REGULATORY UPDATES: HARMONIZATION OF BIOLOGICS REGULATION IN THE ECOWAS REGION

- ECOWAS: Economic Community of West African states
- Consist of fifteen (15) member states within the region:

1. BENIN
2. BURKINA FASO
3. CAPE VERDE
4. COTE D’IVOIRE
5. GAMBIA
6. GHANA
7. GUINEA
8. GUINEA BISSAU
9. LIBERIA
10. MALI
11. NIGER
12. NIGERIA
13. SENEGAL
14. SENEGAL
15. SIERRA LEONE
Harmonization programme launched in Accra-Ghana 2017

Guidelines for review of applications approved and adopted.

Mode of application has been CTD modules I to V.

Formation of Expert Working Group (EWG) for assessment of applications has been completed.
CHALLENGES - REGIONAL HARMONIZATION PROCESS

1. Inadequate Assessors with the requisite technical capacity.

2. Differences in requirements for dossier assessment in member countries and level of technical capacity.

3. Language barrier. (8 Francophones, 5 Anglophones and 2 Lusophones)
THANK YOU

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