Biological Medicines Evaluation and Research Unit (BMERU)

The Biological Medicines Evaluation and Research Unit (BMERU) is a sub-unit of Medicines Evaluation within the South African Health Product Regulatory Authority (SAHPRA). This sub-unit has been existing for a number of years.

What are Biological Medicines - products produced from living organisms or contain components of living organisms. These products are derived from human, animal, or microorganisms by using biotechnology. Biologic drugs are sometimes referred to as biologic response modifiers because they change the manner of operation of natural biologic intracellular and cellular actions.

Biologic products may contain proteins that control the action of other proteins and cellular processes, genes that control production of vital proteins, modified human hormones, or cells that produce substances that suppress or activate components of the immune system.

Types of Biological Medicines currently regulated by BMER are;

1. Blood & Blood Products
    - Blood, Blood Components, and Plasma Derived Medicinal Products (PDMP)

2. Hormones
    - Hormone deficiencies e.g. insulin
    - Growth hormone

3. Monoclonal Antibodies
    - monoclonal antibodies for the treatment of autoimmune diseases and cancers

4. Immunomodulators
    - immunomodulators e.g. beta-interferon for multiple sclerosis

5. Vaccines
    - Vaccines for Immunization in Children and Adults,
    - Tuberculin Testing

6. Biosimilar
    - Is a Biological product that are similar to a reference biological product registered in South Africa in terms of quality, safety and efficacy.

7. Enzymes
    - **Enzymes** e.g. to remove blood clots

Our primary responsibilities are:

New registrations

- Evaluation of applications for registration of biological medicines. These include –

- Review of dossiers for registration of biological medicines;
- Review of applicant's responses to recommendations from expert committees of the SAHPRA and
- Handling all matters relating to biological medicines during review of applications for registration.

Variations

- Evaluation of applications for amendments to registered biological medicines. These include –
  - Review of technical changes to registered biological medicines and "old" biological medicines;
  - Review of clinical aspects of package inserts and patient information leaflets for biological medicines.
  - Provision of technical support to other units (e.g. inspectorate) with respect to matters relating to biological medicines.

Other activities include:

- Communication with the pharmaceutical industry on policy matters affecting the registration and use of Biological Medicines, policy development and optimisation of the registration processes.
- Establishment/Development of framework for regulation Blood and Blood products and Stem cells and cell based therapy following the pronouncement of Blood and blood components on the list of Essential medicines.
- Establishment of relevant framework for regulation of Vaccines, Biosimilar and other biologicals

Read More

Contact Biological Medicines Evaluation and Research Unit (BMERU)

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Mr Mutoti Khamusi, Biological Medicine Manager, South African Health Products Regulatory Authority (SAHPRA), South Africa

Mr Mutoti is a Registered Biological Medicines Regulatory Scientist .He is currently Elected Chairperson of the African Blood Regulator's Forum (ABRF), He is an Expert member of the International Organisation on Biosimilar, also serving as a member of the Blood Transfusion Services (BTS) Specialist Technical Committee Member (STC). Mr Mutoti has over 10 years' experience working as a Biological Medicines regulator, he has extensive knowledge of vaccine, biosimilars, blood and blood products and biological medicines regulation. He has been engaged on different international platforms and presented at the 1st International Symposium on Streptococcus agalactiae Disease (ISSAD), following the first WHO consultation Initiative for vaccine Research, World health Organization GBS Candidate vaccine, London December 2017. During his spare time he enjoys mentoring Science Technology Engineering Mathematics and Innovation (STEMI) learners and students, believes in education as the only solution to socio-economic challenges and poverty.

Guidance, Compliance & Regulatory Information

- List of Guidelines under Developments
    1. Quality, Safety and Efficacy requirements for Biological medicines
       Reference Guidance: **WHO - Guidelines on the quality, safety, and efficacy of Biotherapeutic protein products prepared by recombinant DNA technology**
    2. Variations requirements for adopting the portal submission (Draft)
    3. Plasma Derived Medicines Requirements (Draft)
    4. Guidelines on Registration of Human Vaccines
    5. Stability Guidelines for Biological Medicines - for comment
    6. Specific Biosimilar Guidelines for (planned):
    7. In addition to the Monoclonal Antibodies Guidelines
        - ✓ Biological medicinal products containing recombinant follicle-stimulating hormone
        - ✓ Biological medicinal products containing recombinant erythropoietins
        - ✓ Biological medicinal products containing interferon beta
        - ✓ Biological medicinal products containing recombinant human insulin and insulin analogues
        - ✓ Biological medicinal products containing low-molecular-weight heparins
        - ✓ Biological medicinal products containing recombinant granulocyte-colony stimulating factor

- ✓ Biological medicinal products containing biotechnology-derived proteins as active substance

8. Checklist Specific to Biosimilars (Draft)
9. Blood and Blood Products requirements for ES licenses, Haemovigillance and Inspections

- National Control Laboratory (NCL) – Biological Medicines release laboratory - https://www.ufs.ac.za/health/departments-and-divisions/national-control-laboratory-for-biological-products-home
- Hemovigillance - WHO - A guide to establishing a national haemovigilance system

Pre – Registration Consultation Meetings

- Guidelines
- Types of meetings
- Materials for Meeting
- Procedures

Guidance, Rules, SOPPS, Establishment Registration, Enforcement, Compliance

- Biological Medicines Press Announcement
- Status of the Blood Regulation
- Status of Regenerative Medicines Framework development
- Number of Biosimilars registered and those being reviewed

Immunisation and Annual Influenza Updates

- Immunisation communication, (see 8.2 , Amendments Guidelines for Biological Medicines for submission requirements)

Biological Medicines Advisory Committees

- Public Advisory Committees
- Calendar for the Meetings
- Meeting Materials
- How to become Advisory committee member
- Guidance
- Frequently Asked Questions

RECENTLY PUBLISHED BIOLOGICAL MEDICINES -RELATED GUIDANCES

- News Letter
- Guidance

News and Events – to follow

- What's New for Biological Medicines
- Workshops, Meetings & Conferences (Biological Medicines)

Review process for Review of Biological Medicines

- To follow