Better medicines for children in The United Republic of Tanzania

Situational analysis of the domestic manufacturing industry in The United Republic of Tanzania

Executive summary
Reducing child mortality and improving the health outcomes of children requires the availability and rational use of safe and effective child specific medicines of acceptable quality. The World Health Organization recommends that the best forms to deliver medicine to children are solid oral dosage forms.

This report provides a situational analysis of the domestic pharmaceutical manufacturing industry in The United Republic of Tanzania and its ability to produce paediatric medicines. This work was undertaken as part of the World Health Organization’s Better Medicines for Children project, which seeks to improve access to medicines for children.

This analysis aims to provide information on domestic pharmaceutical manufacturers; determine if they are producing target formulations; assess their existing and potential physical, technical and human resource capacity to produce and assure the quality of paediatric medicines; as well as identify problems limiting their ability to meet quality, safety and efficacy standards and recommend solutions.

Data was collected from five of the seven domestic manufacturers (Keko Pharmaceutical (1997) Ltd, Mansoor Daya Chemicals Ltd, Shelys Pharmaceuticals Ltd, Tanzansino United Pharmaceuticals Ltd, and Zenufa Laboratories Ltd) using a questionnaire recommended by the World Health Organization (Annex III). Two manufacturers, A.A. Pharmaceuticals Ltd and Tanzania Pharmaceutical Industries Ltd, chose not to participate in the study.

The analysis focuses on twenty-two medicines on the World Health Organization Model List of Essential Medicines for Children (Annex II) and the current domestic production of these products, as well as other medicines in the same pharmacological class or paediatric formulation.
The study concludes that Tanzanian pharmaceutical manufacturers have the capacity to manufacture a small number of generic paediatric medicinal formulations. While only two manufacturers comply with good manufacturing practices requirements and have a very small number of medicines registered by the Tanzania Food and Drugs Authority, the industry exhibits the potential for growth. For example, most local manufacturers have the machinery required to produce paediatric formulations; there is a market for paediatric medicines; the public sector prefers generic medicines; national policies and initiatives favour local industry and promote local production; and Tanzanian health research and development institutions are ready to work with local industry to develop paediatric medicinal formulations.

Limitations on the industry include scarce financial resources to upgrade infrastructure to meet quality standards, as well as a lack of qualified technical human resources.

The report makes six recommendations:

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 in working with higher learning and research institutions to develop paediatric formulations under the following arrangement:

   a. Higher learning/research institutions can develop paediatric formulations or molecules and sell to pharmaceutical industries.
   b. 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 programmes, as needed by the domestic pharmaceutical industry. 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.

Strengthening the industry’s ability to manufacture a wide range of paediatric medicines will require deliberate efforts by both the public and private sectors to provide technology transfer and knowledge support.