Workshop on flexibilities in International Intellectual Property Rules and Local Production of Pharmaceuticals for Southern, Central and West African Region
7 – 9 December, 2009
Cape Town, South Africa

Registration of Medicines: Zambian Experience

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Presentation outline

- Zambia’s Geographical position
- Background information
- Registration System for Medicines
- Challenges
- Brief overview of Patents Legal Framework
- Conclusions
Zambia – History, Geography and Economy

Political independence: 1964
Multipartyism: 1991
Landlocked country
Area: 752,612sqkm
Population: 11.2mlnpeople (2005)
Copper is main export earner
Poverty estimates: 70-73%
Least developed country

Pharmaceutical Regulatory Authority of Zambia
Background information

- **Brief history (1)**

The history of medicines regulation in Zambia dates back to 1941 when the Pharmacy and Poisons Act, Chapter 299 of the Laws of Zambia was first enacted. This Act was to provide for the control of the profession of pharmacy and trade in drugs and poisons. The Pharmacy and Poisons Board (PPB) was established under this law to oversee its enforcement.
The Pharmaceutical Act No. 14 of 2004 (1)

• Pharmaceutical Act (No. 14) of 2004 was enacted in August 2004 and came into force in November 2004

• The Act establishes the Pharmaceutical Regulatory Authority as an autonomous body corporate, the PRA Board and a Secretariat

• Clearly stipulates functions of the PRA
The Pharmaceutical Act No. 14 of 2004 (1)

The Act vests powers in the Board to:

• appoint committees to assist in the performance of PRA functions.
• Appoint staff of the PRA including the CEO
• The Act further provides powers for the Minister of Health to make regulations on recommendations of the PRA Board.
Legal basis for medicines registration

• Subject to other provisions, the Pharmaceutical Act requires that all medicines intended to be placed on the Zambian Market be the subject of a product licence or Marketing authorization issued by the Authority.
Requirements for registration of a medicine

• Objective: To protect public Health by ensuring the quality, safety and efficacy of medicines to be placed on the market

• Applicant required to submit a dossier in the prescribed format

• Dossier must contain detailed information on: (1)
  ➢ Quality Assurance including GMP and Quality controls
  ➢ Safety – Toxicological and pharmacological data
  ➢ Efficacy – Clinical data
  ➢ For certain Multisource generic products applicant is required to demonstrate interchangeability with innovator product

• Patent Registration is not a pre-condition for placement of a medicinal product on the market
The Registration System for Medicines

Applicant submits dossier

Preliminary Review

Assessment for completeness

Communication to applicant

Accepted and entered in the SIAMED database

Evaluation

Full review of dossier and Summary report prepared

Decision Making

Medicines Committee Review and decision

Grant/issue of Product licence
Registration system

1. Preliminary Review

- Completeness of application
- Application must be in the required format and supported by detailed technical information as may be appropriate
- Administrative data with respect to the applicant (Prospective PLH) manufacturing site, status of manufacturer, fees paid, samples
- Acknowledgement and entry into PRIMS
Registration system cont...

2. Evaluation:

- This depends on the nature of the application, i.e. Standard application or Fast track
- Timelines for review are yet to be established
- Extent of review depends on the nature of the product, i.e. locally manufactured product, WHO Pqed, Registered by stringent DRAs within and outside the region, new chemical entity or generic application
Registration system...

- Due to insufficient capacities QC is not routinely carried out as part of assessment
- GMP inspections may be carried out on the recommendation of the Medicines Committee
- Assessment report is prepared in the required format and presented to the Medicines Committee with the recommendations on Q, S, E.
Registration System...

- Decision of the Committee may be positive, negative or deferred pending further submission of the required information as may be directed by the Committee.

- If positive, a product license is issued and is subject to certain conditions as may be appropriate; and

- Applicant required to comply with labelling requirements as stipulated under the regulations and expected to pay annual retention as required by the Act.
Registration system...

- If decision of the Medicines Committee is negative, the applicant is informed accordingly and reasons given in writing for non-issuance of the product license

- Applicant may appeal against the decisions of the Authority as per the appeal procedures

- In cases where additional information may be required the applicant is requested to submit within a defined timeframe failure to which the application may be cancelled
Registration system...

- Data in respect of a registered product is maintained by way of a WHO computer-assisted medicines registration programme called SIAMED.

- There is a procedure for variations and all variations need to be notified to the Authority.
Post marketing Surveillance

Monitoring and Evaluation mechanism for licensed medicinal products

- Sampling and testing of products
- Pharmacovigilance activities
- General surveillance activities to ensure adherence to licensing terms and conditions
Challenges

Systems
➢ Poor Infrastructure
➢ Insufficient Human and financial Resources
➢ Inadequate qualified human resources with appropriate skills

Environment
➢ > 90% of products are imported
➢ low levels of Local manufacture activities
Brief on Zambia’s Patent law

- Zambia is in the category of LDCs
- IP laws as they stand today are as was inherited from our colonial powers – in short they are outdated (Patents Act Cap 400 of 1958)
- A patent is granted for 16 years
- The patent owner is responsible for enforcing his rights as stipulated under the Act including detecting of infringements
Conclusion

• The registration of a medicine in Zambia is an independent process and based on assessment of safety, quality and efficacy data
• The current IP regime is outdated and not in line with the current TRIPS agreement
• Legal reforms are underway and under the Ministry of Commerce, Trade and Industry.
• MoH is actively participating in the review activities
Finally...

Thanks to UNCTAD and its for inviting Zambia to attend this timely meeting

Merçi

Obrigado

Thank You for your attention