NIGERIA

Regulating Medicines in Nigeria

STUDY ON PATENT MEDICINES IN NIGERIA

Nigeria prohibits the manufacture and import of unregistered products under the Drugs and Related Products (Registration etc). Decree No 19 of 1993 as amended by Decree No 20 of 1999.

Drugs are regulated in Nigeria by the National Agency for Food and Drug Administration and Control, NAFDAC.

NAFDAC GUIDELINES FOR PROSPECTIVE IMPORTERS OF REGULATED PRODUCTS

When a foreign regulated product is duly registered by NAFDAC, it can be lawfully imported, distributed and sold in Nigeria. The procedures for the importation of such regulated products are as follows:

Importers shall submit to the NAFDAC office whose operations cover the port (air, sea or land borders) where the goods are to be landed, the following documents prior to physical inspection and "formal" sampling of the regulated product:

-Properly completed Customs Bill of Entry.

-Evidence of registration of the regulated product.

-The original of combined Certificate of Manufacture and Free Sale issued by the appropriate Health Authority in the country of the product origin.

-The original certificate of analysis of the product.

-Other additional information required are:

-Evidence of payment of a prescribed fees in bank draft made payable to NAFDAC.

-An undertaking duly signed by the importer that the product would not be sold until confirmed fit for human use by NAFDAC laboratory.

-Address of the importer's warehouse.

-In the case of milk, fish and fishery products, copy of certificate of radiation test issued by an appropriate government agency in the country of origin will be required in addition to (a-above.)

In case of drugs, the following additional documents will be required as well:

-Evidence that the importer is a pharmacist or has employed the services of a pharmacist.

-Copy of the current annual certificate of registration/retention of premises issued by the Pharmacist Council of Nigeria (PCN)

-Copy of the current annual license of the Superintendent Pharmacist issued by the PCN.

-Evidence of a permit issued by NAFDAC Directorate of Narcotics and Controlled Substances if the imported product is a controlled drug or chemical.

DRUG PRODUCTS ON THE FEDERAL GOVERNMENT IMPORT PROHIBITION LIST

-Paracetamol tablets and syrups

-Cotrimoxazole tablets and syrups

-Metronidazole tablets and syrups

-Chloroquine tablets and syrups

-Hematinic formulations:

i.Ferrous sulphate and ferrous gluconate tablets

ii.Folic acid

iii.Vitamin B complex tablets [except modified release formulations]

-Multivitamin tablets, capsules and syrups [except special formulations]

-Aspirin tablets except modified release formulations and soluble aspirin

-Magnesium trisilicate tablets and suspensions

-Piperazine tablets and syrups

-Levamisole tablets and syrups

-Clotrimazole cream

-Ampicillin/Cloxacillin combination capsules

-Ointments – Penicillin/gentamycin

-Pyrantel palmoate tablets and syrups

-Intravenous fluids (Dextrose, Normal Saline etc)

Nigeria's first school of pharmacy: University of Lagos Faculty of Pharmacy. Left, students looking for their exam results. Right, research lab testing drugs. Dr Dodgson photos.

NIGERIA

World Trade Organization

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001 by World Trade Organization

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Arik Air. Three times a week from Freetown to Lagos. Three times a week from New York to Lagos, no stops.

Below, Arik Air office in Freetown, Sierra Leone.

NIGERIA

Innovations and knowledge for future health systems for the poor: Policy Brief was published by Future Health Systems in March 2008.

This brief included results of a study on patent medicine vendors in Nigeria by the University of Ibadan, in collaboration with Future Health Systems Research Program Consortium. Its purpose was to increase understanding of the malaria treatment markets and the role of patent medicine vendors (PMVs), and identify ways to improve malaria treatment.

The policy introduction included: "When someone has a fever they believe to be malaria, they usually go to a private patent medicine vendor for anti-malarial drugs. Although patent medicine vendors are the most common source of malaria treatment in Nigeria, little is known about them. It is important to understand the poorly regulated market in which they work because patients do not know what they are getting. This are a lot of substandard and fake drugs around. Also, the malaria parasite has become highly resistant to the medicines that were used in the past. The government has recently changed its guidelines and recommends that people use artemisinin-combined therapy. But it is not clear how this change in policy has affected the market that provides malaria treatment for most Nigerians."

Ibadan University scientists went to 12 local government areas in 3 states to investigate how malaria is treated, the role of patent medicine vendors, and determine ways to improve malaria treatment.

The scientists interviewed 110 patent medicine vendors and 113 households in 6 urban and 6 rural local government areas from Oyo, Kaduna, and Enugu States. They additionally interviewed 54 community leaders, 55 Patent Medicine Vendor Association officers and 31 government and health officials, and

Scenes from Lagos, Aug 2010. Dr Dodgson photos.

investigated 106 drug shops in the same communities.

The Policy Brief summarizes the findings thus:

-Patent medicine vendors are the largest source of malaria treatment in all areas

-Patent medicine vendors have little knowledge of the new treatment guidelines, and most government officials know little about patent medicine vendors

-Patent medicine vendors sell many different drugs for malaria; the most common and cheapest are least effective

-The recommended treatment, artemisinin-combined therapy, is not readily available, and is the most expensive

-Patent medicine vendors, other health providers, government officials, and community members share concerns about the quality of drugs

-The organisation of the supply chain for pharmaceuticals differs between states, meaning that local knowledge and locally adapted solutions are needed

Summarized from http://www.futurehealthsystems.org/docs/Policy%20Brief%20%20NIGERIA%20March08.pdf.