A Theoretical Framework for Operating Models for African Medicines Agency and Regional Institutions

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A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
Objective

Discuss theoretical frameworks for an operating model for the African medicines Agency, and the proposed regional institutions for regulating medical products.

1. What are the key considerations & the operating environment?
2. What can we learn from the existing models in Africa and elsewhere?
3. How can we make this work in the existing environment?
Introduction

- One of the strategies being pursued as part of harmonisation of medicines regulation in Africa is establishing regional institutions and a African Medicines Agency (Treaty approved 11 February 2019)

- No consensus on the:
  - Operating model of these agencies,
  - Value proposition
  - Roles and responsibilities in a field that appear congested with various actors.
  - Sustainability of these agencies is not clearly demonstrated or understood.
"achieve access to safe, effective, quality and affordable essential medicines and vaccines for all". 

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Three Key Considerations for Regional and Continental Collaboration
Key considerations for Regional & Continental Collaboration

All concepts and levels of cooperation or integration involve an international treaty but also require a high degree of political good will.

- since the partners remain sovereign states keeping (not the right but) the legal power to adopt laws and measures not in line with it

Integration succeeds if it strictly based on the law and if the respect for and the reliable implementation of the law is secured by strong institutions and efficient mechanisms of law enforcement and legal protection.

- The rule of law is a key factor for supra- and international integration, even for the merger of multiple national markets into a single geo-regional market.

- **EU Directive**
  - Harmonisation of national legislation (binds the Member States legislators)
  - Once a directive is adopted, the EU Member States have two years to transpose all its provisions to their national legislation.


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Any chosen regulatory model should generate advantages for all participants and interested parties.

- What advantages (or disadvantages) accrue to each of the key stakeholders or players (current and potential):
  
  - Member states
    - National regulatory authorities
    - National government
    - Ministries of Health
  - Manufacturers (local, regional, foreign)
  - Patients
  - Regional Economic Communities
  - African Union
  - Partners – financial and technical
  - etc...
What is the suitable operational framework for AMA and RECs to achieve universal access to quality assured, safe and efficacious medicines for Africans?
## Comparison of the Regional Entities

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<th>AU</th>
<th>SADC</th>
<th>EAC</th>
<th>EU</th>
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<tbody>
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<td>1</td>
<td>Constitutive elements</td>
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<td></td>
<td>AUC Act</td>
<td>SADC Treaty</td>
<td>EAC Treaty</td>
<td>EU Treaty</td>
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<td>2</td>
<td>Political Organs</td>
<td>Assembly of Union</td>
<td>Summit</td>
<td>European Council</td>
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<td>Pan-African Parliament</td>
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<td>• SADC Parliamentary Forum</td>
<td>• Council of Ministers</td>
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<td>• EALA</td>
<td>EU Parliament</td>
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<td>4</td>
<td>Judicial</td>
<td>Court of Justice (AU Court)</td>
<td>SADC Tribunal</td>
<td>European Court of Justice**</td>
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<td>5</td>
<td>Secretariat</td>
<td>AU Commission</td>
<td>SADC Secretariat</td>
<td>EAC Secretariat</td>
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<td>EU Commission</td>
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## Comparison of the Regional Entities - 2

<table>
<thead>
<tr>
<th></th>
<th>African Union</th>
<th>SADC</th>
<th>EAC</th>
<th>EU</th>
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</thead>
<tbody>
<tr>
<td><strong>6. Decision Making</strong></td>
<td>Two-thirds Majority</td>
<td>Consensus *</td>
<td>Consensus*</td>
<td>Two-thirds (qualified) majority</td>
</tr>
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<td><strong>7. Requirement of State Parties to conform to Community laws</strong></td>
<td>No (but it is implied)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (EU Directives)</td>
</tr>
<tr>
<td><strong>8. Supra-national Elements (Community Law)</strong></td>
<td>No *Summit decisions</td>
<td>No *Protocols</td>
<td>Yes (EAC Laws)</td>
<td>Yes (EU Regulation)</td>
</tr>
</tbody>
</table>

**Supra-national institutions** are largely independent of individual Member States and they are vested with decision-making powers which bind Member States. *Tallberg 2002 West European Politics 23-46*
Is there a suitable operational framework of AU or RECs facilitating the establishment of supra-national entities?
Principle of Subsidiarity - SADC

- **SADC Development Finance Resource Centre**
  - established in July 2003 to serve as a sub-regional centre of excellence to strengthen the SADC Development Finance Institutions (DFIs) Network

- **Legal basis** (*legitimacy*)
  - The founding MOU establishing the Network and the amending addendum are incorporated into the Finance and Investment Protocol of SADC
  - The Network is comprised of those DFIs that have signed the May 2000 MOU, which establishes it as an institutional mechanism of SADC.
  - Currently the SADC DFIs Network has 34 members from 13 SADC Countries.

- **Financing:**
  - Administrative: DFI Network members contributions – Admin
  - Programmes activities funded from donor sources.

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African Regional Intellectual Property Organization (ARIPO) Model

- Created in 1976 by Lusaka Agreement

**Institutional Framework**
- the Council of Ministers,
- the Administrative Council, - Heads of Agencies / Institutions
- the Secretariat, headed by the Director – General

**Model**
- States may chose to be signatory to specific protocols – *Harare Protocol, Swakopmund Protocol, The Banjul Protocol*,
- **Membership** is voluntary – pay annual subscriptions
- **Decision** made by two – thirds majority
- **Dispute resolution** – on interpretation or application of any provisions of the agreement resolved through the organs with Council of Ministers being the final & binding on all the members

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African Regional Intellectual Property Organization (ARIPO)

• **Harare Protocol Dec 1982** – empowers the ARIPO office to receive and process patent and industrial design applications on behalf of States party to the protocol.

**Advantages of ARIPO Membership**

• Pool resources together to avoid duplication of human, material and financial resources,

• Member States have an advantage of economies of scale.

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- Split revenue / fees between ARIPO and Member States
- The ARIPO regional system complements the national industrial property system of its Member States.
- The sovereignty of Member States is preserved
- Flexibility to the users'
- Cost saving to applicants: only one application, only one central process and only one attorney all meant to bring about a multiple-effect protection
Some practical considerations for operational Model for AMA and regional institutions

1. Gains have to be **observable, measurable, and beneficial** to the key players
2. The distribution of gains has to be carefully enumerated, and equitable
   - Split revenue / fees between regional/continental and Member States
3. A degree of national sovereignty surrendered in order to achieve the necessary harmonization at the region or continental level.
4. Regional/continental system should complement the national regulatory system of its Member States.
5. Flexibility to the users’
   - choose between regional/continental or national approach
6. Operational systems that are efficient cost saving to applicants
   - Streamline submission processes, reduce duplications
Models for the Supra-national pharmaceutical legal framework

- **Membership**: Automatic vs Voluntary
- Alignment of domestic laws to be comparable / approximation or similar e.g. AU Model Law
- Division of powers and responsibilities between national and supra-national entities
- Decision making process
- Binding or non-binding decisions at national level
- Dispute resolution mechanism and interpretation
- Functioning national supervision and enforcement
- **Financing**: Membership Fees, Revenue from services, Donor Support, Innovative Financing Models (Social Impact Bonds, Endowment funds)
“Just because we cannot see clearly the end of the road,… that is no reason for not setting out on the essential journey. On the contrary, great change dominates the world, and unless we move with change we will become its victims”

Arthur J. Olsen, Kennedy Exhorts the Poles to Further U.S.-Soviet Friendship, N.Y. TIMES, July 2, 1964, at C6 (quoting Robert F. Kennedy, Farewell Statement at Warsaw, Poland, (July 1, 1964)
The Future ..... 

Individual NMRAs with specific jurisdictions 

transition 

Regulatory Networks 

“A cord of three strands will not be broken”