Quality Impact in the Light of Shortage of Human Resources

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The Eastern African Region has great potential for domestic pharmaceutical production >60%

A growing # of manufacturers → a significantly increasing sales turn over

They sell their products at affordable cost on the very competitive local market to cover some of the local demand e.g. Malaria, HIV and AIDS medicines

Many are investing in facilities, equipment and personnel to reach a higher standard of the pharmaceutical manufacturing process.
Challenges of producing quality-assured medicines 1/2

- Technical standard of production
- Compliance with WHO Good Manufacturing Practices (cGMP)
- Generic manufacturers → Lack of R&D laboratories
- A survey revealed lack of skilled personnel, e.g., pharmacists, chemists, microbiologist, technicians, adequately trained in production, quality control, quality assurance and maintenance of equipment and management.

Because of this unmet demand East African manufacturers either:  
- “Import” skilled personnel from other countries (e.g. India) or  
- They take the risk to manufacture medicines without adequate attention to quality demands.
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- They take the risk to manufacture medicines without adequate attention to quality demands.
Challenging environment/non-routine practice

High skills level

Continuous upgrading of knowledge and skills

Science at finger tips

Frequent audits

Facts and figures: Industrial Career

Grace to disgrace or vice versa?

2010 Status quo:

- Shely's: →5
- TPI: →6
- ZL: →2
- IPL: →1
- KPI: →2
- AAP: →1
- MD: →2
- TNZ: →3

700-800

3%

22
# HR Supply perspectives

## Schools of Pharmacy *

<table>
<thead>
<tr>
<th></th>
<th>MUHAS</th>
<th>SJUT</th>
<th>CUHAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled students</td>
<td>226</td>
<td>211</td>
<td>68</td>
</tr>
<tr>
<td>Ratio student - lecturer</td>
<td>1:10</td>
<td>1:26</td>
<td>1:23</td>
</tr>
<tr>
<td>Laboratory size</td>
<td>Too small</td>
<td>Too small/absent</td>
<td>Absent</td>
</tr>
<tr>
<td>Laboratory equipment</td>
<td>Needs attention</td>
<td>Poor</td>
<td>Absent</td>
</tr>
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## Schools of Pharmaceutical Assistants and Technicians

<table>
<thead>
<tr>
<th></th>
<th>Muhimbili</th>
<th>Muhimbili</th>
<th>RUCO</th>
<th>Bugando</th>
<th>KSP</th>
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</thead>
<tbody>
<tr>
<td>Enrolled students</td>
<td>91</td>
<td>128</td>
<td>141</td>
<td>109</td>
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Source. Study commissioned by GIZ - Deutsche Gesellschaft für Internationale Zusammenarbeit- conducted MMI

## QUALITY IMPACT

- Numbers, Quality, and types

High qualification

Low qualification
A tech transfer initiative “Pharm R&D Lab” has been set up within EAC with the aim

- to create **sufficient numbers of well-trained** pharmacists and technicians,
- build R&D capacity for local and regional drug manufacturers
- create a **centre of excellence** for ongoing **Technology transfer** of GMP compliant development & production of generic formulations
- Offer **technical assistance** to the Drug Regulatory Authority for Auditing and Regulatory affairs,
- Assist regional manufacturers to go for WHO Prequalification
Five Cohorts

Pre-service students practical sessions - 250 (MUHAS) + 170 (St John Uni.)

The Pharm R&D so far has conducted 6 Regional workshops:

- "Validation and Qualification" in a manufacturing areas (in December 2008) (20)
- "Granulation, Tabletting and Coating" in Sept 2009. (23)
- "Quality Control of Medicine" in Dec. 2009. (22)
- "Quality Control of Medicine" in Feb. 2010. (22)
- "Coating and sustained release formulation" Nov 2010 (16)
- "Development and QC of generic medicines Nov 2011 (25)
Attracted key personnel working in the local and regional industry (DR Congo, Uganda, Kenya, Rwanda, Malawi, Zambia and Botswana).
What Partnerships involved?

- **2005/2006 Two training**
  - action medeor, InWEnt, TFDA, TPI, SLF-Moshi; University was invited

- **2007 Lab setting up**
  - PPP: MUHAS, GTZ, action medeor

- **2008 Training began the lab**
  - 4 Regional workshops: MUHAS, TFDA, action medeor, InWEnt and European Union

- **2011 further trainings**
  - 2 Workshops; MUHAS, action medeor, GIZ (formerly GTZ + InWEnt), TFDA, WHO

- **Pipe line**
  - MUHAS/TFDA/NEPAD/action medeor/WHO
  - TesmA Project: MMI, TFDA, FBO, MUHAS, CUHAS, etc
A. Efavirenz tabs

1. 1200 mg Tab

B. Lamivudine/Tenofovir FDC project

1. Pre-formulation studies competed
2. Formulation TRIALS

C. Omeprazole project

1. Pre formulation studies competed
2. Formulation TRIALS on going

2- Master students
1- Master students
Other Initiatives

- Institutionalization of Regulatory training in Africa
  - NEPAD - Forge partnerships
  - Academic inst. → didactic training
  - NMRA → experiential training

- TesmA – Project Strengthening capacity of NMRA to fight substandard and fake medicine
  - North-South
  - South-South

- Testing services to clients
Concluding remarks

- Availability of skilled personnel is still a challenge to local pharmaceutical production
- However, in order for this potential to fully contribute the various stakeholders such as the industry, universities, governments, and NGO will need to work together to address:
  - Quantity
  - Quality
  - Types
Acknowledgments

 ✓ GIZ
 ✓ action medeor
 ✓ MUHAS University