Regulatory status and Quality Assurance of UN life saving medicines in Uganda, August 2015.

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Abstract

Introduction: The mission of the National Drug Authority is "to ensure access to quality, safe and efficacious human and veterinary medicines and other healthcare products through the regulation and control of their production, importation, distribution and use". The objective of the review was to ascertain the: registration status of the UN lifesaving medicines, the number of brands and manufacturers of the UN life saving medicines registered in the country.
Results: 18/26 medicines were registered. All maternal health medicines, Amoxicillin dispersible tablets and Zinc dispersible tablets were registered. 12/18 registered medicines had at least 3 brands and manufacturers registered. The quality assurance of the medicines is ensured through the established regulations and guidelines for GMP requirements for the manufacturers, medicines import control at entry points, laboratory analysis, pharmacovigilance, including post-market surveillance of all medicines. cGMP is a prerequisite for all manufacturers intending to export their medicines into the county. Medicine handlers and the general population are sensitized about proper handling of medicines.
Conclusion: The registration status of the UN life saving medicines is good and the number of brands and manufacturers registered in the country is favorable to guarantee the availability and security of the UN life saving medicines. The QA activities in place ensure that all medicines circulating in the country are of acceptable quality.

Background

The National Drug Authority (NDA) was **established by an Act of Parliament in 1993** currently the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2002 Revised edition). It is mandated to ensure access to efficacious and safe medicines by the Ugandan population through the control of their manufacture, importation, distribution and use.

The national medicine registry was reviewed to ascertain the: registration status of the UN lifesaving medicines, the number of their brands and manufacturers registered in the country. In addition the quality assurance activities were also described.

QA: Sensitization of medicine handlers

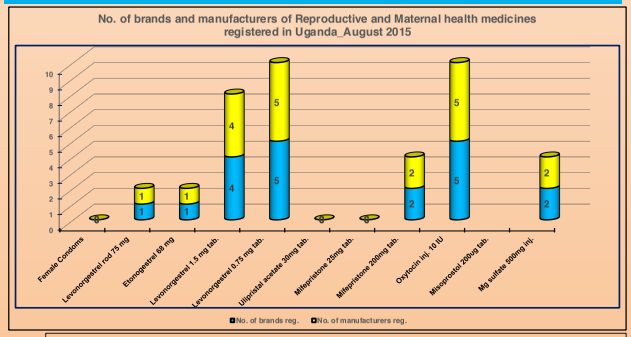
Registration status

Reproductive Health	Maternal Health	Newborn Health	Child Health
Female Condoms	Oxytocin injection 10 IU	Gentamicin 40mg per ml	Amoxicillin 250 or 500mg dispersible tablets
Levonorgestrel rod 75 mg/rod x 2 implant	Misoprostol 200ug tablet	Gentamicin 20 mg per ml	Oral Rehydration Salts (low osmolarity)
Etonogestrel 68 mg /rod x1 implant	Magnesium sulfate 500mg injection	Gentamicin 10 mg per ml	Zinc sulfate syrup (10mg/ml)
Levonorgestrel 1.5 mg tablet		Procaine penicillin 1 g vial	Zinc sulfate 10mg or 20mg dispersible tablets
Levonorgestrel 0.75 mg tablet		Ampicillin injection 250mg or 500mg or 1 g in a vial	Zinc sulfate 20mg regular tablets
Ulipristal acetate 30mg tablet		Ceftriaxone 250mg or 500mg or 1g in a vial	
Mifepristone 25mg tablet		Betamethasone inj. 4mg per ml	
Mifepristone 200mg tablet		Betamethasone inj. 6mg per ml	
		Dexamethasone inj 4mg per ml	
		Chlorhexidine 4% gel or soln	

Key: Registered; Not Registered

Majority of the UN Commission Life Saving commodities are registered

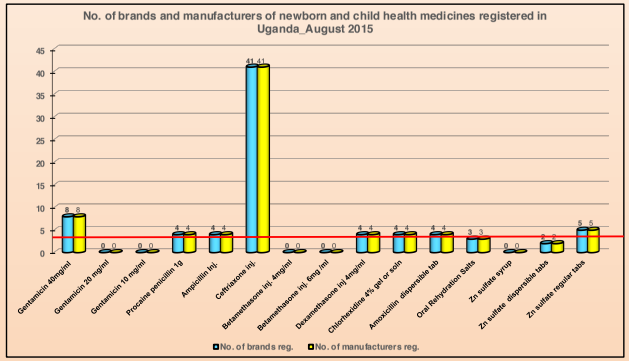
No. of brands & manufacturers of RH and MH medicines registered



Only Levonorgestrel implant and 0.75 mg tablet and Oxytocin 10IU had atleast 3 manufacturers registered

Quality Assurance: GMP Inspection

No.of brands and manufacturers of NBH & CH medicines registered



Medicines with at least 3 brands and manufacturers registered

Quality Assurance activities

- Established regulations and guidelines on GMP requirements for all manufacturers.
- Current GMP Inspection of all manufacturers
- Evaluation and Registration of all medicines
- Information sharing and collaboration with other regulatory bodies, health bodies such as WHO on the quality of medicines.
- Import control at the port of entry into the country.
- Pharmacovigilance including post-market surveillance of all medicines on the market.

Conclusion & Recommendation

- The registration status of the UN life saving medicines is good
- The number of brands and manufacturers registered in the country is favorable to guarantee the availability and security all UN life saving medicines except for female condoms and contraceptive implants for family planning. Thus the authority should consider registration of more brands and manufacturers of implants to ensure their availability
- The QA activities in place ensure that all medicines circulating in the country are of acceptable quality.