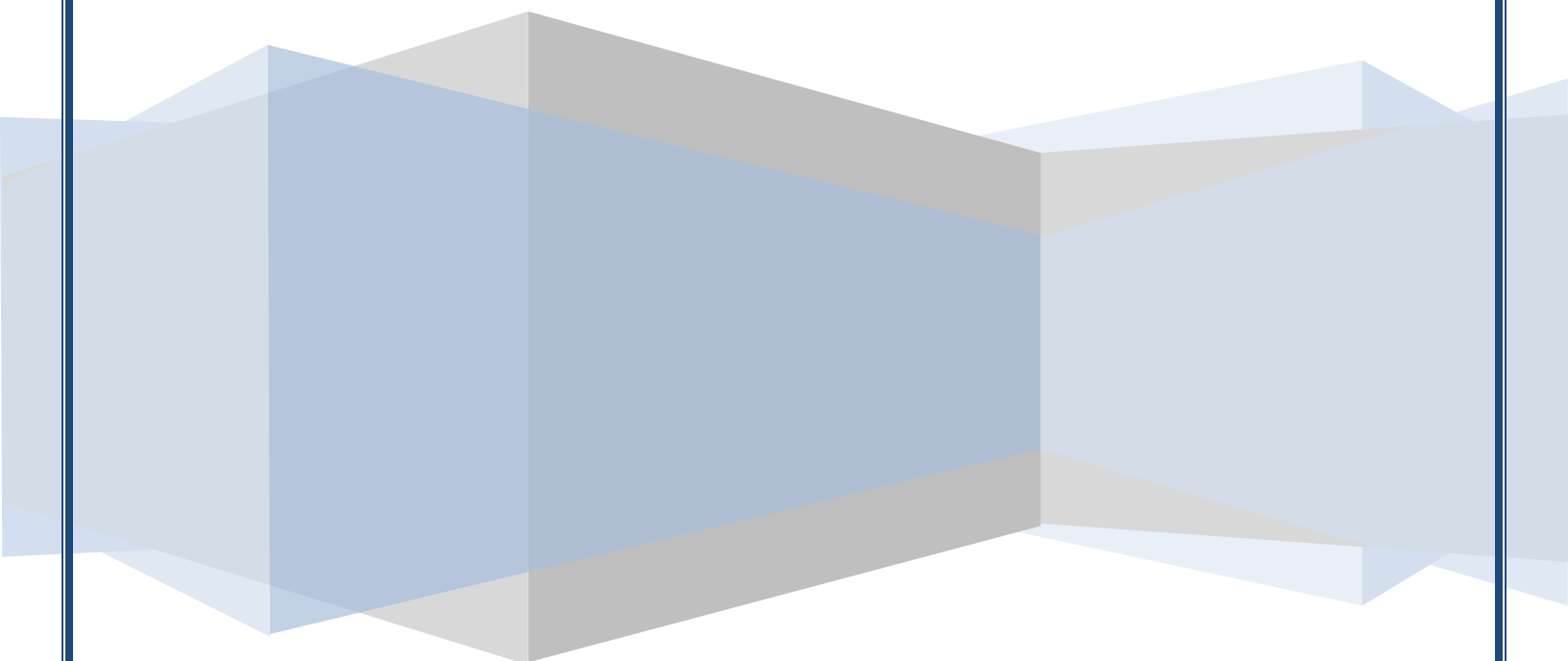


**Guidelines for  
COVISHIELD Covid-19 Vaccination  
Campaign 2021**

**Priority category vaccination for prevention of  
community transmission and mortality**

**Ministry of Health-Sri Lanka**



## COVISHIELD (ChAdOx1 nCoV-19) Corona Virus Vaccine (Recombinant) campaign

### Justification:

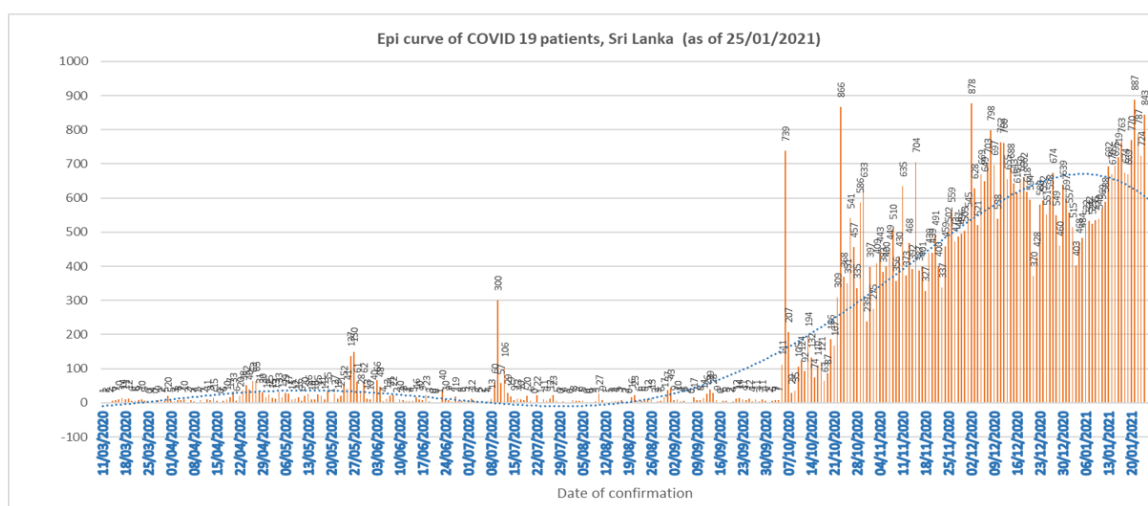
An outbreak of pneumonia of unknown origin was first reported on 31st December 2019 from Wuhan City in Hubei Province of China. On 7<sup>th</sup> January 2020, it was named as “Novel Corona Virus”. On 30/01/2020, WHO has declared it as a Public Health Emergency of International Concern (PHEIC). On 11/02/2020, the WHO named the disease as COVID-19 and on 11/03/2020 declared the outbreak a pandemic.

Sri Lanka reported the first case of COVID-19 on 27<sup>th</sup> January 2020 and thereafter several clusters were experienced in different intensity which were controlled. Afterwards, two large clusters were experienced in the district of Gampaha. In which the fish market related cluster was linked to supply chain involving almost all the districts. The outbreak control activities was continued while the whole country is functioning normally, without travel restrictions and continued humanitarian expatriation activities which also contributed for some imported Covid-19 cases to the country. The epi-curve by 22/01/2021 for the country is as follows and outbreak control activities through contact tracing and quarantine process are continuing.



### **Epidemiology Unit, Ministry of Health**

231, De Saram Place, Colombo 01000, Sri Lanka  
Tele: (+94 11) 2695112, 4740490, 4740491, 4740492 2681548 Fax: (+94 11) 2696583  
email: [chepid@slt.net.lk](mailto:chepid@slt.net.lk), [epidunit@slt.net.lk](mailto:epidunit@slt.net.lk) Web: [www.epid.gov.lk](http://www.epid.gov.lk)



In this background, the Ministry of Health has decided to introduce a safe and efficacious Covid-19 vaccine at the earliest possible instance. Considering the high priority requirement of safeguarding essential health care facilities for the nation, adhering to global Covid-19 vaccination prioritization guidelines and recommended by the National Advisory Committee of on Communicable Diseases (NITAG for the country), the healthcare staff and other support frontline workers (from defense, police/STF, services at ports of entry) are offered the initial

vaccine stocks receiving to the country in January 2021. Other priority groups are attended as with the receipt of consecutive vaccine stocks and the required guidelines will be issued as with the vaccine type and with the priority group for vaccination.

However, country epidemiology and continuation of essential services will be considered by the Ministry of Health for the vaccination to prevent transmission in supply constrains situation.

### **COVISHIELD vaccine (ChAdOx1 nCoV-19 Corona Virus Vaccine-Recombinant):**

This COVISHIELD vaccine is the product of Serum Institute of India (SII) which is the same AstraZeneca (ChAdOx1nCoV-19 Corona Virus Vaccine-Recombinant) vaccine.

Approved for restricted use in emergency use situations in prevention of Covid -19 disease for individuals 18 years of age and older (by 25/01/2021).

It is a recombinant non-replicating viral vector vaccine. Replication defective, safe adenovirus type (ChAdOx1) used as a platform to deliver the glycoprotein (encoding SARS-CoV-2 Spike S) that trigger an immune response in the body against nCoV-19 Corona Virus. The duration of protection is still not specified.

The vaccine is stored at +2<sup>0</sup>C to +8<sup>0</sup>C (needs to protect from freeze and direct sunlight), ready to use liquid non-preservative, multi-dose vaccine of 5ml (10 doses). Shelf-life around 6 months on production and expiry date is available on the product label.

### **Side effects that have been reported with the COVISHIELD vaccine include:**

#### Common

- Tenderness, pain, warmth, redness, itching, swelling or bruising where the injection is given
- Feeling tired (fatigue) and unwell
- Chills or feeling feverish, headache, nausea
- Joint pain or muscle aches
- Mild flu-like symptoms

#### Uncommon

Feeling dizzy, decreased appetite, abdominal pain, enlarged lymph nodes, excessive sweating, itchiness, rash

Very rare : Rare severe adverse reactions are not explained to date (from trials) but rare severe adverse reactions can occur for any pharmaceutical product.

### **Contraindications :**

- Known hypersensitivity to the active substance or to any of the excipients of the COVISHIELD vaccine (List of excipients : L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate (EDTA), Water for injection)
- Immediate or delayed onset **severe allergic /anaphylactic reaction** after a previous dose of the COVISHIELD vaccine
- Immediate or delayed onset anaphylactic or severe allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc
- Pregnancy and lactation (lactation is considered only for the initial 6 months after delivery) (not done clinical trials so far for these 2 categories)
- <18 years (not done clinical trials so far)

### **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 condition before vaccination.

### **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 COVISHIELD vaccine**

- 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)
- Patients with chronic morbidities and/or on regular treatment for the chronic disease conditions : cardiac, neurological, pulmonary, metabolic, renal, malignancy conditions
- Immune-deficiency, HIV, patients on immune-suppression due to any conditions. However, immune response may be less in these patient categories.

## **COVISHIELD covid-19 vaccination campaign :**

The campaign mode Covishield vaccination will be carried out as 2 rounds for the 1<sup>st</sup> dose and 2<sup>nd</sup> dose as with dates declared by the Ministry of Health. Target groups, based on the eligibility will be vaccinated during the campaign as identified and declared by the Ministry of Health as with evolving requirement of the country for the best impact.

The vaccination campaign and the documentation procedure should be completed within 1 week of the campaign completion.

Limited vaccination centres within the district will be available for those who have been temporarily postponed.

### **Target groups**

Target groups will be informed by the Ministry of Health as with the vaccine supply and epidemiological assessment for the best impact for prevention of transmission and prevention of mortality.

### **Identification process of the target group:**

- Relevant target groups should be identified for vaccination based on the prior identified lists by the Head of the institution/ MOH/RE/RDHS/PDHS.

All Heads of the Institutions are required to consider identified numbers lists to calculate vaccine stock requirement and other logistics.

### **Calculation of Vaccine stock requirement for an Institution / District:**

- Calculation of COVISHIELD vaccine requirement for the district is the responsibility of the Regional Epidemiologist. Use the Wastage multiplier factor of 1.11 to get the estimated vaccine requirement.
- Hospitals can request vaccines preferably through the Regional Epidemiologist but Western Province major hospitals can directly request from the Epidemiology Unit or from RMSD.

Number of vaccines doses required for the district = Target population X Wastage factor* 1.11 [assuming 10% wastage ; COVISHIELD vaccine is not considered for open vial policy])
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Number of vaccine vials required= No of vaccine doses /10
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*\*Wastage factor = Expected coverage (100%) / 100% -10% (wastage rate for 10 dose vials) = 1.11*

- The vaccine requirement to the district should be provided to the Epidemiology Unit by the Regional Epidemiologist timely to issue vaccines and other logistics.

### **Vaccine stock management at institutional level:**

- 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 unopened vials returned from the clinic, needs to be stored separately (in returned unopened vial box) in the Ice Lined Refrigerator (ILR) and should be used as the priority in the next clinic session.
- 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)
- Remaining vaccine stocks at the end of the initial round of the campaign should store securely until the 2<sup>nd</sup> round of the campaign.
- These remaining vaccine stocks should mention in the Monthly stock return to RMSD with a copy to the Regional Epidemiologist.
- After the 2<sup>nd</sup> dose of the campaign all remaining vaccine vials should return to RMSD by duly completing the Monthly Stock Return of Vaccine and Injection Safety Devices Vaccine Stock Return (Annexure 1)
- Vaccine stocks should not keep in any of the institutional refrigerators after the 2<sup>nd</sup> dose of the campaign.
- Only selected institutions will allow to keep limited amount of vaccine stocks for the use of vaccination-postponed individuals.

### **Other logistic requirements**

- 0.5ml AD syringes (number equal to number of doses estimated)
- 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
- Assess the adequacy of vaccine carriers to distribute vaccines to all hospital clinics and MOH central clinics.
- Assess the adequacy of ice packs for vaccine transport to all clinics (if inadequate need to re-distribute). Make sure adequate ice packs are in freeze and stored.
- Make sure availability of cold chain capacity to store estimated vaccines (500 doses in 50 vial pack =18.5cm x 9.5 cm x 6 cm = 1056 cm<sup>3</sup> = approximately 1.1L ).
- Vaccines should store in RMSD-cold rooms and preferably in vaccine storing ILR, (Net capacity 200 L with standard capacity 90L) at hospitals and MOH settings adhering to National immunization vaccine storage guidelines. **It is strongly advised not to store COVISHIELD vaccines with other pharmaceutical items other than EPI vaccines.**

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

### **Dosage, schedule and administration**

A dose of 0.5 ml of COVISHIELD vaccine should be administered by intramuscular route (IM) in to the upper arm preferably on the left side.

The 2<sup>nd</sup> dose should be planned in 10 weeks time. Those who receive the 1<sup>st</sup> dose should complete the 2<sup>nd</sup> dose for the protection from the disease.

### **Storage**

- COVISHIELD vaccine should be stored at +2<sup>0</sup> C to +8<sup>0</sup> C temperature at all levels at all the time.
- The vaccine is freeze sensitive and should not expose to freezing temperature at any time.
  - Even though freeze sensitive, shake test is not applicable. If any discoloration of the solution or visible particles are observed, it should not be used)
  - If vaccine vials are exposed to a frozen temperature, it should not be used.
- The vaccine is heat sensitive and should protect from direct sunlight.
- During the clinic session, vaccine vials should be kept in the vaccine carrier until taking a vial out for the vaccination and place in the foam pad until doses are over.
- If any delay occurred during the vaccination, vaccine vial should be kept inside the vaccine carrier.
- COVISHIELD vaccine should be discarded after 6 hours of opening for the 1<sup>st</sup> dose withdrawal from the vial or at the end of the immunization clinic session whichever comes first. (vial opening time needs to be recorded)
- The “open vial policy” is not applicable to this vaccine.

## **Immunization clinic functions during the vaccination campaign**

- All Heads of Institutions are responsible to ensure all eligible persons are vaccinated with the first dose and completed 2<sup>nd</sup> dose in 10 weeks from the first dose.
- Immunization clinic centres should be established in hospitals, MOH offices and in field Immunization clinic centres to vaccinate relevant selected target groups as instructed by the Ministry of Health.
  - Other field level vaccination centres can be organized by assessing the resources, availability of health care staff, other support staff and facilities to conduct the clinic and attending emergency situations.
    - All clinic field level centres vaccinating are advised to communicate with areas MOH/ Regional Epidemiologist/District and Provincial Consultant Community Physicians, for the “emergency tray” preparation and arrangements 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 a minimum staff of 7-persons per clinic as described in the following and adding extra staff should be done with caution considering the requirement, improving the efficiency, space availability and possibility of maintaining and adhering to COVID-19 preventive and infection preventive practices.

- Each vaccination clinic should have **minimum** of 7 persons (as “7-set”) at a time for functioning as a clinic centre (inside the clinic):
  - Medical officer : capable in screening eligibility and handling AEFI
  - 2 persons capable for vaccination : Nursing officers / Public Health Midwives (SPHM/PHM)/Public Health Inspectors (SPHI/PHI) who are trained and skilled in intra-muscular injections and capable to adhere safe injection practices for expected standards of NIP
  - 2 persons at the Registration Desk- skilled in screening eligibility, identify contra-indications, referring for special advices for needy persons, explaining for the consent for vaccination and electronic registration process.
  - 1 person at AEFI area : AEFI monitoring area responsible person for emergency identification and attention
  - 1 minor staff person as assistant to help the process



- Number of teams required for a hospital can vary based on the total staff number estimated to be vaccinated per day.
- The MOH office can conduct one clinic centre per day.
- 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 needs 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 the 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 organize 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 (training on this is already done 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 2<sup>nd</sup> dose vaccination or a fresh Register format can be used for the 2<sup>nd</sup> dose for the convenience. But, ask about the initial dose (1<sup>st</sup> 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 1<sup>st</sup> 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 evidence so far).
  - Take measures to follow up the 2<sup>nd</sup> dose of the vaccination using COVISHIELD vaccine.

### **Important points in eligibility screening**

For males and females:

- Check age: should be above 18 years
- Should not be suffering from acute disease condition : e.g. high fever, cough, shortness of breath, etc
- Ask severe allergic reactions (eg: anaphylaxis, any severe allergic reaction causing difficulty in breathing) to any previous injection treatment or to any vaccine received or due to any other cause previously (requiring hospitalization)
- Should not be in the quarantine period
- Should not be a COVID-19 confirmed patient (tested positive) during last 14 days
- Recent vaccination history within last 2 weeks (refer to the doctor)
- Ask whether have any bleeding disorder (as this is IM injection, small dose of anticoagulants for treatment is not a contraindication)

For females:

- Pregnancy and lactation – should not give

For the 2<sup>nd</sup> dose:

- Ask any allergic reaction to previous dose of COVID-19 (ask in the 2<sup>nd</sup> dose )
- Check the name of the 1<sup>st</sup> dose : should be the same vaccine type
- Check the date / time of the 1<sup>st</sup> dose

- All persons coming for the vaccination should screen adequately for the eligibility, contra-indications and high risk conditions should be asked before vaccination.
- 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 (Annexure 6), sex and health status should be properly completed and provided to the Epidemiology Unit/Regional Epidemiologist at the end of the day with the clinic return.
- Then register the person (electronic web based and paper based - Annexure 4) and issue “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.
- COVISHIELD vaccine vial should not shake before withdraw the vaccine dose.

- Advise to use 0.5ml AD syringes at all possible instances and carefully withdraw the correct dose (0.5ml) by keeping the upper edge of the plunger at the 0.5ml mark in the syringe without any air bubbles.
- Vaccination should be given as IM injection (advise to withdraw and vaccinate by the same person adhering to minimum handling, in order to minimize the possible contamination).
- COVISHIELD vaccine 0.5 ml IM to be given to upper arm preferably on left side.
- After withdrawing the 10<sup>th</sup> dose from the vaccine vial, using the AD syringe, if the remaining amount is adequate for an additional 0.5 ml dose, it is advised to use the 11<sup>th</sup> dose from the vaccine vial. (It is normal to remain vaccine volume after withdrawing the final dose as with the product manufacturer information leaflet). After withdrawing the final dose, the remaining volume if inadequate for one full dose (0.5 ml) should be discarded.
- After vaccination, they should be observed for a minimum of 20 minutes in the clinic for AEFI.
- All vaccination procedure and vaccine management in general should be in accordance with the National guidelines given in the Immunization Handbook (3<sup>rd</sup> 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 (3<sup>rd</sup> Edition), Epidemiology Unit, Ministry of Health.
- Any reported AEFI identified at the clinic needs 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)
- At the end of the clinic compile all the 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.
- 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).

### **Role of PDHS and RDHS on COVISHIELD vaccination campaign**

- Coordinate, monitor and evaluate all the activities related to COVISHIELD vaccination campaign within the province / district.
- Ensure smooth functioning of all the vaccine campaign related activities in the province/ district according to the guidelines issued by the Epidemiology Unit.
- Ensure the availability of a Medical Officer and adequate staff to all Immunization clinics on the campaign day/s by mobilizing staff from other health institutions within the province / district if needed.
- Ensure the availability of adequate number of trained competent persons for IM vaccination at all Immunization clinics on campaign day/s by mobilizing staff from other health institutions within the province / districts if needed.
- Ensure availability of adequate transport facilities on the campaign day/s for efficient and timely distribution of vaccines and other logistics to the clinic centers.

### **Role of Hospital Directors and Heads of Health Care Institutions**

- Coordinate, monitor and evaluate all the activities related to COVISHIELD vaccination campaign within the hospital / institution.
- Identify a focal point to work with the Regional Epidemiologist and with the Epidemiology Unit for relevant advices, submission of returns, web based data managements and other relevant communications.
- Ensure smooth functioning of all the vaccine campaign related activities in the hospital / institution according to the guidelines issued by the Epidemiology Unit.
- Ensure provision of efficient health care services for those who develop AEFI during the COVISHIELD vaccination campaign.
- Timely notification of all reported AEFI to the National AEFI surveillance programme-Epidemiology Unit.
- Assist district level health authorities to carry out the campaign by providing additional health manpower, cold chain facilities and transport facilities whenever needed.

No. 05910.....

[illegible]

[illegible]



# Clinic Vaccine Movement Register Format

Annexure 3

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							
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OPV							
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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 பதிவுலக்கம் 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 தடுப்புகருந்தேற்றிய திகதி Date of Covid 19 Vaccination				වෙනත් කරුණු குறிப்புகள் Remarks
						1 වන මානුව முதலாவது தடவை 1st Dose	2 වන මානුව இரண்டாவது தடவை 2nd Dose			
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
						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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						YYYY	YYYY	YYYY	YYYY	
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						YYYY	YYYY	YYYY	YYYY	



Institution	Immunization centre name	Serial No :
		NIC / Passport No :

### **COVID-19 vaccination**

### **கூற்றுக்கூறு சூறுகூறு சூறுகூறு / சம்மதப் படிவம் / Consent form**

..... வன மவ அடி டின லொடென COVID-19 ஸ்னன சிலெடெவ  
அவண ஸோரஹு லொ ஸூனிலவன், ஸ் சிலெடெவ அஹிவ் ஸூல விலடா ஸூனிலவன், அவண சூன அஹிலவன் ஸ்னன  
மலாஸ்பானஸே ஸோலா ஸிலெடெவன் அவஸ்பாவ ஸலலா டென லஹீ.

ஸம அவலெலய மன COVID-19 ஸ்னன லொ ஸூனிலவன் ஸிலவன வால ஸன ஸலாஹுகின அஹிலய ஸஹி  
அஹுரூலெ சிலெடெவ அவலெல ஸர ஸூனிலவன் அஹுரூல ஸ்னன லொ ஸூனிலவ ஸிலலய ஸர, ஸூறூனன ஸல  
ஸரஹீ.

அனஸன : .....

டினய : .....

.....ஆஹிய ஸான் ஸலாவிட்-19 தஹுப்பூசிலுள் ஸஹ்ஹம் தஹுப்பூசிலு ஸஹ்ஹதல்  
தலாடர்பிலு ஸேஸ்விலுள் ஸேட்கலும், அவல தலாடர்பான தஸவல்கலாஸ்பு ஸெஹ்ஹுக்கலாஸ்ஸலும், அவல  
ஸூறிலுது ஸனக்கு ஸூறனத ஸஹ்தேஸங்கலாஸுக் ஸேட்டுத் தலாஸிலுபஹுத்தலும் ஸ்னத தஹுப்பூசிலு ஸிலலயத்திலு  
ஸூருக்கும் ஸஸாதாரபு ஸணியாளர்கலால் ஸஹ்தர்பபம் வஹங்கப்பட்டது.

ஸ்னத ஸலாவிட்-19 தஹுப்பூசிலுயின் ஸூலம் ஸஹ்பஹும் ஸன்லலகல் ஸஹ்ஹம் அதன் ஸில அரிலதான ஸக்க  
விலாஸலகலா ஸன்ஸு ஸூரிலுது ஸலாண்டதன் ஸின்னர், ஸ்த தஹுப்பூசிலுயினாஸ் ஸலலுத்திலு  
ஸலாஸ்வதலா ஸூலிலு ஸுத்து, அதஹ்கான ஸம்மதத்திலா ஸத்தால் வஹங்குகிலேன்.

ஸலயலாப்பம் : .....

திலகதிலு : .....

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 : .....

# 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	
					1 <sup>st</sup> Dose <input type="checkbox"/>	2 <sup>nd</sup> Dose <input type="checkbox"/>

Age groups	Male					Total	Male					Total	Female					Total	Female					Total
	known healthy						known comorbid conditions *						known healthy						known comorbid conditions *					
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

# උපදෙස් / அறிவுறுத்தல்கள் / Instructions



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

Annexure 7

මගේ COVID-19 එන්නත් කාඩ්පත සුරැකිව තබන්න.

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 එන්නත් රේලා 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 නිලධාරී 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](http://www.epid.gov.lk)

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

නම பெயர் Name:			
ජා.නැ.අ./මගේ 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 ச.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
1 <sup>st</sup> dose			DD/MM/YYYY		
2 <sup>nd</sup> 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

# EPIDEMIOLOGY UNIT

Epid/CV/CR/21/1

## 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) <i>(Number to be vaccinated from the institution / GN area/PHM area/expected number for the clinic session)</i>	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	$F = B - (C + D)$	$C / A \times 100 \%$	$F / (B - D) \times 100 \%$	G

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

Date:.....

## Notification Form for Adverse Events Following Immunization (AEFI)

<b>Patient Information</b>						
Name:			MOH Division:			
Age: <input type="checkbox"/> <input type="checkbox"/> months/years		Sex: Male <input type="checkbox"/> Female <input type="checkbox"/>		Telephone:		
Name & address of the Parent/Guardian:						
<b>Information on the vaccine (primary suspected and other)</b>						
Vaccine (Generic Name)	Vaccine (Trade name)*	Route	Dose (1 <sup>st</sup> 2 <sup>nd</sup> 3 <sup>rd</sup> 4 <sup>th</sup> )	Batch/Lot Number	Expiry date	VVM Status (I, II, III, IV)
Diluent used: Yes <input type="checkbox"/> No <input type="checkbox"/> If "yes", Diluent batch/lot number :                      Expiry date of Diluent :						
<i>*Trade name is necessary only in private sector immunization</i>						
Place vaccine administered:					Date:	
Person vaccine administered: Doctor <input type="checkbox"/> PHNS/Nurse <input type="checkbox"/> PHM <input type="checkbox"/> PHI <input type="checkbox"/>					Time:                      am/pm	
<b>Adverse Events</b>						
<b>Local Adverse Events Requiring investigation</b>		Injection site abscess <input type="checkbox"/> BCG Lymphadenitis <input type="checkbox"/> Severe local reaction <input type="checkbox"/>				
<b>CNS Adverse Events Requiring Investigation</b>		Vaccine associated paralytic poliomyelitis <input type="checkbox"/> GBS <input type="checkbox"/> Encephalopathy <input type="checkbox"/> Encephalitis <input type="checkbox"/> Meningitis <input type="checkbox"/> Seizures Febrile <input type="checkbox"/> Seizures Afebrile <input type="checkbox"/>				
<b>Other Adverse Events Requiring Investigation</b>		Anaphylaxis <input type="checkbox"/> Persistent screaming <input type="checkbox"/> Osteitis / Osteomyelitis <input type="checkbox"/> Hypotonic Hyporesponsive Episode <input type="checkbox"/> Toxic Shock Syndrome <input type="checkbox"/>				
<b>Adverse Events Not Requiring Investigation</b>		Allergic reaction <input type="checkbox"/> Arthralgia <input type="checkbox"/> High fever (>39°C / 102°F) <input type="checkbox"/> Nodule at the injection site <input type="checkbox"/>				
<b>Other Adverse Events</b>		a) b)				
<i>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</i>						
Date & Time onset of adverse event:						
Date & Time referring to medical care :						
<b>Medical History/Other</b>				<b>Outcome</b>		
				Hospitalized: Yes No    If "Yes": Hospital:		
				BHT:                      Still in the hospital <input type="checkbox"/> Discharged <input type="checkbox"/>		
				Outcome: Recovered completely <input type="checkbox"/> Partially recovered <input type="checkbox"/> Death <input type="checkbox"/>		
<b>Reporting source</b>						
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  $>39^{\circ}\text{C}$

#### 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.