Annex II

University of Oxford- Astrazeneca Covid – 19 Vaccine

Fact Sheet for Recipients

What is in this Fact Sheet?

1. What COVID-19 Vaccine AstraZeneca is and what it is used for?
2. What you need to know before you are given COVID-19 Vaccine AstraZeneca?
3. How COVID-19 Vaccine AstraZeneca is given?
4. Possible side effects

1. What COVID-19 Vaccine AstraZeneca is and what it is used for?

COVID-19 Vaccine AstraZeneca is used for preventing COVID-19 caused by the SARS-CoV-2 virus. COVID-19 Vaccine AstraZeneca is given to adults aged 18 years and older. The vaccine causes the immune system (the body's natural defenses) to produce antibodies and specialized white blood cells that work against the virus, so giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

As with any vaccine, the 2-dose vaccination course of COVID-19 Vaccine AstraZeneca may not fully protect all those who receive it. It is not known how long you will be protected for.

2. What you need to know before you are given COVID-19 Vaccine AstraZeneca?

The vaccine must not be given:

- If you are allergic to the active substance or any of the other ingredients of this vaccine.

One dose (0.5 ml) contains:

Chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein ChAdOx1-S* , not less than 2.5 × 108 infectious units.

The other excipients are L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80 (E 433), sucrose, disodium edetate (dihydrate), water for injections.

This medicine contains less than 1 mmol sodium (23 mg) per 0.5 ml dose, that is to say essentially 'sodium-free'. This medicine contains 2 mg of alcohol (ethanol) per 0.5 ml dose. The small amount of alcohol in this medicine will not have any noticeable effects.

Warnings and Precautions:

Talk to your doctor, pharmacist or nurse before you are given COVID-19 Vaccine AstraZeneca:

- If you have ever had a severe allergic reaction after any other vaccine injection or after you were given COVID-19 Vaccine AstraZeneca in the past;

- If you have ever fainted following any needle injection;

- If you have a severe infection with a high temperature (over 38°C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold;

- If you have a problem with bleeding or bruising, or if you are taking an anticoagulant medicine (to prevent blood clots);

- If your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressant's or cancer medicines).

Children and Adolescents:

COVID-19 Vaccine AstraZeneca is not recommended for children aged below 18 years.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

Driving and Using Machines:

Some of the possible side effects of COVID-19 Vaccine AstraZeneca listed below may temporarily reduce your ability to drive and use machines. If you feel unwell after vaccination, do not drive or use machines. Wait until any effects of the vaccine have worn off before you drive or use machines.

3. How COVID-19 Vaccine AstraZeneca is given?

COVID-19 Vaccine AstraZeneca is given as an injection of 0.5 ml into a muscle (usually in the upper arm). During and after each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction. You will receive 2 injections of COVID-19 Vaccine AstraZeneca. The second injection to be given at 12 weeks after the first injection. You will be told when you need to return for your second injection. When COVID-19 Vaccine AstraZeneca is given for the first injection, the second injection to complete the vaccination course should also be with COVID-19 Vaccine AstraZeneca.

4. Possible Side Effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them. If you notice any side effects not mentioned below, please tell your doctor, pharmacist or nurse.

Get urgent medical attention if you get symptoms of a **severe allergic reaction.** Such reactions may include a combination of any of the following symptoms: feeling faint or light- headed, changes in your heartbeat, shortness of breath, wheezing, swelling of your lips, face, or throat, hives or rash - nausea or vomiting, stomach pain.

The following side effects may occur with COVID-19 Vaccine AstraZeneca:

Very Common (may affect more than 1 in 10 people):

- tenderness, pain, warmth, itching, or bruising where the injection is given

- feeling tired (fatigue) or generally feeling unwell

- chills or feeling feverish

- headache

- feeling sick (nausea)

- joint pain or muscle ache

Common (may affect up to 1 in 10 people)

- swelling or redness where the injection is given - fever (>38°C)

- being sick (vomiting) or diarrhea

Uncommon (may affect up to 1 in 100 people)

- sleepiness or feeling dizzy

- decreased appetite

- enlarged lymph nodes

- excessive sweating, itchy skin or rash

Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed above.

You can also report side effects directly via the platform you used to register or by calling 1214.

Annex VIII
SOP for COVID 19 Astrazeneca vaccine distribution

Ministry of Public Health		Subject: **COVID19 Astrazeneca Vaccine distribution**		
	Edition: 1	Updating Date: 14/02/2021	Effective date: 14/02/2021	Page 1 of 4

Purpose

To instruct and guide healthcare Workers and MOPH employees involved in the processes and procedures related to the AZD1222 Vaccination program on how to administer and dispatch the AstraZeneca AZD1222 vaccine.

2. Scope

Healthcare workers in Vaccination Centers

MOPH employees (Preventive Medicine Department, Warehouse)

3. Responsibilities

Head of the Preventive Medicine Department, MOPH

Astrazeneca Executive committee, MOPH.

4. Policy:

4.1. **Definition:** The Astrazeneca (AZD1222, previously known as ChAdOx 1 ncov 19) is a novel recombinant replication-deficient chimpanzee adenovirus carrying a gene encoding the S protein antigen of SARS-COV-2. The genetic material in the vaccine, once injected into a person, enables the synthesis of spike proteins that triggers an immune response that protects against the COVID19 caused by the novel coronavirus.

4.2. **Intended use**: Individuals aged 18 years and above.

4.3. **Administration:** The recommended schedule is two doses (0.5 ml) given intramuscularly into the deltoid muscle. WHO recommends an interval of 8 to 12 weeks between the doses.

4.4. **Co-administration with other vaccines**: There should be a minimum interval of 14 days between this vaccine and any other vaccine against other conditions.

4.5. **Contraindications:** A history of anaphylaxis to any component of the vaccine is a contraindication to vaccination. The vaccine contains the following: recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-cov-2 spike glycoprotein. Produced in genetically modified human embryonic kidney cells. Other excipients are L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate.

4.6. **Precautions**: No severe allergic reactions or anaphylaxis caused by AZD1222 have been recorded in the context of clinical trials. However, as for all vaccines, AZD1222 should be given under health care super vision, with the appropriate

medical treatment available in case of allergic reaction. As for any other vaccine, an observation period of 15 min after vaccination should be ensured.
Anyone with an acute febrile illness (body temperature over 38.5C) should postpone vaccination until they are afebrile. However, the presence of a minor infection, such as a cold, or a low-grade fever should not delay vaccination.

4.7. WHO recommends the vaccine for use in persons aged 65 years and older.

4.8. Vaccination is recommended for persons with comorbidities (obesity, cardiovascular disease and diabetes) which have been classified as having a higher risk against COVID-19..

4.9. Pregnant women should receive AZD 1222 only if the benefit of vaccination to the pregnant woman outweighs the potential vaccine risks, such as if they are health at high risk of exposure or have comorbidities that place them is a high-risk group for severe COVID-19. Woman who is a part of a group recommended for vaccination, e.g., health workers, should be offer a vaccination on an equivalent basis.

4.10. Persons living with HIV who are part of a group recommended for vaccination should be vaccinated.

4.11. Immunocompromised persons who are part of a group recommended for vaccination may be vaccinated.

4.12. Persons with autoimmune conditions who are part of a group recommended for vaccination may be vaccinated.

4.13. Vaccination may be offered regardless of a person's history of symptomatic or asymptomatic SARS-CoV-2 infection.

4.14. Viral or serological testing for prior infections is not recommended for the purpose of decision-makings about vaccination.

4.15. Currently available data indicate that symptomatic reinfection within 6 months after an initial infection is rare. Thus, persons with PCR-confirmed SARS-CoV-2 infection in the preceding 6 months may delay vaccination until near the end of the period.
Persons with PCR-CoV-2 infection may delay vaccination for 6 months.

Persons who previously received passive antibody therapy for COVD-19. vaccinations should be deferred for at least 90 days to avoid interference of the antibody treatment whit vaccine-induced immune responses.

4.16. SARS-CoV-2 viruses undergo evolution. Some new virus variant may be associated with higher transmissibility, disease severity, risk of reinfection, or a change in antigenic composition resulting in lower vaccine effectiveness.
In view of this, WHO currently recommends the use of AZD1222 vaccine according to the Prioritization Roadmap even if variant are present in a country.

4.17. Vaccination logistics:
The vaccine is presented as a 10-dose vial with stopper delivered in packs containing 10 multidose vials. Unopened multidose vials should be stored in a refrigerator (2C to 8C) and should not be frozen. Once a Vial has been opened (first needle puncture), it should be discarded at the end of the immunization session or within six hours of opening, whichever comes first. Within this period, the product may be kept and used at temperature up to 30C.

In order to improve the traceability of biological medical products the name and the batch number of the administered product should clearly have recorded in patient records/vaccination card.

When scheduling vaccination for occupational groups, e.g. health worker, consideration should be given to the reactogenicity profile of AZD1222 vaccine observed in clinical trials, which may occasionally lead to time off work in the 24-48 hours following vaccination.

4.18. **Common side effects:** malaise/fatigue, headache, myalgia, flu-like syndrome, pain at the side of injection, nausea.

4.19. **Disposal:** this vaccine contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of as biohazard waste. Spills should be disinfected with an appropriate antiviral disinfectant.

5. Procedures

5.1. To order vaccination vials from the MOPH, the vaccination center should send a written request to the Department of Preventive Medicine (DPM).

5.2. The DPM coordinates with the MOPH procurement department. The latter should approve the quantities to be sent according to the available appointment per the IMPACT COVID-19 Vaccination platform.

5.3. A written approval (signed by both PMD and Procurement) will be handed to warehouse.

5.4. The vaccination center dispatches a transporter to the MOPH warehouse. The transporter must be equipped by a cooler containing ice packs and a digital thermometer (temperature must be between 2 and 8C during transportation).

5.5. Upon arrival of the transporter to the MOPH warehouse to pick up the vaccine vials:

The MOPH warehouse employees take out the requested number of vials from the refrigerators (2 to 8 C), Warehouse employees must record the date and time of removal from the refrigerator, the lot number of the vaccine and the temperature.

5.6. The number of vaccine vials to be given to the vaccination center is calculated as per the number of IMPACT COVID-19 Vaccination platform appointments given, the warehouse employees double check the number of vaccine vials requested and issue an invoice to the vaccination center.

5.7. The transporter receives and signs the invoice, stores the received vials in a mobile cooler (Temperature between 2 and 8 C) and transports the vaccine vials to the vaccination center.

5.8. The vaccine vials deployment to vaccination centers is done twice per week (Sunday evening and Wednesday evening). The vaccination centers start the process of vaccination the next day.

5.9. The vaccination center must follow the priority guidelines set by the National committee for COVID19 vaccines and vaccinate accordingly.

5.10. If a vaccination center has excess doses left due to no-shows of scheduled patients, the following can be done:

5.10.1 The vaccination center focal person can schedule extra appointments by calling the people scheduled for the following week on the IT platform.

5.10.2 The vaccination center focal person can contact the DPM and inform them of the number of remaining vials and wait for their instructions (DPM might relocate vials to mobile clinics or another vaccination center)

5.10.3 In case the excess vials will be transferred from one vaccination center to another, the receiver center must assure transportation while fully respecting the cold chain mentioned in 5.4.

5.11. Vaccination sites must give all vaccinated persons a Vaccination card that features the following: full name (first, father name and last name), Date of Birth, name of vaccination center, date and time of vaccination, name of vaccine administered and its lot number with the date of the anticipated second dose.

5.12. Vaccination centers must upload the data on a daily basis on the IMPACT Platform Vaccination Centers not abiding by the latter will jeopardize the deployment of future doses.

5.13. PMD should review all appointments on the IMPACT platform. PMD can issue exceptional passes for people with specific medical conditions that require immediate vaccination. Proof of medical conditions must be submitted to PMD for prior review.

6. Revision History

7. References

7.1. Interim recommendations for the use of the AZD1222 (ChAdOx1-S recombinant) vaccine against COVID19 developed by Oxford University and Astrazeneca, WHO, February 10, 2021.

7.2. Recommendations for an EUL of COVID-19 vaccines AZ submitted by AstraZeneca and manufactured by SK bioscience, WHO, February 23, 2021.

7.3. COVID19 Vaccine Astrazeneca solution for injection: package leaflet

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