AstraZeneca vaccine deployment

COVAX vaccine distribution plan

- COVAX allocation plan
  - AstraZeneca vaccine has been allocated to PNG
  - 588,000 doses have been allocated to PNG to be delivered in 2 shipments*
  - Shipment of 132,000 doses arrived April
  - Shipment of 400,000 doses planned in June
  - Additional vaccine tentative plans for shipments of total of 3 million doses during Q3 and Q4

*subject to manufacturing and shipment delays and predicated on fulfilling the requirements for PO

Prioritization of populations for vaccination

Who will receive the vaccine first and why :

Health Workers

- Health workers are in direct contact with COVID-19 patients. We must protect them as they are at high risk of getting infected. They are the frontline workers who are exposed to risk but also take care us when we get sick.

Elderly

- Data shows that the mortality among the elderly is highest. Vaccines will protect the elderly from severe illness and death

People with co-morbidity

- People with co-morbidity are a greater risk of severe illness and death when infected

Priority for the 3% deployment – May 2021

- The initial target population is small ~3% and consists of:
  - Health care workers public and private including all support i.e. pharmacist, lab workers, physiotherapy, dentist, clerks, cleaners, grounds keeper, drivers, security guard at hospital or health facility
  - All frontline workers in COVID-19 response national and provincial
  - Medical and Paramedical students (nursing, lab, CHW)
  - Prison guards/Correctional services
  - Border and immigration/customs officials
  - Port/immigrations officials
  - Airport workers, especially frontline dealing with customers
  - Workers at quarantine facilities/hotels
  - Police
  - Teachers
  - Defense Force personnel
- The fixed site strategy will be used with limited mobile clinics conducted at temporary fixed sites to vaccinate the HCW and other frontline essential workers

Priority for 17% deployment – after July 2021

- The target population will be 17% and will consist of
  - Persons ≥45 years
  - Persons with comorbidities including
    - HTN
    - Diabetes
    - Chronic lung or kidney or liver disease
- Fixed site, mobile and outreach strategies will be used similar to the strategy used in the MR campaign
- This phase would be implemented in the second half of the year
- Microplans for this second phase of deployment will require a separate microplan

Regulatory process for vaccine

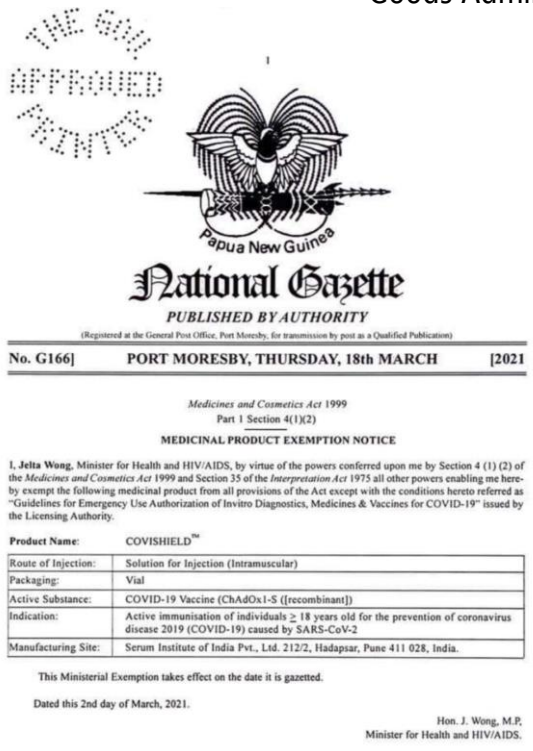
AstraZeneca ChAdOx1 nCoV-19 (AZD1222) vaccine (from 2 manufacturers - SII and SKBio) received Emergency Use Listing (EUL) from WHO in February 2021

AZ vaccine safety and efficacy data has been reviewed by UK, EU, PNG regulatory authorities and has been approved for emergency use

Regulatory approval from PNG authority

Guideline for Emergency Use Authorization of In-vitro Diagnostics, Medicines and Vaccines for COVID-19 in Papua New Guinea

Technical evaluation by Pharmaceutical Services Standards Branch with Therapeutic Goods Administration (Australia)



Papua New Guinea

National Gazette

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No. G166] PORT MORESBY, THURSDAY, 18th MARCH [2021

Medicines and Cosmetics Act 1999
Part 1 Section 4(1)(2)

MEDICINAL PRODUCT EXEMPTION NOTICE

I, **Jelta Wong**, Minister for Health and HIV/AIDS, by virtue of the powers conferred upon me by Section 4 (1) (2) of the *Medicines and Cosmetics Act* 1999 and Section 35 of the *Interpretation Act* 1975 all other powers enabling me hereby exempt the following medicinal product from all provisions of the Act except with the conditions hereto referred as "Guidelines for Emergency Use Authorization of Invitro Diagnostics, Medicines & Vaccines for COVID-19" issued by the Licensing Authority.

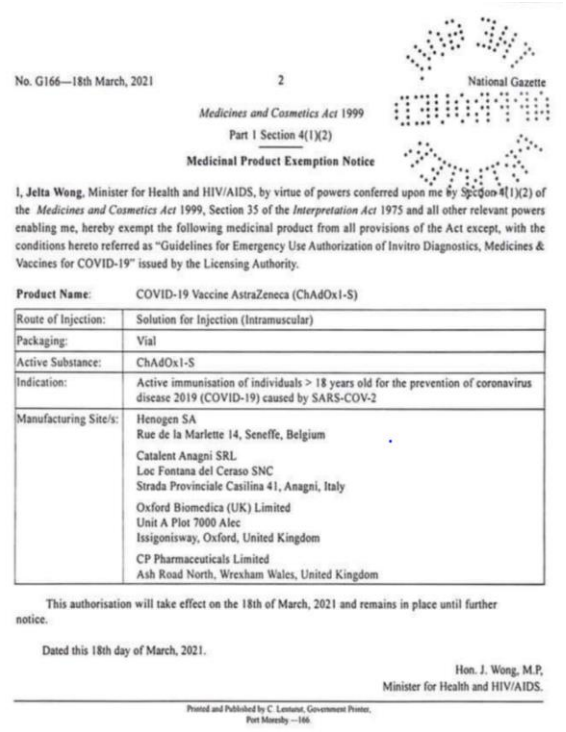
Product Name: COVISHIELD™

Route of Injection:	Solution for Injection (Intramuscular)
Packaging:	Vial
Active Substance:	COVID-19 Vaccine (ChAdOx1-S ([recombinant])
Indication:	Active immunisation of individuals ≥ 18 years old for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2
Manufacturing Site:	Serum Institute of India Pvt., Ltd. 212/2, Hadapsar, Pune 411 028, India.

This Ministerial Exemption takes effect on the date it is gazetted.

Dated this 2nd day of March, 2021.

Hon. J. Wong, M.P,
Minister for Health and HIV/AIDS.



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Medicines and Cosmetics Act 1999
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Product Name: COVID-19 Vaccine AstraZeneca (ChAdOx1-S)

Route of Injection:	Solution for Injection (Intramuscular)
Packaging:	Vial
Active Substance:	ChAdOx1-S
Indication:	Active immunisation of individuals > 18 years old for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-COV-2
Manufacturing Site/s:	Henogen SA Rue de la Marlette 14, Seneffe, Belgium Catalent Anagni SRL Loc Fontana del Ceraso SNC Strada Provinciale Casilina 41, Anagni, Italy Oxford Biomedica (UK) Limited Unit A Plot 7000 Alec Issigonisway, Oxford, United Kingdom CP Pharmaceuticals Limited Ash Road North, Wrexham Wales, United Kingdom

This authorisation will take effect on the 18th of March, 2021 and remains in place until further notice.

Dated this 18th day of March, 2021.

Hon. J. Wong, M.P,
Minister for Health and HIV/AIDS.

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Ministerial Exemptions for Astra Zeneca (SII) and Astra Zeneca (UK) published in the National Gazette

AstraZeneca vaccine

- AZ vaccine has been shown to have an **efficacy** of 63.1% (95% CI 51.8; 71.7) against symptomatic SARS-CoV-2 infection.
- Highly effective protection against severe COVID-19 disease and death
- Vaccination is recommended for persons aged **18 years and above**.
- The **recommended schedule** is two doses given intramuscularly with an interval of 8 – 12 weeks between the doses
- The vaccine will be supplied in 10 dose vials that must be stored at 2-8 degrees
- Current cold chain sufficient to manage the additional planned vaccine supply in incremental shipments
- Uncertainties on the impact of vaccination on **transmission** or viral shedding – still need for Niupela Pasin

Information about AstraZeneca vaccine:

- **Liquid – ready to use**
- **Colorless to slightly brown**, clear to slightly opaque.
- **Do not shake the vial**.
- Should be stored between **+2 to +8°C**
- Limited **shelf life of 6 months from date of manufacture**
- **No VVM label**
- **Discard vial 6 hours after opening**
- Must be provided in **2 doses**

(8 – 12 weeks interval)

- WHO currently recommends the use

of AZ vaccine to priority groups **even if virus variants are present** in a country.

Who should get the COVID-19 vaccine?

- The planned allocation schedule should be followed with respect to priority groups
- Persons living with HIV or who are immunocompromised may be vaccinated after counselling, if they belong to the category recommended for COVID-19 vaccination.
- People who have had COVID-19 previously and fully recovered should be vaccinated.
- **Pregnant women at high risk** of exposure to COVID-19 (e.g. health workers) or who have comorbidities may be vaccinated in consultation with their health care provider

Who should not get the Astra Zeneca vaccine?

- DO NOT give to people with a **history of severe allergic reaction** to any component of the vaccine. (trace amounts of histidine, salts, sucrose, polysorbate 80)
- DO NOT give 2nd dose to any person experiencing anaphylaxis after a 1st dose
- DO NOT give to persons having high fever or with acute severe illness
- DO NOT vaccinate persons in the acute stage of infection with COVID-19, they should remain in isolation
- **NOT** recommended for persons **< 18 years of age**

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)

An AEFI is any untoward medical occurrence following immunization

- does not necessarily have a causal relationship with vaccine usage
- may be an unfavorable symptom about which a vaccine recipient complains

Known minor AEFIs with COVID-19 vaccines

- Pain/ soreness at injection site
- Head ache
- Fatigue
- Muscle pain
- Joint pain
- Fever, chills
- Nausea

THANK YOU