KNOWLEDGE PARTNERSHIP PROGRAMME
HEALTH AND DISEASE CONTROL

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Pharmaceutical Quality Systems in Context of Exports from India to African Countries

Introduction

Poor drug quality is a largely neglected public health challenge. Fast pace of globalisation of pharma industry risks the rapid spread of poor quality drugs. Substandard and Counterfeit are two important categories. 'Sub-standard drugs' includes those drugs that are produced as a result of lack of expertise, poor manufacturing practices, and corruption and complex trade agreements. 'Counterfeit drugs' may contain inactive, incorrect or even toxic ingredients. IMPACT (International Medical Products Anti-Counterfeiting Taskforce) suggests that many developing countries in Africa, Asia and Latin America have regions where more than 30% of drugs on sale may be counterfeit.

Poor quality drugs have serious consequences on increasing morbidity, mortality as well as causes drug resistance and loss of therapeutic efficacy.

Sub-Saharan Africa imports nearly 70% of its drug needs from other countries, approximately half of which is being imported from India. The private sector is the biggest importer in Africa, contributing to more than half the pharmaceutical imports, but conducts very limited due diligence on quality of imported drugs.

Governments/donors/international agencies also import drugs for their programmes. Around 60% of healthcare financing in Africa is from the private sector. For ensuring the quality of imports in Africa, most importers and procurement organisations conduct minimal quality assurance during the procurement process, but instead rely on their respective National Drug Regulatory Authorities (NDRAs).

India is a global pharmacy, especially for the developing world. Indian generics have a major role to play in access to quality and affordable medicines in LICs in Africa. An assessment of pharma quality systems and processes with focus on exports was commissioned under the Knowledge Partnership Programme supported by the DFID of the UK Government. The scope of study covered systems in India for exports, and import systems in Ethiopia, Kenya and Ghana. It further included understanding of procurement processes of few development partners and international procurement agents operating in

The objectives of the project include study of the following:

- Systems and processes for assuring quality of drugs for exports in India.
- Capacity of NDRAs for regulating imports (Ethiopia, Kenya and Ghana).
- Procurement systems adhered to by Development Partners and International procurement agents.

Study Findings:

India: The Drug and Cosmetic Act, 1940 is the central legislation for pharmaceuticals and cosmetics (including medical devices). However, it does not explicitly contain any specific provisions related to the export of pharmaceuticals from India.

The Act grants state DRAs the power to regulate the grant of manufacturing license and sale of pharmaceuticals within their jurisdiction. There are more than 20,000 pharma manufacturing units, some 600,000 pharmacist shops and only 3200 drug inspectors.

In a bid to raise regulatory standards, there is a demand to seek membership of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), which has 44 member countries on board. Central Drugs Standard Control Organization (CDSCO) needs documentation which are company specific including Registration cum Membership certificate (RcMC) and Import Export Code which are product specific, which includes registration certification, Certificate of Pharmaceutical Product (CoPP), Drug Master Files (DMF) and Active Pharmaceutical Ingredient (API) certification.

Production batch documentation should be done which includes Certificate of Analysis and Certificate of Origin. Export shipment documentation is the last step which requires commercial documents.

Africa: A WHO study suggested that most NDRAs have limited capacities to control quality of imports. Although countries under the study (Kenya, Ethiopia, Ghana) have invested only recently in establishing DRAs, policies, guidelines for regulating imports and the capacity of enforcement agencies remains weak. The drug testing lab network is yet to be set up.

Different procurement organisations conduct varying level of quality assurance activities. Private sector buyers seem to be complacent, while international procurement agencies follow rigorous procedures.

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Policy Directions

Based on findings following recommendations are made for range of stakeholders.

CDSCO and state DRAs in India:

- Conduct a detailed mapping and analysis of central and state DRA capacity (human resource, infrastructure and funding) and address the gaps.
- Map India's drug regulatory standards relative to other countries (BRICS).
- Accreditation of drug testing labs in public/private sector & quality assurance.

African Drug Regulatory Authorities and Buyers

• Invest in capacity building of NDRAs to better regulate Indian pharmaceutical exports and guide African buyers to purchase more strategically from India.

• Map list of high-quality drug testing laboratories in Africa.

• Strengthen quality control lab capacity in Africa by catalysing investment and technology transfer for the up-gradation and creation of new laboratories in Africa.

• Strengthening knowledge on complex nature of the Indian pharmaceutical industry, including fragmentation and consolidation in the market; multiple types of quality accreditation of manufacturers; outsourcing, risks of neutral coding; various types of accredited Quality Control laboratories; importance of independent Certificate of Analysis reporting; API quality information.

• Increase awareness about quality laboratories in India for use by NDRAs and global buyers:

- Create a database of Quality Control laboratories in India that are National Acceridiation Board for Testing and Caliberation Lab (NABL), WHO PQ and/or Stringent Drug Regulatory Authority approved. The same list can be expanded for Africa and other countries. Increase awareness of this list through various communication channels.

• Support buyers to strategically source good quality pharmaceuticals from India (through the creation of an International Buyer's Guide).

Indian Pharmaceutical Industry for Promoting Self-Regulation

• Self-regulation in manufacturing comprises of steps taken by a manufacturing company to ensure compliance with international and national regulations (Good Manufacturing Practice, Good Laboratory Practice and Good Clinical Practice etc).

• It can be an effective tool to receive faster approvals, reduce internal fraud and improving industry's public image. It is proposed that industry bodies in the pharma sector would have access to information on global best practices in self-regulation and organise industry action for implementing best practices.

Indian Suppliers and International Buyers/Procurement Agents to Strengthen the Pharmaceutical Supply Chain

•Guidance for suppliers and buyers to use better quality pharmaceutical distributors, wholesalers C&F agents and transporters (as per WHO good distribution practise and good supply practice guidelines):

-Develop a system for accrediting distributors and wholesalers, which would be trusted by suppliers and buyers.

-Map the accredited distributors and make the list available to suppliers and buyers

-Promote the use of accredited distributors.

-Collaborate with organisations such as USP, International Federation of Pharmaceutical Wholesalers (IFPW) and its member organisations (that include Alliance Boots Plc [UK], Cardinal and McKesson [USA]).

KPP is a South-South cooperation programme promoting knowledge sharing in the areas of Food Security, Resource Scarcity and Climate Change; Health and Disease Control; Trade and Investment; and Women and Girls. KPP is funded by the Government of UK's Department for International Development (DFID) and managed by a consortium led by IPE Global Private Limited under its Knowledge Initiative. The main objective of KPP is 'Gathering and uptake of evidence on issues central to India's national development that have potential for replication in LICs and impact on global poverty'.

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