BOMRA
MEDICINES REGULATORY AUTHORITY

Promoting access to safe medicines

WHO-ICDRA Discussions

e utilization of the tswana Medicines thority 20th-24th ber 2021

bsi ISO 9001 Quality Management Systems CERTIFIED
FS 739935

Readiness (Covid-19 Pandemic)

- SADC Technical Working Group meetings. Shared experiences and adopted way forward.

- WHO issued a guidance document for manufacturers “Points to consider for manufacturers of COVID19 vaccines” which assisted respective applicants and evaluators on critical aspects that had to be submitted for products to be considered for emergency use listing (EUL)

- WHO also availed a process to access reports for vaccines that would have already been considered and approved for emergency use listing (EUL)

Readiness (Continued)

WHO access to reports

Through AVAREF presentation highlights

- AVAREF prepared team to deal with Covid vaccine applications Webinars experts WHO, post listing Webinars
- One (1) Assessor with experience in Biological assessment
- Team has been introduced to Biological products – very little experience
- BoMRA already had a policy for assessment of products availed during public emergencies

EUL experience

Shortened our timelines:

15-90 days depending on availability of required information

Less pressure and built confidence on the Assessment team

Access to WHO decisions sometimes challenging due to their internal processes

EUL experience

Currently 7 vaccines are listed for emergency use.

Access to Dossier and report

- Pfizer/BioNTech Tozinameran
- Vaxzevria (AZD1222) – AstraZeneca
- COVID-19 mRNA Vaccine – Moderna Biotech
- COVID-19 vaccine (Ad26.COV2-S, recombinant) – Janssen Cilag

EUL experience

Without Access to Dossier and report

Covaxin TM – Bharat Biotech

COVID 19 Vaccine (Vero Cell), inactivated – Sinovac Lifesciences

COVISHIELD TM – Serum Institute

Under assessment

Gam-COVID-Vac Combined vector vaccine (Sputnik V) – Gamaleya

SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) – Sinopharm

Gam-COVID-Vac Combined vector vaccine (Sputnik V) – Russian Direct Investments

PRODUCTS CURRENTLY LISTED

Vaccine Type	Date of authorization of vaccine for emergency use
Janssen - Ad26.COV 2-S	26/03/2021
Moderna - mRNA-1273	16/04/2021
SII - Covishield	26/02/2021
Pfizer BioNTech - Comirnaty	25/02/2021
Sinovac - CoronaVac	08/04/2021
Bharat - Covaxin	16/04/2021
AstraZeneca - Vaxzevria	09/04/2021

Lessons Learned

- Benefits of Collaborations
- Regulatory capacity and resources to deal with multiple applications within short time frames and to prevent staff burn out-long hours of continuous work
- Expertise for different Applications

Dossier for emergency use listing:

Module 1

- Application Form, GMP certificate issued by WHO, SRAs or PIC/s member states.
- Pharmacovigilance plans, Risk management plans.

Module 2

- Quality Overall Summary (In Word format)
- Quality Information Summary (In Word format)
- Non-clinical summaries
- Clinical summaries

Module 3

- Drug substance quality
- Drug product quality

Module 4

- Non-Clinical study reports – Full reports

Module 5

- Clinical study reports-Full reports (interim with commitment to provide full data as and when available)

THANK YOU

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