HARMONIZATION OF REGULATORY SYSTEMS
THE CEMAC MODEL

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OUTLINE

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I- PROFILE OF OCEAC

- OCEAC: Organization for the Coordination of Endemic Diseases Control in Central Africa

- Executive Agency of the Central African Economic and Monetary Community (CEMAC) for public health matters

- Created in 1963 to deal with health care and research in 6 countries:
  - Cameroon
  - Central African Republic
  - Congo
  - Equatorial Guinea
  - Gabon
  - Chad
II- MISSIONS OF OCEAC

• Coordination – Research - Training - Expertise
• In the most emerging or re-emerging health problems:
  o HIV/AIDS,
  o Malaria,
  o Tuberculoses,
  o Human African Trypanosomiasis,
  o Immunization,
  o Ebola Fever, Chikungunya...
1-- Regional Policy guidance

1- National Regulatory Authorities (NRA): to be autonomous departments
   => to ensure independence, transparency and accountability in decision-making

2- Good regulatory practices to be implemented
   => to meet global standards of quality, safety and efficacy.

3- Regional centers of excellence to be developed
   => To organize training hubs

4- Coordination and harmonization to be supported
   => collaboration between stakeholders (e.g. NRAs, trade officials, professional organizations,...)

Structures:
African Agency (AMA) to be created by African Heads of State and
Regional Economic Communities are encouraged to work towards harmonization of products regulation.
## IV-Key factors for harmonization

<table>
<thead>
<tr>
<th>Level</th>
<th>Key factors</th>
<th>Activities to be promoted</th>
<th>Expected results</th>
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<tbody>
<tr>
<td><strong>Continental</strong></td>
<td>African political commitment</td>
<td>Joint decision by key parties on African Strategy</td>
<td>Political will and shared common vision at continental level</td>
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<td><strong>Regional (policies)</strong></td>
<td>African ownership</td>
<td>RECs own initiative with a political commitment at high level</td>
<td>Political will and shared common vision at regional level</td>
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<td>Good Governance principles implemented</td>
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<td><strong>Regional (strategy)</strong></td>
<td>Existing regional structure for harmonization</td>
<td>Regional key structure with: effective governance and secretariat existing health cooperation</td>
<td>Similar sector development of participating countries Modern legal systems allowing certain flexibilities</td>
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<td><strong>Régional + National : opérationnal</strong></td>
<td>Timeliness, resourcing of initiative</td>
<td>Full political mandate for REC’ health structure including: common policies, operational plans, common products registration standards with CTDs</td>
<td>Commitment for applying Good Regulatory Practice principles: At national level functional regulatory authorities At REC level centres of excellence /hub of resources Both with necessary capacity and resources available</td>
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V- Implementing harmonization in Africa

- **African ownership**: CEMAC has to own initiative with a political commitment at high level
  - Vision of harmonization by CEMAC authorities: to move toward integration

- To establish **effective regulatory systems** for a better control of the industry and therefore the products
- To make **more effective use of available human and financial resources** in the Sub-region
- To facilitate the **movement** of products within the Community
- To improve access to quality **products** at **lowest cost** for all producers
VI- Possible Timeframe for implementing harmonization

Existing regional structure for harmonization: partnership and collaborative process managed by OCEAC

- 2014: Beginning of the collaborative process
- 2014: Creation of the Program
- 2015: Group work and validation of the documents
- 2015: Signature of common rules
- 2015: Projects
VII- ONGOING HARMONIZED PROGRAMMES

• Drug Policy harmonization programme
  o Started in 2008
  o Launched today 20 February 2014, in Libreville, Gabon
  o Partners: NEPAD, WHO, CEMAC, Countries

• “Establishment of a multi country ethics committee"
  Hosted by OCEAC, covering 6 countries in central Africa
  o Started in 2013
  o Will be Launched in March 2014, Douala, Cameroon
  o Partners: EDCTP, CEMAC, Countries
VIII- Conclusion : Opportunities for accelerating access

**Coordination with manufacturers**
News common Guidelines for *mutual recognition* of products/manufacturers qualification

=> To organize and train a regional team of inspectors with common norms to ensure the quality of the products

**Pooling expertise**
The new SOP to include the opportunity
- to recruit experts in specifics fields,
- to organize the management of potential conflicts of interest

**Registration process**
A unique regional team may have a mandate to analyze Technical dossiers of new products:

=> Sharing skills to ensure quality and timeliness for the registration
THANK YOU FOR YOUR ATTENTION