Table 61: Regulation of Biologics in Africa: A Case Study in Ghana

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SCOPE:

The presence and circulation of substandard biological products especially biosimilars and Noncomparable biological products or biogenerics on the markets of most African countries has become a major concern to NRAs in Africa. These products are known to be coming from emerging markets in Asia where strict regulation of these products are absent. What are the existing regulations in Africa? Are they adequate to assure quality and safety? (The issue of harmonization of regulations on biologics among NRAs in Africa and the way forward. The concept of biosimilarity, interchangeability and extrapolation of indications; what is FDA-Ghana perspective. Exposure of Biological products to harsh storage conditions and its impact on Aggregation and immunogenicity.

QUESTIONS FOR DISCUSSION:

1. What are the existing and adequacy of legal framework for the regulation of Biologics in Africa and Ghana as a show case?

2. What are the major differences in terms of the requirements for quality, safety and efficacy between Ghana FDAs key guidelines for biological products/biosimilars and that of other African countries and SRAs EMA, USFDA, WHO etc

3. The challenges of Harmonization of regulations for biological products and biosimilars: Who are the key stakeholders? (NEPAD, WAHO) what are the level of implementation and commitment from NRAs and how could this be strengthened to obviate duplication of submissions by manufacturers?

4. The challenges of Regulation of Biosimilars as biogenerics or Non-comparable biologics. The issue of technical capacity of personnel in NRAs who must review the dossiers of such products from emerging markets in Asia. Existing regulations (Nomenclature, etc)

5. What is the general position of African NRAs and FDA Ghana in particular on the relationship between biosimilarity, interchangeability, substitution, switching and extrapolation of indications for an approved biosimilar product with the reference biological product? What should be the way forward?

6. The concerns for the impact of poor storage, handling and transportation conditions on the quality of biological products and biosimilars in most African countries. What are the consequences of the lack of Good storage and distribution practices on stability, aggregation, potency and immunogenicity of biological and biosimilars, what are the challenges? (Lack of adequate and appropriate cold storage facilities, inappropriate
packaging material for tropical markets), what strategies from the view point of manufacturer’s, distributors and regulators can help address these issues?

7. What are the major challenges of the conduct of clinical trials for biological products in Africa? How can these challenges be addressed? Are the existing regulations on Clinical trials a hindrance to entering African market? Has anybody received such an experience with clinical trials in any part of Africa. What is the way forward to strengthening harmonization of requirements and regulations on conduct of Clinical trials between Africa and other SRAs?

NOTES:
Key points:

Food and Drugs Authority Ghana website [http://www.fdaghana.gov.gh/](http://www.fdaghana.gov.gh/) has a lot of good information regarding the registration pathways and timelines.

Ghana FDA was established in 1992 on the basis of the 1992 Food and Drug Law (PNDCL 305B), later amended by the Food and Drugs ACT of 1996.

Most regulations/guidance are focused on small molecules, infectious disease. Regulations for biologics are somewhat lagging. There are 8 biologics approved.

CTD format (Module 1 to 5) is acceptable; although it is not truly an electronic submission (CD format).

Must have a local representative in Ghana. Review clock 180 days (6 months) to 10 months for standard submission.

Working towards a centralized application to West African Health Organization to cover western/eastern sub-Saharan countries (~3Q 2017 implementation date).

Challenges:

National Health Insurance does not cover specialty products. Currently, products like Insulin and one biologic for breast cancer are covered.

Inspection is required for biologics. Might get a waiver if it was inspected by EMA & TGA and have a GMP certification. $20K per company for inspection. No need for the site to be in production of the product being reviewed during the inspection.

Only registration testing (not lot-release) is required for Biologics, but does NOT include Bioassay (typically Peptide mapping, Size Exclusion Chromatography). Need to provide special reagents/non-compendial Ref. Std.

Submission requires one Drug Product executed batch records, cold chain validation.
Clinical reviewers sometime stratify African American sub-population from the entire clinical population to ensure safety and efficacy in this subpopulation.

Two languages for the label (English and French) are required.

Post-approval supplements similar to EMA guidance (Type I/II).

Ghana adopted ICH E2b for Biosimilars.