Regulatory harmonisation of medical products as a key driver to achievement of universal health coverage in Africa

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

- Background
- Context
- Methods
- Results
- Recommendations
Disparities in health outcomes around the world are emblematic of unequal access to health care. In Africa, lack of harmonised regulatory processes is a critical barrier to timely access to essential medicines. Different regulatory processes result in delays for researchers and manufacturers, who must navigate multiple regulatory systems to register the same health product across multiple countries.

Without regulatory harmonisation, the average registration time for medicines in the East African Community is two years. Regional regulatory harmonisation could accelerate this review timeline by 40% to 60%.

The AU Model Law, adopted in January 2016, provided a framework for member states to increase collaboration, strengthen regulatory capacities, and accelerate product registration. Implementation will require sustained and long-term commitments, funding, and political action.

The purpose of this study was to model the potential health impact of increasing regulatory harmonisation across two regional economic communities in sub-Saharan Africa.
Regulatory harmonisation can involve...

- **Sharing of information** such as inspection findings between regulatory authorities
- **Aligning safety and efficacy** standards and processes used to assess and monitor research and products
- **Conducting joint reviews** of research protocols and product dossiers and inspections of research and manufacturing sites
- **Mutual recognition of assessments and inspections** conducted and decisions made by other regulatory authorities

### Benefits for CONSUMERS
- Expands access to essential health technologies
- Increases choice
- Improves quality of technologies

### Benefits for PUBLIC SECTOR
- Strengthens capacity and infrastructure
- Enables a greater scope and reach
- Reduces delays
- Improves quality assurance

### Benefits for PRIVATE SECTOR
- Streamlines data collection and processes
- Reduces costs
- Accelerates approval processes
- Clarifies regulatory pathways

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Methods

Model results analyzed from 2018–2023

Three scenarios were run:
- Status quo launch time (no regulatory harmonisation)
- One year faster (with regulatory harmonisation)
- Two years faster (with regulatory harmonisation)

Peak coverage of 20% increase over the baseline estimated to occur 5 years after launch
Total annual lives saved from launching amoxicillin dispersible tablets and heat-stable carbetocin in the EAC and Zazibona from 2018-2023:

**RESULTS**

<table>
<thead>
<tr>
<th>Year</th>
<th>Without regulatory harmonisation</th>
<th>With regulatory harmonisation (1 year faster)</th>
<th>With regulatory harmonisation (2 years faster)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>1000</td>
<td>3000</td>
<td>1500</td>
</tr>
<tr>
<td>2019</td>
<td>1500</td>
<td>3500</td>
<td>1800</td>
</tr>
<tr>
<td>2020</td>
<td>2000</td>
<td>4000</td>
<td>2200</td>
</tr>
<tr>
<td>2021</td>
<td>2500</td>
<td>4500</td>
<td>2600</td>
</tr>
<tr>
<td>2022</td>
<td>3000</td>
<td>5000</td>
<td>3000</td>
</tr>
<tr>
<td>2023</td>
<td>3500</td>
<td>5500</td>
<td>3500</td>
</tr>
<tr>
<td>2024</td>
<td>4000</td>
<td>6000</td>
<td>4000</td>
</tr>
</tbody>
</table>

Total incremental lives saved:

- (1 year faster): **11,778**
- (2 years faster): **23,391**

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Invest in regulatory harmonisation domestically and across Africa to enable scale-up

Ensure all regulatory phases and functions are harmonised across products

Domesticate the AU Model Law in all AU member states

Accelerating access to two products due to regulatory harmonisation could lead to >23,000 lives saved in Eastern and Southern Africa. In order to fully realize this potential health impact across Africa, sustained commitments—political, financial, and technical—are required from policymakers and donors alike.
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Link to complete PATH publication:
https://www.path.org/resources/making-case-how-regulatory-harmonisation-can-save-lives-africa/

Link to the Lives Saved Tool (LiST):
https://www.livesavaedtool.org/

Amoxicillin photo: Health Communication Capacity Collaborative website.
https://sbccimplementationkits.org/demandrmnch/about-amox/.


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## APPENDIX I: Coverage rates

### Baseline and peak coverage rates of interventions in the Lives Saved Tool

<table>
<thead>
<tr>
<th>Country</th>
<th>Injectable uterotonics</th>
<th>Oral antibiotics for pneumonia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline coverage of oxytocin (2017)¹</td>
<td>Assumed peak coverage (5 years post-commercial launch of heat-stable carbetocin)</td>
</tr>
<tr>
<td>Burundi</td>
<td>44.6%</td>
<td>53.5%</td>
</tr>
<tr>
<td>Kenya</td>
<td>46.1%</td>
<td>55.3%</td>
</tr>
<tr>
<td>Rwanda</td>
<td>68.0%</td>
<td>81.6%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>46.9%</td>
<td>56.3%</td>
</tr>
<tr>
<td>Uganda</td>
<td>43.0%</td>
<td>51.6%</td>
</tr>
<tr>
<td>Botswana</td>
<td>70.4%</td>
<td>84.5%</td>
</tr>
<tr>
<td>Namibia</td>
<td>65.5%</td>
<td>78.0%</td>
</tr>
<tr>
<td>South Africa</td>
<td>66.5%</td>
<td>79.8%</td>
</tr>
<tr>
<td>Zambia</td>
<td>48.2%</td>
<td>57.9%</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>57.7%</td>
<td>66.2%</td>
</tr>
</tbody>
</table>

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1. Baseline coverage rates in LiST for heat-stable carbetocin are for active management of the third stage of labor, which includes oxytocin. Oxytocin is a similar injectable uterotonic to carbetocin and is currently available in some settings to prevent and treat postpartum hemorrhage.

2. Baseline coverage rates in LiST for amoxicillin dispersible tablets are for oral antibiotics for pneumonia (e.g., syrups). These represent other oral formulations of amoxicillin that are currently available in some settings for treatment of childhood pneumonia.

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APPENDIX 2: Amoxicillin results

Modeling results demonstrating the potential impact of regulatory harmonisation for amoxicillin dispersible tablets

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APPENDIX 3: Carbetocin results

Modeling results demonstrating the potential impact of regulatory harmonisation for heat-stable carbetocin

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APPENDIX 4: Model limitations

• For both medicines, it is recognized that **registration is only one necessary component in launching a product** and that registration alone does not guarantee these medicines will become available.

• This analysis **assumes that heat-stable carbetocin will reach regulatory milestones and begin its global launch in 2018**. However, it is possible that this launch may be delayed or not occur.

• **Amoxicillin dispersible tablets were already available in some markets** when this analysis was undertaken, but given the need to scale more broadly, it was selected for this analysis.

• These two medicines alone **do not represent the total impact of regulatory harmonisation**: they are designed to be used as case studies to highlight what is possible for select emerging medicines.

• **Regulatory harmonisation efforts have improved since the modeling exercise occurred, thus the baseline model scenario may underestimate the recent progress.**