Regulatory Capacity Building in Mozambique: Cooperation with Brazilian Regulatory Authority

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Background

Mozambique is located on the eastern coast of southern Africa. It has eleven provinces: Cabo Delgado, Niassa, Nampula, Tete, Zambezia, Manica, Sofala, Inhambane, Gaza, Maputo Province and Maputo City. The coastline of the country, which spans 2,470km along the entire eastern frontier, borders the Mozambique Channel and the Indian Ocean. To the north of Mozambique lies Tanzania, to the northwest Malawi and Zambia, to the west Zimbabwe, and to the southwest South Africa and Swaziland.
Background

- **President of the Republic:** Armando Emilio Guebuza
- **Area:** 799,390 km²
- **Population (2010):** 22,416,881
- **Climate:** Inter-tropical
- **Capital:** Maputo
- **Official Language:** Portuguese
- **Currency:** Metical (MT)
- **Chief Exports:** Prawns, cashews, cotton, sugar, citrus, copra, coconuts, and timber
- **Chief Imports:** Food, clothing, farm equipment, petroleum, transport equipment, health equipments and consumables, pharmaceutical products.
- **GDP (2009):** +6.4% (+8.8% II TRIM 2010)
- **GDP/Capita (2009):** 454USD
Background – Health Sector

- Life Expectancy (2009): 47.1
- Adult Mortality (2009): 16.4/1000 inhabitants
- Infant Mortality (0-1 years) (2009): 107.9/1000
- Infant and under 5 Mortality (2007): 168/1000
- Maternity Mortality (2005): 520/100000
- Institutional Deliveries:
- HIV Prevalence: 11.5%
- Main Cause of Mortality: Malaria (children), HIV/AIDS (adults), Diarrhoea, Respiratory Infections, Malnutrition (44%).
Background – Health Sector

- **Health Facilities:** 1350 (does not include private sector)
- **Number of Retail Pharmacy:** 361 (40 public)
- **Number of Beds (2009):** 10.7/10,000 inhab
- **Health Budget (2009):** USD309,339,970.24
- **Pharmaceutical Budget (2009):** USD91,263,700
- **Health Professionals:** 33,000 in total, but only 15,000 with a health degree
- **Ration between Health Professionals and Population:**
  - 1 doctor/20,000 inhab
  - 1 nurse/5,000 inhab
  - 1 Pharmacist/70,000 inhab
Pharmaceutical Department

- The Pharmaceutical Department (PD) is the institution responsible for all activities related with medicines regulation and law enforcement.

- This department are responsible for license (products and premises); inspection, pharmacovigilance and post market surveillance, clinical trials and quality control, medicines prices control

- All regulatory activities are regulated by Law 4/98 (Medicines Act) that is supported by many other norms and regulations;
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Pharmaceutical Department

- The department is now in a process to approve the law that will create an independent and autonomous regulatory authority.

- Currently, this department is under direct supervision of the Minister of Health.

- The department has already its own facility (outside the Ministry of Health main building).
Human and Financial Resources

• The PD has 40 employees: pharmacists, biologists, chemistries, economists, public administrative, others.

• Financing:
  • State Budget
  • Donors Budget (mainly WHO)
  • Own revenue

• The department keep 60% of the revenues collected from registration and inspection activities.
The Project with Brazil National Health Surveillance Agency (ANVISA)
History

- May 2008: Because of the project for the implementation of ARV plant in Mozambique with technical assistance of the Brazil, both Governments identified the need to strengthening the PD as a Medicines Regulatory Authority.

- September 2008: Both MoH of Mozambique and Brazil signed in Rio de Janeiro, Brazil, a MoU for the cooperation between ANVISA and PD;

- October 2008: The two MoH and PD and ANVISA signed the Project for the Capacity Building of PD.
Objectives

- The main objective of the project are to promote the capacity and exchange of information and experiences in the areas of pharmaceutical regulations, with emphasis on:
  - Organizational structure of the PD;
  - Medicines and health products registration;
  - Pharmaceutical inspection;
  - Combat of counterfeit medicines;
  - Clinical trials;
  - Pharmacovigilance and Post market surveillance of medicines and health products;
  - Quality control
  - Economic regulation
Expected Results

- By the end of the project, the expectation is that the PD could be able to protect the public health of Mozambican people by controlling the sanitary issues of production and commercialization of medicines and health products.

- To get the results, the capacity building were done both in Mozambique and in Brazil (Mozambicans Professionals went to Brazil and Brazilian Professionals went to Mozambique)
Registration

- All staff were training
- The main areas covered:
  - Registration procedures for medicines, biologic products, herbal products (from submission of dossiers to approval);
  - Control of importation of pharmaceutical products;
  - Bioequivalence and Pharmaceutical Equivalence studies;
Registration – Benefits for PD

- Improvement of all registration “circuit”;

- Development of a generic medicines policy;

- Improvement in control of medicines in circulation in the local market;

- Implementation of a system for to monitor the quality of all registration steps;
Registration – Benefits for PD

- Improvement of database use and establishment of a new database;

- Development of a new guideline for post approval procedures.

- Development of norms for the stability studies;

- Better clarification on legal aspects of the registration (main the ownership of the market authorization certificate)
Inspection

- The capacity building for inspection happened in three phases, two of them in Maputo and one in Brasilia.

- In the first phase, professionals from ANVISA went to Maputo first to analyze our legislation and regulation and second to perform joint inspections in pharmaceutical premises with our inspectors.

- They also gave training on license of premises based in GDP and GMP.
Inspection

- The second phase, also in Maputo, was dedicated to the procedures for the control and management of controlled medicines (psychotropics, narcotics, stupefacients);

- In this phase, a training on false/counterfeiting medicines were performed as well.

- Then the third part of capacity building were performed in Brasilia and 3 inspectors benefit from this. This phase was mainly dedicated to GMP.
Inspection – Benefits for PD

- Elaboration of new procedures (notification, interdiction term, apprehension terms for products and premises);

- Elaboration of norms for the good pharmaceutical importation, distribution, storing and export practices;

- Elaboration of criteria for the application of penalties in pharmaceutical sector.
Clinical Trials

- The capacity building in CT had two phases:
  - Professionals from ANVISA went to PD to help in elaboration of CT regulations and guidelines and also training for CT approval;
  - PD professionals went to ANVISA for the GCP training.
Clinical Trials - Benefits

- Improvement on the evaluation of the CT protocols;

- Elaboration of CT regulation;

- Officials from PD are doing an specialization (distance learning) offered by ANVISA in “Medicines Based on Evidence”;

- PD started collaborating with MoH ethics committee.
Pharmacovigilance

- PD professionals went to ANVISA for training in:
  - Elaboration and evaluation of ADR’s card;
  - Evaluation of periodic safety reports;
  - Participation in Rational Drug Use Congress;
  - Participation in Annual Congress of Risk Managers;

- ANVISA professionals went to PD for training in:
  - Pharmacovigilance (for all PD professionals including the ones located at provincial level).
Pharmacovigilance - Benefits

- Elaboration and approval of National Regulation for the Pharmacovigilance System;
- Training of PD health professionals for the notification of ADRs;
- Expansion of PV activities (allover the country);
- Increasing of ADRs notifications;
- Beginning the evaluation of periodic safety reports;
- Better coopereation with the mainly health programs of MoH (Malaria, HIV/AIDS, TB, Immunization, etc).
Quality Control

- Professionals from ANVISA went to PD to evaluate the actual status of QC (Quality Control) Lab (in a process of modernization);

- Undergoing the development of a QC strategic plan in order to build a new reference QC for medicines, health products, herbal products and small “equipment”.
Economic Regulation

• The capacity building in economic regulation (price control) occurred both in ANVISA and in PD;

• First, 2 officials from PD went to ANVISA to better understand the process of economic regulation. They also had the opportunity to participate in the Pan American Health Organization Seminary for economic regulation, held in Brasilia.

• Second, professionals from ANVISA went to PD to analyze the new price control regulation, developed after the capacity building in ANVISA
Economic Regulation - Benefits

- Development and approval of a new regulation for price control;

- Improvement of all system for the control of prices (approval).
New Legislation and Regulations

- Revision of Medicines Act that will also create the independent authority (undergoing);
- Regulation for National Pharmacovigilance System (DM 53/2010);
- New Essential Drug List Approved (DM 54/2010);
- New Regulation for GDP, GSP, GIP and GEP;
- Norm to recognize ANVISA as an Reference Authority in Mozambique;
- Regulation for the extension of registration to health products, herbal and homeopathic products, cosmetics and disinfectants.
Remaining Activities

• GMP (joint inspection);

• Workshop for the implementation of new price control regulation (involving all interested parties, mainly the private sector);

• Training in management of controlled medicines in Brazil.

• Practical training in quality control in Brazil.
Other Partners Involved

- Brazilian Cooperation Agency – ABC (sponsor);
- WHO;
- WHO AFRO;
- Pan American Health Organization (PAHO).
Conclusion

- During the last two years cooperating with ANVISA the PD has received a considerable benefit. Many things were improved in Mozambique regulatory system, for example:
  - Registration extension to other health products apart from medicines:
  - Celerity in registration evaluation;
  - Development of PV;
  - Improvement of the enforcement in all pharmaceutical chain (public and private);
  - Improvement of the transparency between PD and private stakeholders.
Conclusion

- Despite all the goals achieved, we still have challenges, mainly in:
  - Deepening the knowledge in license of health, herbal and cosmetics products;
  - Strengthening of inspection (law enforcement);
  - Quality control and build a reference QC Lab;
  - Combat false/counterfeiting products;
  - Promotion of Rational Drug Use (with WHO collaboration).
Conclusion

We are glad because ANVISA and ABC are considering the possibility of extending the Project for more two years which will enable us to deepen and improve the regulatory system in Mozambique.
Acknowledgements

- Government of Mozambique (Political will);
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- ABC;
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