Research Article

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Quality assessment of oxytocin injection and misoprostol tablets in Côte d'Ivoire and Senegal

F Guiet Mati[1], C Rerat[2], R Kuwana[2], AS Sougou[1], A Smine[3], S Dagnoko[4], D Fall[5], A Toure[4], SO Sarr[5], F Fofana[4], CS Camara[5], M Widmer[6]

1. Medicines Supply Health Infrastructure, World Health Organization, Brazzaville, Congo
2. Access to medicines and health products, World Health Organization, Geneva, Switzerland
3. Université Internationale de Rabat, Collège des Sciences de la Santé, Morocco
4. Autorité Ivoirienne de Régulation Pharmaceutique (AIRP), Côte d'Ivoire
5. Agence Sénégalaise de Réglementation Pharmaceutique (ARP), Sénégal
6. UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Sexual and Reproductive Health and Research, World Health Organization, Geneva, Switzerland.

Synopsis:
This survey confirms the existence of substandard uterotonics in Senegal and Côte d'Ivoire, attributing the issue to quality assurance gaps prevalent in low- and middle-income countries

Corresponding author
Mariana Widmer, WHO/SRH/MPH, Geneva, Switzerland.
E-Mail : widmerm@who.int

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ABSTRACT

Objective : To assess the quality of oxytocin and misoprostol products available in Côte d'Ivoire and Senegal.
Methods : Samples of oxytocin injections and misoprostol tablets were collected from three different levels of the supply chain in Côte d'Ivoire and Senegal from August to December 2021. The sampling process was done by personnel from the National Medicines Regulatory Authorities, employing a methodology and sampling plan aligned with WHO guidelines for conducting surveys on the quality of medicines. These samples were then transported under controlled conditions to qualified laboratories for quality assessment, where they underwent testing according to the specifications outlined in the 10th Edition of the International Pharmacopeia.
Findings : A total of 196 samples of oxytocin and misoprostol were collected from 130 health facilities across the two countries. Analyses revealed that 30% of the oxytocin and 23% of the misoprostol samples did not meet the quality criteria at all levels of the supply chain in both countries. Furthermore, although oxytocin samples were stored in refrigerators, the absence of proper temperature monitoring equipment was a common finding.
Conclusion : A substantial proportion of oxytocin and misoprostol products available in Côte d'Ivoire and Senegal were found to be substandard. Investing in quality-assured medicines is crucial for delivering safe and effective healthcare, reducing overall healthcare costs, and securing the long-term success of universal health coverage in low-income countries.

Keywords : *postpartum haemorrhage, uterotonics, quality, West Africa*

INTRODUCTION

Postpartum haemorrhage (PPH) is defined as blood loss of at least 500 ml within 24 hours after birth and it affects about 5% of all women giving birth around the world. [1, 2] PPH is the leading cause of maternal mortality worldwide, being responsible for nearly a quarter of all maternal deaths. [3] However, the majority of these deaths could be avoided through timely and appropriate administration of prophylactic uterotonics during labour and delivery.[4] Improving care of women during childbirth to prevent PPH is a necessary step toward the achievement of the Sustainable Development Goals by 2030 [5].

WHO recommends the use of oxytocin injection as an effective uterotonic for the prevention of PPH during the third stage of labour for all births.[4] Importantly, oxytocin is included in the WHO Essential Medicines List and in the UN Commission on Life-Saving Commodities (UNCoLSC).[6] Proper storage conditions for oxytocin are crucial as it is temperature sensitive and should be stored between 2-8°C to maintain its effectiveness.[7-9] In many low- and middle-income country (LMIC) settings, maintaining the required storage conditions for medicines, including oxytocin, can be a challenge.

Deviations from the recommended storage temperature can impact the stability of oxytocin, leading to degradation and potentially compromising its efficacy.[10]

Misoprostol is an affordable generic medicine, suggested as an alternative to oxytocin and listed in the WHO Essential Medicines List.[11] However, it's essential to note that misoprostol is sensitive to humidity and can degrade rapidly if not stored properly.[12]

Ensuring that essential medicines like oxytocin and misoprostol are stored correctly in health facilities is crucial to maintain their effectiveness. The presence of substandard oxytocin and misoprostol in LMICs poses a significant challenge to maternal healthcare. While studies have highlighted this problem in Anglophone countries, there is a lack of data from Francophone African countries.[13] Addressing the quality and availability of these essential medicines is crucial for improving maternal health outcomes. In 2019, West African Economic and Monetary Union countries (WAEMU) took steps to enhance the quality of oxytocin by convening to address this issue in the region. The group formulated and ratified the "Dakar Roadmap," which outlined essential activities to be executed at the national level to enhance the availability of high-quality oxytocin. This collaborative effort aligned with the guidelines established by WHO, UNICEF, and UNFPA on the proper management of oxytocin within the cold chain.[7] This regional initiative meant a significant stride towards ensuring the accessibility and reliability of oxytocin in the region.

Given the crucial role that assured quality and affordable uterotonics play in addressing maternal health disparities worldwide, and in response to the concerns raised by certain West African countries, WHO in collaboration with the National Medicines Regulatory Authorities from Côte d'Ivoire and Senegal conducted a post-marketing surveillance study. This study aimed to evaluate the quality of oxytocin and misoprostol products within these markets, underscoring the commitment to ensuring safe and reliable maternal healthcare interventions in the region.

METHODS

Sampling framework

The post-marketing surveillance (PMS) survey, was coordinated by WHO in partnership with the national regulatory authorities and quality control laboratories of Senegal and Côte d'Ivoire. Both countries, are among the world's 49 poorest countries as identified by the "Every Woman Every Child (EWEC)" movement.[14]

The study protocol, developed by WHO and approved by the National Medicines Regulatory Authorities (NMRAs) in the participating countries, involved a sampling plan based on the Medicines Risk Assessment tool (MedRS) from the United States Pharmacopoeia (USP). The sampling strategy targeted facilities at three levels of the supply chain: level-1 (points of entry to the market, warehouses of importers, central medical stores); level-2 (wholesalers and/or distributors); and level-3 (authorized dispensers such as pharmacies, hospitals, health center depots, health posts, district hospitals, clinics, maternity and treatment center); and followed a 20%:20%:60% ratio (level-1:level-2:level-3) in both public and private health sectors.[15, 16] The highest risk was assigned at the levels where medicines were dispensed directly to the patients with limited or poor management oversight. All regions were targeted considering similarity of conditions throughout the country. In Côte d'Ivoire, 13 out of 31 regions and in Senegal 7 out of 14 regions were selected for sampling the medicines. Ethical approval for the survey was obtained from the relevant committees and Ministries of Health in Côte d'Ivoire and Senegal. Informed consent was not required as the study solely focused on sample collection and storage information.

Sample collection

For this study, a sample was defined as an item collected from each medicine's form, including details such as the name, dosage of active pharmaceutical ingredient (API), dosage form, strength, batch/lot number, and manufacturer, all from the same collection site. For oxytocin, each sample comprised 10 units from the same manufacturer and batch, while for misoprostol, a minimum of 60 tablets from the same manufacturer and batch constituted a sample.

Sample collectors were equipped with logistical support and ensured temperature-controlled storage during sample handling and transportation. They were also responsible for assessing and reporting on the storage conditions of the samples at the health facilities during collection.

Prior to sampling, each country team was required to identify all registered oxytocin and misoprostol brands approved by their national regulatory authorities. The goal was for each country to collect a total of 100 samples (50 oxytocin and 50 misoprostol), all obtained in their original packaging.

Laboratory analysis

The oxytocin samples were tested by the Monash Institute of Pharmaceutical Sciences (MIPS) laboratory in Australia, while the samples of misoprostol were tested by the National Laboratory of the Ugandan National Drug Authority (NDA), from both countries. Testing was conducted according to the guidelines specified in the International Pharmacopoeia (Ph. Int) 10th Edition (2020).[17]

The Ph. Int monograph for oxytocin injection specifies requirements for description, labeling, packaging, identification, assay, pH, particulate matter, and related substances. The Ph. Int monograph for misoprostol tablets outlines specifications for various parameters including

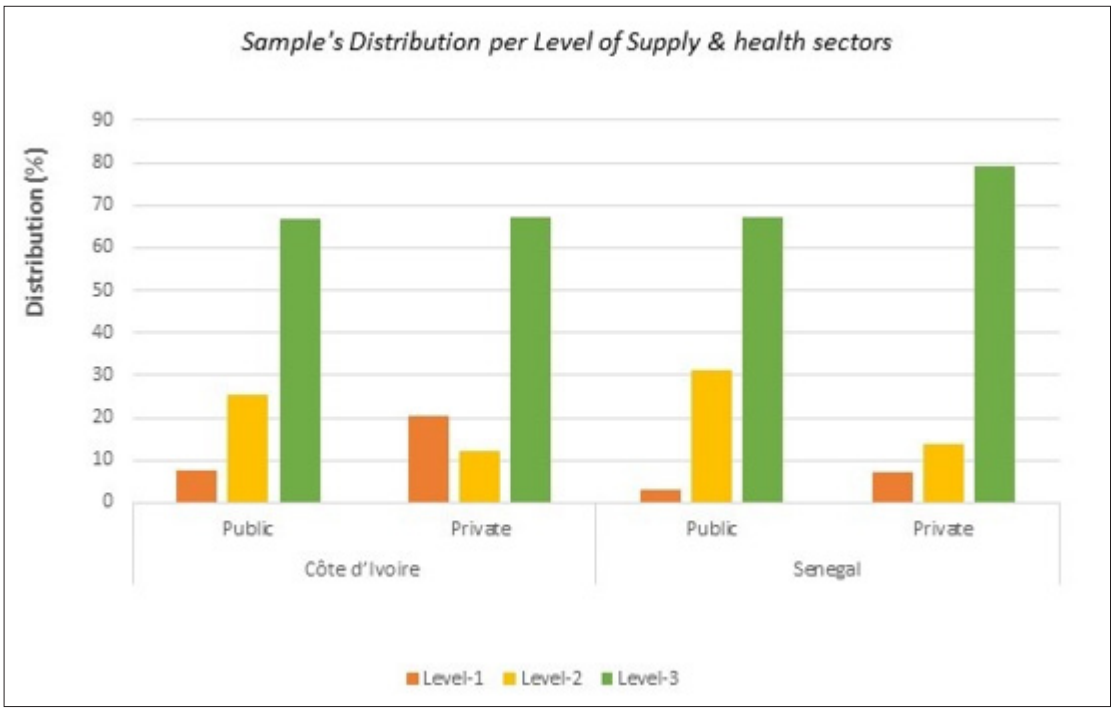
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description, labeling, packaging, storage, identification, assay, uniformity of content, and dissolution.
Any test result that fell outside the acceptance criteria set by the Ph. Int monographs was considered a failed test, leading to the classification of the sample as substandard. In cases where tests for dissolution and uniformity of content failed at level-1, they were deemed inconclusive if there were insufficient sample units available to carry out the subsequent testing levels as outlined in the Ph. Int monograph for misoprostol tablets.

RESULTS

Between August and December 2021, a total of 196 samples of oxytocin injection and misoprostol tablets were collected from 130 health facilities across Côte d'Ivoire and Senegal. Côte d'Ivoire collected 100 samples (52 oxytocin and 48 misoprostol) from 62 facilities, while Senegal collected 96 samples (62 oxytocin and 34 misoprostol) from 68 facilities. Detailed information about the samples of oxytocin and misoprostol collected in both countries can be found in Tables S1 and S2 and in Figures S1 and S2 respectively. Tables 1 and 2 present the products sampled in Côte d'Ivoire and Senegal based on the source of manufacture. Figures 1 and 2 display the distribution of oxytocin and misoprostol samples according to the level of supply in both the public and private sectors in Côte d'Ivoire and Senegal. Notably, the majority of samples (71%) were collected from Level-3 facilities in both countries. Although oxytocin ampules in both countries were stored in refrigerators at all facilities, the sampling teams reported inadequate temperature monitoring equipment and absence of alert systems linked to the refrigerators at the time of sampling. The sampling teams were instructed to verify the registration status of all collected samples with the NMRAs. Table 3 provides information on the registration status at national level and WHO prequalification status of all samples included in this survey.

Figure 1 : Distribution of samples per level of supply and health sector



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Figure 2 : Distribution of oxytocin and misoprostol collectected per health sector

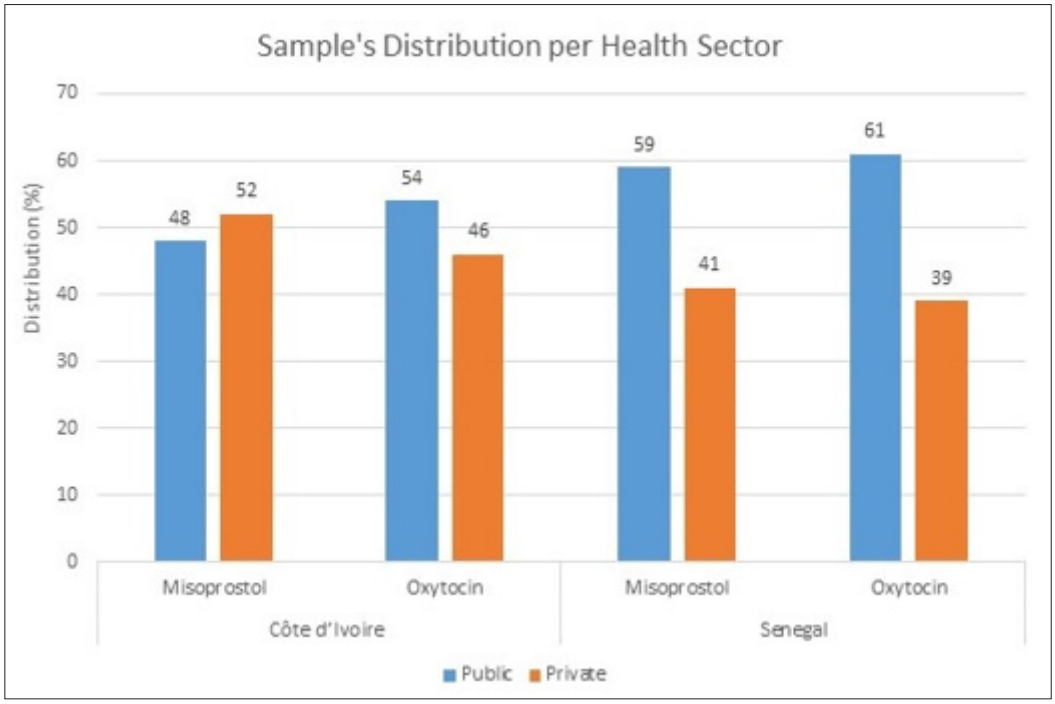
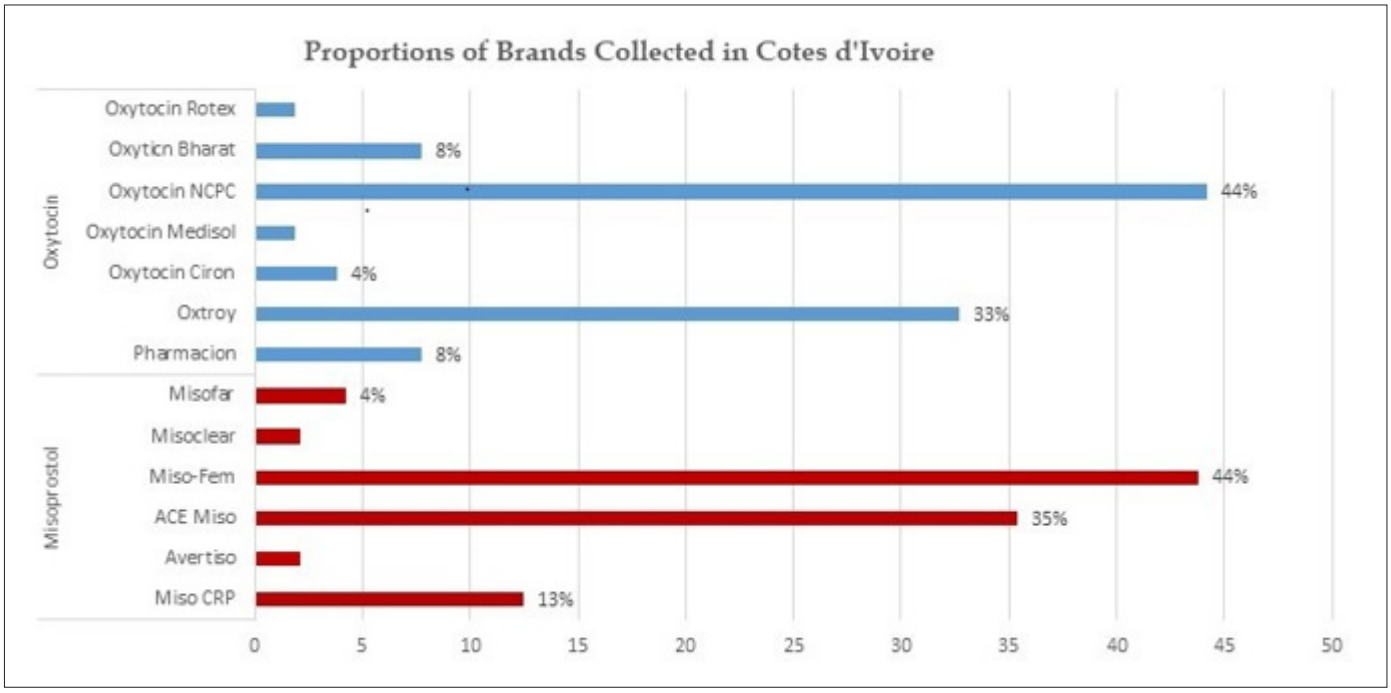


Figure S1 : Proportion of oxytocin and misoprostol brands collected in Cotes d'Ivoire



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Figure S2 : Proportion of oxytocin and misoprostol brands collected in Senegal

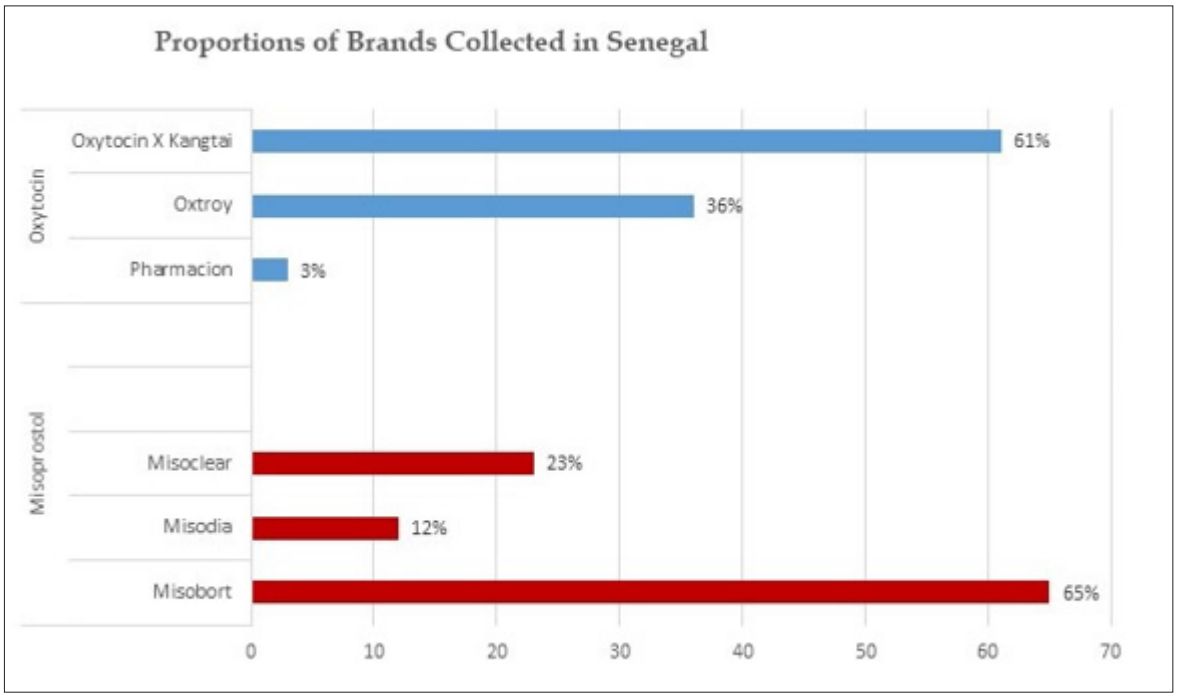


Table 1: Samples of oxytocin and misoprostol from Côte d'Ivoire as per source of manufacture

INN Name	Manufacturer	Batch No.	No. of Samples per batch	Pack Size	Expiry date
Oxytocin Injection 5 IU					
Oxytocin (5 IU)	Rotexmedica Gmbh. Artzeimittel Werk Bunsenstrasse 4-22946 Trittau, Germany	00871	1	10 x 1ml	Oct-23
Oxytocin (5 IU)	North China Pharma Co -NCPC No 217-1 East Heping Road Shijiazhuang Zhuang China	190522	1	10 x 1ml	May-22
		200217	3		Feb-23
		200222	1		Feb-23
		200223	4		Feb-23
		200310	3		Mar-23
		210208	11		Feb-24
Oxytocin (5 IU)	Medisol S.A.S Rue Jacques Monod, Lyon, France	ME011X5	1	10 x 1ml	May-23
Oxytocin (5 IU)	Ciron Drugs Pharma, Ltd. 119/2 Dist Polghor – 401506, India	1EB02241	1	10 x 1ml	May-23
		1EB04265	1		Jun-23
Oxytocin (5 IU)	Troikaa Pharma Ltd. Thol,Gujarat, India	043147	3	3 x 1ml	Sep-22
		043148	3		Jun-23
		043150	4		Jul-23
		043152	2		Aug-23
		043153	5		Aug-23
Oxytocin (5 IU)	Sterile-Gene Life Sciences Ltd. No.45, Mangalam Village Villanur, India	JR00001A	1	10 x 1ml	Nov-22
		JR00001B	3		Nov-22

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Oxytocin (10 IU)	Bharat Parenterals Ltd. Haripura,TA.Savili,Dist. Vadodara-391520, Gujarat, India	00001	2	10 x 1ml	May-22
		00002	1		May-22
		00004	1		May-22
Total Samples		52			
Misoprostol Tablets 200mg					
Misoprostol	Quimica Y Farmaceutica -Spain	P003	2	B/3	May-23
Misoprostol	ACME Formulation Ltd. Ropar Road, Nanalagarh Dist.Solan, Pradesh -India	MCL2107074	1	B/4	Jun-23
Misoprostol	NAARI Pharma Plot 14-16, 55-57, Sector-5, IIE, Pantnagar, Rurdapur -263153, Dist, Udham S. Nagar, Uttarakhand – India	NR00605B	1	B/4	Nov-22
		NR00628D	5		Dec-22
		NR00665B	1		Jan-23
		NR00666C	3		Feb-23
		NR00711A	11		Mar-23
Misoprostol	ACME Formulation Ltd. Ropar Road, Nanalagarh Dist. Solan, Himachal Pradesh, India	ACE2006041	7	B/3	May-22
		ACE2006042	8		May-22
		ACE2103038	1		Feb-23
		ACE2103039	1		Feb-23
Misoprostol	ACME Formulation Ltd. Ropar Road, Nanalagarh Dist. Solan, Himachal Pradesh, India	ACG2002002	1	B/4	Jan-22
Misoprostol	China Resources Zizhu Pharma -N 27, Chaoyang Dist. Beijing 100024, China	45200501	6	B/3	May-22
Total Samples			48		

Table 2: Samples of oxytocin and misoprostol from Senegal as per source of manufacture

INN Name	Manufacturer	Batch N°	# Samples per batch	Pack Size	Expiry date
Oxytocin Injection (5 IU)					
Oxytocin (5 IU)	Troikka Pharmaceuticals Ltd, Thol - 382 728, Gugarat, India	043139	2	3 x 1ml	Jun-2022
		043140	4		Jun-2022
		043142	1		July-2022
		043146	9		Sep-2022
		043147	6		Sep-2022
Oxytocin (5 IU)	Steril-Gene Life Sciences NO: 45, Mangalam Main Road Mangalam Villianur - Puducherry - 605 110, India	JR0001A	1	10 x 1ml	Nov-2022
		JR0001B	1		Nov-2022
Oxytocin (5 IU)	XIER Kangtai Pharmaceuticals Anhui Hongye Pharmaceuticals Ltd. Fengyang Rd, Bengbu , Anhui Province , China	S230Q01	1	10 x 1ml	Jul-2022
		S230Q02	1		Feb-2023
		S230Q03	34		Jul-2023
		S230Q04	2		Jul-2024
Total Samples			62		
Misoprostol Tablets 200 mg					

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Misoprostol	United Biotech (P) Ltd., Bagbania, Baddi-Nalagarh Dist. Solan (HP)- 174 101, India	MBTC1A1	22	B/4	Feb-23
Misoprostol	ACME Formulation Ltd.., Ropar Road, Nalagarh Dist. Solan, Himachal,PRADESH- 174101, India	MCL2008069	5	B/4	Jul-2022
		MCL2105058	1		Apr-2023
		MCL2002019	2		Jan-2022
Misoprostol	ACME Formulation Ltd.., Ropar Road, Nalagarh Dist. Solan, Himachal,PRADESH- 174101, India	MIS2010005	4	B/4	Sep-2022
Total Samples			34		

Table 3: Registration and WHO prequalification status of oxytocin and misoprostol collected from Côte d'Ivoire and Senegal.

INN name	Manufacturer	Registration	WHO Prequalification
Côte d'Ivoire			
Oxytocin	Rotexmedica GmbH, Germany	Not registered	Not prequalified
Oxytocin	NCPC International - China	Not registered	Not prequalified
Oxytocin	CIRON Drugs & Pharma, India	Not registered	Not prequalified
Oxytocin	Troikaa Pharmaceuticals, India	Registered	Not prequalified
Oxytocin	Medisol S.A.S - France	Not registered	Not prequalified
Oxytocin	Steril-Gene Life Sciences, India	Registered	Not prequalified
Oxytocin	Bharat parenterals ltd., India	Not registered	Not prequalified
Misoprostol	Quimica Y Farmaceutica, Spain	Registered	Not prequalified
Misoprostol	China Res. Zizhu Pharma,	Not registered	RH048 Nov., 2016
Misoprostol	ACME Formulation, India	MA expired	RH056 Apr., 2016
Misoprostol	ACME Formulation, India	Not registered	RH056 Apr., 2016
Misoprostol	ACME Formulation, India	Not registered	RH056 Apr., 2016
Misoprostol	NAARI Pharmaceuticals, India	Registered	Not prequalified
Senegal			
Oxytocin	Xier Kangtai pharmaceutical	Registered (Special import authorization)	Not prequalified
Oxytocin	Troikaa pharmaceuticals,	Registered	Not prequalified
Oxytocin	Steril-gene life sciences,	Registered	Not prequalified
Misoprostol	United biotech	Registered (Special import authorization)	Not prequalified
Misoprostol	ACME Formulation (Misoclear)	Registered	WHO-PQ: ref: RH056 (04/2016)
Misoprostol	ACME Formulation (Misodia)	Registered	WHO-PQ: ref: RH056 04/2016

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Table S1. Misoprostol and oxytocin samples collected from Côte d'Ivoire

Sample code	Region	Sampling site	Type of facility	Sector	Level of Supply	Product Name	Sample (200 mg tablets)	Manufacturer	Batch number	Expiry date	Nbr. of units collected
RCI/MSP/C1-03-22/11/2021	Abidjan	UBIPHARM-CI ZI, Abidjan	Central warehouse	Private	1	MISOFAR 200	Misoprostol	Industria Quimica & Farmaceutica VIR, Spain	P003	May-23	56
RCI/MSP/C1-04-22/11/2021	Abidjan	UBIPHARM-CI ZI, Abidjan	Central warehouse	Private	1	MISO-FEM	Misoprostol	Naari Pharma Ltd. India	NR00711A	March-23	56
RCI/MSP/C1-05-22/11/2021	Abidjan	COPHARMED -ABIDJAN	Central warehouse	Private	1	MISOFAR 200	Misoprostol	Industria Quimica & Farmaceutica VIR, Spain	P003	may-23	56
RCI/MSP/C1-06-22/11/2021	Abidjan	COPHARMED -ABIDJAN	Central warehouse	Private	1	MISOCLEAR	Misoprostol	ACME FORMULATION PVT LTD - INDIA	MCL2107074	Jun-23	56
RCI/MSP/C1-07-22/11/2021	Abidjan	COPHARMED -ABIDJAN	Central warehouse	Private	1	MISO-FEM	Misoprostol	Naari Pharma Ltd. India	NR00665B	Jan-23	56
RCI/MSP/C1-08-22/11/2021	Abidjan	DPCI ABIDJAN	Central warehouse	Private	1	MISO-FEM	Misoprostol	Naari Pharma Ltd. India	NR00666C	Feb-23	56
RCI/MSP/C1-09-23/11/2021	SUD COMOE	PHARMACIE BIANOUAN	Private pharmacy	Private	3	MISO-FEM	Misoprostol	Naari Pharma Ltd. India	NR00711A	March-23	56
RCI/MSP/C1-13-24/11/2021	SUD COMOE	PHARMACIE SANWI	Private pharmacy	Private	3	MISO-FEM	Misoprostol	Naari Pharma Ltd. India	NR00628D	déc-22	56
RCI/MSP/C1-16-24/11/2021	SUD COMOE	HOPITAL GENERAL DE MAFERE	Hospital	Public	3	MISOPROSTOL	Misoprostol	CHINA RESOURCES ZIZHU PHARMACEUTICAL Co LTD, CHINA	45200501	May-22	30
RCI/MSP/C1-18-25/11/2021	Abidjan	TEDIS PHARMA Abidjan	Central warehouse	Private	1	MISO-FEM	Misoprostol	Naari Pharma Ltd. India	NR00711A	March-23	56
RCI/MSP/C1-20-25/11/2021	Abidjan	HOPITAL GENERAL D'ADJAME	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006041	May-2	57
RCI/MSP/C1-21-26/11/2021	Abidjan	NPSP-CI, BP V5 Abijan	Central warehouse	Public	1	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2103039	Feb-23	80
RCI/MSP/C1-22-26/11/2021	Abidjan	NPSP-CI, BP V5 Abidjan	Central purchasing	Public	1	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2103038	Feb-23	80
RCI/MSP/C1-25-26/11/2021	Abidjan	PHARMACI AGBAN, 06 BP 1279 Abidjan 06	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00711A	March-23	56
RCI/MSP/C2-04-29/11/2021	INDENIE-DJUANBLIN	DISTRICT SANTITAIRE D'AGNIBILEKROU	Regional Warehouse	Public	2	Misoprostol	Misoprostol	CHINA RESOURCES ZIZHU PHARMACEUTICAL Co LTD, CHINA	45200501	May-22	57
RCI/MSP/C2-06-29/11/2021	INDENIE-DJUANBLIN	HOPITAL GENERAL D'AGNIBILEKROU	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006041	May-22	54
RCI/MSP/C2-07-29/11/2021	INDENIE-DJUANBLIN	PHARMACIE K BOILOT AGNIBILEKROU	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00711A	March-23	32
RCI/MSP/C2-12-30/11/2021	INDENIE-DJUANBLIN	PHARMACIE MARCHE D'ABENGOUROU	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR0066C	Feb-23	40

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RCI/MSP/C2-15-01/12/2021	INDENIE-DJUANBLIN	DISTRICT SANTITAIRE D'ABENGOUROU	Regional Warehouse	Public	2	Misoprostol	Misoprostol	CHINA RESOURCES ZIZHU PHARMACEUTICAL Co LTD, CHINA	45200501	May-22	54
RCI/MSP/C2-17-01/12/2021	INDENIE-DJUANBLIN	CHR ABENGOUROU	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006041	May-22	54
RCI/MSP/C2-20-02/12/2021	IFFOU	HOPITAL GENERAL DE DAOUKRO	Hospital	Public	3	MISO PROSTOL	Misoprostol	CHINA RESOURCES ZIZHU PHARMACEUTICAL Co LTD, CHINA	45200501	May-22	54
RCI/MSP/C2-22-02/12/2021	IFFOU	PHARMACIE DE L'AMITIE	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00711A	March-23	32
RCI/MSP/C2-24-03/12/2021	INDENIE-DJUANBLIN	HOPITAL GENERAL D'ADZOPE	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006041	May-22	54
RCI/MSP/C3-01-29/11/2021	LÔH-DJIBOUA	CHR DIVO	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006041	May-22	54
RCI/MSP/C3-04-29/11/2021	LÔH-DJIBOUA	PHARMACIE DU MARCHE	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00711A	March-23	32
RCI/MSP/C3-05-29/11/2021	LÔH-DJIBOUA	HOPITAL GENERAL DE LAKOTA	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006041	May-22	54
RCI/MSP/C3-07-29/11/2021	LÔH-DJIBOUA	PHARMACIE DE LAKOTA	Pharmacy	Private	3	AVERTISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACG2002002	Jan-22	32
RCI/MSP/C3-10-29/11/2021	GÔH	DISTRICT SANITAIRE GAGNOA 1	Regional Warehouse	Public	2	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006041	May-22	54
RCI/MSP/C3-12-30/11/2021	GÔH	UBIPHARM CI, Gagnoa	Regional Warehouse	Private	2	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00628D	déc-22	56
RCI/MSP/C3-13-30/11/2021	GÔH	COPHARMED GAGNOA	Regional Warehouse	Private	2	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00666C	Feb-23	56
RCI/MSP/C3-14-01/12/2021	DISTRICT AUTONOME	CHR YAMOUSSOKRO	Hospital	Public	3	MISOPROSTOL	Misoprostol	CHINA RESOURCES ZIZHU PHARMACEUTICAL Co LTD, CHINA	45200501	May-22	54
RCI/MSP/C3-16-02/12/2021	DISTRICT AUTONOME	PHARMACIE DE YAMOUSSOKRO	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00628D	déc-22	56
RCI/MSP/C3-19-02/12/2021	GBÊKÊ	DISTRICT SANITAIRE BOUAKE SUD	Regional Warehouse	Public	2	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006042	May-22	54
RCI/MSP/C3-20-02/12/2021	GBÊKÊ	PHARMACIE EL NISSI	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00711A	March-23	56
RCI/MSP/C3-23-03/12/2021	GBÊKÊ	DPCI BOUAKE	Regional Warehouse	Private	2	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00628D	déc-22	56
RCI/MSP/C3-24-03/12/2021	GBÊKÊ	TEDIS PHARMA BOUAKE	Regional Warehouse	Private	2	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00628D	déc-22	56
RCI/MSP/C4-001-23/11/2021	PORO	HOPITAL REGIONAL DE KORHOGO	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006042	May-22	30

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RCI/MSP/C4-004-23/11/2021	PORO	DISTRICT SANITAIRE DE KORHOGO	Regional Warehouse	Public	2	MISOPROSTOL	Misoprostol	CHINA RESOURCES ZIZHU PHARMACEUTICAL Co LTD, CHINA	45200501	May-22	30
RCI/MSP/C4-005-23/11/2021	PORO	PHARMACIE PALAIS DE JUSTICE, KORHOGO	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00605B	nov-22	40
RCI/MSP/C4-006-24/11/2021	TCHOLOGO	HOPITAL GENERAL DE OUANGOLO	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006042	May-22	30
RCI/MSP/C4-008-23/11/2021	TCHOLOGO	PHARMACIE MODERNE DE OUANGOLO	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00711A	March-23	40
RCI/MSP/C4-011-25/11/2021	BAGOUE	CSUS-PM DE BOUNDIALI	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006042	May-22	39
RCI/MSP/C4-012-25/11/2021	BAGOUE	HOPITAL GENERAL DE BOUNDIALI	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006042	May-22	39
RCI/MSP/C4-014-25/11/2021	BAGOUE	PHARMACIE FATIMA; BOUNDIALI	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00711A	March-23	40
RCI/MSP/C4-015-26/11/2021	KABADOUGOU	HOPITAL GENERAL DE MADINANI	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006042	May-22	39
RCI/MSP/C4-018-27/11/2021	KABADOUGOU	CHR D'ODIENNE	Hospital	Public	3	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006042	May-22	39
RCI/MSP/C4-021-27/11/2021	KABADOUGOU	DISTRICT SANITAIRE D'ODIENNE	Medicines depot	Public	2	ACE MISO	Misoprostol	ACME FORMULATION PVT LTD - INDIA	ACE2006042	May-22	30
RCI/MSP/C4-023-27/11/2021	KABADOUGOU	GRANDE PHARMACIE DU DENGUELE	Pharmacy	Private	3	MISO-FEM	Misoprostol	NAARI PHARMA PRIVATE LIMITED, - INDIA	NR00711A	March-23	32
RCI/OCY/C1-01/22/11/2021	Abidjan	UBIPHARM-CI ZI, Abidjan	Central warehouse	Private	1	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043152	Aug-23	24 amp
RCI/OCY/C1-02/22/11/2021	Abidjan	UBIPHARM-CI ZI, Abidjan	Central warehouse	Private	1	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043153	Aug-23	24 amp
RCI/OCY/C1-10/23/11/2021	SUD COMOE	Pharmacie de BIANOUAN	Pharmacy	Private	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200222	Feb-23	20 amp
RCI/OCY/C1-11/24/11/2021	SUD COMOE	DISTRICT SANITAIRE ABOISSO	Medicines depot	Public	2	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200310	March-23	20 amp
RCI/OCY/C1-12/24/11/2021	SUD COMOE	CHR ABOISSO	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200217	Feb-23	20 amp
RCI/OCY/C1-14/24/11/2021	SUD COMOE	Pharmacie du SANWI	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043153	Aug-23	24 amp
RCI/OCY/C1-15/24/11/2021	SUD COMOE	HOPITAL GENERAL MAFERE	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200217	Feb-23	20 amp
RCI/OCY/C1-1724/11/2021	SUD COMOE	Pharmacie AKA EBA	Private Pharmacy	Private	3	OXYTOCIN 5	Oxytocin	ROTEXMEDICA Werk,Bunsenstrasse 4-22946 Trittau	00871	oct-23	20 amp
RCI/OCY/C1-19/25/11/2021	Abidjan	TEDIS PHARMA,	Central Warehouse	Private	1	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043150	Jul-23	24 amp

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RCI/OCY/C1-23/26/11/2021	Abidjan	NPSP-CI, BP V5 Abidjan	Central Warehouse	Public	1	OXYTOCINE INJECTABLE BP	Oxytocin	CIRON DRUGS &PHARMACEUTICALS PVT.LTD India	1EB02241	may-23	20 amp
RCI/OCY/C1-24/26/11/2021	Abidjan	NPSP-CI, BP V5 Abidjan	Central Warehouse	Public	1	OXYTOCINE INJECTABLE BP	Oxytocin	CIRON DRUGS &PHARMACEUTICALS PVT.LTD India	1EB04265	Jun-23	20 amp
RCI/OCY/C1-26/26/11/2021	Abidjan	Pharmacie d'AGBAN	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043147	sept-22	24 amp
RCI/OCY/C2-01/29/11/2020	Gontougou	Pharmacie des Brons	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043150	Jul-23	24 amp
RCI/OCY/C2-02/29/11/2021	Gontougou	CENTRE DE SANTE RURAL DE SIASSO	Hospital	Public	3	OXYTOCIN INJECTION BP	Oxytocin	NCPC International Corp. China	210208	Feb-24	20 amp
RCI/OCY/C2-03/29//1/2021	INDENIE-DJUANBLIN	DISTRICT SANITAIRE D'AGNIBILEKRO	Regional Werehouse	Public	2	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	20 amp
RCI/OCY/C2-05/29/11/2021	INDENIE-DJUANBLIN	HOPITAL GENERAL AGNIBILEKRO	Hospital	Public	3	OXYTOCIN INJECTION BP	Oxytocin	BHARAT PARENTERALS LTD India	00001	May-22	20 amp
RCI/OCY/C2-08/29/11/2021	INDENIE-DJUANBLIN	Pharmacie MAIRIE-NORD	Pharmacy	Private	3	PHARMA CINON	Oxytocin	STERIL-GENE LIFE SCIENCES(P) LTD India	JR00001A	Nov-22	20 amp
RCI/OCY/C2-09/30/11/221	INDENIE-DJUANBLIN	CENTRE DE SANTE URBAIN DE NIABLE	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	20 amp
RCI/OCY/C2-10/30/11/2021	INDENIE-DJUANBLIN	CENTRE DE SANTE URBAIN D'EBILASSOKRO	Hospital	Public	3	OXYTOCIN INJECTION BP	Oxytocin	BHARAT PARENTERALS LTD India	00001	May-22	20 amp
RCI/OCY/C2-11/30/11/2021	INDENIE-DJUANBLIN	Pharmacie d'EBILASSOKRO	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043150	Jul-23	15 amp
RCI/OCY/C2-13/30/11/2021	INDENIE-DJUANBLIN	Pharmacie du MARCHE	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043153	Aug-23	24 amp
RCI/OCY/C2-14/01/12/2021	INDENIE-DJUANBLIN	DISTRICT SANITAIRE d'ABENGOUROU	Regional Warehouse	Public	2	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	20 amp
RCI/OCY/C2-16/01/12/2021	INDENIE-DJUANBLIN	CENTRE HOSPITALIER REGIONAL d'ABENGOUROU	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200223	Feb-23	20 amp
RCI/OCY/C2-18/01/12/2021	IFFOU	FORMATION SANITAIRE DE PEPRESSOU	Hospital	Public	3	OXYTOCIN INJECTION BP	Oxytocin	BHARAT PARENTERALS LTD Inde	00004	May-22	20 amp
RCI/OCY/C2-19/02/12/2021	IFFOU	HOPITAL GENERAL DE DAOUKRO	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	20 amp
RCI/OCY/C2-21/02/12/2021	IFFOU	Pharmacie de DAOUKRO	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043147	sept-22	24 amp
RCI/OCY/C2-23/03/12/2021	INDENIE-DJUANBLIN	HOPITAL GENERAL D'ADZOPE	Hospital	Public	3	OXYTOCIN INJECTION BP	Oxytocin	BHARAT PARENTERALS LTD India	00002	May-22	20 amp
RCI/OCY/C2-25/03/12/2021	INDENIE-DJUANBLIN	Pharmacie EUREKA	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043153	Aug-23	24 amp

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RCI/OCY/C3-02/29/11/2021	LÔH-DJIBOUA	CENTRE HOSPITALIER REGIONAL DIVO	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	20 amp
RCI/OCY/C3-03/29/11/2021	LÔH-DJIBOUA	Pharmacie du MARCHE	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043152	Aug-23	24 amp
RCI/OCY/C3-06/29/11/2021	LÔH-DJIBOUA	HOPITAL GENERAL DE LAKOTA	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	20 amp
RCI/OCY/C3-08/29/11/2021	LÔH-DJIBOUA	Pharmacie de LAKOTA	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043148	Jun-23	24 amp
RCI/OCY/C3-09/29/11/2021	GÔH	DISTRICT SANITAIRE DE GAGNOA 1	Regional Warehouse	Public	2	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200217	Feb-23	20 amp
RCI/OCY/C3-11/30/11/2021	GÔH	UBIPHARM CI, Gagnon	Regional Warehouse	Private	2	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043148	Jun-23	24 amp
RCI/OCY/C3-15/01/12/2021	DISTRICT AUTONOME YAMOUSSOKRO	CENTRE HOSPITALIER REGIONAL de YAMOUSSOKRO	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200223	Feb-23	20 amp
RCI/OCY/C3-17/02/12/2021	DISTRICT AUTONOME YAMOUSSOKRO	Pharmacie de YAMOUSSOKRO	Pharmacy	Private	3	PHARMA CINON	Oxytocin	STERIL-GENE LIFE SCIENCES(P) LTD India	JR00001B	nov-22	24 amp
RCI/OCY/C3-18/02/12/2021	GBÊKÊ	DISTRICT SANITAIRE BOUAKE SUD	Regional Warehouse	Public	2	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp.China	210208	Feb-24	20 amp
RCI/OCY/C3-21/02/12/2021	GBÊKÊ	Pharmacie EL NISSI	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, Inde	043153	Aug-23	24 amp
RCI/OCY/C3-23-03/12/2021	GBÊKÊ	TEDIS Pharma ,Bouake	Regional Warehouse	Private	2	PHARMA CINON	Oxytocin	STERIL-GENE LIFE SCIENCES(P) LTD India	JR0001B	nov-22	24 amp
RCI/OCY/C4-02/23/11/2021	PORO	HOPITAL REGIONAL de KORHOGO	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	30 amp
RCI/OCY/C4-03/23/11/2021	PORO	DISTRICT SANITAIRE de KORHOGO	Regional Warehouse	Public	2	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200223	Feb-23	30 amp
RCI/OCY/C4-07/24/11/2021	TCHOLOGO	DISTRICT SANITAIRE de OUANGOLO	Regional Warehouse	Public	2	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	30 amp
RCI/OCY/C4-09/23/11/2021	TCHOLOGO	Pharmacie MODERNE	Pharmacy	Private	3	PHARMA CINON	Oxytocin	STERIL-GENE LIFE SCIENCES(P) LTD India	JR0001B	Nov-22	21 amp
RCI/OCY/C4-10/23/11/2021	TCHOLOGO	Pharmacie MODERNE	Pharmacy	Private	3	OCYTOCINE MEDISOL	Oxytocin	MEDISOL S.A.S 11 rue Jacques Monod 69007 Lyon	ME011X5	may-23	25 amp
RCI/OCY/C4-13/25/11/2021	BAGOUE	HOPITAL GENERAL de BOUNDIALI	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	210208	Feb-24	25 amp
RCI/OCY/C4-16/26/11/2021	KABADOUGOU	HOPITAL GENERAL de MADINANI	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200310	March-23	30 amp
RCI/OCY/C4-17/26/11/2021	KABADOUGOU	HOPITAL GENERAL de MADINANI	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	190522	May-22	30 amp
RCI/OCY/C4-19/27/11/2021	KABADOUGOU	CENTRE HOSPITALIER REGIONAL	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200223	Feb-23	30 amp

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RCI/OCY/C4-20/27/11/2021	KABADOUGOU	CENTRE de SANTE URBAIN-PMI	Hospital	Public	3	OCYTOCINE INJECTION	Oxytocin	NCPC International Corp. China	200310	March-23	2.5 amp
RCI/OCY/C4-22/27/11/2021	KABADOUGOU	Grande Pharmacie du DENGUELE	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043148	Jun-23	21 amp
RCI/OCY/C4-24/27/11/2021	KABADOUGOU	Grande Pharmacie du DENGUELE	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043150	Jul-23	21 amp
RCI/OCY/C4-25/27/11/2021	KABADOUGOU	Grande Pharmacie du DENGUELE	Pharmacy	Private	3	OXYTROY	Oxytocin	TROIKAA PHARMACEUTICALS LTD, India	043147	sept-22	21 amp

Table S2: Samples of oxytocin and misoprostol collected from Senegal

Sample Code	Sample site	Type of facility	Sector	Level of Supply	Product name	Manufacturer	Batch number	Expiry date	Number of units collected
SN/DAK/OCT/01/30-08-21	Laborex Senegal	central	Private	1	Oxytocin	STERIL-GENE LIFE SCIENCES (P) Ltd	JR0001A	11/2022	10
SN/DAK/OCT/02/30-08-21	Laborex Senegal	Central	Private	1	Oxytocin	STERIL-GENE LIFE SCIENCES (P) Ltd	JR0001B	11/2022	15
SN/DAK/OCT/22/30-08-2021	PNA central	central	Public	1	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q04	07/2024	10
SN/DAK/OCT/23/30-08-2021	PNA central	central	Public	1	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q04	07/2024	10
SN/DAK/OCT/24/30/-08-2021	Ubipharm Belair	central	Private	1	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043147	09/22	12
SN/DAK/OCT/25/30/-08-2021	UBIPHARM BEL AIR	central	Private	1	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043147	09/22	12
SN/KAF/OCT/01/27-08-21	District de Kaffrine	District sanitaire	Public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/KAF/OCT/02/27-08-21	Poste de santé URBAIN 1	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/KAF/OCT/03/27-08-21	Pharmacie La Kongheuloise	Pharmacy	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043146	09/22	12
SN/KAF/OCT/04/27-08-21	EPS Kaffrine	Hospital	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/KAF/OCT/05/30-08-21	Pharmacie Régionale DE KAFFRINE	Wholesaler regional	Private	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10

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SN/KAF/OCT/06/30-08-21	Poste de santé DIAMAGUEUNE	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/KAF/OCT/07/30-08-21	Pharmacie Ndeye Fary SY	Pharmacy	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043146	09/22	12
SN/KAF/OCT/08/30-08-21	Pharmacie NDOUCOUMANE	Pharmacy	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043146	09/22	12
SN/KAF/OCT/09/30-08-21	Pharmacie Khadimar Rassoul	Pharmacy	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043147	09/22	12
SN/KAO/OCT/01/23-08-21	SODIPHARM KAOLACK	Wholesaler regional	Private	2	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043147	09/22	12
SN/KAO/OCT/02/23-08-21	UBIPHARM KAOLACK	Wholesaler regional	Private	2	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043147	09/22	12
SN/KAO/OCT/03/23-08-21	UBIPHARM KAOLACK	Wholesaler regional	Private	2	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043146	09/22	12
SN/KAO/OCT/04/23-08-21	Pharmacie Kaolackoise	Pharmacy	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043139	06/22	12
SN/KAO/OCT/05/24-08-21	Pharmacie Village Artisanal	Pharmacy	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043146	09/22	12
SN/KAO/OCT/06/25-08-21	Poste de santé Keur SOCE	Poste de santé	Public	3	Oxtroy	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10, inc. 1 broken
SN/KAO/OCT/07/25-08-21	District de Kaolack	District sanitaire	Public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q01 (S230Q03 on box)	07/2023	10
SN/KAO/OCT/08/25-08-21	Poste de santé Keur BAKA	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q01	07/2022	10
SN/KAO/OCT/09/25-08-21	Pharmacie Hopital Régional de Kaolack	Hospital	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q01 (S230Q03 on box)	07/2023	10
SN/KAO/OCT/10/26-08-21	Poste de santé DIALEGNE	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/KAO/OCT/11/26-08-21	Pharmacie Boulevard de la Medina	Officine	Private	3	Oxytocin	TROIKAA PHARMACEUTICALS LTD	431400 (043140 on box)	06/22	12
SN/KED/OCT/11/25-08-2021	Centre de santé Kédougou	Centre de Santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/KED/OCT/12/25-08-2021	District de Kédougou	District sanitaire	Public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10

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SN/KED/OCT/13/25-08-2021	Poste de santé de MAKO	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/KED/OCT/14/25-08-2021	PHARMACIE YA SALAM	Officine	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043140	06/22	12
SN/KED/OCT/15/25-08-2021	PHARMACIE AL MAKHTOUM	Officine	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043139	06/22	12
SN/KED/OCT/16/25-08-2021	PHARMACIE KENYA	Officine	Private	3	Oxytocin	TROIKAA PHARMACEUTICALS LTD	043146	09/22	12
SN/KED/OCT/17/25-08-2021	POSTE DE SANTE DE TOMBORONKOTO	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/KED/OCT/18/26-08-2021	POSTE DE SANTE DE BEMBOU	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/KED/OCT/19/26-08-2021	CENTRE DE SANTE DE SARAYA	Centre de Santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/LOU/OCT/01/23-08-21	Hospital Amadou Sakhir Louga	Hospital	public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	30
SN/LOU/OCT/02/23-08-21	PRA LOUGA	Wholesaler regional	public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/LOU/OCT/04/24-08-21	Pharmacie EL HADJI OMAR TALL	Officine	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043146	09/22	9
SN/LOU/OCT/05/24-08-21	Pharmacie BOROM DAROU	Officine	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043142	07/22	12
SN/LOU/OCT/06/24-08-21	Poste de Santé FASS TOURE	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q02 (S230Q03 on box)	07/2023	10
SN/LOU/OCT/07/24-08-21	Poste de Santé DAROU MARNANE	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/LOU/OCT/08/24-08-21	POSTE DE SANTE MARIEME FAYE SALL	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/LOU/OCT/09/24-08-21	District SANITAIRE DE DAROU MOUSTY	District sanitaire	Public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/SAI/OCT/01/25-08-21	PRA SAINT-LOUIS	Wholesaler regional	Public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/SAI/OCT/02/25-08-21	HOPITAL REGIONAL DE SAINT-LOUIS	Hospital	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10

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SN/SAI/OCT/03/25-08-21	Pharmacie ROKHAYA GAYE	Officine	Private	3	OXYTROY	TROIKAA PHARMACEUTICALS LTD	043146	09/22	12
SN/SAI/OCT/05/26-08-21	District Sanitaire de RICHARD-TOLL	District sanitaire	Public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/2023	10
SN/SAI/OCT/06/26-08-21	Poste de santé THIABAKH	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q02	02/2023	10
SN/SAI/OCT/07/26-08-21	Poste de santé TAOWEY	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/20/26-08-2021	Not reported in country sampling report	Not reported in country sampling report	Not reported in country sampling report	Not reported in country sampling report	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/01/23-08-2021	EPS TAMBA	EPS	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/02/23-08-2021	PHARMACIE NAMOUSSA	Pharmacy	Private	3	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043140	06/22	12
SN/TAM/OCT/03/23-08-2021	POSTE SANTE SINTHIOU MALHEM	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/04/23-08-2021	POSTE SANTE DEPOT TAMBACOUDA	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/05/23-08-2021	POSTE SANTE GOUREL DIADE	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	6
SN/TAM/OCT/06/23-08-2021	PRA TAMBA	Wholesaler regional	Public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/07/24-08-2021	CENTRE DE SANTE TAMBACOUNDA	Centre de Santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/08/24-08-2021	District Tambacouda	District sanitaire	Public	2	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/09/24-08-2021	POSTE DE SANTE DE PONT	Poste de santé	Public	3	Oxytocin	XIER KANGTAI PHARMACEUTICAL CO., LTD	S230Q03	07/23	10
SN/TAM/OCT/10/24-08-2021	DUOPHARM TAMBA	Wholesaler regional	Private	2	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043146	09/22	12

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SN/TAM/ OCT/21/27-08-2021	Not reported in country sampling report	Not reported in country sampling report	Not reported in country sampling report	Not reported in country sampling report	Oxtroy	TROIKAA PHARMACEUTICALS LTD	043147	09/22	12

Results of oxytocin and misoprostol products sampled in Côte d'Ivoire

The quality control results revealed that all 52 oxytocin samples met the monograph specifications for description, identity, pH, and particulate matter. However, 9.6% of the samples tested failed the assay test, and 48% failed the related substances test. This amounts to a 54% failure rate (Table 4). Notably, 92% of the oxytocin samples that failed were not registered with the local NMRA.

The National Laboratory (Laboratoire National de Santé Publique, LNSP) in Côte d'Ivoire conducted identity, pH, and assay tests on the same oxytocin samples tested by MIPS. Their findings indicated that all samples met the requirements for identity and pH tests. However, 33% of the samples failed the assay test according to the Ph. Int monograph. The assay test failure rate reported by LNSP was higher than the MIPS results (Table 5). LNSP did not conduct any out-of-specification investigations for the assay tests on the oxytocin samples, and related substances tests were not performed by LNSP.

The quality control of 47 tested misoprostol samples met the Ph. Int monograph specifications for description, packaging, labeling, identification, and assay tests. One sample was excluded from the analysis due to its expiration. While 95.8% of the samples passed the tests, 2 samples (4.2%) yielded inconclusive results. One sample failed the level-1 uniformity of content test, and the other failed the stage-1 dissolution test. However, due to insufficient units for further testing, both results were deemed inconclusive as per Ph. Int guidelines (Table 6). Substandard oxytocin and misoprostol samples were identified at both level-2 and level-3 of the supply chain in Côte d'Ivoire, mainly within public health facilities (Table 7).

Table 4 : Summary of test results of oxytocin samples from Côte d'Ivoire

Commercial name	Manufacturer	No. batch tested	Assay		Related substances (RS)		Total samples
			Pass	Fail	Pass	Fail	Fail
Pharmacinon	Sterile-Gene Life Sciences Pharma (SGLS), India	4	1	3	4	0	3
Oxtroy	Troikka Formulation	17	17	0	16	1	1
Oxytocin	Medisol SAS, France	1	1	0	1	0	0
Oxytocin	Ciron Pharma, India	2	2	0	2	0	0
Oxytocin	North China Pharmaceutical Co (NCPC), China	23	21	2	0	23	23
Oxytocin	Bharat Parenterals	4	4	0	3	1	1
Oxytocin	Rotexomedica	1	1	0	1	0	0
TOTAL	52	47	5	27	25	28	

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Table 5: Comparison of assay test failures between LNSP and MIPS laboratory from oxytocin samples in Côte d'Ivoire

Oxytocin Samples	Manufacturer	LNSP Lab – Assay test results	MIPS Lab – Assay test results
RCI/OCY/C1-10	NCPC	74.3	89.8
RCI/OCY/C1-11	NCPC	87.9	96.4*
RCI/OCY/C1-12	NCPC	88.8	95.9*
RCI/OCY/C2-02	NCPC	82.5	108.7*
RCI/OCY/C2-08	SGLS Pharma	85.8	89.5
RCI/OCY/C2-09	NCPC	87.6	102.5*
RCI/OCY/C2-19	NCPC	87.3	101.0*
RCI/OCY/C3-06	NCPC	88.4	108.2*
RCI/OCY/C3-09	NCPC	88.1	97.6*
RCI/OCY/C3-15	NCPC	88.2	101.3*
RCI/OCY/C3-17	SGLS Pharma	88.4	88.3
RCI/OCY/C3-18	NCPC	87.1	101.5*
RCI/OCY/C4-07	NCPC	89.0	101.3*
RCI/OCY/C4-09	SGLS Pharma	87.3	88.5
RCI/OCY/C4-13	NCPC	88.8	101.8*
RCI/OCY/C4-17	NCPC	68.5	81.7
RCI/OCY/C4-19	NCPC	88.2	100.2*
Total oxytocin samples that failed the assay test		17	5

Table 6: Failed misoprostol samples from Côte d'Ivoire

Region	Supply Level	INN Name	Manufacturer	Batch No.	Failed Test
Tchologou	Level-2	Misoprostol	ACME Formul.	ACE2006042	UoC at L1
Kabadougou	Level-2	Misoprostol	ACME Formul.	ACE2006042	Diss at S1
47 samples tested out of 48 misoprostol samples collected					2 failed *

Table 7: Quality test results per levels of the supply chain in Côte d'Ivoire

	OXYTOCIN INJECTION			MISOPROSTOL TABLETS		
	No. samples tested	No. samples that pass the test (%)	No. samples that fail the test (%)	No. samples tested	No. samples that pass the test (%)	No. samples that fail the test (%)
LEVEL 1	5	5 (100%)	0 (0%)	9	9 (100%)	0 (0%)
LEVEL 2	9	2 (22.2%)	7 (77.8%)	10	9 (90%)	1 (10%)
LEVEL 3	38	17 (44.7%)	21 (55.3%)	29	28 (96.6%)	1 (3.4%)

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Results of oxytocin and misoprostol products sampled in Senegal

The quality control results revealed that 62 samples of oxytocin met the Ph. Int specifications for description, particulate matter, identity, pH, and related substances tests. However, 5% of the samples failed the assay test (Table 8). Among the three non-compliant samples, two were from public level-3 and one from private level-1 facilities.

The quality control of 33 misoprostol samples met the specifications outlined in the Ph. Int monograph for description, storage, identification, and assay. One sample was excluded from the analysis due to its expiration. Only one sample failed the uniformity of content test. However, due to insufficient tablets to complete the subsequent test stage, the results were reported as inconclusive. Additionally, 41.4% samples failed at the first dissolution stage, but the lack of sufficient units prevented continuation to stage 2, resulting in inconclusive results (Table 9). A significant proportion, 83%, of the failed samples were from the same manufacturer. Overall, the majority of failed misoprostol samples were found in the public sector. Although substandard products were present at all levels of the public sector supply chain, it was predominantly level-3 in the private sector where these were found (Table 9).

Overall, substandard oxytocin and misoprostol samples were identified at level-1 and level-2, and at levels 1-3 respectively (Table 10). In Senegal, the oxytocin and misoprostol samples collected were not tested by the local national laboratory.

Table 8: Failed oxytocin samples from Senegal

Commercial name	Manufacturer	No. batch tested	Assay		Related Substances (RS)		Total Samples
			Pass	Fail	Pass	Fail	Failed
Pharmacinon	Steril-gene life Sci. India	2	1	1	2	0	1
Oxtroy	Troikka Formulation,	22	22	0	22	0	1
Oxytocin	XIER Kangtai Pharma	38	36	2	38	0	2
TOTAL		62	59	3	62	0	3 (4.8%)

Table 9 : Failed misoprostol samples in Senegal

Region	Supply Level	INN Name	Manufacturer	Batch No.	Failed Test
Louga	Level-3	Misoprostol	United Biotech,	MBTC1A1	Diss at S1
Louga	Level-3	Misoprostol	ACME Formul.	MCL2008069	Diss at S1
Louga	Level-3	Misoprostol	United Biotech,	MBTC1A1	Diss at S1
St Louis	Level-2	Misoprostol	United Biotech	MBTC1A1	Diss at S1
St Louis	Level-3	Misoprostol	United Biotech,	MBTC1A1	Diss at S1
Tambacounda	Level-3	Misoprostol	United Biotech,	MBTC1A1	Diss at S1
Tambacounda	Level-3	Misoprostol	ACME Formul.	MCL2010005	Diss at S1
Dakar	Level-1	Misoprostol	United Biotech,	MBTC1A1	Diss at S1
Dakar	Level-1	Misoprostol	United Biotech	MBTC1A1	Diss at S1
Kafferine	Level-3	Misoprostol	United Biotech	MBTC1A1	Diss at S1
Kafferine	Level-3	Misoprostol	United Biotech,	MBTC1A1	Diss at S1
Kafferine	Level-2	Misoprostol	United Biotech,	MBTC1A1	Diss at S1
Dakar	Level-3	Misprostol	ACME Formul.	MCL2008069	UoC at L1

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Table 10 : Quality test results per levels of the supply chain in Senegal

	Oxytocin Injection			Misoprostol Tablets		
	Tested	**Pass**	**Failed (%)**	**Tested**	**Pass**	**Failed**
Level 1	4	3	1 (1.6%)	3	1	2 (6%)
Level 2	15	15	0 (0%)	9	7	2 (6%)
Level 3	43	41	2 (3.2%)	21	8	13 (39%)
Total	62	59	3 (4.8)	33	16	17 (51%)

DISCUSSION

This post-marketing surveillance study revealed that 30% of oxytocin samples (54% in Côte d'Ivoire; 5% in Senegal) and 23% of misoprostol samples (4.2% in Côte d'Ivoire; 41.4% in Senegal) were deemed substandard across all levels of the supply chain in both public and private sectors.

Of significant concern are the findings on substandard oxytocin samples passing the assay test but failing the related substances test as it suggests that impurities in the finished product formulations might be responsible for the non-compliance, rather than degradation of the active pharmaceutical ingredient. This indicates that storage conditions alone might not be the sole cause for the substandard quality of these products. Notably, 44% of the identified substandard oxytocin in Côte d'Ivoire originated from a single manufacturer.

In Côte d'Ivoire, only 4.2% of misoprostol samples were substandard, while in Senegal, 41.4% of misoprostol samples were found to be substandard at the first dissolution test. Given that the majority of these substandard samples from Senegal originated from the same manufacturer and batch, and were collected from various levels of the supply chain with dissolution values below 85%, it is reasonable to deduce that samples from this batch are likely to fail further stages of the dissolution test.

This study represents the first assessment of oxytocin and misoprostol quality in West Africa, showing results consistent with similar surveys conducted in Anglophone African countries[13, 18-22].

The study's limitations included difficulties in obtaining sufficient units per sample, compounded by the packaging of two misoprostol tablets per pack, which impeded the collection of adequate number of units from the same batch. Determining the optimal number of units for testing remains a challenge necessitating a balance between cost considerations, the risk of potential medicine shortages, and technical demands of testing requirements.

It is to be noted that the substandard batches of both misoprostol and oxytocin were withdrawn from the market following investigations by national agencies post-analysis.

The study also evaluated the registration status of the collected products. In Senegal, all the sampled brands were registered by the NMRA; however, in Côte d'Ivoire, only 4 out of the 13 identified brands were registered by the NMRA. This implies a potential prevalence of substandard products in the market, posing a considerable risk to the community. These findings align with other studies conducted LMICs assessing the quality of oxytocin and misoprostol, revealing instances of unregistered or unlicensed medicines.[13, 18-20, 23] Typically, unregistered medicines are commonly discovered in private and informal sectors during such surveys. However, this study identified unregistered medicines in level-2 and level-3 of public health facilities in all regions evaluated, except in Abidjan in Côte d'Ivoire. Furthermore, while most misoprostol products were sourced from WHO prequalified manufacturers, none of the oxytocin samples were sourced from WHO prequalified manufacturers.[24]

This study aimed to enhance the capabilities of the national laboratories in both countries. The LNSP in Côte d'Ivoire conducted all the tests except for related substances due to capacity constraints. Interestingly, all the samples that failed the testing at the MIPS laboratory also failed at the LNSP laboratory. However, the LNSP identified more failed samples compared to the MIPS lab. This variance in results between the MIPS and LNSP laboratories could be attributed to factors such as varying levels of experience in testing these specific medicines, differences in the quality management systems, and the qualifications of personnel, among other reasons.

Lastly, the discovery of similar brands of oxytocin and misoprostol in both Côte d'Ivoire and Senegal underscores the necessity for West African countries to conduct cross-border surveys on the quality of essential medicines. Moreover, some of the oxytocin and misoprostol brands examined in this study were also identified in Rwanda, the Democratic Republic of Congo (DRC), Ghana, and Malawi. [18, 20-22] Sharing information on substandard and falsified medicines among NMRAs, particularly through the WHO Global Surveillance and Monitoring System (GSMS), can significantly aid in identifying reliable suppliers of uterotonic drugs. The study results were shared with the authorities in Côte d'Ivoire and Senegal. Subsequently, the NMRAs swiftly

initiated investigations to identify the underlying causes of substandard products' presence in the market and recalled the substandard product batches from circulation. This underscores the effectiveness and significance of PMS surveys in strengthening health systems. By compiling data based on evidence and conducting comprehensive analyses, informed decisions were taken to protect public health.

To combat the proliferation of falsified and substandard uterotonic medicines, strengthening regulatory systems within these countries is essential. Moreover, it is recommended that a comprehensive and risk-based post-marketing surveillance of oxytocin and misoprostol in the market should be regularly conducted as part of the overall management of these medications and as a mechanism to bolster the national supply chain.

CONCLUSION

A substantial proportion of oxytocin and misoprostol products available in Côte d'Ivoire and Senegal were found to be substandard. Investing in quality-assured medicines is crucial for delivering safe and effective healthcare, reducing overall healthcare costs, and securing the long-term success of universal health coverage in low-income countries.

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Author contributions

All the authors listed on the paper meet the authorship criteria. MW and RK were the initiators of the study and were responsible for conceiving the study and drafting the study protocol. MW, RK, CR, FGM, and ASS were instrumental in organizing the local teams and conducting training on the study procedures. SD, DF, KAT, SOS, FF, and CSC executed the study and made sure that the local authorities concurred with the results of the study. AS contributed to evaluating the study results reports and was responsible for preparing the initial draft of the manuscript. All authors have given their approval for the final manuscript version.

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Conflict of interest

None of the authors has any conflict of interest to declare.

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