Situational analysis report of the domestic production of medicines in paediatric dosage forms in Tanzania

NOVEMBER 2010
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This study involved collaboration with the pharmaceutical industry in Tanzania. They are hereby acknowledged for their participation in the assessment as respondents.

1. INTRODUCTION

1.1 Country profile

The United Republic of Tanzania is a sub-Saharan country located in eastern Africa (Figure 1). The country was formed on 26 April 1964, with the union of the two former sovereign states of Tanganyika and Zanzibar. Tanzania has a land area of 886,100 square kilometres and a population of about 40.7 million. Economically, it is a low income country with a per capita income of US$ 464 and US$ 534 for Tanzania Mainland and Tanzania Zanzibar respectively. The life expectancy is 50 years.(1) The total health expenditure per capita for Tanzania is US$ 23.(2)

1.2 Health Care Services in Tanzania

Since Tanzania became a sovereign state, a number of social service strategies were put in place by the government as a means of reducing poverty. One strategy involved the establishment of a good health care delivery system that would be accessible to all citizens. Efforts have been made to develop and expand the health system throughout the country, as evidenced by the distribution of health facilities in many rural areas and the provision of health services through public private partnerships. Currently, more than 80% of the population lives within 10 km of a health facility.(3)

In order to streamline the health system, the government developed policies and action plans for implementation of the strategies. One such strategy was the development of the National Health Policy in 1990 and its review in 2007. The policy advocates comprehensive basic health services for all Tanzanians without discrimination. The policy aims to improve the health of all Tanzanians by reducing disability and mortality, improving nutritional status,
Figure 1: Map of Tanzania

The policy recognizes that good health is essential for poverty eradication and economic development. The policy puts an emphasis on the fight against HIV/AIDS, tuberculosis and malaria. Furthermore, the policy recommended the construction of health centres and dispensaries in rural areas and the training of mid-level and low-level health workers to staff the facilities. It also recognizes the importance of creating a conducive environment for domestic pharmaceutical manufacturing investment. (3)

The boundaries and names shown on this map do not imply official endorsement or acceptance by the United Nations or ReliefWeb. These maps may be freely distributed. If more current information is available, please update the maps and return them to ReliefWeb for posting.
Ensuring constant availability of essential medicines in an extensive health care system is a challenge for a country with limited resources like Tanzania. Budgetary constraints and a poorly performing health system are major barriers limiting accessibility to medicines. With these obstacles to improving access to essential medicines, the government formulated a National Medicine Policy as a means of ensuring equitable and sustainable access to essential medicines by the general population. The National Medicines Policy of 2008,(4) is an integral component of the National Health Policy. The overall objective of the policy is “to improve and sustain the provision of pharmaceutical services by ensuring the access and rational use of safe, quality, efficacious and affordable medicines to all Tanzanians”.

In 1998, the then Medicine Regulatory Authority (Pharmacy Board) formulated the Guidelines for Submission of Documentation for Registration of Human Medicinal Products and Good Manufacturing Practice for Pharmaceuticals to guide domestic industries in manufacturing medicines that meet specified standards of quality, safety and efficacy.(5)

1.3 Health Services System

With more than 70% of the population living in rural areas the distribution of health facilities has a rural emphasis. In the past, plans for the establishment of health facilities took the facility to population ratio into consideration, but this has been overtaken by the high population growth-rate in some areas.

The health system, and especially the government referral system, assumes a pyramid referral system recommended by health planners, from dispensary to consultant hospital.

The structure of health services at various levels in the country is as follows:

i. Village Health Service:

The village health service is the lowest level of health care delivery in the country. It provides preventive services that can be offered in homes. Usually each village health service has two village health workers, chosen by the village government, who are given a short training before they start providing services.

ii. Dispensary Services:

The dispensary service is the second level of health care delivery. A dispensary serves from 6000 to 10 000 people and supervises all the village health services in its ward.

iii. Health Centre Services:

A health centre is expected to serve 50 000 people, which is approximately the population of one administrative division.

iv. District Hospitals:

District hospitals are important for providing health services in the country. Each district should have a district hospital. For those districts without a hospital, the government normally negotiates with religious organizations to designate their hospitals as district hospitals, which then get subventions from the government on contract terms.
v. Regional Hospitals:

Every region should have a regional hospital. In addition to offering services similar to those at the district level, regional hospitals also have specialists in various fields and offer services that are not provided at district hospitals.(6)

vi. Referral/Consultant hospitals:

This is the highest level of hospital services in the country. Currently there are four referral hospitals serving different zones: the Muhimbili National Hospital in the eastern zone; Kilimanjaro Christian Medical Centre in the northern zone; Bugando Hospital in the lake/western zone; and Mbeya Hospital in the southern Highlands.(6)

1.4 Pharmaceutical services

Medicine plays a very important role in the delivery of health care in Tanzania. Availability of medicines in health facilities is one of the factors motivating people to visit them. It is therefore necessary to maintain an uninterrupted supply of medicine at the service delivery points at all times.

1.4.1 Medicines policy

The National Medicines Policy 2008, provides critical guidance to the pharmaceutical sector. It addresses current developments in the sector, such as the shift from a push to pull supply system; promotion of local manufacturing and new malaria treatments e.g. artemether + lumefantrine. The Pharmaceutical Services Unit at the Ministry of Health and Social Welfare coordinates implementation of the National Medicines Policy. The Pharmaceutical Services Unit’s key roles include: ensuring that the National Medicines Policy operates in accordance with the National Health Policy; ensuring that the Medical Stores Department performs according to the Medical Stores Department Act of 1993; ensuring that adequate funds to procure medicines and related medical supplies are provided to the Medical Stores Department; assisting health facilities with capacity to determine medicine requirements; establishing effective strategies for improving the rational use of medicines; ensuring the quality of medicines through the Tanzania Food and Drugs Authority; establishing effective medicine management and monitoring systems; reducing medicine waste and theft at the health facility level; and ensuring an appropriate allocation of resources to health facilities for medicines that takes into account equity, patient load, morbidity and medicine needs.(7)

1.4.2 Pharmaceutical personnel

The crucial role of human resources for health in health systems was not fully appreciated until recently with the impact of AIDS contributing to the human resources for health crisis in many countries. Many health programmes have consistently experienced shortages of suitable personnel as one of the major constraints in not accomplishing intended objectives of their national medicines and health policies. Tanzania has about 686 pharmacists, 352 pharmacy technicians and 312 pharmaceutical assistants. There is a serious lack of pharmaceutical staff at health facilities and at district and regional levels. The Ministry of Health and Social Welfare has introduced initiatives to increase the number of health workers, including pharmaceutical personnel.(8)
1.4.3 National Medicines Regulatory Authority

The Tanzania Food and Drugs Authority is responsible for the regulation of all matters related to the quality and safety of food, medicines, medical devices, and cosmetics. The regulation of medicines includes control of importation, manufacturing, labeling, storage, promotion, sales, and distribution. Regulatory activities involve the registration of medicines and inspections of ports of entry, drug outlets and pharmaceutical manufacturers. (9)

1.4.4 Management of medicines supply in the health sector

The National Essential Medicines List of Tanzania and the Standard Treatment Guidelines published in 1997 were updated in 2006, in order to reflect changes in current medical knowledge and practice, and in the care and treatment of disease conditions. The two documents aim to help health workers know what treatments are recommended at each level, and which medicines are considered essential. It also provides the Medical Stores Department with a list for medicines procurement. (7)

1.4.5 Supply system

The supply of medicines in Tanzania is done by private wholesale pharmacies and the Medical Stores Department. Private wholesale pharmacies procure medicines from international and local manufacturers and distribute them to retail drug outlets. The Medical Stores Department procures essential medicines in bulk from national and international wholesalers. In turn, it is the main supplier of essential medicines to the public sector and a primary supplier to faith-based and other nongovernment, non-commercial groups providing health services in Tanzania. (10)

1.5 Morbidity and Mortality statistics

Tanzania is one of the developing countries with the highest burden of disease. Malaria remains a major cause of morbidity and mortality in both rural and urban areas. There has also been an increase in the number of cases of illness and deaths due to HIV/AIDS and tuberculosis. The three diseases pose a major threat to the health system in Tanzania Mainland. (1, 11) Health statistics indicate that malaria, acute respiratory infections, pneumonia and diarrhoeal diseases are the major causes of outpatient attendances for populations under five years of age and those aged five years and above. Approximately 133.8 per 1000 children under five years of age die every year in Tanzania. Malaria is the leading cause of death. Malaria accounts for 44% of the mortality among those under five years of age and 34% for those aged five years and above. Pneumonia ranks second followed by anaemia and diarrhoeal diseases, while HIV/AIDS ranks tenth. (1, 11) In many cases, children are dying simply because the medicines they need are not available or affordable. The opportunities for rapid health and economic gain through improved access to medicines are enormous.

2. RATIONALE OF THE ASSESSMENT

Pre-conditions to reducing child mortality and improving the health outcomes of children are the availability and rational use of safe and efficacious child specific medicines of acceptable quality. To be effective, medicines must be carefully chosen and the dose adjusted to suit the age, weight and needs of children. Accurate dosing of medicines for use in
children is essential, particularly those between 0-12 months. A dosing error in a child can have devastating results.

The reduction of child mortality is a global priority expressed in the Millennium Development Goals four, five and six.

According to the United Nations Children’s Fund’s (UNICEF) latest estimate, nearly nine million children under five years of age die each year. This means that 1000 children under five die every hour. More than half of these deaths are caused by diseases, which could be treated with safe, essential, child-specific medicines.

Due to the lack of safe and effective medicines specifically developed and licensed for use in children, healthcare workers and parents often use fractions of adult medicines or prepare makeshift prescriptions of medicines by crushing tablets or dissolving portions of capsules in water. This practice can be unsafe and may result in prolonged illness. The best form of delivering medicines to children is through medicines that can be easily dissolved in water or prepared as a dispersible tablet. In most cases, these medicines are cheaper than liquid medicines and do not require refrigeration or difficult measuring.

One of the challenges in developing medicines for children is a lack of knowledge about the effects certain medicines can have on children. This is largely because fewer clinical trials are conducted in children than in adults.

In May 2007, the World Health Assembly passed resolution WHA 60.20 “Better Medicines for Children”. The resolution set goals and called for action by all Member States, the World Health Organization, and its partners to address the global need for safe, effective, and accessible children’s medicines.

A World Health Organization global campaign named ‘make medicines child size’ was launched on 6 December 2007, to raise awareness and accelerate action to address the need for improved availability and access to safe child-specific medicines for all children under 12 years of age. In 2009, the World Health Organization started the Better Medicines for Children project to improve access to medicines for children. Tanzania has agreed to foster and implement activities under the Better Medicines for Children project, which will be supported financially by the World Health Organization. Ghana and Tanzania are the two African countries involved in the intensive phase of this project, which will take two years.

One aspect of the project aims to encourage generic manufacturers to develop formulations that allow accurate administration of dose to children of varying age and weight for treatment of the major diseases in children. In Tanzania, the project will determine if a targeted selection of child specific medicines are available in appropriate dosage forms in health facilities in the country and work with health care workers and paediatricians on recommended interventions.

The mandate of the Better Medicines for Children technical Working Group is to provide guidance and oversight for the design and implementation of activities to ensure safe, effective, accessible and appropriate use of medicines for children. The tasks of the Better Medicines for Children technical Working Group involve obtaining data from studies and surveys that have been conducted and assessing any relevant information related to medicines for children. It is also provides sound advice and technical support to the Ministry of Health and Social Welfare and stakeholders on issues related to Better Medicines for Children.

As part of the implementation of the project, the Ministry of Health and Social Welfare planned to undertake a survey to explore the capacity of local manufacturers to develop appropriate paediatric formulations.

3. OBJECTIVE OF THE STUDY

The overall objective of the study is to conduct a situational analysis of the domestic production of medicines with an emphasis on a targeted selection of 22 paediatric dosage forms from the World Health Organization Model List of Essential Medicines for Children.

The specific objectives are:

1. To provide background information of pharmaceutical manufacturers including the available infrastructure and resources, as well as good manufacturing practice status for manufacturing paediatric formulations.

2. To ascertain if the target paediatric formulations are being manufactured by domestic manufacturers.

3. To assess the capacity of domestic manufacturers in terms of installed capacity, operating capacity and utilized capacity of machines used for manufacture of paediatric formulations.

4. To assess the quality control capacity of domestic manufacturers of paediatric formulations.

5. To determine the potential of each manufacturer to produce additional paediatric dosage forms.

6. To determine the local manufacturers’ human resource capacity and technical expertise in manufacturing paediatric formulations.

7. To determine the existing gap in meeting the demand of the targeted medicines; and

8. To identify problems facing domestic companies in manufacturing medicines that meet quality, safety and efficacy standards and their respective solutions.

4. SCOPE OF THE STUDY

The situational analysis served as a first step in assessing the technical capacity of domestic pharmaceutical manufacturers to produce a selection of paediatric formulations/dosage forms of medicines. It did not consist of a complete situational analysis and in-depth appraisal of technical feasibility of such production. The medicines included on the World Health Organization Model List of Essential Medicines for Children (Annex II) were
identified as the focus of the study. Data was collected on the current domestic production of these products, as well as other medicines in the same pharmacological class or in paediatric formulation.

5. METHODOLOGY

A literature review of relevant information was done before the field visits began. The questionnaire tool, recommended by the World Health Organization to conduct the situational analysis of domestic production of paediatric medicines, was used to collect the information (Annex III).

Field visits to respective registered local pharmaceutical manufacturers were done. During the visits, the questionnaire was completed after interviewing the chief executive officer and key technical personnel of the companies. The manufacturing premises of selected manufacturers were also visited. Data collection took place between 15 November and 3 December 2010.

6. RESULTS AND DISCUSSION

Seven pharmaceutical manufacturers were visited: A.A. Pharmaceuticals Ltd, Keko Pharmaceutical (1997) Ltd, Mansoor Daya Chemicals Ltd, Shelys Pharmaceuticals Ltd, Tanzania Pharmaceutical Industries Ltd, Tanzansino United Pharmaceuticals Ltd, and Zenufa Laboratories Ltd.

Tanzansino United Pharmaceuticals Ltd could not provide the information requested for the study as they claimed to have stopped production in October 2010, due to organizational problems among company shareholders. Before stopping production, the company was engaged in manufacturing Paracetamol tablets 500 mg, Diclofenac tablets 100 mg and 50 mg, and Ibuprofen tablets 200 mg, mainly for the Medical Stores Department. The manufacturer is not good manufacturing practices compliant.

Furthermore, A.A. Pharmaceuticals Ltd refused to provide information as they claimed that the company was manufacturing only topical pharmaceutical formulations, which were not on the target list of medicines for children. A.A. Pharmaceuticals Ltd is a small pharmaceutical manufacturer with very basic infrastructure for manufacturing medicinal products. The manufacturer is not good manufacturing practices compliant.

6.1 Background information on the manufacturers


According to the Tanzania Food and Drugs Authority, only two pharmaceutical industries, Shelys Pharmaceuticals Ltd, and Zenufa Laboratories Ltd, are allowed to apply for full registration of their medicinal products as they complied with the Tanzania Good
Manufacturing Practices requirements. This means that these two companies are allowed to register their paediatric medicinal formulations after complying with registration requirements. The other companies market their medicinal products under special arrangement of the Tanzania Food and Drugs Authority allowing products based on risk factors.

6.1.1 Mansoor Daya Chemicals Ltd

The first privately owned pharmaceutical industry in the country, Mansoor Daya Chemicals Ltd was established in 1962. In 1964, it started operation as a small-scale pharmaceutical manufacturing plant with facilities for the production of liquid formulations, especially external preparations. It is located along Nyerere Road in Dar es Salaam. However, the company’s early development was slowed for a number of reasons including the limited availability of foreign currency and the government’s sourcing of pharmaceutical products from its own pharmaceutical industries through the National Pharmaceutical Company and Central Medical Store.

Between 1997 and 2007, the company renovated its premises, expanded its activities, and acquired new machinery for manufacturing oral liquid formulations and tablets. Although it has machinery for manufacturing paediatric formulations, the company lacks the technical knowledge for manufacturing them. The company manufactures general products (non beta-lactam products), including some paediatric formulations as shown in Table 1.

The company’s manufacturing facility is not compliant with good manufacturing practices due to a number of critical deficiencies, including the lack of an air handling system and the use of equipment, manufacturing processes, and analytical methods for products, which were not validated. In addition, the design and layout of the manufacturing premises do not provide a logical flow of materials, personnel and processes.

The company has a total of 65 staff with 48 working in production and 8 in quality control. It has a small number of staff with relevant qualifications and expertise in manufacturing medicinal products. It has 2 pharmacists, 1 pharmaceutical technician and 2 chemists among its qualified staff.

All medicinal products being manufactured by the company are sold locally to private market (87%), Medical Stores Department (10%) and nongovernmental organizations (3%). The company’s total revenue in 2009 was TShs 3.5 billion or approximately US$ 2.4 million.

The majority of the company’s raw materials are sourced from China and India, with a few procured from Europe.
### Table 1: Paediatric medicinal formulations manufactured by Mansoor Daya Chemicals Ltd

<table>
<thead>
<tr>
<th>Name of Product</th>
<th>Dosage form</th>
<th>Strength and pack size</th>
<th>Number of units produced in 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-trimoxazole</td>
<td>Suspension</td>
<td>200 mg + 40 mg/5 ml (100 ml)</td>
<td>30 000 bottles</td>
</tr>
<tr>
<td>Multivitamins</td>
<td>Syrup</td>
<td>100 ml</td>
<td>45 900 bottles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vitamin A BP 3000 IU</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vitamin D₃ BP 400 IU</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vitamin B₁ BP 1.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vitamin B₂ BP 0.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pyridoxine hydrochloride BP 1 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vitamin B₁₂ BP 0.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>D-Panthenol BP 2.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ascorbic acid BP 10 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nicotinamide BP 10 mg</td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Syrup</td>
<td>120 mg/5 ml (100 ml)</td>
<td>83 000 bottles</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Tablets</td>
<td>500 mg</td>
<td>93 400 000 tablets</td>
</tr>
</tbody>
</table>

### 6.1.2 Keko Pharmaceuticals (1997) Ltd

Keko Pharmaceuticals (1997) Ltd was the second pharmaceutical manufacturer to come into operation. In 1982, it started as a department of the Ministry of Health and Social Welfare with the sole aim of supplying pharmaceuticals to the then Central Medical Stores. It is located at Keko Mwanga in Dar es Salaam. The facility was built in 1976, with the assistance of the Chinese Government. It operated as a medium-scale manufacturer with facilities for the production of tablets, capsules and large volume parenterals, including some paediatric formulations as shown in Table 2. The facility was privatized in 1997, due to poor performance for over three years. The government has 40% shares in the company. Currently, the facility manufactures beta lactam and non-beta lactam formulations in the forms of tablets, capsules and dry syrups in separate buildings. The infusion section is no longer operational.

The manufacturing facility of the company does not comply with good manufacturing practices requirements due to critical deficiencies in manufacturing and quality control of medicinal products, as well as validation of equipment, manufacturing processes and analytical methods for products.

It has a total of 56 staff with 47 working in production and 9 in quality control. In the production department, 17 staff have qualifications ranging from certificate, diploma to degree (including 2 pharmacists). The quality control department has 9 staff with qualifications in science. The company has an expert in quality assurance from India.

All medicinal products being manufactured by the company are sold locally to private market (40%) and the Medical Stores Department (60%). The total revenue for the company in 2009 was TShs 8 billion or approximately US$ 5.5 million.

The major sources of raw materials for the company are China and India. Currently, the company is doing research on artemether + lumefantrine combination for treatment of malaria, as well as a number of antiretroviral formulations.
Table 2: Paediatric medicinal formulations manufactured by Keko Pharmaceuticals (1997) Ltd

<table>
<thead>
<tr>
<th>No.</th>
<th>Name of Product</th>
<th>Dosage form</th>
<th>Strength and pack size</th>
<th>Number of units produced in 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Amoxicillin</td>
<td>Suspension</td>
<td>125 mg/5 ml (100 ml)</td>
<td>60 000 bottles</td>
</tr>
<tr>
<td>2.</td>
<td>Co-trimoxazole</td>
<td>Tablets</td>
<td>Sulfamethoxazole 400 mg + Trimethoprim 80 mg</td>
<td>100 000 000 tablets</td>
</tr>
<tr>
<td>3.</td>
<td>Paracetamol</td>
<td>Tablets</td>
<td>500 mg</td>
<td>400 000 000 tablets</td>
</tr>
<tr>
<td>4.</td>
<td>Mebendazole</td>
<td>Tablets</td>
<td>100 mg</td>
<td>100 000 000 tablets</td>
</tr>
</tbody>
</table>

6.1.3 Tanzania Pharmaceutical Industries Ltd

Tanzania Pharmaceutical Industries Ltd was established in 1976, under government ownership. It was built with the assistance of the Finnish Government and managed by Orion Pharmaceuticals. It has facilities for the production of tablets, capsules and syrups, as well as some paediatric formulations as shown in Table 3. As was the case for Keko, Tanzania Pharmaceutical Industries Ltd was closed in 1993, privatized in 1995, and resumed production in 1997, after undergoing renovation. The plant has also secured support from a development partner who is assisting them in the production of antiretrovirals.

The government has 40% shares in the company while the remaining shares are owned by Diocare Ltd, a private company. Tanzania Pharmaceutical Industries Ltd undertakes contract manufacturing for other companies. Most of the products manufactured by the company are supplied to the Medical Stores Department.

Currently, the company has 75 and 13 personnel working in the production and quality control departments respectively. It has a number of personnel with relevant qualification and experience in pharmaceutical manufacturing. It procures most of its starting materials from China, Europe and India.

Table 3: Paediatric medicinal formulations manufactured by Tanzania Pharmaceutical Industries Ltd

<table>
<thead>
<tr>
<th>No.</th>
<th>Name of Product</th>
<th>Dosage form</th>
<th>Strength and pack size</th>
<th>Number of units produced in 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Co-trimoxazole</td>
<td>Suspension</td>
<td>200 mg + 40 mg/5 ml (100 ml)</td>
<td>214 065 bottles (2009) 607 353 bottles (until September 2010)</td>
</tr>
<tr>
<td>2.</td>
<td>Erythromycin</td>
<td>Suspension</td>
<td>100 ml</td>
<td>608 006 bottles</td>
</tr>
<tr>
<td>3.</td>
<td>Paracetamol</td>
<td>Syrup</td>
<td>120 mg/5 ml (100 ml)</td>
<td>363 880 bottles</td>
</tr>
<tr>
<td>4.</td>
<td>Paracetamol</td>
<td>Tablets</td>
<td>500 mg</td>
<td>67 900 000 tablets</td>
</tr>
<tr>
<td>5.</td>
<td>Phenobarbitol</td>
<td>Tablets</td>
<td>30 mg 100 mg</td>
<td>19 906 000 tablets 4 128 000 tablets</td>
</tr>
<tr>
<td>6.</td>
<td>Phenytoin</td>
<td>Tablets</td>
<td>100 mg</td>
<td>4 414 000 tablets</td>
</tr>
<tr>
<td>7.</td>
<td>Salbutamol</td>
<td>Tablets</td>
<td>4 mg</td>
<td>4 198 000 tablets</td>
</tr>
<tr>
<td>8.</td>
<td>Quinine</td>
<td>Tablets</td>
<td>300 mg</td>
<td>9 611 000 tablets (2009) 13 175 000 (until September 2010)</td>
</tr>
</tbody>
</table>
6.1.4 Shelys Pharmaceuticals Ltd

Shelys Pharmaceuticals Ltd was established in 1984, as a private enterprise mostly for manufacturing syrups. The company started its operations in Kipawa, Temeke District before shifting to a new facility in Mwenge. It began as a private company and was not subjected to the conditions faced by publicly owned pharmaceutical manufacturers. It had the flexibility to grow quickly and expand from the manufacturing of syrups to include other formulations, such as tablets and capsules, and some paediatric formulations as shown in Table 4. The company manufactures beta lactam and non-beta lactam formulations in separate buildings.

**Table 4: Paediatric medicinal formulations manufactured by Shelys Pharmaceuticals Ltd**

<table>
<thead>
<tr>
<th>No.</th>
<th>Name of Product</th>
<th>Dosage form</th>
<th>Strength and pack size</th>
<th>Number of units produced in 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Amoxicillin</td>
<td>Suspension</td>
<td>125 mg/5 ml (100 ml)</td>
<td>3 600 000 bottles</td>
</tr>
<tr>
<td>2.</td>
<td>Co-trimoxazole</td>
<td>Suspension</td>
<td>200 mg + 40 mg (100 ml)</td>
<td>720 000 bottles</td>
</tr>
<tr>
<td>3.</td>
<td>Iron Syrup</td>
<td>Syrup</td>
<td>Ferrous Sulphate 100 mg</td>
<td>720 000 bottles</td>
</tr>
<tr>
<td>4.</td>
<td>Mebendazole</td>
<td>Chewable tablet</td>
<td>100 mg (6 tablets)</td>
<td>6 000 000 tablets</td>
</tr>
<tr>
<td>5.</td>
<td>Multivitamins</td>
<td>Syrup</td>
<td>Vitamin A BP 3000 IU</td>
<td>360 000 bottles</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamin D3 BP 1000 IU</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamin B1 BP 1.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamin B2 BP 0.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pyridoxine hydrochloride BP 1 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>D-Panthenol BP 2.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ascorbic acid BP 10 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Nicotinamide BP 10 mg</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Oral rehydration salts</td>
<td>Solution</td>
<td>Packet to make 1 litre solution</td>
<td>18 000 000 sachets</td>
</tr>
<tr>
<td>7.</td>
<td>Paracetamol</td>
<td>Syrup</td>
<td>120 mg/5 ml (100 ml)</td>
<td>1 440 000 bottles</td>
</tr>
<tr>
<td>8.</td>
<td>Erythromycin</td>
<td>Suspension</td>
<td>125 mg/5 ml</td>
<td>1 200 000 bottles</td>
</tr>
<tr>
<td>9.</td>
<td>Paracetamol</td>
<td>Tablet</td>
<td>100 mg</td>
<td>6 000 000 tablets</td>
</tr>
<tr>
<td>10.</td>
<td>Paracetamol</td>
<td>Tablet</td>
<td>500 mg</td>
<td>1 020 000 000 tablets</td>
</tr>
<tr>
<td>11.</td>
<td>Phenobarbital</td>
<td>Tablet</td>
<td>30 mg</td>
<td>24 000 000 tablets</td>
</tr>
<tr>
<td>12.</td>
<td>Zinc</td>
<td>Dispersible tablet</td>
<td>20 mg</td>
<td>24 000 000 tablets</td>
</tr>
<tr>
<td>13.</td>
<td>Quinine Sulphate</td>
<td>Tablet</td>
<td>300 mg</td>
<td>24 000 000 tablets</td>
</tr>
<tr>
<td>14.</td>
<td>Albendazole</td>
<td>Chewable tablet</td>
<td>200 mg/400 mg</td>
<td>14 400 000 tablets</td>
</tr>
<tr>
<td>15.</td>
<td>Albendazole</td>
<td>Suspension</td>
<td>100 mg/5 ml</td>
<td>240 000 bottles</td>
</tr>
<tr>
<td>16.</td>
<td>Ciprofloxacin</td>
<td>Caplet</td>
<td>500 mg</td>
<td>7 200 000 caplets</td>
</tr>
</tbody>
</table>

The company constructed a new facility at Mwenge, Kinondoni District, Dar es Salaam and started manufacturing operations in July 2006. The facility attained good manufacturing practices standards, having separate general and penicillin blocks. The company has penetrated and established markets in neighbouring countries, including Burundi, the Democratic Republic of Congo, Ghana, Kenya, Madagascar, Mauritius, Mozambique, Rwanda, Uganda, Zambia, and Malawi where it even exports paediatric medicinal formulations. It has invested in a similar plant in Kenya. The largest South African pharmaceutical manufacturing company, Aspen, has invested with Shelys by acquiring share holdings.

The company sells its finished dosage products to the Medical Stores Department (20%), private sector (50%), nongovernmental organizations (10%) and exports (20%) of its annual production. It has 330 personnel, with 300 in production and 30 in quality control. It has a
sufficient number of qualified and experienced staff in manufacturing medicinal products. It sources raw materials from China, Germany, India, and the United States of America.

The company is approved by the Tanzania Food and Drugs Authority and the Pharmaceutical Inspection Co-operation Scheme as a good manufacturing practices compliant facility.

The total revenue collected by the company in 2009 was TShs 30 billion or approximately US$ 21 million.

6.1.5 Zenufa Laboratories Ltd

Zenufa Laboratories Ltd is a relatively new facility, which became operational in 2007. It produces tablets, capsules, and syrups (beta lactams and non beta lactams), and some paediatric formulations as shown in Table 5. It is a private company with 50% of its sales to the Medical Stores Department; 35% to the private market; 10% to nongovernmental organizations, such as the Red Cross and Action Medeor; and 5% are exported.

The company’s revenue for 2009 was US$ 3.6 million. It has a total of 65 staff with 50 working in production and 15 in quality control. It has a sufficient number of qualified staff for production and quality control of pharmaceuticals.

The company is approved by the Tanzania Food and Drugs Authority as being compliant with good manufacturing practices.

**Table 5: Paediatric medicinal formulations manufactured by Zenufa Laboratories Ltd**

<table>
<thead>
<tr>
<th>No.</th>
<th>Name of Product</th>
<th>Dosage form</th>
<th>Strength and pack size</th>
<th>Number of units produced in 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Amoxicillin</td>
<td>Suspension</td>
<td>125 mg/5 ml (100 ml)</td>
<td>800 000 bottles</td>
</tr>
<tr>
<td>2.</td>
<td>Co-trimoxazole</td>
<td>Suspension</td>
<td>200 mg + 40 mg (100 ml)</td>
<td>100 000 bottles</td>
</tr>
<tr>
<td>3.</td>
<td>Mebendazole</td>
<td>Chewable tablet</td>
<td>100 mg (6 tablets)</td>
<td>2 000 000 tablets</td>
</tr>
<tr>
<td>4.</td>
<td>Mebendazole</td>
<td>Syrup</td>
<td>100 mg/5 ml (100 ml)</td>
<td>75 000 bottles</td>
</tr>
<tr>
<td>5.</td>
<td>Paracetamol</td>
<td>Syrup</td>
<td>120 mg/5 ml (100 ml)</td>
<td>800 000 bottles</td>
</tr>
<tr>
<td>6.</td>
<td>Multivitamins</td>
<td>Syrup</td>
<td></td>
<td>50 000 bottles</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamin A BP 3000 IU</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamin D3 BP 400 IU</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamin B1 BP 1.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamin B2 BP 0.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pyridoxine hydrochloride BP 1 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Vitamin B12BP 0.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>D-Panthenol BP 2.5 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ascorbic acid BP 10 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Nicotinamide BP 10 mg</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Erythromycin</td>
<td>Suspension</td>
<td>125 mg/5 ml</td>
<td>100 000 bottles</td>
</tr>
<tr>
<td>8.</td>
<td>Prednisolone</td>
<td>Tablet</td>
<td>5 mg</td>
<td>10 000 000 tablets</td>
</tr>
<tr>
<td>9.</td>
<td>Salbutamol</td>
<td>Tablet</td>
<td>4 mg</td>
<td>10 000 000 tablets</td>
</tr>
<tr>
<td>10.</td>
<td>Paracetamol</td>
<td>Tablet</td>
<td>500 mg</td>
<td>200 000 000 tablets</td>
</tr>
<tr>
<td>11.</td>
<td>Quinine sulphate</td>
<td>Tablet</td>
<td>300 mg</td>
<td>3 000 000 tablets</td>
</tr>
</tbody>
</table>
6.1.6 Tanzansino United Pharmaceuticals Ltd and A.A. Pharmaceuticals Ltd

Tanzansino United Pharmaceuticals Ltd and A.A. Pharmaceuticals Ltd chose not to participate in the study. Tanzansino is partly owned by the National Service of Tanzania and Holley Pharm Ltd, a private Chinese company.

6.2 Capacity of domestic manufacturers

The five manufacturers that participated in the study have analytical capability and good machinery for manufacturing paediatric formulations. They have the required laboratory equipment, such as high performance liquid chromatography, ultra violet spectrophotometer, and stability chambers. The facilities are capable of analyzing most of the imported raw material and their own finished products. They contract some of the analytical work to the government Central Laboratory Agency when the need arises. The facilities’ in-process quality control laboratories also had the necessary equipment. However, some domestic pharmaceutical facilities, with the exception of Shelys Pharmaceuticals Ltd and Zenufa Laboratories Ltd, are still having problems with validation, premises design and layout, documentation, and air handling systems. Furthermore, the microbiological facilities of Mansoor Daya Chemicals Ltd and Tanzania Pharmaceutical Industries Ltd did not address the requirements of good manufacturing practices guidelines.

Despite the moderate increase in investments and the production of essential medicines by the domestic manufacturers, their market share, both private and Medical Stores Department has not gone beyond 30%.

The manufacturing capacity in terms of machinery is higher than the capability of the facilities, as reflected in the production capacities of Keko Pharmaceuticals (1997) Ltd, Mansoor Daya Chemicals Ltd, Shelys Pharmaceuticals Ltd, Tanzania Pharmaceutical Industries Ltd, and Zenufa Laboratories Ltd found in Annexes IV-VIII.

Furthermore, data obtained from domestic pharmaceutical facilities indicated that there has been no steady increase in production of targeted products (Annexes IX–XI) for Keko Pharmaceuticals (1997) Ltd, Mansoor Daya Chemicals Ltd, Shelys Pharmaceuticals Ltd, Tanzania Pharmaceutical Industries Ltd and Zenufa Laboratories Ltd. Owners of the facilities claimed that a number of factors have contributed to this lack of growth, particularly the under-capitalization prevailing in all industries and the small market for their products due to stiff competition against similar imported products.

6.3 Capability in human resources and technology

Technical personnel had inadequate knowledge and skills in developing paediatric formulations. This is attributed to a lack of thorough expertise in pharmaceutical manufacturing among technical personnel of the local pharmaceutical industries. Inadequate training in pharmaceutical manufacturing in the curriculum of the local pharmacy training institutions may be one of the factors contributing to the inability of manufacturers to produce paediatric formulations. Furthermore, Tanzania has not benefited from foreign investment in the pharmaceutical industry. This contributes to a lack of opportunities for the transfer of technology in formulating paediatric formulations.
When asked what production changes would be required to manufacture paediatric medicinal formulations, Zenufa Laboratories Ltd, identified the following adaptations:

(a) Tablet to a dispersible tablet or oral dispersible tablet of the same medicine
- Add powerful disintegrants
- If disintegrants are already included, quantity of the same could be increased
- Add sweetening agents (in some cases)
- Add flavouring agents (in some cases)
- Need for low humidity environment, could mean employment of dehumidifiers

(b) Suspension of one medicine to a suspension of a different medicine
- Reduce or remove flavours and sweeteners (in some cases)
- Use smaller bottles
- Use dropper for dispensing doses or measuring cups graduated to 0.5 ml intervals

(c) Injection of one medicine to an injection of a different medicine
- Change excipients to the ones compatible with the different medicine (Preformulation studies)
- Adjust the strength of the product to the level required for paediatrics

(d) Package and label of an existing product to a paediatric product
- Label and leaflet to show the exact dosage in terms of body weight rather than age
- Include dropper or measuring cup in package

(e) Tablet to a granule formulation in a sachet of the same medicine
- Add sweetening agents (in some cases)
- Add flavouring agents (in some cases)
- Sachet will contain amount of drug equivalent to single dose
- Instruction that if some of the material still remains after dissolving the content, a patient should take all the content of the sachet

In addition, most of the manufacturers have requested technology for manufacturing paediatric medicinal formulations, especially dispersible tablets.

6.4 Problems facing domestic manufacturers

Most of the facilities, especially those established between the 1970’s and early 1980’s, were not built in accordance with current good manufacturing practices standards. This is because the acquired premises were not meant for pharmaceutical manufacturing. Consequently, renovations to upgrade these facilities to good manufacturing practices requirements are immense and cost analysis favours building new facilities.

The small amount of capital invested by some of the manufacturers in setting up premises and procuring equipment is another factor hindering their compliance with standards.

It has also been noted that even manufacturers who complied with good manufacturing practices were also facing difficulties in meeting the requirements for registration of medicines. The guidelines require a manufacturer to establish that a medicinal product complies with quality, safety and efficacy specifications for marketing authorizations. The
main challenge for the manufacturers is to justify the efficacy of their generic medicinal products by conducting bioequivalence studies. Most of the manufacturers were not able to submit bioequivalence data for their medicines as required by the guidelines.

According to the Tanzania Food and Drugs Authority, only 40 generic medicines have been fully registered, the rest are under provisional registration.

6.5 Potential to produce paediatric medicines

Local pharmaceutical manufacturers have the potential to manufacture paediatric medicines as demonstrated by the following:

- Most local manufacturers have machinery for manufacturing paediatric formulations.
- There is a market for paediatric medicines.
- The public sector prefers generic medicines.
- There are policies and/or legislative frameworks favouring local industries.
- National initiatives to promote local pharmaceutical production exist.
- There are vibrant health research and development institutions in the country that are ready to collaborate with local manufacturers in developing paediatric medicinal formulations.
- Flexibilities within the Agreement on Trade-related aspects of Intellectual Property Rights allow member countries like Tanzania to manufacture patented paediatric medicines.

6.6 Contract manufacturing

Mansoor Daya Chemicals Ltd and Tanzania Pharmaceutical Industries Ltd undertake contract manufacturing for other companies, including paediatric medicines. None of the companies visited were sub-contracting the manufacture of their medicines to other companies.

6.7 Research and development

Only Zenufa Laboratories Ltd has established in-house research and development capacity. It is now working on the following formulations: Aceclofenac tablets, Antifungal lotion, Liniment Alba, Eusol, Benzoyl Benzoate Emulsion, Xylometazoline HCl nasal drops 0.1% and 0.05%, Azithromycin capsules, Albebenda-Z Suspension capsules, Multivitamin Drops, Cyproheptidine HCl oral Solution, Quinine drops, Albendazole tablets, Albebendazole Suspension, Calamine lotion, Stavudine capsules, Zidovudine capsules, Gripe water, Hemoglobin B12 syrup, Fluconazole tablets, Single RDU multivitamin tablet, Multiple RDU vitamin tablet, Lamivudine+Zidovudine tablets, Lamivudine oral solution and Lamivudine tablets.
7. RECOMMENDATIONS

Due to the strategic nature of paediatric medicines and their improvement of the health status of children, deliberate efforts by public and private sectors to promote the manufacture of paediatric formulations in our local industries are required. It is therefore recommended that:

(1) The government should endeavour to create an environment that will promote the growth of pharmaceutical industries and attract investments and technology transfer in the sector.

(2) Local manufacturers should take a leading role and work hand in hand with high learning/research institutions to develop paediatric formulations under the following arrangement:
   i. Higher learning/research institutions can develop paediatric formulations or molecules and sell to pharmaceutical industries.
   ii. Pharmaceutical industries can propose an ideal paediatric formulation or molecule and higher learning/research institutions can develop it at a fee.

Furthermore, pharmaceutical industries and higher learning/research institutions may exchange expertise by allowing field attachment of academicians/researchers to pharmaceutical industries.

(3) The World Health Organization and the United Nations Industrial Development Organization should be requested to assist local pharmaceutical manufacturers with technology for developing medicinal formulations for children.

(4) The government should increase the intake of pharmacy students in pharmacy institutions, as needed by the local pharmaceutical industries. An emphasis should also be placed on pharmaceutical manufacturing training.

(5) The government should support an initiative establishing a miniature pharmaceutical manufacturing industry for training pharmacy students including those from Muhimbili University of Health and Allied Science and St. Luke’s Foundation in Kilimanjaro.

(6) Local pharmaceutical industries should be advised and encouraged to establish a research and development department for conducting pilot studies on pharmaceutical formulations.

8. CONCLUSION

The study reveals that local pharmaceutical manufacturers have the capacity to manufacture a small number of generic paediatric medicinal formulations. Only two manufacturers comply with good manufacturing practices requirements with a very small number of medicines registered by the Tanzania Food and Drugs Authority. This situation is alarming and calls for multisectoral collaboration to provide technology transfer and knowledge support to local pharmaceutical industries to manufacture a wide range of paediatric medicines.
REFERENCES

BIBLIOGRAPHY


ANNEXES

Annex I: TERMS OF REFERENCE FOR THE SITUATIONAL ANALYSIS OF THE DOMESTIC PRODUCTION OF MEDICINES IN PAEDIATRIC DOSAGE FORMS

1. BACKGROUND INFORMATION

The Ministry of Health and Social Welfare with the support of the World Health Organization is working on a project to improve access to essential paediatric medicines for children and their rational use. The project, known as ‘Better Medicines for Children’, will determine if child specific medicines are available in appropriate dosage forms in health facilities in the country and work with health care workers and paediatricians on recommended interventions.

The project will also work with domestic pharmaceutical manufacturers to identify medicines that should be available to treat the major diseases in children and promote their availability.

These terms of reference serve as a guide to an assignment of assessing the quantitative and technical capacities of domestic pharmaceutical manufacturers in manufacturing paediatric medicines.

2. SCOPE OF THE ASSIGNMENT

The focus of the study will be on domestic manufacturers. The situational analysis will serve as a first step in assessing the technical capacity of domestic pharmaceutical manufacturers to produce paediatric formulations/dosage forms of medicines. It will not consist of a complete situational analysis and in-depth appraisal of technical feasibility of such production. Medicines included on the World Health Organization Model List of Essential Medicines for Children (Annex II) were identified as the focus of the study. Data will be collected on the current domestic production of these products, as well as other medicines in the same pharmacological class or in paediatric formulations.

In view of the above, the consultant will undertake a situational analysis in order to establish the following:

2.1 Background information of pharmaceutical manufacturers which shall include the available infrastructure and resources, as well as good manufacturing practice status for manufacturing paediatric formulations.

2.2 The target paediatric formulations being manufactured by domestic manufacturers.

2.3 The capacity of domestic manufacturers in terms of installed capacity, operating capacity and utilized capacity of machines used for manufacture of paediatric formulations.
2.4 The capacity of domestic manufacturers on the quality control of paediatric formulations

2.5 Potential of domestic manufacturers to produce paediatric or additional paediatric dosage forms

2.6 Domestic manufacturers’ capability in terms of human resource and technical expertise in manufacturing paediatric formulations

2.7 The existing gap in meeting the demand of the targeted medicines

2.8 Problems facing domestic companies in manufacturing medicines that meet standards in terms of quality, safety and efficacy and their respective solutions.

3. METHODOLOGY

The consultant will describe in detail in the final report, the approach or methodology used in undertaking the assignment in the specified period of time. The consultant is anticipated to use the available tool on situational analysis of domestic production of paediatric medicines as recommended by the World Health Organization.

The consultant shall visit the available registered pharmaceutical manufactures to collect the required information.

4. EXPECTED OUTPUT

The consultant will prepare a summary report of the data collected and its statistical analysis. The report will include a list of the products currently produced by each manufacturer that are included on, or have relevance to, the list of target paediatric medicines. In addition, qualitative information will be collected on the technical feasibility of domestic manufacturers to produce target paediatric medicines. The report with conclusion and recommendations will be submitted to the Head of the Project.

5. DURATION OF THE ASSIGNMENT

The assignment is scheduled to be completed within one month from the date of commencement.

6. TERMS OF PAYMENT

To be agreed prior to the commencement of the assignment.
## Annex II: Target medicines for paediatric use

<table>
<thead>
<tr>
<th>Therapeutic category (ATC level 3)</th>
<th>Medicine</th>
<th>Formulation</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-lactam antibacterials, pencillin</td>
<td>1. Amoxicillin</td>
<td>Suspension</td>
<td>125 mg/5 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dispersible tablet</td>
<td>250 mg disperseable tablet</td>
</tr>
<tr>
<td>Beta-lactam antibacterials, pencillin</td>
<td>2. Amoxicillin/clavulanic acid</td>
<td>Suspension</td>
<td>125 mg+31.25 mg/5 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dispersible tablet</td>
<td>250 mg + 125 mg</td>
</tr>
<tr>
<td>Antimalarials</td>
<td>3. Artemether + Lumefantrine</td>
<td>Dispersible tablet</td>
<td>20 mg + 120 mg</td>
</tr>
<tr>
<td>Antimalarials</td>
<td>4. Artesunate + amodiaquine</td>
<td>Tablet</td>
<td>50 mg + 153 mg or 200 mg (i.e. hydrochloride)</td>
</tr>
<tr>
<td>Antimalarials</td>
<td>5. Artesunate + mefloquine</td>
<td>Tablet</td>
<td>50 mg + 250 mg (i.e. hydrochloride)</td>
</tr>
<tr>
<td>Antimalarials</td>
<td>6. Artesunate + sulfadoxine/pyrimethamine (SP)</td>
<td>Tablet</td>
<td>50 mg + (500 mg + 25 mg)</td>
</tr>
<tr>
<td>Inhalants for obstructive airway disease</td>
<td>7. Beclometasone</td>
<td>Inhaler</td>
<td>100 mcg/dose</td>
</tr>
<tr>
<td>Beta-lactam antibacterials, pencillin</td>
<td>8. Benzylpenicillin</td>
<td>Injection</td>
<td>600 mg = 1 million IU</td>
</tr>
<tr>
<td>Antiepileptics</td>
<td>9. Carbamazepine</td>
<td>Suspension</td>
<td>100 mg/5 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chewable tablet</td>
<td>100 mg</td>
</tr>
<tr>
<td>Beta-lactam antibacterials, other</td>
<td>10. Ceftriaxone</td>
<td>Injection</td>
<td>500 mg vial</td>
</tr>
<tr>
<td>Antibacterials</td>
<td>11. Chloramphenicol</td>
<td>Injection</td>
<td>1 g vial</td>
</tr>
<tr>
<td></td>
<td>12. Cotrimoxazole</td>
<td>Dispersible tablet</td>
<td>100 mg + 20 mg</td>
</tr>
<tr>
<td>Psycholeptics, Anxiolytics</td>
<td>13. Diazepam</td>
<td>Rectal solution</td>
<td>2.5 mg/ml</td>
</tr>
<tr>
<td>Iron preparations</td>
<td>14. Ferrous salt</td>
<td>Suspension</td>
<td>30 mg Fe/5 ml</td>
</tr>
<tr>
<td>Antibacterials</td>
<td>15. Gentamycin</td>
<td>Injection</td>
<td>10 mg/ml</td>
</tr>
<tr>
<td>Antiinflammatory, non-steroidalals</td>
<td>16. Ibuprofen*</td>
<td>Tablet</td>
<td>200 mg</td>
</tr>
<tr>
<td>Drugs for treatment of tuberculosis</td>
<td>17. Isoniazid</td>
<td>Scored tablet</td>
<td>50 mg</td>
</tr>
<tr>
<td>Opioids</td>
<td>18. Morphine</td>
<td>Oral solution</td>
<td>10 mg/5 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immediate release tablet</td>
<td>10 mg</td>
</tr>
<tr>
<td>Electrolytes with carbohydrates</td>
<td>19. Oral rehydration solution (ORS)</td>
<td>Sachet</td>
<td>To make 500 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sachet</td>
<td>To make 1 litre</td>
</tr>
<tr>
<td>Other analgesics and antipyretics</td>
<td>20. Paracetamol</td>
<td>Suspension</td>
<td>120 mg/5 ml or 125 mg/5 ml</td>
</tr>
<tr>
<td>Antiepileptics</td>
<td>21. Phenobarbital</td>
<td>Injection</td>
<td>200 mg/ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oral liquid</td>
<td>3 mg/ml</td>
</tr>
<tr>
<td>Antiepileptics</td>
<td>22. Phenytoin</td>
<td>Suspension</td>
<td>25 or 30 mg/5 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chewable tablet</td>
<td>50 mg</td>
</tr>
<tr>
<td>Beta-lactam antibacterials, pencillin</td>
<td>23. Procaine penicillin</td>
<td>Injection</td>
<td>1 g = 1 million IU</td>
</tr>
<tr>
<td>Adrenergics, inhalants (drugs for obstructive)</td>
<td>24. Salbutamol</td>
<td>Inhaler</td>
<td>100 mcg/dose</td>
</tr>
<tr>
<td>Therapeutic category (ATC level 3)</td>
<td>Medicine</td>
<td>Formulation</td>
<td>Strength</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>airway disease)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A and D, incl. combinations of the two</td>
<td>25. Vitamin A</td>
<td>Capsules</td>
<td>100,000IU</td>
</tr>
<tr>
<td>Other mineral supplements</td>
<td>26. Zinc</td>
<td>Tablet (dispersible)</td>
<td>10 mg or 20 mg</td>
</tr>
</tbody>
</table>
Annex III

MINISTRY OF HEALTH AND SOCIAL WELFARE OF TANZANIA
AND WORLD HEALTH ORGANIZATION

Situational Analysis of the Domestic Production of
Medicines in Paediatric Dosage Forms

Introduction
The Ministry of Health and Social Welfare with the support of the World Health Organization is working on a project of improving access to essential paediatric medicines for children and their rational use. The Project known as ‘Better Medicines for Children’ would determine if child specific medicines were available in appropriate dosage forms in health facilities in the country.

The project would also work with domestic pharmaceutical manufacturers to identify medicines that should be available to treat the major diseases in children and promote their availability.

In view of that your organization being a key stakeholder in the manufacturer of paediatric formulations is requested to provide information by filling this questionnaire.

Objective
To conduct a situational analysis of the domestic production capacity of medicines with an emphasis on paediatric dosage forms.

Scope
The focus of the study will be on domestic manufacturers. The situational analysis will serve as a first step in assessing the technical capacity of domestic pharmaceutical manufacturers to produce paediatric medicinal formulations/dosage forms. It will not consist of a complete situational analysis and in-depth appraisal of the technical feasibility of such production.

A list of 22 target paediatric medicines have been identified as the focus of the study. Data will be collected on the current domestic production of these products as well as other medicines in the same pharmacological class or in paediatric formulation.

Expected output
A summary report of the data collected will be prepared. It will include a mapping of domestic manufacturers in a given country, and for each, a list of the products currently manufactured that are included on, or have relevance to, the list of target paediatric medicines. In addition, a limited set of qualitative information will be collected on the technical feasibility of domestic manufacturers to produce to priority paediatric medicines. A summary report will be provided through the WHO country office to the Ministry of Health and Social Welfare.
Methods
Data collection will occur through visits or via email to domestic pharmaceutical manufacturers. Three generic data collection forms have been developed and should be completed for each domestic manufacturer:

- Data Collection Form - Part 1: "Background Information on Manufacturer" (complete one per Manufacturer)
- Data Collection Form - Part 2: "Manufacturing and starting materials" (complete one per Manufacturer)
- Data Collection Form - Part 3: "Potential to produce additional paediatric dosage forms" (complete one per Manufacturer)
- Data Collection Form - Part 4: "Product Information" (complete one per Manufacturer)
Data Collection Form - Part 1:

Background Information on Manufacturer

• Name of Manufacturer

• Address of Manufacturer

• Contact Person who provided information
  Name: ____________________________  Phone: ____________________________
  Email: __________________________

• Address(es) of manufacturing site(s), if different from above

• Date Company was founded/established

• Year manufacturing site was built and any modifications

• Ownership structure (private, state, public, mix). Owned by another company?

• Does your company undertake contract manufacture for other companies?
  □ Yes  □ No
• Do you sub-contract to other companies?

☐ Yes ☐ No
If Yes, please list products and/or services:

• What was the company's total revenue last year (specify currency)?


• Who are the company's customers? Tick all that apply and indicate approximate proportion of total volume sold (currency).

☐ Domestic: %
  ☐ Government: %
  ☐ Private Sector: %
  ☐ Other (e.g. NGOs, please specify): %
  ☐ International Donors: %
  ☐ Export: %

• What are the company's production activities? Tick all that apply.

☐ Primary (manufacture of Active Pharmaceutical Ingredients (APIs) and intermediates)
  ☐ Secondary (finished dosage forms)
  ☐ Tertiary (packaging and labelling of products)

• How many people are employed the main manufacturing site?

Total:
In production:
In quality control:

• Do you have any in-house research and development capacity?

☐ Yes ☐ No
If Yes, please list products and/or services:

• Indicate the Good Manufacturing Practices standards with which the company complies:

☐ WHO
☐ PIC/EU
☐ FDA
☐ Other:
• Dates of last two inspections by the National Regulatory Authority:


• Authorities other than the National RA who have inspected the company:


• Are you currently receiving techn./financial support from external agencies?

☐ Yes ☐ No

If Yes, please describe (including type of support and current status):


Data Collection Form - Part 2:

Manufacturing and starting materials

- If your company is manufacturing penicillin or other beta-lactam products, does this production take place in separate building provided with its own air-handling system?
  - Yes
  - No
  - Not manufacturing beta-lactam products.

- Are there any additional products that you are licensed to produce but are not producing?
  - Yes
  - No
  - If yes, please list and explain reasons for not producing (e.g. lack of raw materials, supply chain problems, no sterile manufacturing capacity, lack of trained staff, change in recommended treatment):

- Starting materials sources for the company's major products?
Data Collection Form - Part 3:

Potential to produce additional paediatric dosage forms

- What additional technical requirements would be needed to add/change current production to include additional paediatric formulations and dosage forms: dispersible tables, oral dispersible tablets, suspensions and injections?
  (For example, human resources - number and skills, equipment purchase and maintenance, special storage requirements, etc.)
• **More specifically, what would be required to change production from a:**

| (a) tablet to a dispersible tablet or oral dispersible tablet of the same medicine? |
| (b) suspension of one medicine to a suspension of a different medicine? |
| (c) injection of one medicine to an injection of a different medicine? |
| (d) package and label of an existing product to a paediatric product? |
| (e) tablet to a granule formulation in a sachet of the same medicine? |
**Data Collection Form - Part 4:**

**Product Information**

For each product listed below (Target Medicines for Paediatric Use) and any others in the same pharmacological class, please complete the "Product Information" pages.

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Beta-lactam antibacterials, Penicillin</td>
<td>• Amoxicillin</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

Dosage Form/Strength: Suspension 125 mg/5ml (100ml)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):  
  - International Pharmacopoeia
  - United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
  - Registered for export only
  - Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Pharmacological Class**

<table>
<thead>
<tr>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Artemether + Lumefantrine</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

Dosage Form/Strength: tablet 20 mg + 120 mg (16 tablets)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):  
  - International Pharmacopoeia
  - United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
  - Registered for export only
  - Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Beclometasone</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Inhaler 50mcg/dose (200 doses)

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):  

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- **Number of Units produced per year:**
- **List any other countries where product is currently registered and marketed:**

**Comments:**

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<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Cotrimoxazole</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Paediatric tablet, Trimethoprim 20 mg + Sulphamethoxazole 100 mg

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):  

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- **Number of Units produced per year:**
- **List any other countries where product is currently registered and marketed:**

**Comments:**
### Pharmacological Class

<table>
<thead>
<tr>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Antimalarials</td>
</tr>
<tr>
<td>• Artemether + Lumefantrine</td>
</tr>
</tbody>
</table>

#### Product (INN/Brand Name):

Dosage Form/Strength: Tablet 20 mg + 120 mg (16 tablets)

#### Finished Product Specifications:

- [ ] British Pharmacopoeia (BP)
- [ ] European Pharmacopoeia (EP)
- [ ] International Pharmacopoeia
- [ ] United States Pharmacopoeia (USP)
- [ ] Other - specify (e.g. "in-house"):

#### Status of Registration:

- [ ] Registered and currently marketed
- [ ] Registered for export only
- [ ] Registered but not marketed
- [ ] Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

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### Pharmacological Class

<table>
<thead>
<tr>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Beta-lactam antibacterials, other</td>
</tr>
<tr>
<td>• Ceftriaxone</td>
</tr>
</tbody>
</table>

#### Product (INN/Brand Name):

Dosage Form/Strength:

#### Finished Product Specifications:

- [ ] British Pharmacopoeia (BP)
- [ ] European Pharmacopoeia (EP)
- [ ] International Pharmacopoeia
- [ ] United States Pharmacopoeia (USP)
- [ ] Other - specify (e.g. "in-house"):

#### Status of Registration:

- [ ] Registered and currently marketed
- [ ] Registered for export only
- [ ] Registered but not marketed
- [ ] Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
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<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Co-trimoxazole</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Suspension 200 mg + 40 mg/5ml (100ml)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house")

Status of Registration:
- Registered and currently marketed
- Registered but not marketed

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Iron preparations</td>
<td>• Iron tablet</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Ferrous Sulphate 200 mg + 250 ug (60 mg elemental iron)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house")

Status of Registration:
- Registered and currently marketed
- Registered but not marketed

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron preparations</td>
<td>Iron syrup</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Ferrous Sulphate 100 mg per 5ml

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"): International Pharmacopoeia
- United States Pharmacopoeia (USP)

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- **Number of Units produced per year:**

- **List any other countries where product is currently registered and marketed:**

**Comments:**

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<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tetracycline eye ointment</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Ointment

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"): International Pharmacopoeia
- United States Pharmacopoeia (USP)

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- **Number of Units produced per year:**

- **List any other countries where product is currently registered and marketed:**

**Comments:**
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Mebendazole</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Chewable tablet 100 mg (6 tablets)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):  
- International Pharmacopoeia
- United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Mebendazole</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Syrup 100 mg/5ml (30ml)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):  
- International Pharmacopoeia
- United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nystatin Drops</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: 100,000 IU/ml (30ml)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- International Pharmacopoeia
- United States Pharmacopoeia (USP)
- Other - specify (e.g. "in-house"):

Status of Registration:
- Registered and currently marketed
- Registered for export only
- Registered but not marketed
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nystatin suspension</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength:

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- International Pharmacopoeia
- United States Pharmacopoeia (USP)
- Other - specify (e.g. "in-house"):

Status of Registration:
- Registered and currently marketed
- Registered for export only
- Registered but not marketed
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Multivitamins</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: **specify**

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house")

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Electrolytes with carbohydrates</td>
<td>• Oral rehydration solution (ORS)</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Packet to make 1 litre of solution

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house")

Status of Registration:
- Registered and currently marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Electrolytes with carbohydrates</td>
<td>• Oral rehydration solution (ORS)</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Packet to make 500ml of solution

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Ciprofloxacin</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Tablet

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Ciprofloxacin</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Suspension

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"): International Pharmacopoeia
- United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

---

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Other analgesics and antipyretics</td>
</tr>
<tr>
<td></td>
<td>• Paracetamol</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Syrup 120 mg/5ml (100ml)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"): International Pharmacopoeia
- United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Erythromycin</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Syrup, 125 mg/5ml

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"): International Pharmacopoeia
- United States Pharmacopoeia (USP)

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**

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<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Prednisolone</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Tablet

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"): International Pharmacopoeia
- United States Pharmacopoeia (USP)

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Other analgesics and antipyretics</td>
<td>• Prednisolone</td>
</tr>
</tbody>
</table>

**Prednisolone**

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Suspension

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g., "in-house"): International Pharmacopoeia
- United States Pharmacopoeia (USP)

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Other analgesics and antipyretics</td>
<td>• Paracetamol</td>
</tr>
</tbody>
</table>

**Paracetamol**

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Tablet 100 mg

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g., "in-house"): International Pharmacopoeia
- United States Pharmacopoeia (USP)

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**
<table>
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<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Other analgesics and antipyretics</td>
<td>• Paracetamol</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Tablet 500 mg

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):
- International Pharmacopoeia
- United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Antiepileptics</td>
<td>• Phenobarbital</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength:

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):
- International Pharmacopoeia
- United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
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<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Antiepileptics</td>
<td>• Phenytoin</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength:

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):
- International Pharmacopoeia
- United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

---

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adrenergics, inhalants (drugs for obstructive airway disease)</td>
<td>• Salbutamol</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Tablet

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):
- International Pharmacopoeia
- United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Other mineral supplements</td>
<td>• Zinc</td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: 20 mg dispersible tablet (100 tablets)

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"): United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Quinine</td>
<td></td>
</tr>
</tbody>
</table>

Product (INN/Brand Name):

Dosage Form/Strength: Tablet 300 mg

Finished Product Specifications:
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"): United States Pharmacopoeia (USP)

Status of Registration:
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

Comments:
<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Vitamin A 100000IU</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:**

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):  

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**

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<table>
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<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>• Vitamin A 200000IU</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:**

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house"):  

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**
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<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Albendazole</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Chewable tablet 200 mg (2 tablets)

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house")(USP)

**Status of Registration:**
- Registered and currently marketed
- Registered but not marketed
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**

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<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Albendazole</td>
</tr>
</tbody>
</table>

**Product (INN/Brand Name):**

**Dosage Form/Strength:** Suspension 100 mg/5ml (20ml)

**Finished Product Specifications:**
- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- Other - specify (e.g. "in-house")(USP)

**Status of Registration:**
- Registered and currently marketed
- Registered for export only
- Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

**Comments:**
**General Comments:**

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<td>Comment 2</td>
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<tr>
<td>Comment 4</td>
</tr>
<tr>
<td>Comment 5</td>
</tr>
<tr>
<td>Comment 6</td>
</tr>
<tr>
<td>Comment 7</td>
</tr>
</tbody>
</table>

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Domestic production of medicines in paediatric dosage forms -- Page 49
Annex IV: Shelys Pharmaceuticals Ltd - Production capacity in terms of dosage forms

<table>
<thead>
<tr>
<th>Dosage form</th>
<th>Year</th>
<th>Installed capacity (millions)</th>
<th>Operating capacity (millions)</th>
<th>Utilized capacity %</th>
<th>Unutilized capacity %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>2007/2008</td>
<td>6500</td>
<td>5100</td>
<td>36</td>
<td>64</td>
</tr>
<tr>
<td></td>
<td>2008/2009</td>
<td>6500</td>
<td>5100</td>
<td>35</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td>2009/2010</td>
<td>6500</td>
<td>5100</td>
<td>37</td>
<td>63</td>
</tr>
<tr>
<td>Capsules (Including penicillin products)</td>
<td>2007/2008</td>
<td>2160</td>
<td>1700</td>
<td>17</td>
<td>83</td>
</tr>
<tr>
<td></td>
<td>2008/2009</td>
<td>2160</td>
<td>1700</td>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>2009/2010</td>
<td>2160</td>
<td>1700</td>
<td>16</td>
<td>84</td>
</tr>
<tr>
<td>Liquid Orals</td>
<td>2007/2008</td>
<td>108</td>
<td>85</td>
<td>11</td>
<td>89</td>
</tr>
<tr>
<td></td>
<td>2008/2009</td>
<td>108</td>
<td>85</td>
<td>15</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>2009/2010</td>
<td>108</td>
<td>85</td>
<td>18</td>
<td>82</td>
</tr>
<tr>
<td>Dry Syrups (Including penicillin products)</td>
<td>2007/2008</td>
<td>18</td>
<td>14</td>
<td>14</td>
<td>86</td>
</tr>
<tr>
<td></td>
<td>2008/2009</td>
<td>18</td>
<td>14</td>
<td>16</td>
<td>84</td>
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<tr>
<td></td>
<td>2009/2010</td>
<td>18</td>
<td>14</td>
<td>23</td>
<td>77</td>
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</table>

Annex V: Zenufa Laboratories Ltd - Production capacity in terms of dosage forms

<table>
<thead>
<tr>
<th>Dosage form</th>
<th>Year</th>
<th>Standard capacity (millions)</th>
<th>Operating capacity (millions)</th>
<th>Utilized capacity %</th>
<th>Unutilized capacity %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>2008/2009</td>
<td>2956</td>
<td>2660</td>
<td>4.4</td>
<td>95.6</td>
</tr>
<tr>
<td></td>
<td>2009/2010</td>
<td>2956</td>
<td>2660</td>
<td>5.0</td>
<td>95.0</td>
</tr>
<tr>
<td>Capsules</td>
<td>2008/2009</td>
<td>700</td>
<td>630</td>
<td>5.3</td>
<td>94.7</td>
</tr>
<tr>
<td></td>
<td>2009/2010</td>
<td>700</td>
<td>630</td>
<td>7.9</td>
<td>92.1</td>
</tr>
<tr>
<td>Liquid Orals</td>
<td>2008/2009</td>
<td>47</td>
<td>42</td>
<td>2.7</td>
<td>97.3</td>
</tr>
<tr>
<td></td>
<td>2009/2010</td>
<td>47</td>
<td>42</td>
<td>4.6</td>
<td>95.4</td>
</tr>
<tr>
<td>Dry syrups</td>
<td>2008/2009</td>
<td>30</td>
<td>27</td>
<td>1.2</td>
<td>98.8</td>
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<tr>
<td></td>
<td>2009/2010</td>
<td>30</td>
<td>27</td>
<td>2.4</td>
<td>97.6</td>
</tr>
</tbody>
</table>

Annex VI: Tanzania Pharmaceutical Industries Ltd - Production capacity in terms of dosage forms in 2009-2010

<table>
<thead>
<tr>
<th>MACHINE</th>
<th>Capacity per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression (Tabulating)</td>
<td>31 230 240 Tablets</td>
</tr>
<tr>
<td>Capsulation</td>
<td>3 346 000 Tablets</td>
</tr>
<tr>
<td>Liquid Line</td>
<td>144 000 Bottles</td>
</tr>
</tbody>
</table>

N.B. The manufacturer was able to provide the information as indicated above
### Annex VII: Mansoor Daya Chemicals Ltd - Production capacity in terms of dosage forms

<table>
<thead>
<tr>
<th>Dosage form</th>
<th>Year</th>
<th>Standard capacity (millions)</th>
<th>Operating capacity (millions)</th>
<th>Utilized capacity %</th>
<th>Unutilized capacity %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>2007/2008</td>
<td>325</td>
<td>300</td>
<td>52</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td>2008/2009</td>
<td>450</td>
<td>400</td>
<td>55</td>
<td>45</td>
</tr>
<tr>
<td></td>
<td>2009/2010</td>
<td>450</td>
<td>400</td>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>

### Annex VIII: Keko Pharmaceuticals Industries (1997) Ltd - Production capacity in terms of dosage forms

<table>
<thead>
<tr>
<th>Dosage form</th>
<th>Year</th>
<th>Standard capacity (millions)</th>
<th>Operating capacity (millions)</th>
<th>Utilized capacity %</th>
<th>Unutilized capacity %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>2007/2008</td>
<td>1680</td>
<td>862.58</td>
<td>51.34</td>
<td>48.66</td>
</tr>
<tr>
<td></td>
<td>2008/2009</td>
<td>1680</td>
<td>576.24</td>
<td>34.30</td>
<td>65.7</td>
</tr>
<tr>
<td></td>
<td>2009/2010</td>
<td>1680</td>
<td>651.74</td>
<td>38.79</td>
<td>61.21</td>
</tr>
<tr>
<td>Capsules</td>
<td>2007/2008</td>
<td>608</td>
<td>66.00</td>
<td>10.85</td>
<td>89.14</td>
</tr>
<tr>
<td></td>
<td>2008/2009</td>
<td>608</td>
<td>92.00</td>
<td>15.13</td>
<td>84.86</td>
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<tr>
<td></td>
<td>2009/2010</td>
<td>608</td>
<td>158.00</td>
<td>25.98</td>
<td>74.01</td>
</tr>
<tr>
<td>Dry syrup</td>
<td>2007/2008</td>
<td>1.2</td>
<td>0.015</td>
<td>1.25</td>
<td>98.75</td>
</tr>
<tr>
<td></td>
<td>2008/2009</td>
<td>1.2</td>
<td>0.195</td>
<td>16.25</td>
<td>83.75</td>
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<tr>
<td></td>
<td>2009/2010</td>
<td>1.2</td>
<td>0.005</td>
<td>0.41</td>
<td>99.58</td>
</tr>
</tbody>
</table>

#### DOSAGE FORM: TABLETS

<table>
<thead>
<tr>
<th>GENERIC NAME</th>
<th>STRENGTH</th>
<th>PRODUCTION (Units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>300 mg &amp; 500 mg</td>
<td>230 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-trimoxazole</td>
<td>480 mg</td>
<td>35 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluconazole</td>
<td>150 mg &amp; 200 mg</td>
<td>200 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Griseofulvin</td>
<td>500 mg</td>
<td>200 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>200 mg</td>
<td>1 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketoconazole</td>
<td>200 mg</td>
<td>2 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metronidazole</td>
<td>200 mg &amp; 250 mg</td>
<td>40 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>500 mg</td>
<td>460 000 000</td>
</tr>
<tr>
<td>Pen V (Phenoxymethyl Penicillin)</td>
<td>250 mg 72 000 000</td>
<td>109 000 000</td>
</tr>
<tr>
<td>Other tablets</td>
<td></td>
<td>809 600 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1 650 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capacity*</td>
<td></td>
<td>3 000 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spare capacity*</td>
<td></td>
<td>1 350 000 000</td>
</tr>
</tbody>
</table>

#### DOSAGE FORM: CAPSULES

<table>
<thead>
<tr>
<th>GENERIC NAME</th>
<th>STRENGTH</th>
<th>PRODUCTION (Units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Capsules</td>
<td>250 mg</td>
<td>65 911 100</td>
</tr>
<tr>
<td>Ampicillin Capsules</td>
<td>250 mg</td>
<td>20 000 000</td>
</tr>
<tr>
<td>Cloxacillin Capsules</td>
<td>250 mg</td>
<td>16 000 000</td>
</tr>
<tr>
<td>Doxycycline capsule</td>
<td>100 mg</td>
<td>34 000 000</td>
</tr>
<tr>
<td>Other Capsules</td>
<td></td>
<td>154 088 900</td>
</tr>
<tr>
<td></td>
<td></td>
<td>290 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capacity*</td>
<td></td>
<td>1 700 000 000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spare capacity*</td>
<td></td>
<td>1 410 000 000</td>
</tr>
</tbody>
</table>

#### DOSAGE FORM: GRANULES FOR ORAL SUSPENSION (DRY SYRUP)

<table>
<thead>
<tr>
<th>GENERIC NAME</th>
<th>STRENGTH</th>
<th>PRODUCTION (Units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxycillin (100 ml bottle)</td>
<td>125mg/5ml</td>
<td>1 100 000</td>
</tr>
<tr>
<td>Other dry syrups</td>
<td>800 000</td>
<td>800 000</td>
</tr>
<tr>
<td></td>
<td>1 900 000</td>
<td>2 200 000</td>
</tr>
<tr>
<td></td>
<td>14 000 000</td>
<td>14 000 000</td>
</tr>
<tr>
<td></td>
<td>12 100 000</td>
<td>11 800 000</td>
</tr>
</tbody>
</table>

Domestic production of medicines in paediatric dosage forms -- Page 52

<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tablets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Paracetamol</td>
<td>500 mg</td>
<td>1000's</td>
<td>0</td>
<td>72 391</td>
<td>101 338</td>
</tr>
<tr>
<td>2</td>
<td>Cotrimoxazole</td>
<td>480 mg</td>
<td>1000's</td>
<td>0</td>
<td>4948</td>
<td>3774</td>
</tr>
<tr>
<td>3</td>
<td>Metronidazole</td>
<td>200 mg</td>
<td>1000's</td>
<td>0</td>
<td>5478</td>
<td>7023</td>
</tr>
<tr>
<td>4</td>
<td>Aspirin</td>
<td>300 mg</td>
<td>1000's</td>
<td>0</td>
<td>6461</td>
<td>6796</td>
</tr>
<tr>
<td>Capsules</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Amoxicillin</td>
<td>250 mg</td>
<td>1000's</td>
<td>0</td>
<td>11 790</td>
<td>15 969</td>
</tr>
<tr>
<td>2</td>
<td>Ampicillin</td>
<td>250 mg</td>
<td>1000's</td>
<td>0</td>
<td>4406</td>
<td>6036</td>
</tr>
<tr>
<td>3</td>
<td>Cloxacillin</td>
<td>250 mg</td>
<td>1000's</td>
<td>0</td>
<td>3841</td>
<td>10 688</td>
</tr>
<tr>
<td>4</td>
<td>Ampiclox</td>
<td>500 mg</td>
<td>1000's</td>
<td>0</td>
<td>2194</td>
<td>4308</td>
</tr>
<tr>
<td>Syrups/Susp/DSs</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Amoxycillin DS</td>
<td>125 mg/5 ml</td>
<td>100 ml</td>
<td>0</td>
<td>246 086</td>
<td>450 868</td>
</tr>
<tr>
<td>2</td>
<td>Ampicillin DS</td>
<td>125 mg/5 ml</td>
<td>100 ml</td>
<td>0</td>
<td>32 768</td>
<td>90 098</td>
</tr>
<tr>
<td>3</td>
<td>Cloxacillin DS</td>
<td>125 mg/5 ml</td>
<td>100 ml</td>
<td>0</td>
<td>46 305</td>
<td>107 965</td>
</tr>
<tr>
<td>4</td>
<td>Cotrimoxazole sp</td>
<td>240 mg/5 ml</td>
<td>100 ml</td>
<td>0</td>
<td>224 109</td>
<td>277 528</td>
</tr>
<tr>
<td>5</td>
<td>Metronidazole sp</td>
<td>200 mg/5 ml</td>
<td>100 ml</td>
<td>0</td>
<td>70 167</td>
<td>253 821</td>
</tr>
<tr>
<td>6</td>
<td>Paracetamol sp</td>
<td>120 mg/5 ml</td>
<td>100 ml</td>
<td>0</td>
<td>256 346</td>
<td>288 719</td>
</tr>
<tr>
<td>7</td>
<td>Quinine sp</td>
<td>50 mg/5 ml</td>
<td>100 ml</td>
<td>0</td>
<td>131 867</td>
<td>384 989</td>
</tr>
</tbody>
</table>


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<td>1000's</td>
<td>25 000</td>
<td>10 000</td>
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<td>Aspirin</td>
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<td>1000's</td>
<td>40 000</td>
<td>90 000</td>
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</tr>
</tbody>
</table>

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*All capacities based on 3 shift/day and 25 days per month.*