SAHPRA’s governing Acts

Medicines & Related Substances Act of 1965

• **Efficient, effective and ethical assessment and regulation** of health products that meet defined standards of quality, safety, efficacy and performance;
• **Transparent, fair, objective and timeous assessment** and registration;
• In executing its functions, the Authority may enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act.

Hazardous Substances Act Act 15 of 1973

• Within the Medicines Act, “medical device” means any **instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article contemplated in the Hazardous Substances Act, 1973** (Act No. 15 of 1973).
• The Hazardous Substances Act (HSA) provides for the **efficient, effective and ethical evaluation** and registration of non-ionizing radiation emitting devices and radioactive nuclides.
Based on technical assessment by internal and contracted experts in consultation with the expert committee members.

APPEAL REVIEW
As set out in Section 24 (A) of the Medicine and Related Substances Act.

APPLICANT WITH FAILED APPEAL RESERVES THE RIGHT TO APPEAL TO THE MINISTER IN WRITING WITHIN 30 DAYS UPON PAYMENT OF PRESCRIBED FEE.

REGULATION 48 PROVIDES HOW THE APPEAL COMMITTEE CAN BE APPOINTED AND THE PROCEDURES THAT COULD BE FOLLOWED.
Governance framework

1. PFMA Schedule 3A Public Entity
2. Entity of National Department of Health
3. Governance structures in place
4. Mandate: Safety, Quality, Efficacy and Performance

- Autonomous entity
- Operates independently
- Previously Medicines Control Council within the National Department of Health.
- 4th year of operation as a schedule 3A public entity
- Accountable and reports to the Minister of Health and Parliament through the SAHPRA board
- The board is appointed by the Minister
- The board has a governance and strategic oversight role
- Regulates all health products for human and animals use
SAHPRA process and procedures align with international regulators

• The regulatory requirements applied by SAHPRA are consistent and harmonized with those of other regulators

• Alignment and Reliance on the WHO Prequalification and Emergency Use Listing
  – International Coalition of Medicines Regulatory Authorities (ICMRA) and WHO
    – forum to support strategic coordination and international cooperation among global medicine regulatory authorities
    – Members include, SAHPRA (SA), USFDA (USA), TGA (Australia), Health Canada (Canada), EMA (Europe), NAFDAC (Nigeria), ANVISA (Brazil) to name a few

• SAHPRA’s role spans three critical areas
  1. QUALITY
  2. SAFETY
  3. EFFICACY

• Post market surveillance is a critical part of oversight of the products along the value chain
Vaccines authorization process
Key steps of COVID-19 vaccine assessment

1. APPLICANT: Verify that the applicant is licensed, SAHPRA compliant and has the capacity for control, vigilance and safety reporting.

2. PLACE: Ensure each production site complies with Good Manufacturing Practice. Evaluate drug substances, product, packaging and testing.

3. PRODUCTION: Ensure that the production process adheres to best practice - assess Chemistry, Manufacturing and Control (CMC).

4. NON-ClinICAL DATA ASSESSMENT: Evaluate pre-clinical data to ensure that the vaccine trial meets all regulatory requirements for vaccines.

5. SAFETY, EFFICACY & QUALITY TESTING: Phase 1-Phase 3 Clinical trials on human recipients to assess safety data and provide evidence of the vaccine's ability to prevent COVID-19.

6. VACCINE APPROVAL: Ensure that vaccine schedule is aligned to the clinical data, product labelling and patient information leaflet.

7. APPEAL: Rejected applicants can appeal to the CEO within 20 days. They can further appeal to the Health Minister.

8. TRACEABILITY AND SURVEILLANCE: Verify all relevant documents, reports and any other necessary information. Key components are batch, production, and cold chain documentation.
Assessment of CGMP

Compliance of Good Manufacturing Practice

Sites producing drug substance (DS), drug product (DP), filling, packing, testing

NOTE

• Inspections performed at sites that are not GMP certified must be executed by an authority SAHPRA aligns with

• SAHPRA is a member of WHO Pharmaceuticals Inspections Cooperation (PICS). Thus, other regulators can rely on the inspection outcome by SAHPRA

• SAHPRA has an upcoming PICS audit in 2021
Assessment of CMC

CHEMISTRY | MANUFACTURING | CONTROL

FOCUS ON HOW DRUG SUBSTANCE AND DRUG PRODUCT ARE:

- Manufactured
- Characterized
- Impurities are monitored and controlled
- Control tests and limits are justified within specified limits
- Test methods are used
- Tests are validated
- Standards are referenced and used
- Packaged – packing materials and stability
Key steps of COVID-19 vaccine assessment

1. **APPLICANT**
   - Verify that the applicant is licensed, SAHPRA compliant and has the capacity for control, vigilance and safety reporting.

2. **PLACE**
   - Ensure each production site complies with Good Manufacturing Practice. Evaluate drug substances, product, packaging and testing.

3. **PRODUCTION**
   - Ensure that the production process adheres to best practice - assess Chemistry Manufacturing and Control (CMC).

4. **NON-CLINICAL DATA ASSESSMENT**
   - Evaluate pre-clinical data to ensure that the vaccine trial meets all regulatory requirements for vaccines.

5. **SAFETY, EFFICACY & QUALITY TESTING**
   - Phase 1-Phase 3 Clinical trials on human recipients to assess safety data and provide evidence of the vaccine’s ability to prevent COVID-19.

6. **VACCINE APPROVAL**
   - Ensure that vaccine schedule is aligned to the clinical data, product labelling and patient information leaflet.

7. **APPEAL**
   - Rejected applicants can appeal to the CEO within 20 days. They can further appeal to the Health Minister.

8. **TRACEABILITY AND SURVEILLANCE**
   - Verify all ingredients and manufacture dates are correct and verify all deterioration, expiration and quality period; lot restriction, moduleId, and cold chain preservation.
5 SAFETY, EFFICACY & QUALITY TESTING

Phase 1-Phase 3 Clinical trials on human recipients to assess safety data and provide evidence of the vaccine’s ability to prevent COVID-19

THE KEY ASPECTS OF VACCINE EVALUATION

CLINICAL STUDIES ASSESSMENT

ASSESSMENT OF SAFETY DATA

• Requires an adequate number of vaccine recipients and monitoring for a sufficiently long time
• Safety is monitored across all three phases of clinical trials

ASSESSMENT OF EFFICACY DATA

• Requires robust evidence of the vaccine's ability to prevent infection/reduce disease severity from well-conducted phase 3 clinical trials in humans
• Clinical data does not have to be generated in SA only
• SAHPRA may require data considering the local disease burden or disease epidemiology i.e in case of COVID-19 SAHPRA required efficacy against variants of concern

ASSESSMENT OF RISK MANAGEMENT PLAN

• Applicant’s ability to record and report side effects
• In the case of COVID-19, assessment of efficacy against emerging variants of concerns is critical
Key steps of COVID-19 vaccine assessment

1. APPLICANT: Verify that the applicant is licensed, SAHPRA compliant and has the capacity for control, vigilance and safety reporting.

2. PLACE: Ensure each production site complies with Good Manufacturing Practice. Evaluate drug substances, product, packaging and testing.

3. PRODUCTION: Ensure that the production process adheres to best practice - assess Chemistry, Manufacturing and Control (CMC).

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6. VACCINE APPROVAL: Ensure that vaccine schedule is aligned to the clinical data, product labelling and patient information leaflet.

7. APPEAL: Rejected applicants can appeal to the CEO within 20 days. They can further appeal to the Health Minister.

8. TRACABILITY AND SURVEILLANCE: Verify all information, keep a record of all actions, conduct regular lab testing, perform third-party audit and conduct a final validation.
LOT RELEASE TESTING

- Lot release is part of the regulation of vaccines and involves the independent assessment of each individual lot of a licensed vaccine before it is released onto the market
- Conducted by the SA National Control Lab for Biological products
- SAHPRA contracted lab to provide lot release testing for all locally manufactured and imported vaccines
- The WHO Guidelines for Independent Lot Release of Vaccines by Regulatory Authorities describe the role and responsibilities of a NCL:
  - NCLs support regulatory authorities
  - Control the quality of medicinal (biological) products available on the market
  - Monitor manufacturing process of each lot of imported vaccine
  - Monitor manufacturing process of each lot of locally manufactured vaccine
- Accreditation
  - SANAS ISO 17025:2017
  - GMP licenced (SAHPRA)
  - WHO approved
COVID-19 vaccines updates
<table>
<thead>
<tr>
<th>Manufacturer / WHO EUL holder</th>
<th>Name of Vaccine</th>
<th>NRA of Record</th>
<th>Platform</th>
<th>EOI accepted</th>
<th>Pre-submission meeting held</th>
<th>Dossier accepted for review*</th>
<th>Status of assessment**</th>
<th>Decision data***</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Biontech Manufacturing GmbH</td>
<td>BNT162b2/COMIRNATY Tozinameran (INN)</td>
<td>EMA</td>
<td>Nucleoside modified mRNA</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>Finalized:</td>
<td>31/12/2020</td>
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<td></td>
<td></td>
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<td>Additional sites:</td>
<td>30/06/2021</td>
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<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>- Baxter Oncology GmbH Germany (DP)</td>
<td>08/07/2021</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Novartis Switzerland</td>
<td>16/07/2021</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>- Mibe (Dermapharm) Germany (DP)</td>
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<td></td>
<td></td>
<td></td>
<td>- Pfizer Perth, Australia</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fresenius Kabi, USA</td>
<td></td>
</tr>
<tr>
<td>2. AstraZeneca, AB</td>
<td>AZD1222 Vaxzevria</td>
<td>EMA</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>Core data finalized</td>
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<td>MFDS KOREA</td>
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<td>Finalized: Additional sites:</td>
<td>16 April 2021</td>
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<td>- SK-Catalent</td>
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<td>- WuXi (DS)</td>
<td>04 June 2021</td>
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<td>- Chemo Spain</td>
<td>23 July 2021</td>
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<td></td>
<td>- Amylin Ohio US (DP)</td>
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</tr>
<tr>
<td>4. AstraZeneca, AB</td>
<td>AZD1222 Vaxzevria</td>
<td>Japan MHLW/PMDA</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>Finalized</td>
<td>09 July 2021</td>
</tr>
<tr>
<td>5. AstraZeneca, AB</td>
<td>AZD1222 Vaxzevria</td>
<td>Australia TGA</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>Finalized</td>
<td>09 July 2021</td>
</tr>
<tr>
<td>6. Serum Institute of India Pvt. Ltd</td>
<td>Covishield (ChAdOx1_nCoV-19)</td>
<td>DCGI</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>Finalized</td>
<td>15 Feb 2021</td>
</tr>
</tbody>
</table>
## Status of COVID-19 vaccines within WHO EUL/PQ Evaluation process

### 8. Johnson & Johnson
- **Ad26.COV2.S**
- **NRA of Record:** EMA
- **Platform:** Recombinant, replication-incompetent adenovirus type 26 (Ad26) vector vaccine encoding the (SARS-CoV-2) Spike (S) protein
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Finalized
- **Decision date:** 25 June 2021
- **Application Date:** 07/01/2021
- **Authorisation:** Issued 22/01/2021

### 9. Moderna
- **mRNA-1273**
- **NRA of Record:** USFDA
- **Platform:** mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Finalized
- **Decision date:** 06 August 2021
- **Application Date:** 07/01/2021
- **Authorisation:** Issued 22/01/2021

### 10. Sinovac
- **COVID-19 Vaccine (Vero Cell), inactivated/Coronavac™**
- **NRA of Record:** NMIPA
- **Platform:** Inactivated, produced in Vero cells
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Finalized
- **Decision date:** 07 May 2021
- **Application Date:** 04/11/2020
- **Authorisation:** Conditional Market authorization on 30/03/2021

### 11. Sputnik V
- **Russian NRA**
- **Platform:** Human Adenovirus Vector-based Covid-19 vaccine
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** On hold, awaiting completion of rolling submission
- **Decision date:** Anticipated date will be set once all data is submitted and follow-up of inspection observations completed
- **Application Date:** 23/02/2021
- **Authorisation:** Issued 30/04/2021

### 12. Bharat Biotech, India
- **SARS-CoV-2 Vaccine (Vero Cell), inactivated/COVAXIN**
- **NRA of Record:** DCGI
- **Platform:** Whole-Virion inactivated Vero Cell
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Ongoing
- **Decision date:** To be confirmed
- **Application Date:** 03/02/2021
- **Authorisation:** Issued 10/03/2021

### 13. SinoPharm
- **Inactivated SARS-CoV-2 Vaccine (Vero Cell)**
- **NRA of Record:** NMIPA
- **Platform:** Inactivated, produced in Vero cells
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Ongoing
- **Decision date:** To be confirmed
- **Application Date:** 22/06/2021
- **Authorisation:** Issued 08/07/2021

### 14. NVX-CoV2373/Covaxin
- **NRA of Record:** NMIPA
- **Platform:** Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Rolling data started in August 2021
- **Decision date:** To be confirmed
- **Application Date:** 23/02/2021
- **Authorisation:** Issued 30/04/2021

### 15. CoV2 preS dTM-AS03 vaccine
- **NRA of Record:** DCGI
- **Platform:** Recombinant nanoparticle preS protein vaccine formulated with Matrix-M™ adjuvant
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Rolling data started in August 2021
- **Decision date:** 10 August 2021
- **Application Date:** 03/02/2021
- **Authorisation:** Issued 10/03/2021

### 16. Sinopharm
- **LHC**
- **NRA of Record:** NMIPA
- **Platform:** Inactivated, produced in Vero cells
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Finalized
- **Decision date:** 06 August 2021
- **Application Date:** 04/11/2020
- **Authorisation:** Conditional Market authorization on 30/03/2021

### 17. SinoVac
- **CoronaVac**
- **NRA of Record:** NMIPA
- **Platform:** Inactivated, produced in Vero cells
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Finalized
- **Decision date:** 06 August 2021
- **Application Date:** 04/11/2020
- **Authorisation:** Conditional Market authorization on 30/03/2021

### 18. Novavax
- **NVX-CoV2373/Covaxin**
- **NRA of Record:** DCGI
- **Platform:** Recombinant nanoparticle preS protein vaccine formulated with Matrix-M™ adjuvant
- **EOI accepted:** Yes
- **Pre-submission meeting held:** Yes
- **Status of assessment:** Rolling data started in August 2021
- **Decision date:** 10 August 2021
- **Application Date:** 23/02/2021
- **Authorisation:** Issued 30/04/2021

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*All information is as of 19 August 2021.*
<table>
<thead>
<tr>
<th>Manufacturer / WHO FER holder</th>
<th>Name of Vaccine</th>
<th>NRA of Record</th>
<th>Platform</th>
<th>EOI accepted</th>
<th>Pre-submission meeting held</th>
<th>Dossier accepted for review*</th>
<th>Status of assessment**</th>
<th>Decision data***</th>
</tr>
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<tbody>
<tr>
<td>20.</td>
<td>Zhejiang Medical &amp; Biotechnology, China</td>
<td>Zvcorona</td>
<td>EMA</td>
<td>mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)</td>
<td>✔️</td>
<td></td>
<td>Planned for Q4 of 2021, at request of the applicant</td>
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<tr>
<td>22.</td>
<td>IMBCAMS, China</td>
<td>CANC-19</td>
<td>NMPA</td>
<td>Inactivated</td>
<td></td>
<td>Not accepted, still under initial development</td>
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<tr>
<td>23.</td>
<td>BioCubaFarma - Cuba</td>
<td>Soberana 01, Soberana 02, Soberana Plus Abdala</td>
<td>CECMED</td>
<td>SARS-CoV-2 spike protein conjugated chemically to meningococcal B or tetanus toxoid or Aluminum</td>
<td></td>
<td></td>
<td>Awaiting information on strategy and timelines for submission</td>
<td></td>
</tr>
</tbody>
</table>

1. Beijng Institute of Biological Products Co Ltd
2. Wuhan Institute of Biological Products Co Ltd

* Dossier Submission dates: more than one date is possible because of the rolling submission approach. Dossier is accepted after screening of received submission.
*** Anticipated decision date: this is only an estimate because it depends on when all the data is submitted under rolling submission and when all the responses to the assessors' questions are submitted.
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Applicant</th>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>J&amp;J Ad-26</td>
<td>Janssen</td>
<td>4/11/2020</td>
<td>Submission of a rolling review application (Rolling review Part 1)</td>
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<tr>
<td>AZ/ RPharm</td>
<td>RPharm/AZ</td>
<td>15/12/2020</td>
<td>Rpharm-Russian Manufacturer</td>
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<td></td>
<td>RPharm</td>
<td>18/01/2020</td>
<td>Establish Rpharm local Intend for S21 and rolling submission</td>
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<tr>
<td>AZ/SII-ChadOX</td>
<td>NDoH</td>
<td>31/12/2020</td>
<td>Section 21 NDoH granted 22 Jan 2021</td>
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<tr>
<td>Pfizer/BioNtec Comirnaty mRNA</td>
<td>Pfizer</td>
<td>7/01/2021</td>
<td>Submission for Reliance review application</td>
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<tr>
<td></td>
<td></td>
<td>03/02/2021</td>
<td>Section 21 application 04/02/2021</td>
</tr>
<tr>
<td>Sputnik V Ad-26 and Ad-5</td>
<td>Lamar Pharmaceuticals</td>
<td>11/02/2021</td>
<td>Applicant to provide details of vaccine and available data, Applicant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>18/02/2021</td>
<td>to submit Section 21 and rolling review for registration 23/02/2021</td>
</tr>
<tr>
<td>Sinovac CoronaVac (Vera-cell)</td>
<td>Numulox/Curanto Pharma</td>
<td>18/02/2021</td>
<td>Intend to submit Section 21</td>
</tr>
<tr>
<td>Sputnik V Ad-26 and Ad-5</td>
<td>Dr Reddy (Pty) Ltd</td>
<td>08/04/2021</td>
<td>Proceed with submission of application (A submission to be made as</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>rolling review submission)</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Applicant</td>
<td>Date</td>
<td>Outcome</td>
</tr>
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<td>-------------------------------------------------------------------------</td>
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<tr>
<td>UB-612 Mutitope Peptide-Based Vaccine (MPV) Against COVID-19</td>
<td>Vaxxinity</td>
<td>16/04/2021</td>
<td>Will establish local presence of Vaxxinity. Data up to phase II available; phase 3 India commenced in March 2021. Intend for EUL WHO mid 2021</td>
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<tr>
<td>Coronavac (Vera-cell)</td>
<td>Solace</td>
<td>16/04/2021</td>
<td>Applicant not licensed for Pharmaceuticals and will apply for SAHPRA license. Applicant required to gain more knowledge and information of their product</td>
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<tr>
<td>Covaxint</td>
<td>Bharat Biotech Limited (Usembe Healthcare)</td>
<td>05/05/2021</td>
<td>A submission to me made for a rolling review</td>
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<tr>
<td>Sinopharm</td>
<td>LHC Pharmaceutical</td>
<td>11/06/2021</td>
<td>Submitted application subsequently</td>
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<td>Sputnik V Ad-26 and Ad-5</td>
<td>Mbabala Biotech</td>
<td>11/06/2021</td>
<td>Contract with RDIF requested</td>
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<td>ZIfivax</td>
<td>Advance Medicals/Bliss Pharma</td>
<td>14/06/2021</td>
<td>Proceed with submission of application</td>
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<tr>
<td>Moderna</td>
<td>Tautomer (Pty) Ltd</td>
<td>22/06/2021</td>
<td>Intention for booster-No stock of Moderna for 2021</td>
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<td>Sputnik V Ad-26 and Ad-5</td>
<td>E Trade Health Solutions (Pty) Ltd</td>
<td>03/07/2021</td>
<td>E-Trade brought in MC PHARMA as Applicant for duplicate of Sputnik V</td>
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<tr>
<td>Section 21 for</td>
<td>Applicant</td>
<td>Application Date</td>
<td>Status</td>
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<td>---------------</td>
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<tr>
<td>Sputnik V</td>
<td>Dr Reddys</td>
<td>30/04/2021</td>
<td>Sequence 0002 submitted on 08 June 2021 outstanding sequences of data still awaited from the applicant. Review of the submitted information in progress</td>
</tr>
</tbody>
</table>
COVID-19 safety report
The overall safety monitoring of vaccines – Reporting

Tools for reporting

• Med Safety App
• E-Reporting portal on SAHPRA Website
• Paper-Based system
  – Captured into Vigilance Hub – Back office of Med Safety App
  – Captured at district, provincial, National or SAHPRA
  – Vigilance Hub is accessible by both SAHPRA & NDoH
  – Data on Vigilance Hub feeds directly into VigiFlow system
The overall safety monitoring of vaccines

• In 2017, The National Immunisation Safety Expert Committee (NISEC) was appointed

• NISEC is a non-statutory standing Ministerial appointed Expert Committee responsible for:
  – Review and assessment of all reported serious and severe adverse events following immunisation (AEFIs)
  – Review of individual serious and unusual AEFIs
  – Perform causality assessment of AEFIs
  – Provide feedback on the causality assessment outcome to relevant stakeholders e.g. SAHPRA
  – Submit recommendations to National Department of Health who also engages with the serious AEFIs reporters
Data reported on microsite
# AEFI Data Analysis

<table>
<thead>
<tr>
<th>Vaccine name</th>
<th># of ICSRs</th>
<th># of fatalities</th>
<th>Total Vaccinations</th>
<th>Prevalence of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comirnaty</td>
<td>2148</td>
<td>76</td>
<td>9,798,502</td>
<td>0,77/100 000</td>
</tr>
<tr>
<td>COVID-19 Vaccine Janssen</td>
<td>622</td>
<td>10</td>
<td>2,367,541</td>
<td>0,42/100 000</td>
</tr>
<tr>
<td>Total</td>
<td>2770</td>
<td>86</td>
<td>12,166,043</td>
<td>0,71/100 000</td>
</tr>
</tbody>
</table>

*9 798 502 = 6 629 517 1st Dose + 3 168 985 2nd Dose  
*2 367 541 = National roll-out only

It should be noted that all the AEFIs reported under the Sisonke Phase 3b study are not included in this analysis

**Data up to 31 August 2021**

ICRS: individual case reports
## NISEC Causality Assessment

<table>
<thead>
<tr>
<th>Cases with NISEC</th>
<th>Death cases</th>
<th>Other cases</th>
<th>Total number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases causality assessed</td>
<td>40</td>
<td>107</td>
<td>147 (121 COVID-19 vaccines)</td>
</tr>
<tr>
<td>Follow-up cases</td>
<td>15</td>
<td>21</td>
<td>36 (All for COVID-19 vaccines)</td>
</tr>
<tr>
<td>Cases under review</td>
<td>31</td>
<td>13</td>
<td>44 (36 for COVID-19 vaccines)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Causality assessed</th>
<th>Death cases</th>
<th>Other cases</th>
<th>Total number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comirnaty</td>
<td>35</td>
<td>41</td>
<td>76</td>
</tr>
<tr>
<td>J&amp;J Vaccine</td>
<td>5</td>
<td>40</td>
<td>45</td>
</tr>
</tbody>
</table>

**Outcome of death cases**
- 34 cases are co- incidental
- 6 insufficient information provided


**Other cases under assessment**
- Myocarditis/pericarditis
- Capillary leak syndrome
- Guillain-Barre Syndrome
- Vascular disorders etc
SHAPRA’s role extends beyond COVID-19 vaccines

S21 AUTHORISATION FOR NEW REPURPOSED THERAPIES
- Dexamethasone
- Tocilizumab

AUTHORISATION OF VACCINES
- COVID-19 Vaccines
- Astra Zeneca
- Pfizer
- Janssen
- Sinovac

MEDICAL DEVICES AND IVDs
- Molecular PCR SARs-COV-2 tests
- Antibody and Antigen tests
- PPE used in high risk settings
- Ventilators

CLINICAL TRIALS
- COVID-19 therapies
- COVID-19 vaccines

Regulatory oversight during COVID-19 pandemic
THANK YOU