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SAHPRA Covid-19 vaccines update

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Contents

- Overview of SAHPRA
- Summary of Pre-meetings on Covid-19 Vaccines
- Covid-19 vaccine applications for registration
- Section 21 Covid- 19 vaccine applications
- Covid-19 Vaccines clinical trials

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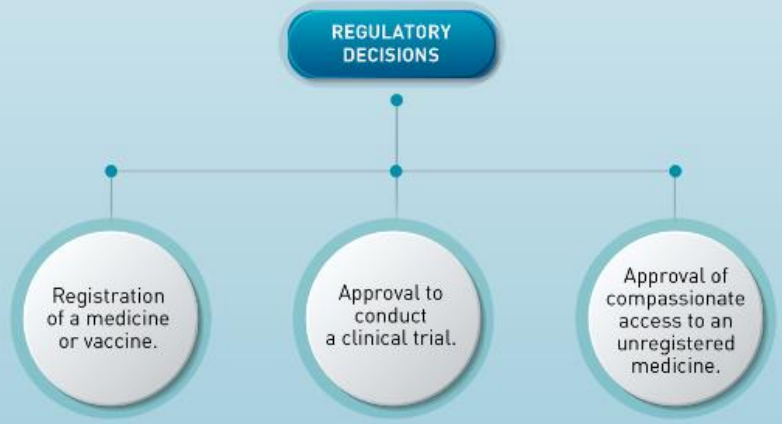
SAHPRA Responsibilities – all health products



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Pre-submission meetings with manufacturers /vaccine applicants

Several pre-submission meetings were held with prospective applicants to advise on the following:

- Application requirements
- Establishing the available information, the applicant has to support the application
- Types of reviews and documentation required for each route
- Possibility of Reliance where evaluation reports from other NRA which SAHPRA aligns with are available

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Pre-Submission Meetings

Vaccine	Applicant	Date	Objectives of applicants
J&J Ad-26	Janssen	4/11/ 2020	Submission of a rolling review application (Rolling review Part 1)
AZ/ RPharm	RPharm/AZ	15/12/2020	Rpharm-Russian Manufacturer
	RPharm	18/01/2020	Establish Rpharm local Intend for S21 and rolling submission
AZ/SII-ChadOX	NDoH	31/12/2020	Section 21 NDoH granted 22 Jan 2021
Pfizer/Biontec Comirnaty mRNA	Pfizer	7/01/2021 03/02/2021	Submission for Reliance review application Section 21 application 04/02/2021
Sputnik V Ad-26 and Ad-5	Lamar Pharmaceuticals	11/02/2021 18/02/2021	Applicant to provide details of vaccine and available data, Applicant to submit Section 21 and rolling review for registration 23/02/2021
Sinovac CoronaVac (Vera-cell)	Numalox/Curanto Pharma	18/02/2021	Intend to submit Section 21

Expedited review approaches for COVID-19 Vaccines

- **Rolling reviews of submissions** - *reviewing data that is available and accepting ongoing data in batches for review*
- **Reliance** - *an act whereby the National Regulatory Authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision.*
  - Includes reliance on National Control Laboratories.
  - The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.
- **Joint reviews with WHO** - *a collaborative review approach with WHO Prequalification (PQ) program, SAHPRA's external and internal evaluators are part of this collaborative review.*

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Section 21 of the Medicines Act

- **Equivalent to Emergency Use Authorisation in other jurisdictions**

- **Section 21. Authority may authorize sale of unregistered medicines, medical devices or IVDs for certain purposes.—**

  (1) The Authority may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any medicine, medical device or IVD which is not registered.

  (2) Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

  (3) The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).

- Supported by Regulation 29 and the guideline

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Application submitted to SAHPRA for market authorization

Name	Date of Submission	Status
J&J Ad-26	11/12/2020-Part1 of Rolling review	Under review
	08/02/2021 Part 2 of Rolling review	In Evaluation of rolling review 2
	03/03/2021 part 3 of rolling review	Rolling review pack 3 submitted (Outstanding documents as submitted to EMA submitted to SAHPRA on 17/03/2021)
Pfizer/Biontec Comirnaty	08/01/2021 Verification review	SAHPRA commenced full review
Sputnik V (Lamar Pharma)	23/02/2021 (rolling)	Under review
Sinovac-Coronavac (Curanto Pharma)	10/03/2021	Under review

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Section 21 COVID-19 Vaccine applications

Section 21 for	Applicant	Date	Status
AZ/SII ChadOx	NDoH	Applied 7/01/2021	Authorized 22/01/2021
Pfizer/Biontech Comirnaty	Pfizer	03/02/2021 (application received)	Authorized on 10/03/2021
Sputnik V	Lamar	23/02/2021	Under review
Sinovac Coronavac	Curanto	10/03/2021	Under review

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SAHPRA approved Covid-19 Vaccine studies

	Vaccines:	Intervention	Applicant And Sponsor	Phase	Short Title
1	20200407 ChAdOx1 nCoV-19_ZA_ phI/IIa	Adenoviral vector vaccine ChAdOx1 nCoV-19	- Applicant: Respiratory and Meningococcal Pathogens Research Unit (RMPRU) -Sponsor University of Oxford /Astrazeneca	I/IIa	Safety, immunogenicity and efficacy of non-replicating ChAdOx1 SARS-CoV-2 vaccine in South African adults living without HIV; and safety and immunogenicity in adults living with HIV
2	20200420 2019-nCoV-501	SARS-CoV-2 rS nano-particle vaccine	Applicant: PPD Sponsor: Novavax, Inc - Prof Madhi (NPI)	IIa/b	Efficacy, Immunogenicity, and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With Matrix-M1™ Adjuvant in South African Adults Living Without HIV; and Safety and Immunogenicity in Adults Living With HIV

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SAHPRA approved Covid-19 Vaccine studies

	Vaccines:	Intervention	Applicant	Phase	Short Title
3	20200431 C4591001 0431	mRNA-BNT162 COVID-19 Vaccines	Pfizer Laboratories Sponsor: BioNTech RNA Pharmaceuticals GmbH	Phase 1/2/3	Safety, Tolerability, Immunogenicity, and Efficacy Of SARS-COV-2 RNA Vaccine candidates against COVID-19 in Healthy Adults
4	20200434 VAC31518COV3001	Adenovirus serotype 26 (Ad26) vector Ad26.COV2.S	IQVIA RDS Clindepharm (PTY)LTD Sponsor: Janssen Vaccines & Prevention B.V	III	Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older

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SAHPRA approved Covid-19 Vaccine studies

	Vaccines:	Intervention	Applicant	Phase	Short Title
5	20200434 _AMD VAC31518COV 3009	Adenovirus serotype 26 (Ad26) vector Ad26.COV2.S	IQVIA RDS Clindepharm (PTY)LTD Sponsor: Janssen Vaccines & Prevention B.V	III	Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older
6	20200465 Sisonke	Ad26.COV2.S	Applicant and Sponsor South African Medical Research Council (SAMRC)	Phase 3B	Open-label, single-arm phase 3B implementation study to monitor the effectiveness of the single shot Ad26.COV2.S COVID-19 vaccine among health care workers in South Africa

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SAHPRA approved Covid-19 Vaccine studies

	Vaccines:	Intervention	Applicant	Phase	Short Title
7	20200402	BCG Vaccine	TASK Applied Science	III	Reducing morbidity and mortality in health care workers exposed to SARS-CoV-2 by enhancing non-specific immune responses through Bacillus Calmette-Guérin (BCG) vaccination
8	20200432	MMR Vaccine (Measles, Mumps, and Rubella Virus Vaccine Live)	Prof B Biccard Prof S Delany-Moretlwe	III	Effectiveness of MR or M-M-R II ® vaccine in preventing COVID-19 disease in healthcare workers (CROWN CORONATION)

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SAHPRA approved Covid-19 Vaccine studies

	Vaccines:	Intervention	Applicant	Phase	Short Title
9	20200446 AW_001_ProVI VA-SA-1	hAd5-S-Fusion+N-ETSD ADENOVIRAL PLATFORM	Applicant: Dr Amy Ward Sponsor: Immunity Bio Inc.	Phase 1b	Phase 1b Open-Label Study of the Safety, Reactogenicity, And Immunogenicity Of A Prophylactic Covid-19 Vaccination Using A 2nd Generation E1/E2b/E3-Deleted Adenoviral Platform In Healthy South African Adults (Proviva-Sa-1)
10	20200458	Recombinant SARS-CoV-2 Spike [S]-Trimer Fusion Protein (SCB-2019)	Applicant IQVIA Sponsor: Clover Biopharmaceuticals AUS Pty Ltd	Phase II/III	A Double-Blind, Randomized, Controlled, Phase 2/3 Study to Evaluate the Efficacy, Immunogenicity, and Safety of AS03-Adjuvanted Recombinant SARS-CoV-2 Trimeric S-protein Subunit Vaccine (SCB-2019) for the Prevention of SARS-CoV-2-mediated COVID-19 in Participants Aged 18 years and Older

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SAHPRA Covid-19 Vaccine studies in process

- 4 Covid-19 vaccine clinical trials which were submitted recently are under review. 2 of these are in pregnant women and 1 in children.

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Thank you