

Regulatory status and Quality Assurance of UN Commission life saving medicines in Zimbabwe, August 2015



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Abstract

Introduction: The Medicines Control Authority of Zimbabwe (MCAZ) mandate is to ensure that medicines and medical devices circulating in the country are safe, effective and of acceptable quality. The MCAZ's mandate is to protect public and animal health by ensuring that accessible medicines, allied substances and medical devices are safe, effective and of good quality. The objective of the review was to establish the current regulatory status of the UN Commission life saving medicines in Zimbabwe. The data was collected through searching the MCAZ drug register for registered alternatives.

Results: There is an established quality assurance system for medicines through registration before use, cGMP certification manufacturers, import and export controls, licensing of medicine distributors and post market surveillance. Each category of the continuum of care (RH, MH, NBH and CH) have at least a commodity and a manufacturer registered. Female condoms, amoxicillin dispersible tablet and magnesium sulfate injection are currently not registered. Only oxytocoan injection, gentamicin 40mg per ml, ampicillin injection and ceftriaxone injection have at least 3 different brands and manufacturers registered but 8/14 registered commodities have at least two brands registered.

Conclusions: The regulatory environment in place ensures medicines circulating in the country are safe, effective and of acceptable quality, however the limited number of registered brands and manufacturers of some of the commodities could be a threat to commodity availability and security.

Background

The Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an act of Parliament. The Medicines and Allied Substances Control Act (MASCA) [chapter 15:03] and the mandate of MCAZ is to protect public health ensuring that medicines and medical devices on the market are safe, effective and of good quality. This is achieved through enforcement of adherence to standards by manufacturers and distributors. The quality office ensures that all activities in the organization are carried out in accordance with international standards. Furthermore the Authority is committed to providing a high quality, accurate and timely service to all our stakeholders and consistently seek ways to meet and improve the requirements of all their customers.

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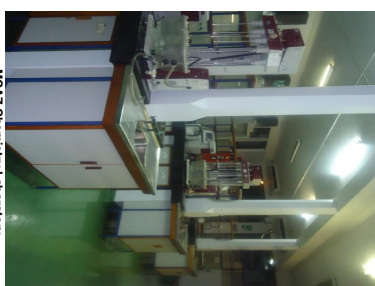
MCAZ Team



Quality Assurance Measures



MCAZ inspectors during cGMP inspection of Sterile facility in India - May 2013



MCAZ Chemistry Laboratory

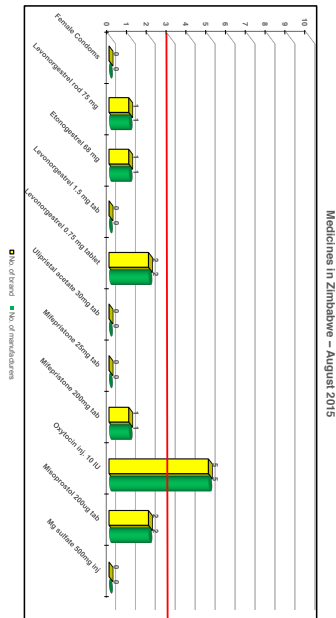
Quality Assurance Activities

- ❖ All medicines are registered before use
- ❖ Initial and routine cGMP inspections of the manufacturers is conducted
- ❖ All medicine distributors licensed
- ❖ Routine inspection of medicine distributors and dispensers (pharmacies, wholesalers, hospitals etc.)
- ❖ Pre-distribution laboratory analysis of all medicines is conducted
- ❖ Post Marketing Surveillance
- ❖ Import and export controls of all medicines

Registration status

Reproductive Health	Maternal Health	Newborn Health	Child Health	KEY
Female Condoms	Chrysolin injection 10 IU	Gentamicin 40mg/ml	Ampicillin	Registered
Emergency Contraceptive Pills	Magnesium sulfate 500mg injection	Gentamicin 20 mg/ml	Oral Rehydration Salt	Registered
Emergency Contraceptive Pills		Gentamicin 10 mg/ml zinc sulfate syrup	Zinc sulfate regular tab	Registered
Emergency Contraceptive Pills		Roxidone penicillin 1g	Zinc sulfate regular tab	Registered
Emergency Contraceptive Pills		Ampicillin injection	Zn sulfate regular tab	Registered
Emergency Contraceptive Pills		Ceftriaxone inj		Registered
Emergency Contraceptive Pills		Becloethasone inj		Registered
Emergency Contraceptive Pills		Becloethasone inj		Registered
Emergency Contraceptive Pills		Chlorhexidine 4% gel or soln		Registered

No. of brands & manufacturers registered



Conclusions & Recommendations

- ❖ The regulatory environment and mechanisms are in place to ensure that all medicines in the country are safe, effective and of acceptable quality.
- ❖ At least one or more brands of UNCOLSC are registered except for female condoms, amoxicillin dispersible tablet and magnesium sulfate injection.
- ❖ Of the registered UNCOLSC, only oxytocoan injection, gentamicin 40mg per ml, ampicillin and ceftriaxone injections have at least 3 different brands and manufacturers registered.
- ❖ To ensure availability and security of all UNCOLSC, the regulatory authority should endeavour to have:
 - all UNCOLSC registered
 - at least 3 different brands and manufacturers of each UNCOLSC

