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தொலைபேசி) 0112698507 , 0112694033
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SUWASIRIPAYA
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சுகாதார அமைச்சு
Ministry of Health

මගේ අංකය)EPID/400/n-CoV/Vaccine
எனது இல)
My No.)

ඔබේ අංකය)
உமது இல)
Your No.)

දිනය)
திகதி) 2022/05/14
Date)

DDG/NHSL
All Provincial Directors of Health Services
Regional Directors of Health
Directors/ Teaching, Provincial General, General, Base hospitals

Provision of 3 doses of Covid-19 vaccination for severely immunosuppressed children 12-19 years of age with COMIRNATY - Covid 19 mRNA Vaccine (Nucleoside modified -Pfizer BNT) vaccine

A third dose of COMIRNATY Covid 19 mRNA (Nucleoside modified-Pfizer BNT) vaccination, as a primary vaccination dose will be started for children aged 12-19 years, with severely immunosuppressed. The children considered for the third dose are individuals with primary or acquired immunodeficiency states at the time of the first dose vaccination started from 01/10/2021 onwards.
Vaccination of these children with the 3rd dose will be commenced from 10/05/2022.

The conditions to be considered for children with primary or acquired immunodeficiency states at the time first dose of vaccination are as follows:

- Acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who were under treatment or within 12 months of achieving cure at the time of vaccination.

- Individuals under follow up for chronic lymphoproliferative disorders, including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia, and other plasma cell dyscrasias (Note: this list is not exhaustive).

- Adults and children aged 12 years and over with immunosuppression due to HIV/AIDS with a current CD4 count of <200 cells/µl.

- Primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/µl) or with a functional lymphocyte disorder

- Those who had received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the 24 months before vaccination.

- Those who had received a stem cell transplant more than 24 months before vaccination but had ongoing immunosuppression or graft versus host disease (GVHD).

- Persistent agammaglobulinaemia (IgG < 3g/L) due to primary immunodeficiency (e.g., common variable immunodeficiency, X-linked or autosomal recessive agammaglobulinaemia) or secondary to disease/therapy Individuals on immunosuppressive or immunomodulating therapy at the time of vaccination including:
    - Those who were receiving immunosuppressive therapy for a solid organ transplant at the time of vaccination.
    - Those who were receiving or had received in the previous 3 months targeted therapy for autoimmune diseases, such as JAK inhibitors or biologic immune modulators, including B-cell targeted therapies (including rituximab, but in this case, the recipient would be considered immunosuppressed for 6 months), T-cell co-stimulation modulators, monoclonal tumor necrosis factor inhibitors (TNFi), soluble TNF receptors, interleukin (1L)-6 receptor inhibitors., IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors. (Note: this list is not exhaustive).
    - Those who were receiving or had received immunosuppressive chemotherapy or radiotherapy for any indication in the 6 months before vaccination

Individuals with chronic immune-mediated inflammatory disease who were receiving or had received immunosuppressive therapy prior to vaccination, including:

- High dose corticosteroids (equivalent to ≥20mg prednisolone per day) for more than 10 days in the month before vaccination.
- Long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the 3 months before vaccination.
- Non-biological oral immune-modulating drugs, such as methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6- mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the 3 months before vaccination.
- Certain combination therapies at individual doses lower than above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the 3 months before vaccination Individuals who had received high dose steroids (equivalent to >40mg prednisolone per day for more than a week) for any reason in the month before vaccination.

The procedure to be followed are as follows:

- An in-charge Paediatrician / Physician needs to be identified for the vaccination centre by the hospital Director to endorse the eligibility of vaccination and closely monitor the vaccination process.
- Children with underlying medical conditions with severe immunosuppression should be identified and a specialist Paediatrician or Physician should advise whether the child or young persons are meeting with the eligibility criteria and on the timing of the third dose.
- The recommended time will be at least 8 weeks from the last dose to be completed 3 primary doses.
- It is advised to complete the 2nd dose for those who have not received and complete the 3rd dose for those who have received the 2nd dose.

- All Consultant Paediatricians, Physicians and Consultants in other relevant specialities are advised to identify eligible children and young persons to complete the primary vaccination at the earliest to protect them early.
- Regional Epidemiologists, MO/MCH, MOOH and all field level public health staff are advised to refer eligible children with specified conditions mentioned above to hospitals where vaccination centres are functioning.
- Above advise is applicable to identify children in the community, in child disability homes and probational institutions in their respective areas and refer eligible individuals to the nearest Covid-19 vaccination centre in the nearest hospital for the vaccination.
- All hospitals above the level of Base hospitals where Consultants are available will be considered to conduct vaccination centres.
- These recommendations are given based on the risks of developing severe COVID-19 complications clearly outweigh the potential adverse events of the vaccine (AEFI) and requirement of early protection of children with severe immunosuppression.
- Directors in hospital are advised to make vaccine estimates in advance based on the recommendations of relevant Consultants in the hospital.
- It is advised to request minimum required vaccine stocks with the plan to get down additional stocks as with the requirement.
- The vaccines taken out from the Ultra-Low Temperature (ULT) freezer (from -70^{0}C) will not be able to re-freeze in ULT freezer.
- Vaccines supplied to the hospital should be stored only in the 2^0-8^{0}C in the Ice Lined Refrigerator (ILR) adhering to the national vaccine storage guidelines issued by the Epidemiology Unit. Even though hospital has ULT freezer (-70^{0}C) , Comirnaty-Pfizer vaccine should not be stored at ULT freezer as it is transported in 2^0-8^{0}C.
- Advised strictly to follow the COMIRNATY, Covid 19 mRNA (Nucleoside modified -Pfizer BNT) vaccination guidelines issued on 05/07/2021 by the Epidemiology Unit, Ministry of Health can find in www.epid.gov.lk) for vaccine storage, vial preparation, administration, prepare, follow up and surveillance of Adverse Events Following Immunization(AEFI).
- Consent form for children is attached herewith and it needs to be completed and signed by the guardian before vaccination. (Annexure 1)
- Each vial of COMIRNATY, Covid 19 mRNA (Nucleoside modified -Pfizer BNT) has 6 doses to vaccinate (follow the guidelines issued on 05/07/2021 by the Epidemiology Unit, Ministry of Health.
- Need to maintain regular communications with the Consultant Epidemiologists at the Epidemiology Unit and Regional Epidemiologists in respective districts on the vaccination process to receive required vaccine supply and technical guidance in achieving maximum coverage of eligible children for their protection from Covid-19.
- Directors are responsible for the vaccination clinic organization with Consultant Paediatricians, Physicians and other relevant specialities.
    - Adhere to infection prevention and control measures.
    - Seating arrangements needs to be planned for children and accompanying care givers.
    - More than one registration desks should be arranged for registration procedure to prevent standing time
    - Identify vaccination in-charge focal point in the hospital, preferably a Consultant Paediatrician/Physician to get approval and advices for the vaccination
    - Need to deploy adequately trained and competent staff for vaccination (vaccine vial preparation and vaccination)
    - Identify vaccination data entry team in the hospital to enter vaccination data in to the vaccine tracker.

- The individual vaccination data should be entered in to the web based "Vaccine tracker" system.
    - National Identity Card (NIC) number to be entered to the vaccine tracker
        - If the child is 16 years of age and above and having a NIC

- Those who are not having a NIC and below 16 years advised to enter the parent/guardian NIC,enter the mother/father/guardian NIC number followed by a hyphen "-" and then "C" to indicate the "child" and then order of the child in the family.eg- If the child is the second child of the mother, UID is: 778260893V-C2 or 197782600893-C2

➢ At the end of each day, total number vaccinated needs to be provided to the Epidemiology Unit, copying to Regional Epidemiologist in respective districts.

If you need any further clarification, please contact the Chief Epidemiologist of the Epidemiology Unit. Additional resource materials are available in

Thank you,

Dr. Asela Gunawardena
Director General of Health Services

Dr. ASELA GUNAWARDENA
Director General of Health Services
Ministry of Health
"Suwasiripaya"
385, Rev. Baddegama Wimalawansa Thero Mawatha
Colombo 10.

Cc:

i. Hon. Minister of Health
ii. Secretary, Ministry of Health
iii. Additional Secretary (Public Health Services)
iv. Deputy Director General (PHS) -1
v. Deputy Director General (MS)
vi. Chief Epidemiologist
vii. Director/MCH/FHB
viii. Presidents/ College of Paediatricians, Physicians, Internal Medicine
ix. Provincial and district CCPs
x. Regional Epidemiologists
xi. MOO/MCH

Annexure 1

No :-EPID/400/n-Cov/Vaccine

නිදන්ගත රෝගී තත්ත්වයෙන් පෙළෙන දරුවන් සඳහා කොවිඩ් 19 - ෆයිසර් එන්නත ලබා දීමට කැමැත්ත ප්‍රකාශ කිරීමේ පත්‍රිකාව

நீண்டகால நோயைக்கொண்ட சிறுவர்களுக்கு கோவிட் 19 பைசர் தடுப்பூசியை வழங்குவதற்கான சம்மதப்படிவம்

Consent Form for Pfizer Vaccination for Immunization of children with underlying medical conditions against COVID-19

මාගේ දරුවා .... නමැති නිදන්ගත රෝගී තත්ත්වයෙන් පෙළෙන බැවින්, කොවිඩ් 19 රෝගය වැළඳුනහොත් සංකූලතා ඇතිවීමේ වැඩි හැකියාවක් ඇති බව හා ෆයිසර් එන්නත ලබා ගැනීමෙන් කොවිඩ් 19 රෝගයෙන් සැලකිය යුතු ආරක්ෂාවක් සැලසෙන බව දැනගතිමි.

එබැවින්, කොවිඩ් 19 - ෆයිසර් එන්නත මාගේ දරුවාට ලබා දීමට මෙයින් කැමැත්ත ප්‍රකාශ කරමි.

எனது பிள்ளை .... நீண்டகால நோயினால் பாதிக்கப்பட்டிருப்பதால், கோவிட் தொற்றானது எனது பிள்ளைக்கு சிக்கல்களை தோற்றுவிப்பதற்கான சாத்தியக்கூறுகள் இருப்பதனால் பைசர் தடுப்பூசியானது கணிசமான பாதுகாப்பை அளிக்கின்றது.

இதனால் நான் என்னுடைய பிள்ளைக்கு பைசர் தடுப்பூசி வழங்குவதற்கு சம்மதிக்கின்றேன்.

As my child suffers from a chronic disease called ...., I learned that having COVID – 19 is more likely to cause complications and getting the Pfizer vaccine provides significant protections against COVID – 19.

Therefore, I hereby express my consent to vaccinate my child with the Pfizer – COVID – 19 vaccine.

1. දරුවාගේ නම
   பிள்ளையின் பெயர்
   Name of Child

   a) වයස/வயது /Age ______ Years

   b) ලිපිනය/முகவரி /Address

2. මව/පියා/භාරකරුගේ නම
   தாய்/தந்தை/ பாதுகாவலரின் பெயர்
   Mother/Father/Guardian's Name

   a) ජා.හැ.ප. අංකය/தே.அ.அ.இல. / NIC ______ දරුවා/ பிள்ளை/ Child

   b) දු.ක.අංකය/தொலைபேசி இல./ Contact No

....
අත්සන/ கையொப்பம் / Signature

විශේෂඥ මතය
விசேட வைத்திய நிபுணருடைய பரிந்துரை
Specialist Recommendation

Clinic No :-..

....
Signature

Date :- .... / ....../.............

ක්‍රියා පටිපාටිය/ **செயன்முறை /Process**

නිර්දේශය **Recommendation** பரிந்துரை → ලියාපදිංචිය **Registration** பதிவுகள் → එන්නත්කරණය **Vaccination** தடுப்பூசியேற்றல் → පසුවිපරම **Observation** அவதானிப்பு