AMA | African Medicines Agency

WHAT IS

AFRICAN MEDICINES AGENCY (AMA)?

AMA will be established as a Specialized Agency of the African Union (AU) to improve access to quality, safe and efficacious medical products in Africa.

01 Coordination and strengthening of ongoing initiatives to harmonize medicines regulation, promote cooperation and mutual recognition of regulatory decisions.

02 Carrying out regulatory oversight of selected medical products and providing technical guidance to State Parties and RECs.

03 Pooling expertise and capacities and strenthening networking for optimal use of the limited resources available.

ORGANS OF THE AMA

A The Conference of parties

B Governing Board

C The Secretariat

D Technical Committees

Functions of the AMA Technical committees

The technical committees shall be responsible for carrying out specific assessments and conducting scientific reviews of dossiers, including quality aspects, and clinical trail applications; inspection of manufacturing facilities; and providing scientific opinion to facilitate the proper functioning of the AMA. These may be either permanent or ad hoc structures.

A Conduct scientific reviews and provide guidelinesd and opinions releventto the work of the AMA at the request of the Board and Secretariat, in a timely manner;

B Identify and advise the AMA on relevent scientific, regulatory, medical and public health issues;

C Develop harmonized medical products regulatory policies and standards, and scientific guidelines for consideration and approval by the Board and Conference of State Parties;

D Contribute to capacity development programmes for the AMA in their areas of expertise.

E Carry out any other functions as may be assigned to it by the Board or the Director General.

AMA will serve six main functions

Marketing authorization:
The AMA shall be responsible for evaluation and decision making with regard to selected medical products for treatment of priority diseases/conditions as determined by the African Union.

Inspection:
The AMA shall undertake coordination on the inspection of manufacturing sites, and share information on a regular basis in regard to all products that it has authorized for marketing.

Market surveillance:
The AMA shall coordinate the collection and sharing of information on all medical products including SF medical products.

Safety monitoring:
The AMA shall be responsible for making regulatory decisions concerning products selected for treatment of priority diseases/conditions as determined by Member States, based on availible safety information. In addition, the AMA will collect and store information on the quality and safety of medical products and share them with all its States Parties as well as globally. It will also establish collaboration with global and regional centres in the area of safety monitoring.

Oversight of clinical trails:
The AMA shall coordinate joint reviews of applications for the conducting of clinical trails.

Quality control:
The AMA shall coordinate and network quality control laboratory services for national and regional regulatory authorities.