POST-MARKET QUALITY SURVEILLANCE PROJECT
MATERNAL HEALTHCARE PRODUCTS
(OXYTOCIN AND ERGOMETRINE)
ON THE GHANAIAN MARKET

REPORT OF FIRST ROUND

Joint Project of:

Ghana Food and Drugs Authority (FDA)
Laboratory Services Department

and

The Promoting the Quality of Medicines Program

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About Ghana FDA

The Ghana Food and Drugs Authority is the statutory body established by law in Ghana to regulate the manufacture, import, export, supply, storage, distribution, and sale of medicines and food to ensure quality and safety as well as promote public health.

About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID) and implemented by the United States Pharmacopeial Convention (USP), is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicines quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally.

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Executive Summary

Post-marketing quality surveillance was carried out to assess the quality of uterotonics (Oxytocin and Ergometrine) on the Ghanaian market between August and September 2012. A total of 303 samples— 185 Oxytocin injection, 103 Ergometrine injection, and 15 Ergometrine tablets—were sampled from both public and private hospitals, clinics, medical stores, pharmaceutical outlets, and the informal sector across the ten regions of Ghana.

The samples were assessed with respect to:

- Source and registration (marketing authorization) status;
- Cold chain status (for injectables) at the time of sampling from the distribution channel;
- Recommended storage conditions by the manufacturer; and,
- Content of active pharmaceutical ingredient (assay) and sterility.

Eighty-six percent (86%) of the Oxytocin samples found on the market were manufactured in China, whereas 90.68% of Ergometrine samples were manufactured in India. Of those collected and tested, 8.11% of Oxytocin samples and 57.63% of Ergometrine samples had been issued marketing authorizations: Two companies supplying Oxytocin and one company supplying Ergometrine injection. All the samples of Ergometrine tablets were from companies that did not hold marketing authorizations. The origin of 10% of the Oxytocin samples and 4.24% of the Ergometrine samples could not be established.

It was observed that almost all of the injectables were not stored according to the recommended storage conditions (2°–8°C) either of some manufacturers or of the official compendia, the *U.S. Pharmacopeia* and *British Pharmacopeia*; the only exception was one Regional Medical Store.

In addition, the storage conditions recommended by the manufacturers of more than 50% of both the Oxytocin and Ergometrine injections were not consistent with recommendations in the official compendia. This indicates a lack of awareness of the appropriate storage conditions for these uterotonic products. Twenty (20) samples of both Oxytocin and Ergometrine had no labeling information providing batch number manufacture and expiry dates, making it difficult to establish their authenticity and valid shelf-life.

Out of the 169 Oxytocin samples assayed, 55.62% failed. Of the 99 Ergometrine injection samples, 73.74% failed, and all of the 11 (100%) Ergometrine tablets tested failed assay. Two (2) samples of Oxytocin injection and three (3) samples of Ergometrine tablets (two of the three Ergometrine tablets had the same batch number) were determined to be counterfeit products.

Due to resource constraints, a random sample of 80 products (40 Oxytocin and 40 Ergometrine injections) was subjected to sterility testing. Of the 40 Oxytocin samples randomly selected for sterility testing, 97.5% failed either Assay or Sterility testing, or both; 94.87% of the 40 Ergometrine injection samples tested for sterility failed either Assay or Sterility testing, or both.

The results of this project established that an extremely high percentage of uterotonics available on the Ghanaian market do not meet required standards of quality. This situation could have serious implications for maternal mortality in the country.

A number of regulatory actions have been taken by the Ghana FDA, including product recalls, and those suspected of being involved in criminal acts have been referred to the police.

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- Promoting the Quality of Medicines program for providing technical assistance.

ACRONYMS

BP	British Pharmacopeia
FDA	Food and Drugs Authority – Ghana
PMS	Post-marketing surveillance
PoM	Prescription-only Medicines
PQM	The Promoting the Quality of Medicines Program
USAID	United States Agency for International Development
USP	United States Pharmacopeial Convention

1.0 INTRODUCTION

The Food and Drugs Authority (FDA) of Ghana and the United States Pharmacopeial Convention (USP) have been collaborating since 2008 to promote the quality of medicines sold and distributed on the Ghanaian Market. Funded by the United States Agency for International Development (USAID), USP has implemented activities to monitor the quality of antimalarial medicines circulating in the country's markets, first through its Drug Quality and Information program and, currently, through its Promoting the Quality of Medicines (PQM) program. Year 2012 marked expansion of the program to include the sampling and testing of analgesics commonly prescribed to control malarial fever and of Maternal Healthcare products, namely Oxytocin and Ergometrine (Ergonovine), to prevent postpartum hemorrhage.

This report focuses only on the sampling and testing of the Maternal Healthcare products Oxytocin and Ergometrine.

The objective of this study was to determine for all Oxytocin injection and Ergometrine (tablets and injections) products distributed and sold on the Ghanaian Market:

1. If they conform to the specifications and standards listed by the manufacturer upon which their marketing authorizations were granted; and,
2. If there were unregistered and/or counterfeits products within this therapeutic group circulating in Ghana's markets.

2.0 SAMPLING

Sampling was carried out at established sentinel sites across the country between the period of August 8 and September 5, 2012 according to the following parameters:

Sentinel sites	10 (all regions in Ghana)
Targeted products	Oxytocin and Ergometrine
Targeted number of samples	400 (20 samples per product per site)

- Cold chain status was documented at the time of sampling.
- Manufacturer's recommended storage conditions as per the package insert was noted.
- Irrespective of the condition of storage at the time of sampling at the distribution point, cold chain was maintained during storage and transportation to the FDA Laboratory.
- Sampling covered the following sectors:

Public Sector	Medical Stores (Central/Regional) Government Hospitals/Clinics Quasi-government Hospitals/Clinics
Private Sector	Private Hospitals/Clinics Mission Hospitals/Clinics Distributors and Wholesalers Retail Pharmacies Licensed Chemical Sellers Informal Sector

All the samples were maintained at 2°–8° C while transported to and stored at the FDA Laboratory prior to analysis.

A total of 303 samples were collected from the 10 regions in the country by the following breakdown:

2.1 SAMPLING OF OXYTOCIN INJECTION

Table 1. Samples as per Sentinel Site

Sentinel Sites	No. of Samples
Accra	21
Sunyani	20
Koforidua	15
Bolgatanga	18
Kumasi	25
Cape Coast	20
Wa	10
Ho	18
Takoradi	21
Tamale	17
Total	**185**

Figure 1. Distribution

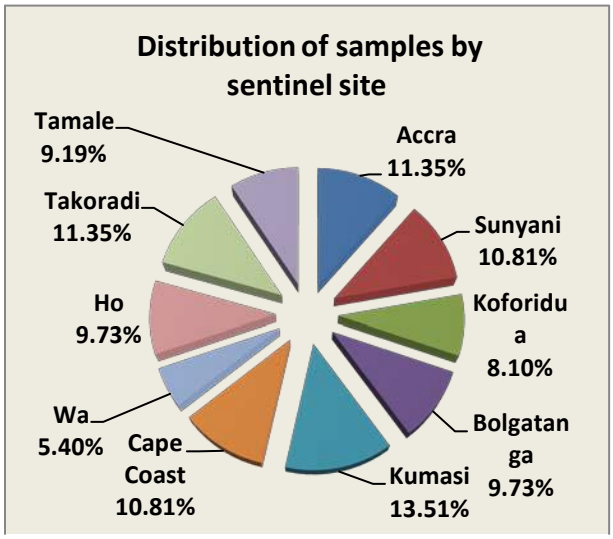
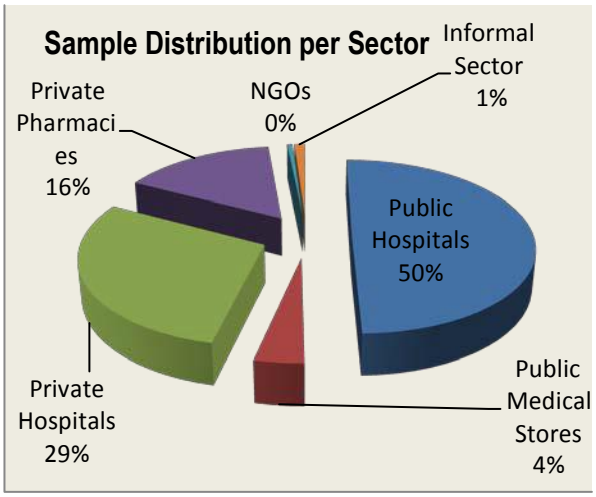


Table 2. Samples as per Sector

Sector	No. of Samples
Public – Hospitals/Clinics/ Health Centers	92
Public – Medical Stores	7
Private – Hospitals/Clinics/ Maternity Homes	54
Private – Distributors/ Wholesalers/ Retail Pharmacies/Licensed Chemical sellers	29
NGOs	1
Informal Sector	2
Total	**185**

Figure 2. Distribution



2.2 SAMPLING OF ERGOMETRINE (INJECTION & TABLETS)

Table 3. Samples as per Sentinel site

Sentinel Sites	No. of Samples		
	Total	Injections	Tablets
Accra	9	9	0
Sunyani	20	14	6
Koforidua	12	10	2
Bolgatanga	6	6	0
Kumasi	15	14	1
Cape Coast	20	17	3
Wa	5	4	1
Tamale	5	5	0
Ho	15	14	1
Takoradi	11	10	1
Total	**118**	**103**	**15**

Figure 2. Distribution

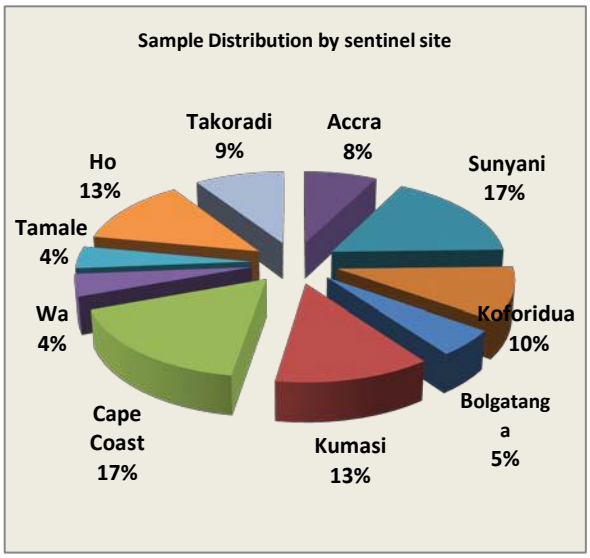
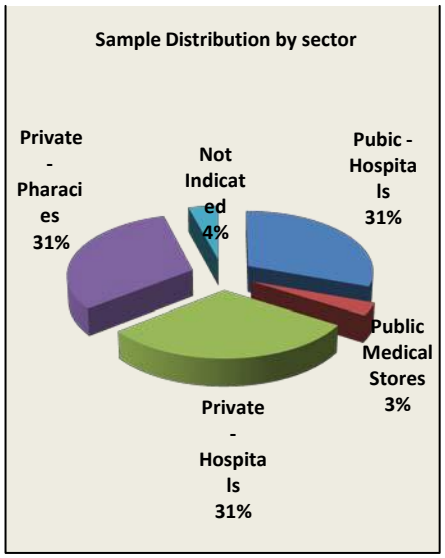


Table 4. Samples as per Sector

Sector	No. of Samples		
	Total	Injections	Tablets
Public – Hospitals/Clinics/ Health Centres	36	34	2
Public - Medical Stores	4	3	1
Private – Hospitals/Clinics/ Maternity Homes	36	33	3
Private- Distributors/Wholesalers/ Retail Pharmacies/ Licensed Chemical sellers	37	28	9
Unknown	5	5	0
Total	**118**	**103**	**15**

Figure 2. Distribution



2.3 TOTAL NUMBER OF SAMPLES

OXYTOCIN INJECTION	185 (61.0%)
ERGOMETRINE INJECTION & TABLETS	118 (39.0%)
TOTAL	**303**

3.0 FINDINGS AND TEST RESULTS

3.1 FINDINGS AND EVALUATION OF SAMPLES

It was observed that almost all of the injectables were not stored according to the recommended storage conditions (2°–8° C) either of some manufacturers or of the official compendia, the *U.S. Pharmacopeia* (*USP*) and *British Pharmacopeia* (*BP*). The only exception was one Regional Medical Store (Ho), where the products were stored properly at 6° Celsius.

Two (2) samples of Oxytocin and three (3) samples of Ergometrine (2 tablets and 1 injection) were sampled from the informal sector and licensed chemical shops, respectively. Uterotonics are prescription-only medicines (PoM) and can be dispensed only by health facilities and pharmacies.

3.1.1 LABELING AND PACKAGE INSERTS

More than 50% of the package inserts for the Oxytocin and Ergometrine injections indicated a storage temperature of 2 ^{o}–20 ^{o} C, which is contrary to the standard stated in both the *USP* and *BP* (2°–8°C). A total of 20 samples, i.e., 14 samples of Oxytocin and 6 samples of Ergometrine had no vital information—i.e., batch numbers, manufacture and expiry dates—on the container closure system.

3.1.2 MANUFACTURERS AND REGISTRATION STATUS

Oxytocin

Samples of Oxytocin found on the market were manufactured in China (86%), Pakistan (3%), and Switzerland (1%). The country of origin of 10% of the samples could not be established. The products whose country of origin could be established were manufactured by 13 different companies, of which only two (2) companies had their products registered in Ghana (Table 5).

Ergometrine

Samples of Ergometrine found on the market were mainly from India (90.68%) and Belgium (5.08%). The country of origin of 4.24% of the samples could not be established. The products whose country of origin could be established were manufactured by nine (9) different companies, of which only one (1) company had its product registered in Ghana. As to dosage form, 87.3% of the samples were injectables and 12.7% were tablets (Table 6).

3.2 TESTING OF SAMPLES

3.2.1 PHYSICO-CHEMICAL ANALYSIS

The products were tested using monographs in *BP* 2012 for Oxytocin and Ergometrine Injections, respectively, and in *USP35-NF30* for the analysis of Ergometrine Tablets. The summary of the results obtained from the analysis is given in Table 7 below. USP Chemical reference standards USPRS–Oxytocin and USPRS–Ergonovine Maleate were used as standards for the analysis. Because some of the samples were labeled as *BP*, Syntocinon® Injection from Novartis was used as a comparator for Oxytocin samples labeled as *BP*.

- **Oxytocin Assay Results**

Table 7a. Results per Sentinel Site

Sentinel Sites	No. of Samples	No. Assayed	Passed Assay	Failed Assay	% Failure
Accra	21	16	8	8	50.0
Sunyani	20	18	5	13	72.2
Koforidua	15	14	9	5	35.7
Bolgatanga	18	15	3	12	80.0
Kumasi	25	23	9	14	60.9

Sentinel Sites	No. of Samples	No. Assayed	Passed Assay	Failed Assay	% Failure
Cape Coast	20	20	12	8	40.0
Wa	10	9	3	6	66.7
Ho	18	17	7	9	52.9
Takoradi	21	21	12	10	47.6
Tamale	17	16	7	9	56.3
Total	**185**	**169**	**75**	**94**	**55.6**

Table 7b. Results per Sector

Sector	No. of Samples	No. Assayed	Passed Assay	Failed Assay
Public - Hospitals	92	83	38	45
Public - Medical Stores	7	7	4	3
Private - Hospitals	54	50	22	28
Private - Pharmacies	29	26	9	17
NGOs	1	1	1	0
Informal Sector	2	2	1	1
Total	**185**	**169**	**75**	**94**

TOTAL NUMBER OF SAMPLES COLLECTED 185

TOTAL NUMBER OF SAMPLES ASSAYED 169 (91.4%)

TOTAL NUMBER OF SAMPLES NOT ASSAYED 16 (9.6%)

NB: Sixteen (16) samples were not tested due to insufficient sample size and breakdown of the cold chain during transportation.

TOTAL NUMBER OF SAMPLES PASSED 75 (44.38%)

TOTAL NUMBER OF SAMPLES FAILED 94 (55.62%)

Two (2) samples out of those that failed assay had no active pharmaceutical ingredient (API) — one from a private hospital in Kumasi, marked Batch no. 110615, and the other from a private pharmacy in Koforidua, marked Batch no. 110894. These products could thus be considered to be counterfeits.

- **Ergometrine Maleate Assay Results**

Table 7d. Results per Sentinel Site

Sentinel Sites	No. of Samples			No. Assayed			Passed Assay			Failed Assay		
	Total	Injections	Tablets	Total	Injections	Tablets	Total	Injections	Tablets	Total	Injections	Tablets
Accra	9	9	0	7	7	0	1	1	0	6	6	0
Sunyani	20	14	6	19	13	6	3	3	0	16	10	6**
Koforidua	12	10	2	12	10	2	2	2	0	10	8	2
Bolgatanga	6	6	0	6	6	0	2	2	0	4	4	0
Kumasi	15	14	1	15	14	1	4	4	0	11	10	1
Cape Coast	20	17	3	18	17	1	8	8	0	10	9	1
Wa	5	4	1	5	4	1	0	0	0	5	4	1
Tamale	5	5	0	4	4	0	0	0	0	4	4	0
Ho	15	14	1	14	14	0	5	5	0	9	9	0
Takoradi	11	10	1	10	10	0	1	1	0	9	9	0
Total	**118**	**103**	**15**	**110**	**99**	**11**	**26**	**26**	**0**	**84**	**73**	**11**

Table 7e. Results per Sector

Sector	No. of Samples			No. Assayed			Passed Assay			Failed Assay		
	Total	Injections	Tablets	Total	Injections	Tablets	Total	Injections	Tablets	Total	Injections	Tablets
Public - Hospitals	36	34	2	35	33	2	12	12	0	23	21	2
Public - Medical Stores	4	3	1	3	3	0	1	1	0	2	2	0
Private - Hospitals	36	33	3	33	31	2	6	6	0	27	25	2
Private Pharmacies	37	28	9	35	28	7	7	7	0	28	21	7
Unknown	5	5	0	4	4	0	0	0	0	4	4	0
Total	**118**	**103**	**15**	**110**	**99**	**11**	**26**	**26**	**0**	**84**	**73**	**11**

TOTAL NUMBER OF SAMPLES COLLECTED	118
TOTAL NUMBER OF INJECTIONS	103 (87.3%)
TOTAL NUMBER OF TABLETS	15 (12.7%)
TOTAL NUMBER OF SAMPLES ASSAYED	110 (93.2%)
TOTAL NUMBER OF INJECTIONS ASSAYED	99
TOTAL NUMBER OF TABLETS ASSAYED	11
TOTAL NUMBER OF SAMPLES NOT ASSAYED	8
TOTAL NUMBER OF INJECTIONS NOT ASSAYED	4
TOTAL NUMBER OF TABLETS NOT ASSAYED	4
TOTAL NUMBER OF SAMPLES PASSED	26 (23.64%)
TOTAL NUMBER OF INJECTIONS PASSED	26 (26.26%)
TOTAL NUMBER OF TABLETS PASSED	0
TOTAL NUMBER OF SAMPLES FAILED	84 (76.36%)
TOTAL NUMBER OF INJECTIONS FAILED	73 (73.74%)
TOTAL NUMBER OF TABLETS FAILED	11 (100%)

The inability to test eight (8) of the samples was due to insufficient sample size and the breakdown of the cold chain during transportation.

Out of the products that failed assay, three (3) Ergometrine Maleate tablet samples collected from Sunyani had no active ingredient—two with the batch number 1165 obtained from a retail pharmacy and a licensed chemical seller marked and labeled as manufactured by PHARMA CHEMI ANTWERP – BELGIUM, and one from a private Maternity Home, with no batch number or manufacturer. Thus these products could be considered counterfeits.

3.2.2 STERILITY TEST

A total of eighty (80) samples were selected at random, forty (40) each of Oxytocin and Ergometrine injections and subjected to sterility testing as per the monograph of *BP 2012*. Sterility testing is required for injectables; however, all samples could not be tested for sterility due to resource constraints.

The results obtained for the sterility test are indicated in Tables 8a-b below.

- **Oxytocin**

Table 8a. Combined Results of Assay and Sterility Tests for Oxytocin Samples Randomly selected for Sterility Testing

Sentinel Site	Sector	Batch No.	Assay	Sterility Test	Final Conclusion
Accra	Public Hospital	120224	Passed	Failed	Failed
	Private NGO	100352	Failed	Failed	Failed
	Private Clinic	475	Failed	Passed	Failed
	Private Pharmacy	110711	Failed	Passed	Failed
Sunyani	Public Medical Store	110825	Passed	Failed	Failed
	Public Hospital	nil	Not assayed	Failed	Failed
	Private Pharmacy	110615	Failed	Failed	Failed
	Private Hospital	110615	Failed	Failed	Failed
Koforidua	Public Health Centre	110313	Failed	Failed	Failed
	Public Hospital	110711	Failed	Failed	Failed
	Private Hospital	110313	Passed	Failed	Failed
	Public Hospital	110711	Passed	Failed	Failed
Bolgatanga	Private Clinic	110313	Failed	Passed	Failed
	Public Hospital	110711	Failed	Passed	Failed
	Public Health Centre	110711	Failed	Failed	Failed
	Private Pharmacy	nil	Not assayed	Passed	Passed
Kumasi	Private Hospital	110894	Passed	Failed	Failed
	Private Pharmacy	110615	Failed	Failed	Failed
	Public Hospital	110894	Passed	Failed	Failed
	Public Hospital	110894	Passed	Failed	Failed
Cape Coast	Public Medical Store	120224	Passed	Failed	Failed
	Private Pharmacy	100352	Failed	Failed	Failed
	Public Hospital	120225	Passed	Failed	Failed
	Private Hospital	110894	Failed	Failed	Failed

Sentinel Site	Sector	Batch No.	Assay	Sterility Test	Final Conclusion
Wa	Public Medical Store	110615	Failed	Failed	Failed
	Private Pharmacy	110825	Passed	Failed	Failed
	Public Hospital	90716	Failed	Failed	Failed
	Private Pharmacy	101011	Passed	Failed	Failed
Ho	Private Hospital	101220	Passed	Failed	Failed
	Private Pharmacy	110711	Failed	Failed	Failed
	Public Medical Stores	110711	Failed	Failed	Failed
	Public Hospital	110894	Failed	Failed	Failed
Takoradi	Public Medical Stores	120224	Passed	Failed	Failed
	Private Pharmacy	110711	Failed	Failed	Failed
	Public Hospital	110894	Passed	Failed	Failed
	Public Hospital	100352	Failed	Failed	Failed
Tamale	Public Hospital	120224	Passed	Failed	Failed
	Public Health Centre	101011	Failed	Failed	Failed
	Public Hospital	110894	Failed	Failed	Failed
	Public Medical Stores	110894	Passed	Failed	Failed

NUMBER OF OXYTOCIN SAMPLES THAT FAILED BOTH ASSAY & STERILITY 18
NUMBER OF OXYTOCIN SAMPLES THAT PASSED ASSAY BUT FAILED STERILITY 16
NUMBER OF OXYTOCIN SAMPLES THAT FAILED ASSAY BUT PASSED STERILITY 4
NUMBER OF OXYTOCIN SAMPLES NOT ASSAYED BUT FAILED STERILITY 1
NUMBER OF OXYTOCIN SAMPLES NOT ASSAYED BUT PASSED STERILITY 1

Forty (40) samples of Oxytocin injection were randomly selected for sterility testing. Out of this number, 18 (45%) failed both the assay and sterility tests; 16 (40%) passed assay but failed sterility; and, 4 (10%) failed assay but passed sterility.

Two (2) samples were not assayed, but were tested for sterility: One (1) sample passed the sterility test but the other failed.

Thus, 39 (97.5%) of the 40 samples of Oxytocin injection that were tested for sterility failed sterility and/or assay. The quality of the one (1) remaining sample that was not assayed, but passed the sterility test, cannot be conclusively assessed.

- **Ergometrine**

Table 8b. Combined Results of Assay and Sterility Tests for Ergometrine Injection Samples Randomly Selected for Sterility Testing

Sentinel Site	Sector	Batch No.	Assay	Sterility Test	Final Conclusion
Accra	Public Hospital	nil	Failed	Passed	Failed
	Private Clinic	PCP 540	Failed	Passed	Failed
	Private Pharmacy	EB07146	Failed	Failed	Failed
	Public Hospital	EB07146	Failed	Failed	Failed
Sunyani	Private Licensed Chemical Store	EB01042	Passed	Failed	Failed
Sunyani (Cont.)	Public Hospital	EB07146	Passed	Failed	Failed
	Private Maternity Home	BETI-003	Failed	Passed	Failed
	Public Hospital	10EA03	Failed	Passed	Failed
Koforidua	Public Hospital	EB07146	Passed	Failed	Failed
	Private Pharmacy	BETI-001	Failed	Failed	Failed
	Public Hospital	EB07146	Passed	Failed	Failed
	Private Clinic	EB07146	Failed	Failed	Failed
Bolgatanga	Private Pharmacy	EB01042	Passed	Failed	Failed
	Public Hospital	EB07146	Passed	Failed	Failed
	Public Clinic	BETI-001	Failed	Failed	Failed
	Private Clinic	BETI-005	Failed	Failed	Failed

Sentinel Site	Sector	Batch No.	Assay	Sterility Test	Final Conclusion
Kumasi	Private Pharmacy	EB07146	Failed	Passed	Failed
	Private Pharmacy	NPE-214	Failed	Failed	Failed
	Private Maternity Home	EB01042	Passed	Passed	Passed
	Public Hospital	EB07146	Failed	Passed	Failed
	Public Hospital	EB07146	Failed	Failed	Failed
Cape Coast	Public Medical Stores	EB01042	Passed	Failed	Failed
	Private Pharmacy	NPE-270	Failed	Failed	Failed
	Public Hospital	EB01042	Passed	Passed	Passed
	Private Licensed Chemical Seller	NPE-214	Failed	Passed	Failed
Wa	Public Medical Store	EB07146	Failed	Failed	Failed
	Private Pharmacy	BETI-002	Failed	Passed	Failed
	Public Hospital	EB07146	Failed	Passed	Failed
Tamale	Unknown	EB07146	Failed	Passed	Failed
	Unknown	9EA125	Failed	Passed	Failed
	Unknown	AETI-001	Failed	Passed	Failed
Ho	Public Hospital	EB07146	Failed	Failed	Failed
	Private Hospital	EB07146	Failed	Failed	Failed
Ho (Cont.)	Private Pharmacy	EB07146	Failed	Failed	Failed
	Private Hospital	EB07146	Failed	Failed	Failed

Sentinel Site	Sector	Batch No.	Assay	Sterility Test	Final Conclusion
Takoradi	Public Hospital	EB01042	Failed	Failed	Failed
	Public Hospital	V10029	Failed	Failed	Failed
	Public Hospital	EB02079	Failed	Failed	Failed
	Public Medical Stores	8EA23	Failed	Failed	Failed

NUMBER OF ERGOMETRINE INJECTION SAMPLES THAT FAILED BOTH ASSAY & STERILITY	18
NUMBER OF ERGOMETRINE INJECTION SAMPLES THAT PASSED ASSAY BUT FAILED STERILITY	7
NUMBER OF ERGOMETRINE INJECTION SAMPLES THAT FAILED ASSAY BUT PASSED STERILITY	12
NUMBER OF ERGOMETRINE INJECTION SAMPLES THAT PASSED BOTH ASSAY AND STERILITY	2

Thirty-nine (39) samples of Ergometrine injection were randomly selected for sterility testing. Out of this number, 18 (46.15%) failed both assay and sterility tests; 7 (17.95%) failed the sterility test but passed assay; 12 (30.77%) passed the sterility test but failed assay; and, 2 (5.13%) passed both assay and the sterility test.

Thus, 37 (94.87%) of the 39 samples of Ergometrine injection tested for sterility failed the sterility test and/or assay.

4.0 DISCUSSION AND CONCLUSIONS

4.1 DISCUSSION

The following observations were made with respect to the project.

4.1.1 Sampling

A number of products were sampled from distribution channels that were not authorized (e.g., licensed chemical sellers and the informal sector) to supply the category of products that are classified as PoM.

- **Oxytocin**

Out of the 185 samples of Oxytocin injection collected, the highest number came from hospitals and related facilities, a total of 146 (78.9%). Public hospitals accounted for 92 (49.7%) and private hospitals for 54 (29.2%). Private pharmacies and related facilities accounted for 29 (15.7%) of the samples.

- **Ergometrine**

Out of a total of 118 Ergometrine products sampled, 103 (87.3%) were injections and 15 (12.7%) were tablets. Hospitals and related facilities accounted for a total of 67 (65.0%) of the injections; public hospitals accounted for 34 (33.0%); and private hospitals for 33 (32%). Private pharmacies and related facilities accounted for 37 (35.9%).

4.1.2 Storage Conditions and Labeling Information

It was observed that almost all the injectables were not stored according to the recommended storage conditions (2°–8°C) of some of the manufacturers and of the official compendia (*USP* and *BP*); the only exception was one Regional Medical Store.

It was noted that recommended storage conditions for more than 50% of both Oxytocin and Ergometrine injections were not consistent with recommendations in the official compendia. It would appear that there is a lack of awareness of the appropriate storage conditions for these uterotonic products.

Twenty (20) samples of both Oxytocin and Ergometrine had no labeling information to indicate their batch number or manufacturing and expiry dates, making it difficult to establish their authenticity and valid shelf-life.

4.1.3 Marketing Authorization

Only 8.11% of Oxytocin samples and 57.63% of Ergometrine samples had a marketing authorization. These came from three (3) companies, two supplying Oxytocin and one supplying Ergometrine injection. None of the samples of Ergometrine tablets were from companies that have marketing authorizations.

The origin of 10% of the Oxytocin samples and 4.24% of the Ergometrine samples could not be established.

4.14 Test Results

- **Assay Results**

Out of the 169 Oxytocin samples assayed, 94 (55.62%) failed. Also, 73 (73.74%) out of 99 samples of Ergometrine injection and all of the 11 (100%) samples of Ergometrine tablets failed assay.

- **Results of Samples subjected to both Sterility Test and Assay**

Of the 40 Oxytocin samples randomly selected for sterility testing, 39 (97.5%) failed the sterility test and/or assay; 37 (94.87%) of the 39 samples of Ergometrine injection tested for sterility failed the sterility test and/or assay.

The high failure rate for these uterotonics can be attributed to the following:

1. The proliferation of unregistered products whose quality and product information has not been assessed by the FDA.
2. Absence of cold storage for a significant number of these products due to a lack of awareness of their appropriate storage conditions.

The outcome of this project raises an issue which has serious public health implications due to the therapeutic indications for these products.

4.2 CONCLUSIONS

The outcome of this project has established that a high percentage of uterotonics available on the Ghanaian market (65.50% for Oxytocin and 82.73% for Ergometrine) do not meet the required standards for quality. The situation could have serious implications with regards to maternal mortality in the country.

5.0 RECOMMENDATIONS

The following recommendations are made for consideration by the management of the FDA and other key stakeholders:

1. Immediate recall of all substandard and counterfeit products.
2. Institute appropriate legal action against the distributors of the products found to be counterfeit.
3. Strictly enforce all regulations in respect of product registration.
4. Adopt a clear policy on the storage requirements for uterotonics.
5. Strictly enforce the Good Storage and Distribution Practices (GSDP) regulation for distributors and wholesalers of uterotonics.
6. Strictly enforce regulations in respect to the supply and dispensing of PoMs.
7. Organize a stakeholder's forum to educate persons involved in the storage and distribution of these products. Provide a general overview of product stability and the need to store products under appropriate storage condition.
8. Conduct further rounds of post-marketing surveillance for uterotonics.
9. Conduct a study to assess the status of awareness and compliance to GSDP for cold chain storage facilities in the country.