WHAT’S NEEDED FOR A STRONG REGULATORY SYSTEM IN AFRICA

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

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

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

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

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

TO ENSURE
- SAFETY
- EFFICACY
- QUALITY

AFRICAN POPULATION DISTRIBUTION COMPARED TO THE REST OF THE WORLD

AFRICAN MEDICINES AGENCY

ECOWAS
UEMOA
IGAD / AMU /
CEN-SAD
ECCAS
EAC
SADC
COMESA

AFRICAN MEDICINES AGENCY

MOVING TOWARDS REGULATORY HARMONIZATION

Source: AMRH 2015

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

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.

MOVING TOWARDS REGULATORY HARMONIZATION

54 COUNTRIES REGULATORY AGENCIES

5 REGIONAL REGULATORY AGENCIES

1 REGULATORY AGENCY