FOOD AND DRUGS AUTHORITY
FDA
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"FDA GHANA EXPERIENCE IN MAGHP REVIEW PROCEDURE"

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OUTLINE

- FDA; mandate and activities
- Drug Evaluation and Registration
- FDA's involvement in MAGHP procedure

✓Participation

✓Experiences

✓Difficulties and challenges faced

✓Possible ways to improve procedure

Food and Drugs Authority ; mandate and activities

- WHO Maturity level 3 agency
- Authority involved in the regulation of food and

medicines (allopathic, herbal, veterinary), vaccines and biological products, medical devices, cosmetics, household chemicals, Tobacco and substance of abuse, pharmacovigilance activities, review and approval of clinical trials, import and export control

- ISO 9001-2015

Medicine Evaluation and Registration

- New medicinal product applications for registration
  - New Chemical Entities
  - Generics

New registration applications are classified as Fast Track, Low Risk and High Risk

a. Public Health Program drugs: TB, HIV, Malaria, Reproductive Health, Neglected Tropical Diseases

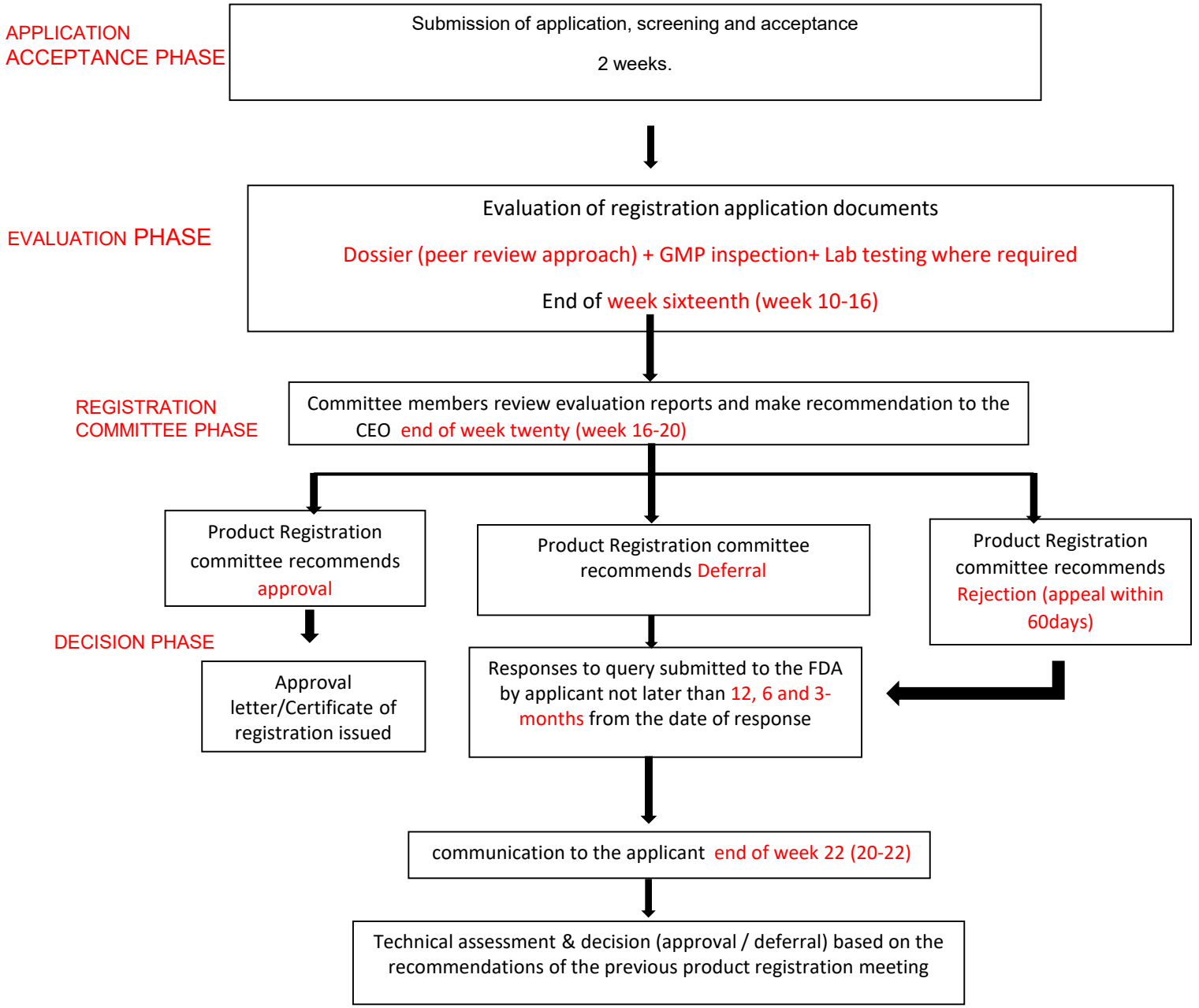
b. WHO prequalified drugs

c. Drugs approved through the centralized procedure of the European Medicines Agency

d. Drugs registered by "stringent regulatory bodies" eg. SwissMedic, UK, USA, Canada, Japan, Australia

b, c and d- reliance

b-collaboration



Please note

1. The processing time is a clock system and stops when the FDA request for further document / clarification/ justification from the client

2. The counting of weeks in the chart therefore does not include time periods when applicant is expected to submit further documentation, clarification / justification to the FDA

3. Time for handling appeal will not be counted as part of the regular processing time.

4. The time between the date on letters from the FDA to the date of receipt of letters by applicant will not be counted.

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FDA's involvement in MAGHP procedure

- **Assessment**

Product in new indication for treatment of MDR-TB

3 experts involved- clinical inputs

- **Scientific advise**

development plan to support registration of a new dispersible formulation of the fixed-dose combination artemether-lumefantrin intended for neonates and infants with a bodyweight below 5 kg. The proposed formulation contains 2.5mg artemether and 30mg lumefantrine (new ratio 1:12 of the two active substances). The currently authorized preparation contain the active substances in a ratio of 1:6.

1 expert- clinical and quality inputs

Experience

- Capacity building from exchange of information and knowledge sharing amongst all experts involved in the review during review meetings
- In depth inputs of having experts from different fields (clinical, non-clinical, quality) resulting in greater outcome
- The MAGHP provides opportunities for sharing of information, learning from other regulators, leverage from collaborative effort gained than each NMRA working independently, adequate timeline to make input.
- Confidence and reliance in Swissmedic procedure

✓Decision making based on inputs from all participants involving equal opportunity for divergent views.

✓Understanding of the Swissmedic review procedure on process/application involved

Experience- cont

- ✓Adequate background information on applications (scientific opinion or assessment)
- ✓Understanding and appreciation of approach for handling request and application for scientific opinion request

- ✓Enhanced transparency by making available initial Swissmedic review report and basis for arriving at opinions

- Our expectations were met in terms of inclusion of our comments into final list of questions sent to the applicant and the final decision made
- Sharepoint as a convenient tool for the information exchange.

Difficulties and challenges faced

- No legal agreement between FDA and Swissmedic for reliance on the collaborative MAGHP procedure.
- Difficulty of combining official office work with the participation in Swissmedic review meeting
- Involvement of only 1 participant sometimes limits the technical input as participants may not be experts in all the areas of quality, safety and efficacy
- Lack of access to documents for intended application prior to technical discussions
- Swissmedic not making the scope of the application clear from onset

- Break in electronic connectivity that makes it difficult hearing speakers and inputs being discussed and no opportunity to reconnect when there is lost in connectivity during meetings
- No applications so far received by NRA based on MAGHP procedure

✓Possible ways to improve procedure

- Consideration for legal agreement with FDA for complete recognition of Swissmedic approvals/decisions
- The scope of the procedure should be updated to include Product Life Cycle Management including variations and possibly Post Approval Change Management Protocol (ICH Q12).

- Participants should be taken through the procedure with key highlights on the goal and scope prior to every review meeting.
- Participants involved with procedure should be made focal persons at their respective NMRAs with clearly defined responsibilities and motivation to remain committed to this work.
- More than 1 expert in instances involving complete assessment review should be involved from each NMRA by Swissmedic
- An early submission of the dossier to all NMRAs involved will certainly be an advantage to the various NMRAs to enable adequate preparation and inputs at review meetings.
- Information to MAH holders/applicants or manufacturers on availability of MAGHP procedure and its relevance and their role/involvement

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