

FDA ALERT ON THE USE OF SUBSTANDARD UTEROTONICS IN HOSPITALS AND CLINICS

Reports from the 2014 joint FDA-USP annual product quality monitoring exercise indicate the presence and use of substandard uterotonics in hospitals and clinics throughout the country.

This disturbing occurrence not only poses a serious risk to maternal health but also endangers national efforts at attaining the MDG 4 & 5 which aimed at reducing child mortality and improving maternal health.

The reports also noted that some of these substandard medicines found during the current surveillance were detected during the 2012-2013 uterotonics monitoring exercise of which FDA issued an alert warning the public particularly health institutions to desist from using these unsafe medicines.

The substandard brands of uterotonics found are as listed below:

OXYTOCIN

NO	BRAND	MANUFACTURER
1	Oxytocin Injection	Alliance Pharma Ltd
2	Zytocin Injection	Hubei Tiannyao Pharmaceutie Pharma Ltd, UK
3	Philoxy Oxytocin Injection	Greenfield Pharmaceuticals, Tianzhou Jiangsu Province China
4	Hanbet Oxytocin Injection	Zhejiang Ruixin Pharm Co. Ltd, China
5	Lytocin Injection	Jiangsu Huayang Pharmaceutical Co Ltd, China
6	Syntostan Injection	CSPC Ouyi pharmaceutical Co. Ltd, China
7	Pitons Oxytocin Injection	Shanxi Shuguag Pharm. Co. Ltd, China
8	Oxytocin Injection	Anhui Medihel Co. Ltd, China
9	Noxytocin	Scott Edil Pharmacia Ltd, India

ERGOMETRINE

NO	BRAND	MANUFACTURER
1	Embassy Ergometrine Injection	Laborate Pharmaceuticals Ltd, India
2	Ergometrine maleate Injection	Laboratoires Sandersm, S.A, China
3	Ergometrine maleate Injection	Laboratoires STEROP, Belgium
4	Elfa-Ergot	Nitin Lifesciences Haryana, India

The FDA is by this reiterating its warning to the public especially health facilities to refrain from stocking and dispensing these unsafe medicines to the public.

The report also noted with concern inappropriate storage and transportation of uterotonics in some facilities. The uterotonics should be kept at 2-8°C throughout their shelf life.

FDA is therefore urging health facilities to:

1. Ensure that medical products are duly registered before purchasing for use
2. Ensure that the recommended storage conditions are maintained throughout the shelf life of the products

SIGNED

CHIEF EXECUTIVE : **HUDU MOGTARI**