

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 | 9.LIBERIA |
| 2.BURKINA FASO | 10.MALI |
| 3.CAPE VERDE | 11.NIGER |
| 4.COTE D'IVOIRE | 12.NIGERIA |
| 5.GAMBIA | 13.SENEGAL |
| 6.GHANA | 14.SENEGAL |
| 7.GUINEA | 15.SIERRA LEONE |
| 8.GUINEA BISSAU | |

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

MEDAASE



www.fdaghana.gov.gh