Evaluation of WHO Listed Essential Medicines for Hematology & Oncology Registered In Botswana

Tinaye Seosenyeng

Background

In Botswana there are some challenge of unreliable supply and of Hematology / Oncology (HemOnc) medicines that are related to:

- Some essential WHO listed medicines not registered with Botswana Medicines Regulatory Authority (BOMRA) which then requires registration exemption application with supporting patient and product safety and registration documents that may not be readily available.
- Over reliance on one or two BOMRA registered product manufacturers which results in failure to supply in case of pandemics, natural disasters, change of government regulations, legislations ,sanctions or shortage of raw materials.
- Continuing to purchase branded originator medicines at high patent prices because there is no registered alternative or generic medicine that would .
- Threat of counterfeit and substandard medicines because of procuring products without obtaining the necessary certification.

Objectives

- Promote patient access to safe cost effective medicines
- Promote registration of medicines through Botswana Medicines Regulatory Authority in order to ensure patient safety
- Promote efficient cost effective supply chain of medicines through increasing the number of medicine suppliers

Methods

Compare the WHO list of Essential Medicines for HemOnc with the BOMRA list of registered medicines in order to establish

1. The number of WHO Essential HemOnc Medicines registered in Botswana
2. Establish the number of manufacturers of HemOnc medicines that have registered their products in Botswana

Discussion

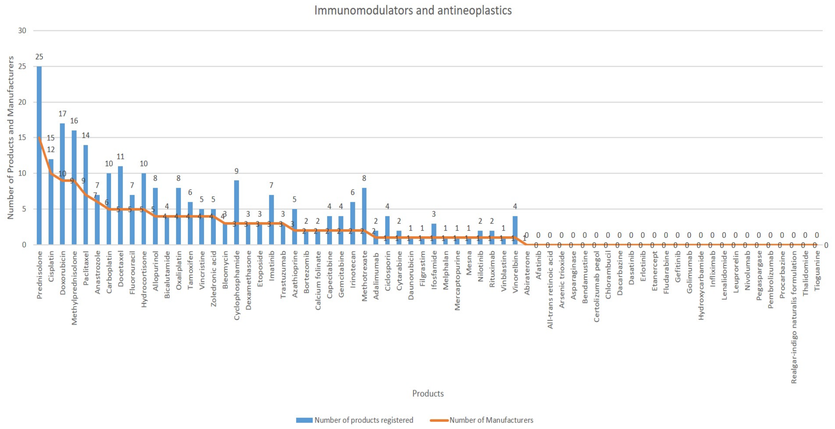
- Almost 50% WHO listed essential HemOnc medicines are not registered with BOMRA which limits patient access to such products since BOMRA does not have information regarding their safety and efficacy. This requires that a long tedious product import exemption application process in order to procure such products.
- Although some products such as Phytomenadion have long come off patent Botswana market continue to use highly priced Branded Originator medicines because there is no registered generic option.
- On average there is only 1 or 2 manufacturers registered for more than 50% of the products on the WHO Essential HemOnc Medicines list. This poses a threat product shortage in case of enforceable manufacturing challenges.

Conclusion

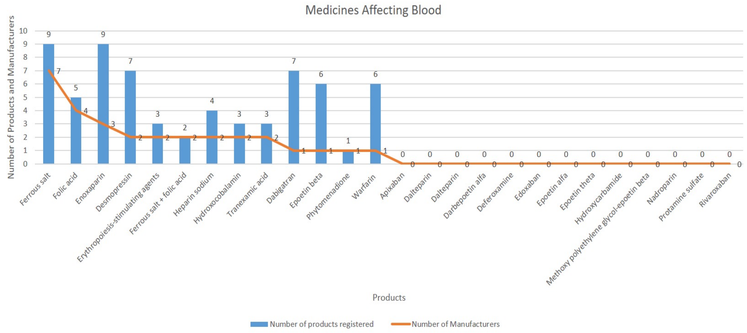
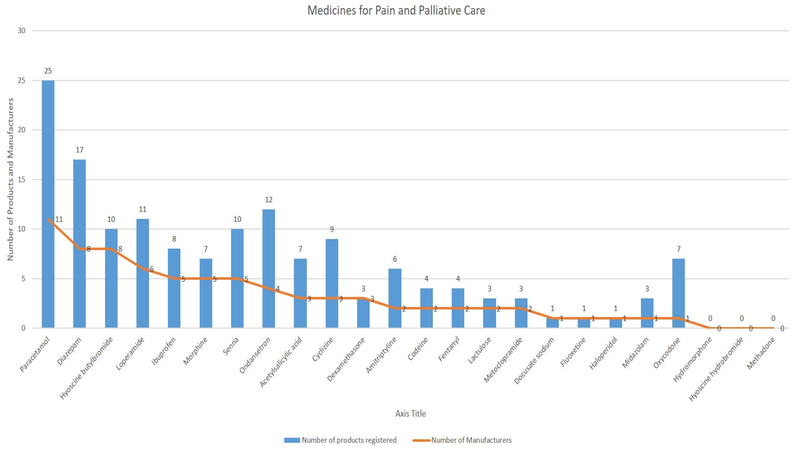
- There is a great need to appeal to the Manufacturers of the HemOnc medicines to register their products with BOMRA
- Furthermore there is a need for sourcing the documentation listed below that is required for import exemption supporting documentation in order to ensure that those products are from credible manufacturers and can be traced back to the point origin in case of product recall or any manufacturing flaws.
- There is also a need for regulatory authorities to priorities registering medicines listed in the WHO essential medicines list since they meet the medical needs of the majority of the population

Graphics

BOMRA Registered Immunomodulators and Antineoplastics



BOMRA Registered Medicines Affecting Blood



BOMRA Registered Medicines for Pain and Palliative Care