

**TECHNICAL COOPERATION AND CAPACITY BUILDING:
"CLUSTER" A OF THE DEVELOPMENT AGENDA**

BRAZIL

Addendum

The present document reproduces additional information, received from the delegation of Brazil by means of a communication dated 28 October 2009, as an addendum to document IP/C/W/513 of 20 June 2008.

In the light of the document IP/C/W/513, Brazil presents the following form of stock-taking of capacity building activities as an example of cooperation that complies with WIPO's Development Agenda principles. The aim of this addendum is to demonstrate that the 14 recommendations from the cluster A of WIPO Development Agenda can be easily fulfilled in capacity building activities.

1. SUMMARY	
Project Code:	Project BRA04/044 S136 (Technical Cooperation Project between Developing Countries, financed by the Brazilian Cooperation Agency from the Ministry of External Relations of Brazil).
Title:	Strengthening the Mozambican Drug Regulatory Authority as a pharmaceuticals regulation agency – institutions involved: ANVISA (Brazil) and the Pharmaceuticals Department of the Ministry of Health (Mozambique).
Development Agenda Recommendation:	WIPO technical assistance shall be, inter alia, development-oriented, demand-driven and transparent, taking into account the priorities and the special needs of developing countries, especially LDCs, as well as the different levels of development of Member States and activities should include time frames for completion. In this regard, design, delivery mechanisms and evaluation processes of technical assistance programs should be country specific.

Project Budget:	Overall costs: US\$ 453,236.00
Project Duration:	16 months: Project start date: October 2008 Project end date: February 2010
Brief Description of Project:	The main purpose of the project is to strengthen the capacity of the Mozambican Drug Regulatory Authority in the regulation of the country's pharmaceutical sector, aiming at providing the society with medicines of assured quality, safety and efficacy. The scope of the project is to provide a broad overview of the main regulatory functions of a National Regulatory Authority (NRA), according to ANVISA's expertise, such as registration of medicines, focused on generic drugs; economic regulation of medicines; pharmaceutical inspections; laboratories; combat falsified medicines and surveillance of medicines under special control; clinical trials; pharmacovigilance; post-market surveillance of medicines and health services.
2. PROJECT DESCRIPTION	
2.1. INTRODUCTION TO THE ISSUE/CONCERN	
<p>This project responds to WHO's recommendation regarding the creation of a national regulatory authority in Mozambique responsible for the health surveillance and regulation of the pharmaceutical sector in the country. Such authority should have technical as well as financial capacity to provide the society with products of assured quality, safety and efficacy as well as accessible prices.</p> <p>Furthermore, the strengthening of the Mozambican NRA is associated with the bilateral project of construction of an antiretroviral plant in the country through the technology transfer of production of a Brazilian Public Laboratory (FIOCRUZ, Ministry of Health). Considering the future production of medicines in the country, the State must be responsible not only for the access of drugs but also for the health surveillance of the products being marketed, through a recognized health authority. In this sense, the technical cooperation project aims at strengthening the national regulatory authority of Mozambique by structuring the institution and training its personnel and managers.</p> <p>This project is in accordance with article 67 of the TRIPS Agreement that deals with the need for technical cooperation in favor of developing and least-developed country Members. In addition, as there is a specific activity under the project concerning capacity building on intellectual property matters and its relation to public health, the project also contributes to the TRIPS Agreement by providing legal assistance for strengthening the capacity of intellectual property offices within developing countries (Article 67 – Technical Cooperation - Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.)</p> <p>Capacity building on intellectual property rights and public health issues is also related to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health as well as to the Global Strategy on Public Health, Innovation and Intellectual Property.</p>	

2.2. OBJECTIVES

Development goal: To support the Mozambican government initiative in promoting and protecting public health, through the sanitary control of products and services submitted to health surveillance and regulation.

Objective 1: To strengthen the national drug regulatory authority of Mozambique, through capacity building of human resources and the exchange of information and experiences on pharmaceutical regulation, such as organizational structure, quality control, marketing and licensing authorization, economic regulation of medicines, pharmaceutical inspections, clinical trials, pharmacovigilance and post-market surveillance.

2.3. DELIVERY STRATEGY

The bilateral technical cooperation project, financed by the Brazilian Cooperation Agency, is in accordance with the guidelines and priorities established by the Brazilian Foreign Policy. It is aimed at strengthening the bonds of cooperation between developing countries, especially South American neighbors, Latin American countries and African countries, notably Portuguese speaking countries who are members of the Portuguese Speaking Countries Community (CPLP). Furthermore the South-South cooperation is another priority of the government that aims at fostering the exchange of information and experiences and the mutual knowledge amongst developing countries and Least Developed Countries.

The principles of the Brazilian Foreign Policy and the South-South cooperation directly related to it are the values of solidarity, mutual knowledge and respect, autonomy, sovereignty and independence. With that in mind, the technical cooperation seeks to respect these values and aims at respecting the independence of Mozambique regarding decision-making procedures and on national needs and priorities. In this sense, the role of Brazil is to support the African country in its decision making process, in accordance with its reality. ANVISA contributes to this objective by sharing its experience and regulatory framework and also benefits from the Mozambican experience.

Scope:

The project is limited to the financial resources approved to its implementation and to the timeframe of the project. Besides that, the financial and human resources limitation of Mozambique might be a restriction to the acquisition of the knowledge being shared by ANVISA and by the implementation of the regulatory agenda within the country. Also the health difficulties that face the African country as well as the variety of actors that participate in the sanitary arena, including international donors, bilateral agencies, international organizations, non-governmental organizations might be an obstacle to the government's decision making procedures.

Risks:

- (i) Limited financial resources and limited qualified human resources to implement the regulatory functions of the NRA
- (ii) Financial resources and timeframe of the project might be insufficient to achieve the development goal of the project.
- (iii) Other priorities could restrict the capacity of the NRA to implement all the regulatory functions required by the WHO.