FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT COMIRNATY VACCINE

Q1: Which COVID-19 vaccine and what indication(s) is being registered?
A1: The Drug Control Authority (DCA) in its 352nd meeting has granted Pfizer (M) Sdn. Bhd.'s COMIRNATY Concentrate for Dispersion for Injection (Belgium) a CONDITIONAL REGISTRATION on 8th January 2021. Subsequently, a second source of the same vaccine (Germany) was also granted conditional registration in the 354th DCA meeting on 2nd March 2021. COMIRNATY contains 30 mcg of nucleoside-modified mRNA strand formulated as an RNA-lipid nanoparticle that encodes the viral spike (S) protein of SARS-CoV-2.

On 15th June 2021, the DCA in its 359th meeting has approved the use of this vaccine to individuals aged 12 years and above, an extension of the previous conditional registration approved indication to individuals aged 18 years and above.

On 8th October 2021, the DCA in its 365th meeting concluded that a booster dose of COMIRNATY may be administered at least 6 months after the second dose in individuals aged 18 years and above. In addition, a third dose may be given at least 28 days after the second dose to individuals aged 12 years and above who are severely immunocompromised.

On 6th January 2022, the DCA in its 368th meeting approved a new formulation (Tris/Sucrose formulation) for COMIRNATY 30 mcg and 10 mcg. COMIRNATY 10 mcg is approved solely to be used in children aged 5 to 11 years.

Q2: What are the conditions of the registration?
A2: Since the application was based on rolling submission of the latest data, the Product Registration Holder (PRH) will need to ensure all outstanding documents are submitted and deemed satisfactory by NPRA according to the timeline given.

Apart from that, the PRH is required to monitor the safety profile of the registered vaccine and inform NPRA as soon as possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP) as well as submitting Monthly Safety Summary Report to NPRA.

The validity of this conditional approval is one (1) year. During this period, the DCA will periodically be updated with all necessary information related to the quality, safety and efficacy of this vaccine. The registration can be revoked if the conditions are not fulfilled by the PRH or if the benefit over risk of the vaccine is no longer deemed beneficial.

Q3: Why is COMIRNATY granted a conditional registration?
A3: Clinical studies for COMIRNATY are currently still on-going. The current final analysis provided clearly show a positive benefit over risk and hence making this available to the nation. However, further monitoring of the efficacy and safety will be needed in order to ensure that the benefit over risk of this vaccine remains positive.

Q4: Who can be given COMIRNATY?
A4: COMIRNATY is indicated for the active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals **5 years of age and above**.

The use of this vaccine should be in accordance with the recommendations by the Ministry of Health Malaysia.

For children aged 5 to 11 years old, a different concentration of the vaccine **MUST** be used. Please refer to Q11.

Q5: Who may be given COMIRNATY?
A5: At the moment, there are limited clinical evidence to support vaccination in these population: immunocompromised, autoimmune disorders, pregnant or breastfeeding women. However, the decision to use the vaccine in these population should be made in close consultation with a healthcare professional after considering the benefits and risks.

Q6: Who cannot be given COMIRNATY?
A6: COMIRNATY should not be given to individuals who are known to have allergic reactions to any of the ingredients in the vaccine (mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate),2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide,1,2-Distearoyl-sn-glycero-3- phosphocholine, and cholesterol), sucrose, buffering agents (PURPLE CAP: potassium chloride, potassium dihydrogen phosphate, sodium chloride and disodium phosphate dihydrate) OR (GREY or ORANGE CAP: trometamol and trometamol hydrochloride).

The second dose of the vaccine **should not be given** to individuals who had a severe allergic reaction after the first dose of this vaccine.

Please consult your doctor if you:
- have any form of allergies, bleeding disorder, or taking any blood thinning medications
- recently or currently receiving treatment for cancer, organ or stem cell transplantation
- had a previous history of COVID-19 infection, had previously received another COVID-19 vaccine (whether during an immunisation program or was involved as a subject in a COVID-19 clinical study) or previously received passive antibodies therapy for COVID-19

Q7: How COMIRNATY is given?
A7: For individual aged 12 years and above: As a primary course, COMIRNATY should be injected into the deltoid muscle of the upper arm as a course of 2 doses (0.3mL each) 21 days apart using COMIRNATY vial with a PURPLE or a GREY vial cap . A booster dose of COMIRNATY may be given approximately 6 months after the second dose in individuals aged 18 years and above. The need for when and who to be given the booster dose will be determined by local recommendation.

Severely immunocompromised individuals aged 12 years and above may receive a third dose (defined as within the primary course) of COMIRNATY at least 28 days after the second dose.

For individuals aged 5 to 11 years old: COMIRNATY should be injected into the deltoid muscle of the upper arm as a course of 2 doses (0.2mL each) with a minimum of 21 days apart using COMIRNATY vial with an ORANGE vial cap. The COVID-19 Immunisation Task Force (CITF) has determined that an interval of 8 weeks to be given in these population.

Q8: How well does COMIRNATY prevent COVID-19?

A8: In the final analysis of the phase III clinical trial, the vaccine was 95% effective in preventing symptomatic COVID-19 disease following completion of 2 doses of the vaccine regime.

Q9: How long will COMIRNATY provide protection?

A9: As the clinical trial is still currently ongoing, no data is available to inform about the duration of protection that the vaccine will provide. This however will be made known once updated data is available.

Q10: Can people who have already had COVID-19 get COMIRNATY?

A10: Available data indicate that COMIRNATY is safe when given in people with evidence of prior COVID-19 disease. Since previously infected individuals can be at risk of COVID-19 (i.e. reinfection), vaccination may be offered to them. The need for when the vaccination after a SARS CoV-2 infection to be given will be determined by CITF.

Q11: Can children receive COMIRNATY?

A11: Currently in Malaysia, the vaccine is indicated for individuals aged 5 years and above. This is because there is limited data to determine the effectiveness and safety of this vaccine in those under 5 years old. Hence children below the age of 5 should not take the vaccine until further data is made available.

For children aged 5 to 11 years old, a new formulation with different concentration **MUST** be used. This is visibly identified by an ORANGE vial label and vial cap.

Q12: What are the side effects of COMIRNATY?

A12: COMIRNATY can cause the following side effects:

- Very common side effects (may affect more than 1 in 10 people): injection site pain and/or swelling, tiredness, headache, muscle pain, joint pain, diarrhoea, chills and fever (more frequently observed after the second dose compared to the first dose).
- Common side effects (may affect up to 1 in 10 people): injection site redness (very common in children 5 to 11 years of age), vomiting and nausea.
- Uncommon side effects (may affect up to 1 in 100 people): enlarged lymph nodes (more frequently observed after the booster dose), feeling unwell, arm pain, sleeping

difficulty, injection site itching, allergic reactions such as rash, itching, hives or swelling, feeling weak or lack of energy/sleepy, decreased appetite, excessive sweating and night sweats.

- Rare side effects (may affect up to 1 in 1,000 people): temporary one-sided facial drooping.
- Very rare side effects (may affect up to 1 in 10,000 people): inflammation of the heart muscle (myocarditis) (higher in younger males) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain.
- Not known side effects (frequency cannot be estimated from the available data): severe allergic reaction, palpitations or chest pain, extensive swelling of the vaccinated limb, swelling of the face (may occur in vaccine recipients who have had facial fillers), a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme).
- There is a remote chance that the vaccine could cause a severe allergic reaction even though the causal relationship has not been ascertained yet. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. Signs of a severe allergic reaction can include difficulty in breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body or dizziness and weakness.
  Recipient will be monitored for 15-30 minutes after the administration of this vaccine at the vaccination centre.

During marketing of COMIRNATY in Malaysia, NPRA will monitor its use to ensure effectiveness and safety. Please inform your healthcare providers or report any side effects to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Q13: What should I do after I am vaccinated?

A13: All individuals should continue to follow the preventive measures as recommended. Practice the 3Ws (**Wash**, **Wear**, **Warn**), avoid the 3Cs (**Crowded** space, **Confined** space, **Close** conversation), get vaccinated and boosted and practice **TRIIS** (**T**est, **R**eport, **I**solate, **I**nform and **S**eek Treatment).

Q14: What's the difference(s) between the 4 conditionally registered COMIRNATY in Malaysia?

Approved products	COMIRNATY Concentrate for Dispersion for Injection **MAL21016022AZ (1st source)**	COMIRNATY Concentrate for Dispersion for Injection **MAL21036039ASZ (2nd source)**	COMIRNATY (Tris/Sucrose) 30 mcg Solution for Injection **MAL22016036AZ**	COMIRNATY 10mcg Concentrate for Dispersion for Injection **MAL22016037AZ**
Vial Cap Colour				
Population indicated	12 years old and above			5 to 11 years old
Volume (dose) to be administered	0.3ml (30 mcg)			0.2ml (10 mcg)
Dilution prior to usage	Required		**NOT** required	Required
Number of doses per vial	6		6	10
Packing size (no. of vials)	195		10	10
Formulation	Current		New	New
Currently being used in Malaysia?	Yes		Not at the moment	Yes

For further information regarding COMIRNATY, please refer to the Package Insert and Patient Information Leaflet.

COMIRNATY Concentrate for Dispersion for Injection (MAL21016022AZ)
(https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21016022AZ)
COMIRNATY Concentrate for Dispersion for Injection (MAL21036039ASZ)
https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21036039ASZ
COMIRNATY 10mcg Concentrate for Dispersion for Injection MAL22016037AZ
(https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL22016037AZ)
COMIRNATY (Tris/Sucrose) 30 mcg Solution for Injection MAL22016036AZ
(https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL22016036AZ)

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