REGULATION OF BIOLOGICAL PRODUCTS IN GHANA-CURRENT TRENDS

FOOD AND DRUGS AUTHORITY GHANA

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REGULATION OF BIOLOGICAL PRODUCTS – OVERVIEW

• LEGAL MANDATE, Public Health Act 851 2012

• FDA-GHANA GUIDANCE DOCUMENTS (Adopted ICH, EMA & WHO)

• THE HIGHEST PRIORITIES (Biosimilars; Quality, abridged Non Clinical & Clinical studies, Pharmacovigilance-Technical Advisory committee)

• ACCELERATED DEVELOPMENT OF CRITICAL MEDICINES (Fast track approval for WHO prequalified Biological products, Flexibility in CMC for Clinical trials, has adopted WHO guideline for clinical trial emergencies)

• TRENDS IN REGULATORY HARMONIZATION (NRAs in Sub-Saharan Africa which is being spearheaded by WAHO/NEPAD)