Challenges in national regulation of critically needed medicines

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Tanzania Food and Drugs Authority (TFDA)

- **Semi-autonomous Executive Agency** under the Ministry of Health and Social Welfare
  - established in 2003 under the Tanzania Food, Drugs and Cosmetics Act, Cap 219.

- **Regulatory body** mandated to regulate safety, quality and effectiveness of food, medicines, cosmetics and medical devices.

- **Mission** - “to protect and promote public health by ensuring safety, quality and effectiveness of food, medicines, cosmetics and medical devices”.

- **Vision** - “to be the leading African Regulatory Authority in ensuring safety, quality and effectiveness of food, medicines, cosmetics and medical devices for all”.

www.tfda.or.tz
Challenges of medicines regulation

- Adequacy of **legislations** to address all regulatory requirements & mandates
- Management structures and processes – good regulatory practices
- Human resources capacity (number and skills) and resources (financial & infrastructure).
- **Lack of harmonized GMP requirements** and **inspection procedures** among regulators in importing and exporting countries & **within the same region**.
- **Market control**
  - Inspecting all consignments/batches imported
  - Control of substandard/spurious/falsely-labeled/falsified/counterfeit (SSFFC) medical products
Challenges ... SSFFC medical products

• SSFFC anti-malarial, *Metakelfin tablets* were found on the market in March 2009.
  – Lab analysis confirmed lack of *Pyrimethamine 25mg*, while *Sulphamethoxypyrazine* was available at 0.4% (acceptance limits 90-110%)
  – Several batches were confiscated from the private pharmacies
<table>
<thead>
<tr>
<th>Metakelfin 500 mg</th>
<th>Metakelfin 500 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMPOSITION</strong></td>
<td><strong>COMPOSITION</strong></td>
</tr>
<tr>
<td>Active substance: Pyrimethamine, 5 mg.</td>
<td>Active substance: Pyrimethamine, 5 mg.</td>
</tr>
<tr>
<td>Protect, as reserve in treatment of malaria caused by P. falciparum (as adult and juvenile forms), P. vivax, P. ovale, P. malariae (as adult forms only).</td>
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</tr>
<tr>
<td>Each tablet contains 2-methyl-4-phenyl-6-pyrimidinol (pyrimethamine) 5 mg.</td>
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</tr>
<tr>
<td><strong>INDICATIONS</strong></td>
<td><strong>INDICATIONS</strong></td>
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<tr>
<td>Treatment and prophylaxis of malaria caused by P. falciparum, P. vivax, P. ovale, P. malariae.</td>
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</tr>
<tr>
<td><strong>ADVERSE REACTIONS</strong></td>
<td><strong>ADVERSE REACTIONS</strong></td>
</tr>
<tr>
<td>None expected.</td>
<td>None expected.</td>
</tr>
<tr>
<td><strong>CONTRAINDICATIONS</strong></td>
<td><strong>CONTRAINDICATIONS</strong></td>
</tr>
<tr>
<td>None known.</td>
<td>None known.</td>
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<tr>
<td><strong>PRECAUTIONS</strong></td>
<td><strong>PRECAUTIONS</strong></td>
</tr>
<tr>
<td>None known.</td>
<td>None known.</td>
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<tr>
<td><strong>DOSAGE AND ADMINISTRATION</strong></td>
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</tr>
<tr>
<td>- Children: 5 mg/kg body weight orally in a single dose.</td>
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</tr>
<tr>
<td>- Adults: 1 tablet - 1 tablet</td>
<td>- Adults: 1 tablet - 1 tablet</td>
</tr>
<tr>
<td><strong>PACKAGING</strong></td>
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</tbody>
</table>
Counterfeit **Laifin** (with Sulphamethoxazole) was being sold/dispensed as **Laefin** (with Sulfametopyrazine) in September, 2011.
Metronidazole tablets were found being sold as Antimalarial Quinine Sulphate tablets in February, 2012.
WHO Support to NMRAs in Africa

• Capacity building programmes of regulatory & industry staff since 2002
  – Assessment of medicines quality, safety and efficacy
  – GMP compliance based on WHO Guidelines

• Participation in WHO Prequalification of Medicines Programme since 2001
  – Assessment of dossiers submitted to WHO PQ
  – GMP inspection as observers
  – Rotational post at WHO HQ (8 fellows – 2 Kenya, 3 Uganda, 3 Tanzania)
WHO – EAC Joint Pilot Project

- Launched in March 2010 involving two products
  - **Abacavir** (as sulphate) 60mg tablets for oral suspension & **Amikacin** 500mg/2ml injection solution
  - Applications simultaneously submitted to WHO PQ and EAC NMRAs
  - Assessments conducted in Copenhagen - WHO PQ Programme expertise to provide direct support to EAC assessors (2 from each NMRA)

- Products prequalified and registered in countries simultaneously – **accelerated access**

- Platform for **mutual recognition** of regulatory decisions in future (medicines harmonization process in EAC)
EAC Medicines Regulatory Harmonization Project

- First Regional Economic Community in Africa to launch (March, 2012) the project (2012-2016) under the African Medicines Registration Harmonization Initiative (AMRHI).
  - **Purpose** - To harmonize medicines registration in the EAC Partner States in order to increase the rapid availability of safe, efficacious and good quality essential medicines
  - **Project Goal** - To have a harmonized and functioning medicines registration system within the East Africa Community in accordance with national and internationally recognized policies and standards [WHO & ICH]

- Project is coordinated by the EAC Secretariat in collaboration with the Partners – NEPAD Agency, WHO, the World Bank, others.
Key achievements of TFDA (2003 – 2013)

- Key regulatory systems, processes and procedures in place.
  - Marketing authorization/registration
  - GMP Inspection
  - Market control (post-marketing surveillance)
  - Pharmacovigilance
  - Clinical trials control


- Increased staff - 185 in 2013 vs. 52 in 2003
Conclusions

• **Progress recorded in capacity building** of medicines regulatory systems in Africa - thanks to WHO and other partners.
  – Challenges remain in assuring access to **safe, efficacious generic medicines of acceptable quality**.

• The future is **regional collaboration and co-operation** for effective medicines regulation especially in Africa.

• **EAC Medicines Regulation Harmonization Project** is a **showcase** for medicines regulatory harmonization
  – sets an **example** for other regional economic communities in Africa.
Thank you