඳව ඇතිවූ ගැටළු විසඳා ගැනීමටත්, අවශ්‍ය ප්‍රශ්න ඇසීමටත් එන්නත් මධ්‍යස්ථානයේ සෞඛ්‍ය නිලධාරීන් අවස්ථාව සලසා දෙන ලදී.

එම අවබෝධය මත COVID-19 එන්නත ලබා ගැනීමෙන් සිදුවන වාසි සහ කලාතුරකින් ඇතිවිය හැකි අතුරුඵල පිලිබඳව අවබෝධ කර ගැනීමෙන් අනතුරුව එන්නත ලබා ගැනීමට තීරණය කර, කැමැත්ත පල කරමි.

අත්සන : ..... දිනය : .....

.....ஆகிய நான் கொவிட்-19 தடுப்பூசிகள் மற்றும் தடுப்பூசி ஏற்றுதல் தொடர்பில் கேள்விகள் கேட்கவும், அவை தொடர்பான தகவல்களைப் பெற்றுக்கொள்ளவும், அவை குறித்து எனக்கு இருந்த சந்தேகங்களைக் கேட்டுத் தெளிவுபடுத்தவும் இந்த தடுப்பூசி நிலையத்தில் இருக்கும் சுகாதாரப் பணியாளர்களால் சந்தர்ப்பம் வழங்கப்பட்டது.

இந்த கொவிட்-19 தடுப்பூசியின் மூலம் ஏற்படும் நன்மைகள் மற்றும் அதன் மிக அரிதான பக்க விளைவுகளை நன்கு புரிந்து கொண்டதன் பின்னர், இத் தடுப்பூசியினைச் செலுத்திக் கொள்வதென முடிவு எடுத்து, அதற்கான சம்மதத்தினை இத்தால் வழங்குகிறேன்.

கையொப்பம் : ..... திகதி : .....

I ..... have received the opportunity to ask questions, receive relevant information and clarify my doubts on COVID-19 vaccines and vaccination, given from the vaccination centre today from the health staff in the centre.

After I understand the benefits and possible rare adverse events of the COVID-19 vaccine, I have decided and consented to get the vaccination.

Signature : ..... Date : .....

Annexure 6

MINISTRY OF HEALTH

COVID-19 vaccination : Immunization Clinic Tally Sheet - Different age groups

EPID/CV/TS 04	
Sheet No	

Date	Institution name	District	MOH area	Clinic centre name	Vaccine Name	
					1st Dose ☐	2nd Dose ☐

Age groups	Male known healthy					Total	Male known comorbid conditions *					Total	Female known healthy					Total	Female known comorbid conditions *					Total
60 years and above	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
50 – 59 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
40 – 49 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
30 – 39 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
20 – 29 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
Less than 20 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	

* *Diabetes mellitus, Hypertension, Cardio vascular diseases, Cerebro-vascular diseases, Kidney diseases, Liver diseases, Chronic lungs diseases, Malignancies, History of transplant, Immune compromised patients and any other chronic medical conditions*

Annexure 7

උපදෙස් / அறிவுறுத்தல்கள் / Instructions

ඔබගේ COVID-19 එන්නත් කාඩ්පත සුරැකිව තබාගන්න.

இந்த கொவிட்-19 தடுப்பூசி அட்டையினை நீங்கள் பாதுகாப்பாக வைத்திருப்பதை உறுதிப்படுத்துங்கள்

Make sure you protect this COVID-19 vaccination card

සෞඛ්‍ය නිලධාරීන් ලබාදුන් නියමිත දිනයේදී සහ වේලාවේදී නියමිත උපදෙස් මත COVID-19 එන්නතේ ඊළඟ මාත්‍රාව ලබා ගැනීමට මතක තබා ගන්න.

சுகாதாரப் பணியாளர்களால் அறிவுறுத்தப்பட்டதற்கு அமைவாக, அடுத்த தடவை கொவிட்-19 தடுப்பூசியினை பெற்றுக் கொள்ள வேண்டிய நாளில், குறித்த நேரத்தில் சென்று அதனைப் பெற்றுக்கொள்ள மறவாதீர்கள்

Remember to get the next dose of the COVID-19 vaccine on due date and time as instructed by the Health staff

වැඩිදුර විස්තර සඳහා තම ප්‍රදේශයේ සෞඛ්‍ය වෛද්‍ය නිලධාරි හෝ සෞඛ්‍ය අමාත්‍යාංශයේ වසංගත රෝග විද්‍යා අංශය අමතන්න

மேலதிக தகவல்களுக்கு தொடர்பு கொள்ளுங்கள்: உங்கள் பகுதி சுகாதார வைத்திய அதிகாரி அல்லது தொற்றுநோய் விஞ்ஞானப் பிரிவு, சுகாதார அமைச்சு. தொ

For further information contact: Medical Officer of Health in your area or Epidemiology Unit, Ministry of Health.

දුරකථන/பே.எண்/Telephone. 0112695112

www.epid.gov.lk

සෞඛ්‍ය අමාත්‍යාංශය - ශ්‍රී ලංකාව
சுகாதார அமைச்சு
Ministry of Health, Sri Lanka

COVID-19 එන්නත් කාඩ්පත
கொவிட்-19 தடுப்பூசி அட்டை
COVID-19 Vaccination card

නම பெயர் **Name:**			
ජා.හැ.අ./ගමන් බලපත්‍ර අංකය தே.அ.அட்டை/கடவுச்சீட்டு இலக்கம் **NIC number/Passport number**			
වයස வயது **Age**		**ස්ත්‍රී පුරුෂ භාවය** பாலினம் **Sex**	
ලිපිනය முகவரி **Address**			
දුරකථන අංකය தொடர்பு இலக்கம் **Contact number**			
දිස්ත්‍රික්කය மாவட்டம் **District**			
සෞ. වෛ. නි. ප්‍රදේශය சு.வை.அ பிரிவு **MOH area**			
ග්‍රාම නිලධාරී වසම கிராம அலுவலர் பிரிவு **Grama Niladhari area**			
ලේඛනයේ අනුක්‍රමික අංකය பதிவேட்டில் உள்ள தொடரிலக்கம் **Serial Number in the register**			

COVID-19 vaccination details

COVID-19 vaccine	Name of the Vaccine	Place of vaccination	Date of Vaccination	Batch number	Remarks
1st dose			DD/MM/YYYY		
2nd dose			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		

නැවත එන්නත ලැබිය යුතු දිනය / அடுத்த வருகைக்கான திகதி / Next appointment date

DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY
DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY

COVID-19 vaccination campaign: Immunization Clinic Return

Vaccine name: ……..

(to be completed in 2 copies by the responsible officer in the hospital /MOH office/ field clinic /other institutional clinic and return one copy to Regional Epidemiologist at the end of the clinic session and keep one as a clinic copy)

District: ……, Institution name: …….. MOH area: ……..

Clinic name:…… Date: ……..

Date	Total estimated/actual number to be vaccinated (Target) *(Number to be vaccinated from the institution / GN area/PHM area/expected number for the clinic session)*	Number of vaccine doses received	Total number vaccinated (per day)	Number of vaccine doses returned	Number of doses discarded	Coverage %	Wastage %	Number of AEFI reported
	A	B	C	D	F = B - (C + D)	C / A X 100 %	F / (B – D) X 100 %	G

Name: …….. Designation:…… Signature:……

Date:……

Notification Form for Adverse Events Following Immunization (AEFI)

Patient Information

Name: MOH Division:

Age: ☐ ☐ months/years Sex: Male ☐ Female ☐ Telephone:

Name & address of the Parent/Guardian:

Information on the vaccine (primary suspected and other)

Vaccine (Generic Name)	Vaccine (Trade name)*	Route	Dose (1st, 2nd, 3rd, 4th)	Batch/Lot Number	Expiry date	VVM Status (I, II, III, IV)

Diluent used: Yes ☐ No ☐ If "yes', Diluent batch/lot number : Expiry date of Diluent :

**Trade name is necessary only in private sector immunization*

Place vaccine administered: Date:

Person vaccine administered: Doctor ☐ PHNS/Nurse ☐ PHM ☐ PHI ☐ Time: am/pm

Adverse Events

Local Adverse Events Requiring investigation	Injection site abscess ☐ BCG Lymphadenitis ☐ Severe local reaction ☐
CNS Adverse Events Requiring Investigation	Vaccine associated paralytic poliomyelitis ☐ GBS ☐ Encephalopathy ☐ Encephalitis ☐ Meningitis ☐ Seizures Febrile ☐ Seizures Afebrile ☐
Other Adverse Events Requiring Investigation	Anaphylaxis ☐ Persistent screaming ☐ Osteitis / Osteomyelitis ☐ Hypotonic Hyporesponsive Episode ☐ Toxic Shock Syndrome ☐
Adverse Events Not Requiring Investigation	Allergic reaction ☐ Arthralgia ☐ High fever (>39^{0}C / 102^{0}F) ☐ Nodule at the injection site ☐
Other Adverse Events	a) b)

Instruction: Before reporting an AEFI, please refer to the definition for the relevant AEFI given in overleaf and make sure that reporting event agrees with the criteria stipulated in the definition

Date & Time onset of adverse event:

Date & Time referring to medical care :

Medical History/Other	Outcome
	Hospitalized: Yes No If "Yes": Hospital: BHT: Still in the hospital ☐ Discharged ☐ Outcome: Recovered completely ☐ Partially recovered ☐ Death ☐

Reporting source

Date of the notification: Institution & Designation: Telephone:

Name & Signature of the notifying officer/General Practitioner:

(Medical Officers who attend any patient suffering from Adverse Effects Following Immunization shall notify in this form to the Medical Officer of Health the area of the patients residence)

Definitions of Adverse Events Following Immunization

All of the following adverse events should be reported if temporally related to immunization. Unless otherwise specified this includes all such events occurring within four weeks of a vaccine administration.

1. Local Adverse Events

a. Injection – Site Abscesses

Occurrence of a fluctuant or draining fluid – filled lesion at the site of injection with or without fever.

Bacterial :- Existence of purulence, inflammatory signs, fever, positive Gram stain, positive culture, or finding of neutrophils. Predominance of content will support a bacterial site abscess, but the absence of some of these signs will not rule it out.

Sterile :- There is no evidence of bacterial infection following investigation.

b. Lymphadenitis (includes Suppurative Lymphadenitis)

Occurrence of either

At least one lymph node, 1.5 cm in size (one adult finger width) or larger or a draining sinus over a lymph node.
Almost exclusively caused by BCG and occurring within 2 to 6 months after receipt of BCG and on the same side as inoculation (mostly axillary).

c. Severe Local Reaction : Redness and/or swelling centered at the site of injection and one or more of the following:

1. swelling beyond the nearest joint:
2. pain, redness and swelling for more than 3 days duration; or
3. Requires hospitalization.

2. Central Nervous System Adverse Events

a. Vaccine Associated Paralytic Poliomyelitis

Acute onset of flaccid paralysis within 4-30 days of receipt of oral poliovirus vaccine (OPV), or within 4-75 days after contact with a vaccine recipient, with neurological deficits remaining 60 days after onset, or death.

b. Guillan-Barre Syndrome (GBS)

Acute onset of rapidly progressive, ascending, symmetrical flaccid paralysis, without fever at onset of paralysis and with sensory loss. Cases are diagnosed by cerebrospinal fluid (CSF) investigation showing dissociation between cellular count and protein content. GBS occurring with 30 days after immunization should be reported.

c. Encephalopathy:

Cases occurring within 72 hours after vaccination should be reported. Encephalopathy is an acute onset of major illness temporally linked with immunization and characterized by any two of the following three conditions: Seizures; Severe alteration in level of consciousness lasting for one day or more; and distinct change in behaviour lasting one day or more.

d. Encephalitis:

(Any encephalitis occurring within 1 – 4 weeks following immunization should be reported). Encephalitis is characterized by the above mentioned symptoms and signs of cerebral inflammation and, in many cases, CSF pleocytosis and/or virus isolation.

e. Meningitis:

Acute onset of major illness with fever, neck stiffness/positive meningeal signs (Kernig, Brudzinski). Symptoms may be subtle or similar to those of encephalitis, CSF examination is the most important diagnostic measure: CSF pleocytosis and/or detection of microorganism (Gram stain or isolation).

f. Seizures:

Seizures lasting for several minutes to more than 15 minutes and not accompanied by focal neurological signs or symptoms. Seizures may be Febrile Seizures or Afebrile.

3. Other Adverse Events requiring investigation

a. Anaphylactic shock:

Circulatory failure (e.g. alteration of the level of consciousness, low arterial blood pressure, weakness or absence of peripheral pulses, cold extremities secondary to reduced peripheral circulation, flushed face and increased perspiration) with or without bronchospasm and/or laryngospasm/ laryngeal edema leading to respiratory distress occurring immediately after immunization.

b. Persistent Screaming:

Inconsolable continuous crying lasting at least 3 hours accompanied by high-pitched screaming

c. Hypotonic-Hypo responsive Episode (HHE) (shock collapse):-

Sudden onset of pallor or cyanosis, decreased level or loss of responsiveness, decreased level of muscle tone (occurring within 48 hours of vaccination). The episode is transient and self limiting

d. Osteitis/ Osteomyelitis:

Inflammation of the bone either due to BCG immunization (occurring within 8 to 16 months after immunization) or caused by other bacterial infection

e. Toxic-Shock Syndrome:

Abrupt onset of fever, vomiting and watery diarrhea within a few hours of immunization, often leading to death within 24-48 hours.

4. Other adverse events not requiring investigation

a. Allergic Reaction :

Characterized by one or more of the following:

1. skin manifestations (e.g. hives, eczema);
2. wheezing;
3. facial or generalized oedema

b. Arthralgia: Persistent joint pain lasting longer than 10 days. Transient: Joint pain lasting up to approximately 10 days.

c. High Fever:

The Endogenous elevation of at least one measured body temperature >39 ^{0}C

d. Nodule at the injection site:

Presence of a discrete or well demarcated firm soft tissue mass or lump at the injection site that is sometimes referred to as a subcutaneous nodule, antigen cyst or granuloma, in the absence of abscess formation, erythema and warmth.

5. Other severe and unusual events occurring within 4 weeks after immunization and not covered under categories 1 - 4.

Any unexplained sudden death of a vaccine recipient temporally linked (with 4 weeks) to immunization, where no other clear cause of death can be established, should be reported. In addition, any unusual events should be reported.