The Special approval for Spikevax during public health emergency or pandemic situation by the Brunei Darussalam Medicines Control Authority (BDMCA) is for use and supply as directed by the Government of Brunei Darussalam.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Spikevax dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multidose vial that contains 10 doses of 0.5 mL each or a maximum of 20 doses of 0.25 mL each.

One dose (0.5 mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).

One dose (0.25 mL) contains 50 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).

Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Dispersion for injection
White to off white dispersion (pH: 7.0 – 8.0).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

4.2 Posology and method of administration

Posology

Primary series
Individuals 18 years of age and older
Spikevax is administered as a course of 2 (two) 100 microgram doses (0.5 mL each). It is recommended to administer the second dose 28 days after the first dose (see sections 4.4 and 5.1).

Booster dose
Individuals 18 years of age and older
A booster dose (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) of Spikevax may be administered intramuscularly at least 6 months after the second dose in individuals 18 years of age and older. The decision when and for whom to implement a third dose of Spikevax should be made based on available vaccine effectiveness data, taking into account limited safety data (see sections 4.4 and 5.1).

The interchangeability of Spikevax with other COVID-19 vaccines to complete the primary vaccination course or the booster dose (0.25 mL, 50 micrograms) has not been established. Individuals who have received one dose of Spikevax (0.5 mL, 100 micrograms) should receive a second dose of Spikevax (0.5 mL, 100 micrograms) to complete the primary vaccination course.

Severely immunocompromised aged 12 years and older
A third dose (0.5 mL, 100 micrograms) may be given at least 28 days after the second dose to individuals who are severely immunocompromised (see section 4.4).

Paediatric population
The safety and efficacy of Spikevax in children and adolescents less than 18 years of age have not yet been established. No data are available.

Elderly population
No dosage adjustment is required in elderly individuals ≥65 years of age.

Method of administration

The vaccine should be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm.

Do not administer this vaccine intravascularly, subcutaneously or intradermally.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering the vaccine, see section 4.4.

For instructions regarding thawing, handling and disposal of the vaccine, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Hypersensitivity and anaphylaxis

Anaphylaxis has been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination. The second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Spikevax.

Myocarditis and pericarditis

Very rare cases of myocarditis and pericarditis have been observed following vaccination with Spikevax. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.

Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

The risk of myocarditis after a third dose (0.5 mL, 100 micrograms) or booster dose (0.25 mL, 50 micrograms) of Spikevax has not yet been characterised.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

The efficacy and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Spikevax may be lower in immunocompromised individuals.

The recommendation to consider a third dose (0.5 mL) in severely immunocompromised individuals (see section 4.2) is based on limited serological evidence with patients who are immunocompromised after solid organ transplantation.

Duration of protection

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.

Limitations of vaccine effectiveness

Individuals may not be fully protected until 14 days after their second dose. As with all vaccines, vaccination with Spikevax may not protect all vaccine recipients.

Excipients with known effect

Sodium
This vaccine contains less than 1 mmol sodium (23 mg) per 0.5 mL dose, that is to say, essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concomitant administration of Spikevax with other vaccines has not been studied.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited experience with use of Spikevax in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). Administration of Spikevax in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Breast-feeding

It is unknown whether Spikevax is excreted in human milk.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

4.7 Effects on ability to drive and use machines

Spikevax has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

The safety of Spikevax was evaluated in an ongoing Phase 3 randomised, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Spikevax (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older.

The most frequently reported adverse reactions were pain at the injection site (92%), fatigue (70%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23%), axillary swelling/tenderness (19.8%), fever (15.5%), injection site swelling (14.7%) and redness (10%). Adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.

Overall, there was a higher incidence of some adverse reactions in younger age groups: the incidence of axillary swelling/tenderness, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting and fever was higher in adults aged 18 to < 65 years than in those aged 65 years and above. Local and systemic adverse reactions were more frequently reported after Dose 2 than after Dose 1.

Participants 18 years of age and older (booster dose)

The safety, reactogenicity, and immunogenicity of a booster dose of Spikevax are evaluated in an ongoing Phase 2, randomised, observer-blind, placebo-controlled, dose-confirmation study in participants 18 years of age and older (NCT04405076). In this study, 198 participants received two doses (0.5 mL, 100 micrograms 1 month apart) of the Spikevax vaccine primary series. In an open-label phase of this study, 167 of those participants received a single booster dose (0.25 mL, 50 micrograms) at least 6 months after receiving the second dose of the primary series. The solicited adverse reaction profile for the booster dose (0.25 mL, 50 micrograms) was similar to that after the second dose in the primary series.

Tabulated list of adverse reactions

The safety profile presented below is based on data generated in a placebo-controlled clinical study on 30,351 adults ≥ 18 years of age.

Adverse reactions reported are listed according to the following frequency convention:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness (Table 1).

Table 1: Adverse reactions from Spikevax clinical trials and post-authorisation experience in individuals 18 years of age and older

MedDRA System Organ Class	**Frequency**	**Adverse reaction(s)**
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness
	Rare	Acute peripheral facial paralysis** Hypoaesthesia
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash

		Delayed injection site reaction
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site. Other lymph nodes (e.g., cervical, supraclavicular) were affected in some cases.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the Spikevax group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination

The reactogenicity and safety profile in 343 subjects receiving Spikevax, that were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system through the Adverse Event Following Immunisation (AEFI) Reporting Form available from the National Adverse Drug Reaction Monitoring Centre (NADRMC) and the nearest government pharmacy facility (hospital/health centre) and include batch/Lot number if available. The completed AEFI Reporting Form should be returned to the nearest government pharmacy facility (hospital/health centre) or e-mailed at nadrmc.dps@moh.gov.bn.

4.9 Overdose

No case of overdose has been reported.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccine, other viral vaccines, ATC code: J07BX03

Mechanism of action
Spikevax contains mRNA encapsulated in lipid nanoparticles. The mRNA encodes for the full-length SARS-CoV-2 spike protein modified with 2 proline substitutions within the heptad repeat 1 domain (S-2P) to stabilise the spike protein into a prefusion conformation. After intramuscular injection, cells at the injection site and the draining lymph nodes take up the lipid nanoparticle, effectively delivering the mRNA sequence into cells for translation into viral protein. The delivered mRNA does not enter the cellular nucleus or interact with the genome, is non-replicating, and is expressed transiently mainly by dendritic cells and subcapsular sinus macrophages. The expressed, membrane-bound spike protein of SARS-CoV-2 is then recognised by immune cells as a foreign antigen. This elicits both T-cell and B-cell responses to generate neutralising antibodies, which may contribute to protection against COVID-19.

Clinical efficacy in adults
The adult study was a randomised, placebo-controlled, observer-blind Phase 3 clinical study (NCT04470427) that excluded individuals who were immunocompromised or had received immunosuppressants within 6 months, as well as participants who were pregnant, or with a known history of SARS-CoV-2 infection. Participants with stable HIV disease were not excluded. Influenza

vaccines could be administered 14 days before or 14 days after any dose of Spikevax. Participants were also required to observe a minimum interval of 3 months after receipt of blood/plasma products or immunoglobulins prior to the study in order to receive either placebo or Spikevax.

A total of 30,351 subjects were followed for a median of 92 days (range: 1-122) for the development of COVID-19 disease.

The primary efficacy analysis population (referred to as the Per Protocol Set or PPS), included 28,207 subjects who received either Spikevax (n=14,134) or placebo (n=14,073) and had a negative baseline SARS-CoV-2 status. The PPS study population included 47.4% female, 52.6% male, 79.5% White, 9.7% African American, 4.6% Asian, and 6.2% other. 19.7% of participants identified as Hispanic or Latino. The median age of subjects was 53 years (range 18-94). A dosing window of –7 to +14 days for administration of the second dose (scheduled at day 29) was allowed for inclusion in the PPS. 98% of vaccine recipients received the second dose 25 days to 35 days after dose 1 (corresponding to -3 to +7 days around the interval of 28 days).

COVID-19 cases were confirmed by Reverse Transcriptase Polymerase Chain Reaction (RT PCR) and by a Clinical Adjudication Committee. Vaccine efficacy overall and by key age groups are presented in Table 2.

Table 2: Vaccine Efficacy Analysis: confirmed COVID-19[#] regardless of severity starting 14 days after the 2nd dose – Per-Protocol Set

Age Group (Years)	Spikevax			Placebo			
	Subjects N	COVID-19 Cases n	Incidence Rate of COVID-19 per 1,000 Person-Years	Subjects N	COVID-19 Cases n	Incidence Rate of COVID-19 per 1,000 Person-Years	% Vaccine Efficacy (95% CI)*
Overall (≥18)	14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)**
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)
≥65 to <75	2,953	4	5.586	2,864	22	31.744	82.4% (48.9, 93.9)
≥75	630	0	0	688	7	41.968	100% (NE, 100)

[#]COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least 2 systemic symptoms or 1 respiratory symptom. Cases starting 14 days after the 2nd dose.
*Vaccine efficacy and 95% confidence interval (CI) from the stratified Cox proportional hazard model
** CI not adjusted for multiplicity. Multiplicity adjusted statistical analyses were carried out in an interim analysis based on less COVID-19 cases, not reported here.

Among all subjects in the PPS, no cases of severe COVID-19 were reported in the vaccine group compared with 30 of 185 (16%) cases reported in the placebo group. Of the 30 participants with severe disease, 9 were hospitalised, 2 of which were admitted to an intensive care unit. The majority of the remaining severe cases fulfilled only the oxygen saturation (SpO2) criterion for severe disease (≤ 93% on room air).

The vaccine efficacy of Spikevax to prevent COVID-19, regardless of prior SARS-CoV-2 infection (determined by baseline serology and nasopharyngeal swab sample testing) from 14 days after Dose 2 was 93.6% (95% confidence interval 88.6, 96.5%).

Additionally, subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across genders, ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

Immunogenicity in participants 18 years of age and older – after booster dose (0.25 mL, 50 micrograms)
The safety, reactogenicity, and immunogenicity of a booster dose of Spikevax are evaluated in an ongoing Phase 2, randomised, observer-blind, placebo-controlled, dose-confirmation study in participants 18 years of age and older (NCT04405076). In this study, 198 participants received two doses (0.5 mL, 100 micrograms 1 month apart) of the Spikevax vaccine as primary series. In an open-label phase, 149 of those participants (Per-Protocol Set) received a single booster dose (0.25 mL, 50 micrograms) at least 6 months after receiving the second dose in the primary series. A single booster dose (0.25 mL, 50 micrograms) was shown to result in a geometric mean fold rise (GMFR) of 12.99 (95% CI: 11.04, 15.29) in neutralising antibodies from pre-booster compared to 28 days after the booster dose. The GMFR in neutralising antibodies was 1.53 (95% CI: 1.32, 1.77) when compared 28 days post dose 2 (primary series) to 28 days after the booster dose.

Elderly population
Spikevax was assessed in individuals 18 years of age and older, including 3,768 subjects 65 years of age and older. The efficacy of Spikevax was consistent between elderly (≥65 years) and younger adult subjects (18-64 years).

Paediatric population
The European Medicines Agency has deferred the obligation to submit the results of studies with the Spikevax in one or more subsets of the paediatric population in prevention of COVID-19 (see section 4.2 for information on paediatric use).

Conditional approval
This medicinal product has been authorised under a so-called 'conditional approval' scheme. This means that further evidence on this medicinal product is awaited. The European Medicines Agency will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproductive and developmental toxicity.

General toxicity
General toxicity studies were conducted in rats (intramuscularly receiving up to 4 doses exceeding the human dose once every 2 weeks). Transient and reversible injection site oedema and erythema and transient and reversible changes in laboratory tests (including increases in eosinophils, activated partial thromboplastin time, and fibrinogen) were observed. Results suggests the toxicity potential to humans is low.

Genotoxicity/carcinogenicity
In vitro and in vivo genotoxicity studies were conducted with the novel lipid component SM-102 of the vaccine. Results suggests the genotoxicity potential to humans is very low. Carcinogenicity studies were not performed.

Reproductive toxicity
In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of mRNA (100 micrograms) and other ingredients included in a single human dose of Spikevax was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. SARS-CoV-2 antibody responses were present in maternal animals from prior to mating to the end of the study on lactation day 21 as well as in foetuses and

offspring. There were no vaccine-related adverse effects on female fertility, pregnancy, embryo foetal or offspring development or postnatal development. No data are available of Spikevax vaccine placental transfer or excretion in milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lipid SM-102 (heptadecan-9-yl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate)
Cholesterol
1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG)
Trometamol
Trometamol hydrochloride
Acetic acid
Sodium acetate trihydrate
Sucrose
Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products or diluted.

6.3 Shelf life

Unopened vial
9 months at -25ºC to -15ºC.

The unopened vaccine may be stored refrigerated at 2°C to 8°C, protected from light, for maximum 30 days. Within this period, up to 12 hours may be used for transportation.

Once thawed the vaccine should not be re-frozen.

The unopened vaccine may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions.

Punctured vial
Chemical and physical in-use stability has been demonstrated for 12 hours at 2°C to 25ºC after initial puncture (within the allowed use period of 30 days at 2°C to 8ºC and 24 hours at 8°C to 25ºC). From a microbiological point of view, the product should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Store frozen between -25ºC to -15ºC.
Store in the original carton to protect from light.
Do not store on dry ice or below -50ºC.
For storage conditions after thawing and first opening see section 6.3.

Transportation of thawed vials in liquid state at 2°C to 8°C
If transport at -50°C to -15°C is not feasible, available data support transportation of one or more thawed vials in liquid state for up to 12 hours at 2°C to 8°C (within the 30 days shelf life at 2°C to 8°C). Once thawed and transported in liquid state at 2°C to 8°C, vials should not be refrozen and should be stored at 2°C to 8°C until use.

6.5 Nature and contents of container

5 mL dispersion in a vial (type 1 or type 1 equivalent glass) with a stopper (chlorobutyl rubber) and a flip-off plastic cap with seal (aluminium seal).

Each vial contains 5 mL.

Pack size: 10 multidose vials

6.6 Special precautions for disposal and other handling

The vaccine should be prepared and administered by a trained healthcare professional using aseptic techniques to ensure sterility of the dispersion.

The vaccine comes ready to use once thawed.

Do not shake or dilute. Swirl the vial gently after thawing and before each withdrawal.

Spikevax vials are multidose.

Ten (10) doses (of 0.5 mL each) or a maximum of twenty (20) doses (of 0.25 mL each) can be withdrawn from each vial.

Pierce the stopper preferably at a different site each time. Do not puncture the vial more than 20 times.

An additional overfill is included in each vial to ensure that 10 doses of 0.5 mL or a maximum of 20 doses of 0.25 mL can be delivered.

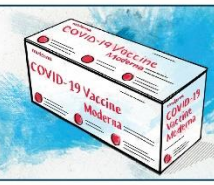
Thawed vials and filled syringes can be handled in room light conditions.

Frozen Storage

Store frozen between –25° to –15°C

Do not store on dry ice or below -50°C

Store in the original carton to protect from light.



Thaw Each Vial Before Use

Vial images for illustrative purposes only

2 hours and 30 minutes in refrigerator

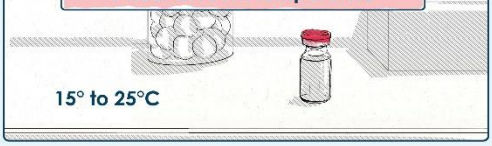
2° to 8°C
(within the 30 days shelf life at 2° to 8°C)

Let vial sit at room temperature for 15 minutes before administering

OR

1 hour at room temperature

15° to 25°C



Instructions Once Thawed

Unpunctured Vial

Maximum times

30 days — Refrigerator
2° to 8°C

24 hours — Cool storage up to room temperature
8° to 25°C

After first dose has been withdrawn

Maximum time

12 hours — Refrigerator or room temperature

Vial should be held between 2° to 25°C. Record the date and time of discard on the vial label.

Discard punctured vial after 12 hours.

Withdraw each dose of vaccine from the vial using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another. **The dose in the syringe should be used immediately.**

Once the vial has been punctured to withdraw the initial dose, the vaccine should be used immediately and be discarded after 12 hours.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

NEVER **refreeze thawed vaccine**

Administration

Swirl vial gently after thawing and before each withdrawal.
The vaccine comes ready to use once thawed. **Do not shake or dilute.**

Prior to injection, inspect each dose to:

Confirm liquid is **white to off-white** in colour in both vial and syringe.

Verify syringe volume.

The vaccine may contain white or translucent product-related particulates.

If dosage is incorrect, or discolouration and other particulate matter is present, do not administer the vaccine.

7. PRODUCT OWNER

Moderna Switzerland GmbH
Peter Merian-Weg 10
4052 Basel
Switzerland

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 April 2021

9. DATE OF REVISION OF THE TEXT

5 March 2022

CONFIDENTIAL

For national level office use only
BRN: _____ Initial / Follow- up

Ministry of Health, Brunei Darussalam

ADVERSE EVENT FOLLOWING IMMUNISATION (AEFI) REPORTING FORM

Please report **all** adverse events following immunisation. Do not hesitate to report if some details are not known. **MANDATORY FIELDS** are marked with *. **Identities of reporter and patient** will be kept confidential.

(1) PATIENT *

Patient name: _____ **Patient Address:** _____ **Telephone:** _____

Date of birth:_____ **Weight, if known (kg):** ___ **Gender:** ☐ **M** ☐ **F** **Pregnant** ☐ **Lactating** ☐ **Medical record no. / BruHims no.:**_____

Identity card no.:_____ **Nationality:** _____ **Ethnic group:** ☐ Malay ☐ Chinese ☐ Other (please specify):_____

(2) ADVERSE EVENT *

Serious: ☐ Yes ☐ No ***If yes (please tick all that apply):*** ☐ Death ☐ Life threatening ☐ Congenital abnormality ☐ Hospitalisation ☐ Disability ☐ Medically significant (please specify): _____

Adverse event(s) (please tick all that apply):

- ☐ Severe local reaction
  - ○ *>3days* ○ *Beyond nearest joint*
- ☐ Seizures
  - ○ *Febrile* ○ *Afebrile*
- ☐ Abscess
- ☐ Sepsis
- ☐ Encephalopathy
- ☐ Toxic shock syndrome
- ☐ Thrombocytopenia
- ☐ Anaphylaxis
- ☐ Fever≥38°C
- ☐ Others (please specify): _____

Date & Time AEFI started: _____ ☐☐ Hr ☐☐ Min

Treatment of AEFI: ☐ *Yes* ☐ *No* ***If yes*** (please specify): _____

Adverse event(s) of special interest (AESI) following Covid-19 vaccination (please tick all that apply):

- ☐ Acute aseptic arthritis
- ☐ Acute cardiovascular injury
- ☐ Acute disseminated encephalomyelitis
- ☐ Acute liver injury
- ☐ Acute kidney injury
- ☐ Acute respiratory distress syndrome *(Microangiopathy, Heart Failure, Stress cardiomyopathy, Coronary Artery disease, Arrhythmia, Myocarditis)*
- ☐ Anaphylaxis
- ☐ Anosmia, ageusia
- ☐ Chilblain-like lesions
- ☐ Coagulation disorder *(Thromboembolism, Haemorrhage)*
- ☐ Enhanced disease following immunisation
- ☐ Erythema multiforme
- ☐ Generalised convulsion
- ☐ Guillain Barre Syndrome
- ☐ Meningoencephalitis
- ☐ Multisystem inflammatory syndrome in children
- ☐ Single Organ Cutaneous Vasculitis
- ☐ Thrombocytopenia
- ☐ Others (please specify): _____

Date & Time AESI started: _____ ☐☐ Hr ☐☐ Min

Treatment of AESI: ☐ *Yes* ☐ *No* ***If yes*** (please specify): _____

Outcome: ☐ Recovered ☐ Recovering ☐ Recovered with sequelae ☐ Not recovered ☐ Unknown ☐ Died (Date of Death): _____

☐ *Autopsy done:* ☐ *Yes* ☐ *No* ☐ *Unknown*

(3) SUSPECTED VACCINE *

Health facility (place vaccine administered): _____

Vaccine							Diluent (if applicable)			
Vaccine brand name, manufacturer & strength	**Date of vaccination**	**Time of vaccination**	**Route**	**Dose (1ST, 2ND, etc)**	**Batch/ Lot number**	**Expiry date**	**Name**	**Batch/ Lot number**	**Expiry date**	**Date and time of reconstitution**
1.										
2.										
3.										

(4) OTHER RELEVANT INFORMATION *(Additional pages may be attached)*

Past medical history (including history of similar reaction or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction) and other relevant information (e.g. other cases, laboratory data, autopsy if conducted): _____

_____

(5) REPORTING OFFICER*

Reporter's Name: _____ Signature: _____

Designation & Department: _____ Institution Address: _____

Tel No: _____ Email: _____ Date patient notified event to health system: _____ Today's date: _____

(6) NATIONAL OFFICE USE ONLY

Date reporting form received: _____ **Investigation needed**: ☐ Yes ☐ No ***If yes, date investigation planned:*** _____

Comments: _____

CONFIDENTIAL

GUIDANCE ON AEFI REPORTING

WHAT TO REPORT?

An adverse event following immunisation (AEFI) is any untoward medical occurrence which follows immunisation, which does not necessarily have a causal relationship with the usage of the vaccine. An adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. Reported adverse events can either be true adverse events, i.e. really a result of the vaccine or immunisation process, or coincidental events that are not due to the vaccine or immunisation process but are temporally associated with immunisation.

HOW TO REPORT?

The AEFI Reporting form can be obtained from the National Adverse Drug Reaction Monitoring Centre and the nearest government pharmacy facility (hospital/ health centre). This form should be filled as completely as possible and returned to the address below or to the nearest government pharmacy facility (hospital/ health centre).

SUBMISSION OF FOLLOW-UP REPORTS

Any follow-up information for an AEFI that has already been reported can be sent to us in another form or *via* any other modes of reporting. Please state that it is a follow-up report, indicating the date and reference number of the initial report.

FOLD HERE FIRST

To:

National Adverse Drug Reaction Monitoring Centre (NADRMC)
c/o Pharmacovigilance Section
1st Floor, Department of Pharmaceutical Services Building
Simpang 433, Rimba Highway
Kg Madaras, Bandar Seri Begawan
BB1514
Brunei Darussalam
Telephone Number: +673 2392398/ 2393301 Ext 201, 206, 207
Fax Number: +673 2393097
E-mail: nadrmc.dps@moh.gov.bn

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