WHAT'S NEEDED FOR A STRONG REGULATORY SYSTEM IN AFRICA

IFPMA

INNOVATION

- Transparent regulatory pathways
- Expedited review for innovative medicines
- Agency collaboration and work-sharing

GOOD MANUFACTURING PRACTICES

- Risk based approach to assessment
- Alignment of GMP requirements
- Harmonization of inspections and supporting mechanisms

TO ENSURE

- SAFETY
- EFFICACY
- QUALITY

PHARMACOVIGILANCE

- Reporting system in place
- Clear responsibilities for all stakeholders
- Efficient and effective processes

QUALITY STANDARDS

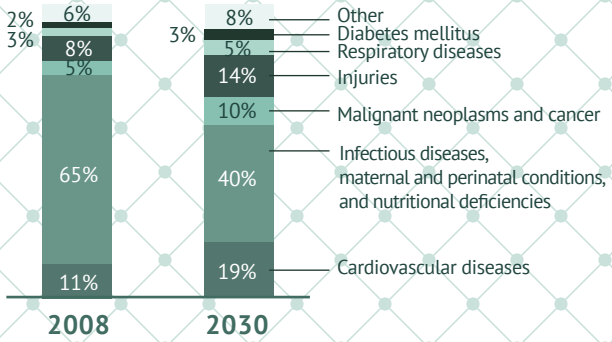
- Ensure patients receive good quality medicines
- Quality systems for manufacturers
- Global standards for quality aspects

AFRICAN POPULATION DISTRIBUTION

COMPARED TO THE REST OF THE WORLD

DISEASE BURDEN IS CHANGING IN AFRICA

FORECASTED DEVELOPMENT OF DISEASE PATTERNS IN AFRICA, LONG TERM.

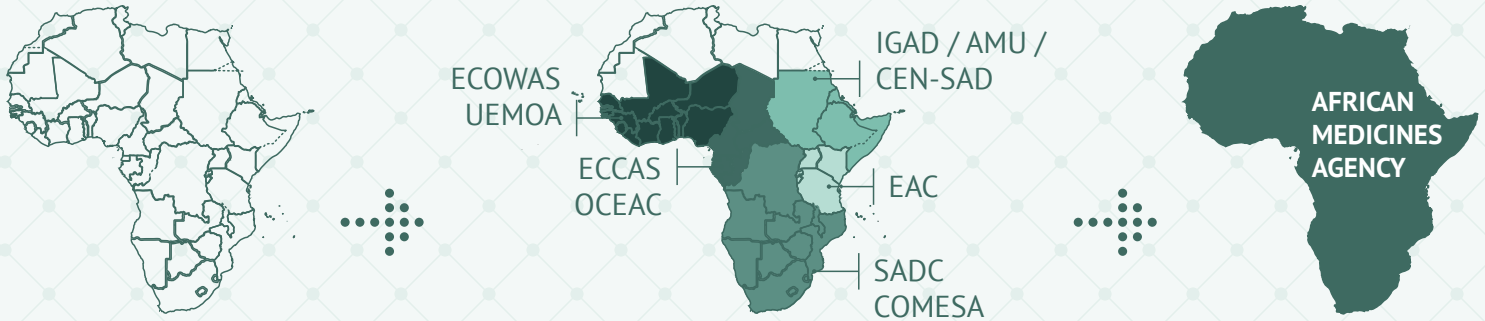


Source: WHO, Strategy and Analysis.
Note that percentages may not add up to 100 due to rounding.

5 YEARS LONGER for medicines to be available for patients in Africa in some cases.

MOVING TOWARDS REGULATORY HARMONIZATION

Source: AMRH 2015



54 COUNTRIES REGULATORY AGENCIES

5 REGIONAL REGULATORY AGENCIES

1 REGULATORY AGENCY

TO GET THERE, IFPMA CAN HELP

- *Provide platforms for exchange of ideas and information*
- *Offer technical expertise to support local capacity building*
- *Contribute science-based insights to develop innovative regulatory pathways*
- *Work together so medicines can reach patients in Africa*