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Maternal and Child Health
Integrated Program

REGISTRATION AND DISTRIBUTION OF OXYTOCIN IN UNIJECT® IN MALI

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The scope of this work is to define the registration process for Oxytocin in Uniject® (OiU) and to recommend some options for its commercialization and distribution in Mali, primarily in the public sector. I was to travel to Mali on March 26th, 2012, but because of the political events, my trip was cancelled by the United States Agency for International Development (USAID) and I subsequently conducted this work via phone and e-mail. A short list of potential "agents" who can facilitate registration and distribution is provided. However, I did not meet with the organizations and individuals mentioned in this report, and the recommendations are based upon references from in-country people and organizations. Because of the difficult political situation in Mali, and the importance of scaling up the commercialization of this product to improve impact on maternal health, decrease OiU costs and increase its visibility to facilitate its sustainability, some preliminary suggestions are provided with regard to regional commercialization.

Abbreviations and Acronyms

ACAME	Association des Centrales d'Achats Africaines de Médicaments Essentiels (Africa Essential Medicines Central Procurement Association)
AMTSL	Active management of the third stage of labor
API	Active pharmaceutical ingredient
ARV	Antiretroviral
ASACO	Association de Santé Communautaires (Community Health Association)
ASFM	Association des Sages-Femmes du Mali (Malian Midwives' Association)
BA	Birth attendant
CADG	Centrale d'Achat des Génériques
CEDEAO	Communauté Economique des Etats de l'Afrique de l'Ouest (Economic Community Of West African States – ECOWAS)
CSCom	Centres de Santé Communautaires (Community Health Centers)
DOH	Department of Health
DPAV	Dépôt paiement après vente (Supplies are not paid for until after they are sold, and unsold inventories are the property of the manufacturer)
DPM	Direction de la Pharmacie et du Médicament (Pharmacy and Medications Directorate)
FASFACO	Fédération des associations de sages-femmes d'Afrique du Centre et de l'Ouest (West and Central African Confederation of Midwives)
HCP	Health care provider
IDA	International Dispensary Association
JICA	Japan International Cooperation Agency
MCHIP	Maternal and Child Health Integrated Program
MDG	Millennium Development Goal
MOH	Ministry of Health
MS	Market share
MMV	Medicines for Malaria Venture
MSH	Management Sciences for Health
NEML	National Essential Medicines List
OiU	Oxytocin in Uniject®
OOAS	Organisation Ouest Africaine de la Santé (West African Health Organization)
PPH	Postpartum hemorrhage
PPM	Pharmacie Populaire du Mali
SBA	Skilled birth attendant
TBA	Traditional birth attendant
TT	Tetanus toxoid
TTI	Time Temperature Indicator
UEMOA	Union économique et monétaire ouest-africaine (West Africa Economic and Monetary Union)
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Registration

The registration of Oxytocin in Uniject® (OiU) is required prior to its distribution, and the dossier should follow the "Arreté interministeriel #2203" dated 20 September 2005. Dr. Sékou Dembélé, head of the Pharmacy and Medications Directorate (Direction de la Pharmacie et du Médicament – DPM) registration division, and Mr. Drissa Traoré, delegated by the DPM, are expecting the OiU dossier to initiate the registration process.

The registration of OiU is required prior to its distribution, and contact has been established with Dr. Sékou Dembélé, director of the regulatory department at the DPM, the Mali National Drug Regulatory Authority. Dr. Dembélé indicated that he welcomes the product and will facilitate its registration. He also delegated a former DPM employee, Mr. Drissa Traoré, to be the point person for this registration. He and Mr. Traoré provided the following information about the OiU registration process:

The dossier should follow the "Arreté interministeriel #2203" dated 20 September 2005 (see Appendix A). Because oxytocin itself qualifies as a generic drug, Dr. Dembélé indicated that OiU is considered a branded product. The dossier should therefore include the following information and should be submitted in French: "Article 8: The market authorization dossier for branded specialties includes":

1°) The written request with name and contact information of the market authorization's applicant and, if he is not the manufacturer, that of the manufacturer;

2°) A complete technical dossier in two copies in French;

3°) A summary of the product characteristics in French in 20 copies;

4°) Sufficient Active Pharmaceutical Ingredient (API) and excipient for sample lot analysis; *that may not be necessary and will be further discussed with the DPM;*

5°) 30 samples with packaging and draft notice in French;

6°) Wholesaler price as well as price with insurance and freight in FrCFA; and

7°) The receipt of payment for filing fees.

The filing cost is 300,000 FrCFA (or approximately 600US$) for a branded product and 150,000 FrCFA for a generic product. Theoretically there is a drug commission meeting every three months to review applications. However, in reality, the drug commission does not meet this regularly and may meet only once a year. The market authorization is valid for five years. For registration beyond Mali, there is a Common Technical Dossier proposed by the "Union économique et monétaire ouest-africaine" (UEMOA) for West African countries (in Appendix A); however, at this time, country-by-country registration is necessary. An excerpt of the Malian "September 20, 2005 decree # 2203, Article 8" follows:

> Article 8: The application packet for marketing authorization for proprietary medicinal products other than those referred to in articles 9 and 11, below, and category 4 traditional herbal medicines and herbal medicines defined in Article 10 below, should include:
>
> 1. a written request containing the name and full address of the applicant requesting marketing authorization, and when the applicant does not manufacture the drug, the name and address of manufacturer;
>
> 2. two copies of the complete technical file in French comprised of:
>   - Structural formula for the drug form,

- The techniques and results of monitoring active ingredients,
- The techniques and results of quality control of the drug,
- Techniques and manufacturing conditions,
- The names of expert analysts, biologists and clinicians,
- Reports on analytical tests, biological tests and clinical trials,
- The results of stability testing and storage of the finished product
- A certified copy of the visa from the country of origin,

3. Twenty (20) copies of a summary, in French, of product characteristics, with the name of the proprietary and the international nonproprietary name of the active ingredient(s), medication form, dosage, presentation and route of administration. The qualitative and quantitative composition of active ingredient(s) and excipients, the pharmacological class, therapeutic indications, contra-indications, side effects, precautions for use and warnings; use in pregnancy and lactation, drug interactions, dosage and route of administration, what to do in case of overdose, incompatibilities, and the shelf life if applicable before and after reconstitution, storage conditions, packaging; possible inclusion in a list of poisonous substances.

4. Sufficient quantity of the product for analysis of the active ingredients and excipients, the same batch as those used in the manufacture of the sample provided;

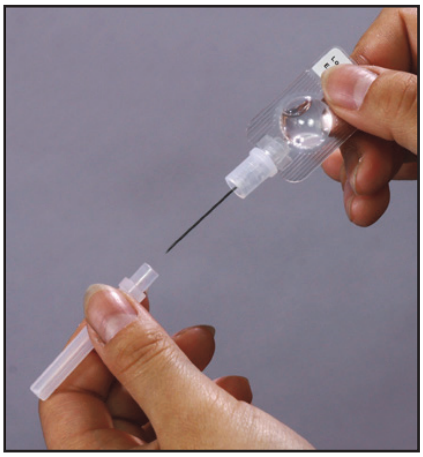
5. Thirty (30) samples for each form, presentation and dosage, of the product to be sold to the public, accompanied by a draft copy of the package insert for small packages, or for large packages for veterinary products:
   - 10 samples of 500mL bottles;
   - 03 samples of boxes with 100 to 400 tablets;
   - 0 I samples of packages with 500 or more pills;
   - 20 samples of 1 kg sachets of powder and 1 liter bottles;
   - 10 samples of 5 kg sachets of powder and 5 liter bottles;
   - 05 samples of 10 kg sachets of powder and 10 liter bottles;
   - 15 samples of 2 kg sachets of powder;

6. The wholesale price without tax and the price with 'Cost Insurance and Freight' (CIF) in FrCFA which the applicant proposes to sell the product to wholesalers of Mali;

7. A copy of the receipt for payment of the application for marketing authorization fees set by regulation.

The Context

The context is favorable for OiU introduction given the high demand for oxytocin and OiU in Mali, a strong awareness of active management of the third stage of labor (AMTSL) and OiU, demand by women aware who request the "vaccine against hemorrhage" (oxytocin) and a specific 2009 Ministry of Health (MOH) action plan to train *matrones* (auxiliary midwives) to use oxytocin in the context of AMTSL. In addition, Uniject® technology is known in Mali because it was introduced with tetanus toxoid (TT) vaccine in 2004 by UNICEF and Save the Children and used by traditional birth attendants (TBAs). The Time Temperature Indicator (TTI) is perceived as a very positive feature, allowing OiU use in facilities with limited or uncertain cold chain.



Oxytocin in Uniject

The relatively higher price of OiU compared to oxytocin in ampoules favors a niche strategy in the public sector, whereby OiU may be used where oxytocin ampoules cannot be used. This may be for prevention by authorized lower cadres of health care personnel who may have difficulty using the ampoules and can more easily use the Uniject® device; or in the event of emergency; or when authorized personnel are assisting births alone; or when there are stock-outs, either for prevention or for treatment. The demand is potentially strong for broader use in the private sector, which is an important complement to public sector distribution, allowing increased access and potential supply in the event of public sector stock-out. However, there is some uncertainty with regard to immediate OiU introduction in the public sector given the current political instability (May 2012) and the need for government approval for registration of the product.

The context is overall favorable to distribute OiU in Mali:

- **Oxytocin is used routinely for the prevention of postpartum hemorrhage as part of AMTSL.** In theory, women purchase a delivery kit that includes oxytocin in addition to gloves, antiseptic, compresses, suture kit, etc. Oxytocin is purchased when the woman comes to the facility in labor from the hospital pharmacy or in private pharmacies, if not available at the facility. The price of oxytocin is usually included within the overall delivery fee unless purchased in a private pharmacy.
- **There is a high demand for oxytocin in Mali.** The public sector uterotonic market is estimated at approximately 300,000 ampoules per year,[1] primarily as generic oxytocin, while the private market is estimated at 160,000 Syntocinon® (oxytocin) ampoules per year and 10 000 Methergin® (ergometrine) ampoules per year.[2] Currently, only physicians are authorized to use misoprostol for obstetric or gynecologic reasons, and its use for prevention or treatment of postpartum hemorrhage (PPH) is being studied. Oxytocin is thought to be used for prevention of PPH in approximately 80% of deliveries in the public sector in Mali, and it is also largely used in the private sector although there is no quantitative estimate of this use.[3] In a 2006 U.S. Agency for International Development (USAID)/Management Sciences for Health (MSH) evaluation, oxytocin use in the context of AMTSL was observed during 70% of deliveries in Bamako and during only 40% of deliveries outside of Bamako.[4]

[1] Source: Dr. Adama Dembélé, head, procurement, PPM.
[2] Source: Dr. Adama Sanogo, head, procurement, Copharma Mali; these are sales regardless of the indication.
[3] Source: Mali Midwives Association.
[4] Revue de la politique et des procédures d'utilisation des ocytociques pour la GATPA, MSH, 2006, accessed on 12/04/12 at: http://pdf.usaid.gov/pdf_docs/PNADH559.pdf.

- In Mali, out of 626,610 "expected" births in 2008, 61% (383,209) occurred in public facilities, with 54% (340,035) occurring in community health centers (CSComs) and 7% (43,174) occurring in referral health centers (CSRéf).[5] **Of all births occurring in public facilities, *matrones* attend approximately 60% of them, mostly in CSComs located in rural areas**.[6] *Matrones* had not been authorized to inject oxytocin until an operations research study in 2007–2008 not only demonstrated the safety and feasibility of training *matrones* to apply AMTSL but also showed a clear impact on cases of PPH and mortality from PPH by doing so. Following this study, in 2009, the Minister of Health authorized *matrones* to apply AMTSL and to use oxytocin in the context of AMTSL, and developed a national plan for AMTSL expansion with *matrones* playing a key role in this scale-up.[7,8]
- **Generic and branded oxytocin are both available in public and private pharmacies.** Syntocinon®, branded oxytocin, is priced at 1,225 FrCFA (public price) for three ampoules in private pharmacies.[9] In a 2006 MSH report,[10] the price for an ampoule of Syntocinon was reported at 410 FrCFA compared to branded ergometrin (Methergin®) at 465 FrCFA and generic oxytocin at 155 FrCFA. In the public sector, in that study, CSCom were reported procuring oxytocin and misoprostol respectively at 60 and 70 FrCFA per ampoule and selling them to patients at 65 and 75 FrCFA per ampoule.
- **From the government perspective, there seems to be a demand for OiU**, according to Dr. Cheick Touré, IntraHealth International, Ms. Dicko, the Malian Midwives' Association (ASFM), Dr. Houleymata Diarra, Save the Children/Mali and Dr. Fatouma Tessougué, World Health Organization (WHO)/Mali. OiU was introduced in sites participating in the operations research studying feasibility and safety of *matrones* applying AMTSL, and was very favorably evaluated by providers and managers alike. This study also generated an enthusiastic demand for national introduction of the product. There is an ongoing study comparing misoprostol and OiU use in communities, sponsored by the Aga Khan Foundation, which will allow further clarification on the positioning of both drugs and use in the community context.[11]

Three decision-makers are key with regard to OiU distribution and use in the public sector at the national level:

- Head of the Reproductive Health Division, Department of Health, Ministry of Health – Dr. Binta Keita is currently in this position
- Director of the Pharmacie Populaire du Mali (PPM), Mali's central pharmacy – Dr. Aicha Guindo is currently in this position, and
- Director of the DPM – Pr. Ousmane Doumbia is currently in this position.

Unfortunately, none of the individuals currently holding the above positions could be met or contacted by phone prior to the writing of this report.

In addition to decision-makers at the national level, demand is influenced by orders from the facility, district (cercle) and regional levels. Medical and procurement officers from individual

[5] Source: "Annuaire Système Local d'Information Sanitaire 2008." Available at: http://www.sante.gov.ml/docs/pdf/slis2008.pdf.
[6] Source: Dr. Dolo from the Malian Society for Obstetrics and Gynecology (Societé Malienne de Gynécologie Obstétrique – SOMAGO) and Ms. Dicko from the Malian Midwives' Association (Association des Sages-Femmes du Mali-- ASFM)
[7] Source: IntraHealth, Mali Midwives Associations, Save the Children and Dr. Binta Keita, MOH, the latter at: http://www.pphprevention.org/files/Binta_MaliPresentation_POPPHI.NEW.pdf accessed April 15, 2012.
[8] Source: Plan d'Action National pour la Prévention de l'Hémorragie du Post-Partum (Période 2009–2011).
[9] Source: President of the Mali Pharmacists Association.
[10] Revue de la politique et des procédures d'utilisation des ocytociques pour la GATPA, MSH, 2006, accessed on 12/04/12 at http://pdf.usaid.gov/pdf_docs/PNADH559.pdf.
[11] Source: http://clinicaltrials.gov/ct2/show/NCT01487278; accessed on 12/04/12.

facilities order medications through the district, the district orders medications from the regional stores, and regional stores order medications from the PPM. The health system in Mali operates based on principles of the Bamako Initiative. CSComs are owned and managed by a health committee, so for OiU to be used in a CSCom by health care providers, it has to be ordered by the medical officer responsible for drugs procurement and approved by the "Association de Santé Communautaires" (ASACO – Community Health Association).

- According to representatives from the ASFM and IntraHealth International, there is **strong provider support** for AMTSL, because of the significant reduction in maternal hemorrhage and death resulting from its use. OiU offers several advantages over oxytocin in ampoules: it is pre-filled with the correct dose for prevention and for immediate management of PPH, hence it is easier to use, and it cannot be re-used, thus the risk of infection is decreased. Moreover, **all providers who used OiU were said to have a highly favorable opinion of it and to have since been requesting the product.** There were 24 gynecologists, 500 midwives, 500 obstetrical nurses and over 1,000 *matrones* reported in the public sector in Mali in 2007' however, these data include some, but not all, of the health professionals in the private, faith based, NGO and military sectors.[12] There are frequent interactions between the public and private sectors, as providers often work in both structures, and public sector patients may purchase products in private pharmacies whenever there is a stock-out in the public sector. In addition to the ease of use and decreased infection risk with OiU, OiU has a Time Temperature Indicator, which allows for some flexibility with regard to storage in the cold chain and raises a lot of interest in both the public and private sectors, as attested to by various interviewees including the President of the Mali Pharmacists' Association.
- **From the patients' perspective, there also appears to be high acceptability of oxytocin used for preventing PPH, as evidenced by the number of women who request the "vaccine against hemorrhage".**[13] This information is used in interpersonal communication by *relais communautaires* (social mobilization teams) to promote giving birth at the facility level. These awareness campaigns have positively changed women's behavior, with an increase in the number of women who gave birth in a health facility in many districts. The operations research study in 2007–2008 also showed that women who received oxytocin via the Uniject® device had a favorable impression of it.
- **Globally, there is strong awareness of the importance of maternal health, and significant funding has been allocated to prevent maternal deaths in the context of Millennium Development Goal (MDG) 5, including G8 funding.** In Mali, the United Nations Population Fund (**UNFPA)** is already procuring many reproductive health commodities, and is willing to procure OiU when the Malian government can assume responsibility for procurement, provided that the political context allows for OiU introduction.[14]
- **Uniject® technology is known in Mali because it was introduced with tetanus toxoid (TT) vaccine in 2004** by UNICEF and Save the Children as part of the Saving Newborn Lives project campaign to reduce maternal and neonatal tetanus. During this campaign, TT in Uniject was used by TBAs who still attend a large number of home births in Mali.

However, some obstacles remain to OiU implementation, such as:

- The political context is not favorable in Mali currently, with an interim government and a difficult political situation in the North of the country. However, as OiU has already been tested in Mali, the ASFM and IntraHealth International believe that it could still be

[12] Source: Annuaire Système Local d'Information Sanitaire 2007.
[13] Source: IntraHealth International.
[14] Source: Dr. Luc de Bernis, Senior Maternal Health Advisor, UNFPA.

adopted easily despite the transition period in the country, and they recommend to plan and prepare for such commercialization with a carefully selected agent.

- Injectable oxytocin 10 iu/mL is mentioned on the National Essential Medicines List (NEML) but has not yet been updated to include use by nurses and *matrones*. This list does not reflect new policies that do authorize nurses and *matrones* working in CSComs to administer oxytocin for the prevention of PPH. A revision of this list is planned for 2012.[15] It would be best to have a reference on the list to oxytocin in a pre-filled syringe, although this is not compulsory for OiU use. An excerpt from the 2010 NEML with regard to uterotonic drugs follows, with use by level of care (see Table 1).

Table 1. Excerpt from the National Essential Medicines List

Generic Name	Form	Dosage	Hospitals	CSRéf	CSCom (MD Manager)	CSCom (Nurse Manager)
Oxytocin	Injectable	10 iu/mL;1 mL	+	+	+	-
Oxytocin	Injectable	5 iu/mL;1 mL	+	+	+	+
Misoprostol	Vaginal tablet	25 µg	+	+	-	-

- **The oxytocin tender appears to be valid through mid-2013**, according to Dr. Adama Dembélé, head of procurement at the PPM. However, an OiU order may be possible through direct mutual agreement as it is a unique product given the pre-filled syringe. **The higher price of OiU compared to oxytocin in ampoules favors a niche strategy to complement and not substitute oxytocin ampoules.**

Given the specific advantages of OiU but its higher price and the current uterotonic market, potential OiU market segments may be as follows (see Figure 1 and Appendix B).

- In the public sector:
  - For prevention of PPH, OiU may be used for births attended by authorized personnel such as trained community health workers/*matrones* thus allowing oxytocin use where it would otherwise not be possible without the Uniject® administration device-, as well as for births attended by a single attendant. In the future, if TBAs are authorized, they may become additional users of OiU, provided it is demonstrated that this is feasible, safe, and beneficial and there is a policy change.
  - For treatment or prevention, OiU may be used in the following instances: where there is a single birth attendant, in emergency situations, or if there is a stock-out of generic oxytocin and/or use of oxytocin in ampoule form is not feasible.
- In the private sector:
  - All skilled birth attendants[16] (SBAs) may want to use or be asked by the patient to use OiU for either prevention or treatment. All interviewees indicated a strong potential demand by the private sector.
- In addition, the TTI allows some flexibility for use in facilities with limited or uncertain cold chain; thus OiU may be the drug of choice for prevention or treatment in these facilities.

[15] Source: Dr. Minkalia Maiga, EMP officer, WHO country office.
[16] SBAs in Mali include physicians, midwives, obstetrical nurses and nurses. While *matrones* are not considered SBAs, they have been authorized to apply AMTSL and administer oxytocin for the prevention of PPH.

Please note that these assumptions could not be validated in a larger stakeholders meeting given the cancellation of the trip to Mali.

Table 2. Potential Market Segments for OiU

Place of Birth and Type of BA / Use of Oxytocin	Public Sector		Private Sector		Home	
	SBA	*Matrones*	SBA	*Matrones*	SBAs, *Matrones* or TBAs	No Attendant
Prevention	More than one BA					
	Stock-out, BA working alone					
Treatment	More than one BA					
	Stock-out, Emergency, BA working alone					

Potential market segments for OiUBA = Birth attendant
SBA = Skilled birth attendant
TBA = Traditional birth attendant

Distribution for Sustainable Availability

A local agent is required to facilitate OiU registration and procurement by the PPM. The selected agent should have a successful track record with these activities as well as a good reputation. In addition, the same or other agent(s) should import and distribute OiU into the private sector, and provide relevant information to the health care providers (HCPs) in order to facilitate the market development. Five organizations have been short-listed, with four commercialization scenarios.

POSSIBLE ROLES OF AN "AGENT" IN MALI AND SELECTION CRITERIA

The "agent" may:

- **Facilitate the product registration.**

And/or:

- **Facilitate procurement and, possibly, import by the PPM for distribution into the public sector either via tenders or via direct mutual agreement.**

  For tenders, the "agent" purchases a "book" for 100,000 FrCFA (approximately 192 US$) and responds to tenders that theoretically occur yearly: the "agent" is required to provide administrative and financial information, followed by product technical documentation and price. A specific license is necessary to import pharmaceutical products. An agent may respond to the tender and facilitate procurement by the PPM, whereby when successful, the PPM then orders directly from the pharmaceutical company and the agent does not need to have such import licenses. There may be direct mutual agreement between the PPM and the manufacturer in the case of OiU, as this is a unique pre-filled syringe system; this type of agreement is preferable as OiU has a higher price compared to oxytocin in ampoules.

And/or:

- **Import and distribute to the private sector.**

  Import may be either via a large international distributor with a Mali office (90%), or directly through a local distributor (10%). The two main international distributors in Mali are subsidiaries of the groups Laborex[17] (65% Market Share [MS] and Copharma[18] (25% MS). Both of the distributors are well-established in the region. Prices are fixed, with a set margin for the distributor that is different for public and private sector products. It is possible to differentiate OiU into a branded and a generic product, with different prices, as Sanofi Aventis is doing for Artesunate Amodiaquine: ASAQ Winthrop® is the generic in the public sector and Coarsucam® is the branded product, with a significantly different price. That differentiation allows keeping a minimal price for the public sector; however, it may not be recommended because brand recognition with a similar name in the public and private sectors may be essential to facilitate market development and sustainability, and that assumption should be tested.

And/or:

- **Provide scientific information to HCP.**

  Scientific information on the new product may be provided through training of public sector providers by the MOH and its partners. In addition, marketing agents provide information to HCPs, and as these agents usually manage several products simultaneously, they would add OiU to their product portfolio aimed at professionals providing reproductive health

[17] http://www.laborex-mali.com/lbx10bo.nsf/?Open accessed on 12/04/12. Laborex is an affiliate of Eurapharma.
[18] http://www.copharma.com.ml/ accessed on 12/04/12.

services. Most providers work in both public and private sectors, with the exception of *matrones*, TBAs and community health workers, and the marketing agents visit them in both places (see Table 3).

Table 3. Potential Activities for the OiU "Agent"

Facilitate Registration	Public Sector: Facilitate PPM Procurement	Distribute to Private Sector	Provide Scientific Information	Role beyond Mali
REQUIRED	REQUIRED	±	±	±

Based on the potential roles of the "agent", the following selection criteria have been set to short-list potential agents (see Table 4).

Table 4. Selection Criteria for OiU Agents

Key Criteria	± Additional Criteria "better to have"
▪ Well established company with good reputation ▪ Successful track record with registration of drugs through the DPM ▪ Ability to facilitate PPM procurement ▪ No uterotonic in competition in portfolio ▪ If the "agent" stores and distributes, ability to do so with use of a cold chain ▪ If "agent" imports, relevant licenses and authorizations to do so	▪ "Sensitization" and experience with social products ▪ Already communicates with obstetrics/gynecology providers (physicians, midwives, nurses, etc.) ▪ Interest in developing the OiU private market ▪ Covers most of the Mali territory ▪ Ability and interest to develop the market beyond Mali and relevant strategy

SHORT LIST OF QUALIFIED "AGENTS"

Five companies have been short-listed and are described below (see Table 5); all of the agents mentioned indicated a potential interest in OiU. Details on each company and contact information follow in Appendices C–G.

Table 5. Short List of Companies That Are Qualified Agents

Institution Name	Centrale d'Achat des Génériques (CADG)	Wasulu Pharma	Ethica	Hinane Santé	IDA Foundation
Contact	Dr. Alfred Dembélé	Mr. Soumaila Diallo	Mr. Djinguita Camara	Dr. Cissé	Mr. Nicolas Bablon
Activities	ALL: Respond to PPM tenders, facilitate registration, distribute, do marketing ± work beyond Mali	Registration, marketing,- respond to PPM tenders, looking to distribute: filed for relevant licenses (distributes para pharma) ± work beyond Mali	Registration, marketing, respond to PPM tenders; distribution possible via the same group' extensive work beyond Mali	Registration, marketing, respond to PPM tenders (no distribution, probably no work beyond Mali)	Registration, work with PPM, subcontract private sector distributor (no marketing need [social] marketing firm to complement)
Good reputation	YES for previous social marketing firm; current firm is recent	Probably YES	Probably YES, recommended by Medicines for Malaria Venture (MMV)	Probably YES, recommended by PSI	Excellent for years
Sensitization to "social" products	YES, social marketing firm previously	± provides anti TB to the PPM	± provides antiTB and antiretrovirals (ARVs) to the PPM	YES, working with PSI	YES, "Not-for-profit" supplier
Recommended by	IntraHealth; PSI (worked with PSI with social marketing firm); MSH; many partners	Dr. Sanogo UbiPharm; Dr. Fatoumata Diallo, MSH	MMV; agent of many large international pharmas	PSI	Many NGOs and multilateral organizations as customers
Many years in the business	± NO for this company (2010), YES for Social marketing firm	± (2005)	>20 years for the group	± NO for this company (2010), YES in the field (1995)	YES (1972)
Experience with registration	30 products over the years	40 products over the years	40 products per year	± not with current firm, YES previously (long time ago)	YES, many products each year
Successfully works with PPM	± NO with current company, yes for social marketing firm previously	YES, successfully respond to tenders; provided anti-TB in 2011–12	YES, antibiotics, ARVs, etc.	± NO with current company, YES previously	YES

Institution Name	Centrale d'Achat des Génériques (CADG)	Wasulu Pharma	Ethica	Hinane Santé	IDA Foundation
Will develop the private market	YES	YES	YES	YES	NO, recommend social marketing firm
Communicates with reproductive health (RH) providers	YES for Protec emergency contraception and Ferravit, no uterotonic	YES for non-specialized products, no uterotonic	YES, multiple products, no uterotonic	YES for AB, oflox, rocythromycine, and clomifène and ovules previously, no uterotonic	NO (no communication)
Licenses to import	YES	NO	NO (YES Laborex)	NO	YES
Has cold storage/ transport	Uses Laborex/ Ubipharm structure	NA (no distribution)	Works with all distributors who do have these	NA	NA (works with central pharmacies who do distribution)
Large geo distribution in Mali			Entire country except North	Entire country	NA
Will develop into other francophone African countries	± excellent contacts in social marketing in BF[19] and Senegal, where he would start, yet needs to focus on current company	± he wants to but has not started to do it yet, one of his key drivers for this project	YES, present in 14 countries	± he wants to, but has not started to do it yet and needs to focus on his start-up	YES

POTENTIAL SCENARIOS FOR NATIONAL COMMERCIALIZATION

There are four potential scenarios for OiU commercialization with short-listed agents who are responsible for various activities (see Table 6). For example, in Scenario 1, CADG would conduct all activities including facilitating registration, PPM procurement, marketing and private sector distribution, and could also facilitate possible expansion beyond Mali. Another option would be to adopt Scenario 3, with the IDA Foundation facilitating registration and public sector procurement not only in Mali but in several countries (their main strength). However, the IDA Foundation would need to hire a marketing firm to complement development of the private sector market and may need to subcontract with a distributor for private sector distribution.

[19] Burkina Faso.

Table 6. Four Potential Scenarios for Commercialization of OiU in Mali

	Facilitates Registration	Facilitates PPM Procurement	Does Marketing Communication	Distributes to Private Sector	Expands beyond Mali
Scenario 1: CADG	✔	✔	✔	✔	✔
Scenario 2: Ethica	✔	✔	✔	+ private distributor (Laborex[20])	✔
Scenario 3: IDA Foundation	✔	✔	Need (social) marketing firm	± May subcontract	✔
Scenario 4: Wasulu Hinane	✔	✔	✔	+ private distributor (Laborex, Ubipharm)	✔

[20] Laborex is an affiliate of Eurapharma, itself the parent company of Ethica; hence the private sector distribution may be undertaken by a single group if working with Ethica/Eurapharma.

Beyond Mali

Commercialization beyond Mali and regional scale-up appear critical to facilitate OiU sustainability and increase impact on maternal health. Economies of scale with a regional approach would allow decreased production and registration costs, as well as increased advocacy and visibility, in turn facilitating demand and health impact. AMTSL with oxytocin for the prevention of PPH has been validated in the region, and HCPs regard OiU very favorably. Although the personnel authorized to use oxytocin for prevention or treatment of PPH vary from country to country, regional implementation may be a key tool to increasing access to oxytocin and reducing maternal deaths from PPH. In some but not all of the countries, OiU may be administered in the context of PPH prevention either by TBAs or matrones during births occurring outside of the facility. A possible commercialization scenario involves working with the IDA Foundation to facilitate registration and public sector procurement, complemented by a marketing firm such as Ethica/Propharmed to develop the private market. Organisation Ouest Africaine de la Santé (OOAS – West African Health Organization) and UNFPA may support OiU introduction via advocacy and sensitization, funding and/or pooled procurement.

The context appears favorable as:

- **AMTSL with oxytocin for the prevention of PPH has been validated** in the West African region, and countries have been recommended to implement it. Some West African countries beyond Mali where AMTSL implementation is well on the way include Benin, Burkina Faso, Niger, Senegal and Togo.
- HCPs represented by the Fédération des associations de sages-femmes d'Afrique du Centre et de l'Ouest (FASFACO), the OOAS and Pr. Dolo, President of the Malian Society for Obstetrics and Gynecology, are strongly in favor of OiU regional implementation. They believe that OiU may be a key tool to facilitate reaching the MDG 5 aiming to reduce maternal deaths, by increasing access to oxytocin for prevention and/or treatment of PPH. A large number of births are attended by *matrones* or community-based birth attendants in the region today,[21] and as oxytocin administration is easier with OiU, it would facilitate oxytocin administration in the context of PPH prevention—either as a part of AMTSL or as part of third stage management without controlled cord traction (CCT). Although birth attendants not considered "skilled" are generally not authorized to inject any products, there appears to be a favorable context for authorizing them to inject oxytocin in the Uniject device in the context of PPH prevention during the third stage of labor. The FASFACO, represented by Mrs. Marième Fall, the Executive Secretary, has been instrumental in promoting routine use of AMTSL.
- From a funding perspective, UNFPA and USAID, and possibly the Japan International Cooperation Agency (JICA), appear favorable to introduction of OiU and may support product procurement, advocacy or pilot projects using OiU. In addition, OOAS works with the 15 countries of the Economic Community Of West African States (ECOWAS/CEDEAO - *Communauté Economique des Etats de l'Afrique de l'Ouest*), and may contribute to OiU implementation via advocacy, and possibly pooled procurement as they are currently doing for contraceptives. OOAS provided a strong support for TT in Uniject® campaigns. It is important to note that there are some commonalities with Depo-Provera that is in the process of being commercialized by Pfizer in Africa; both products have similar buyers, HCP and policymakers targets, and they provide a significant advantage, but their higher cost is a barrier to demand.

[21] Source : Fédération des associations de sages-femmes d'Afrique du Centre et de l'Ouest.

A possible commercialization scenario follows: The IDA Foundation would primarily work with central pharmacies and MOHs to facilitate registration and public sector procurement in several countries within the region, as well as manage local stocks. In addition, the IDA Foundation would subcontract with a private sector distributor because the private sector market needs to be developed in parallel to increase access and decrease the risk of stock-outs. Professional associations, MOHs and partners would advocate and sensitize at national, regional and global levels. In addition, a marketing firm such as Ethica, or a social marketing firm such as PSI or Ademas in Senegal (http://www.ademas.sn/), may provide scientific information and contribute to the development of the private sector market. Moreover, the IDA Foundation selects the best-positioned manufacturers with regard to price and to quality; it already works with Gland Pharma for other products, and it could work with BIOL and/or possibly Gland Pharma if warranted and if there is the prospect of large volume demands. Three possible commercialization scenarios follow in Table 7 below.

Table 7. Three Potential Scenarios for Regional Commercialization of OiU

	Facilitate Registration	Facilitate Public Sector Procurement	Communication Marketing	Distribute to Private Sector
Scenario 1:	IDA Foundation	IDA Foundation	Ethica/ Propharmed	+ IDA Foundation subcontracts or Laborex group
Scenario 2	IDA Foundation	IDA Foundation	PSI/Other social marketing firm	+ IDA Foundation subcontracts
Scenario 3	Ethica/ Propharmed	± Ethica/ Propharmed	Ethica/ Propharmed	+ Laborex group
In addition				
OOAS		Pooled procurement	Regional advocacy	
UNFPA	▪ MOH communication and advocacy ▪ Procurement support ▪ Pilot project funding			

Overviews of the IDA Foundation and Ethica/Propharmed may be found in Appendices G and H respectively.

Recommendations

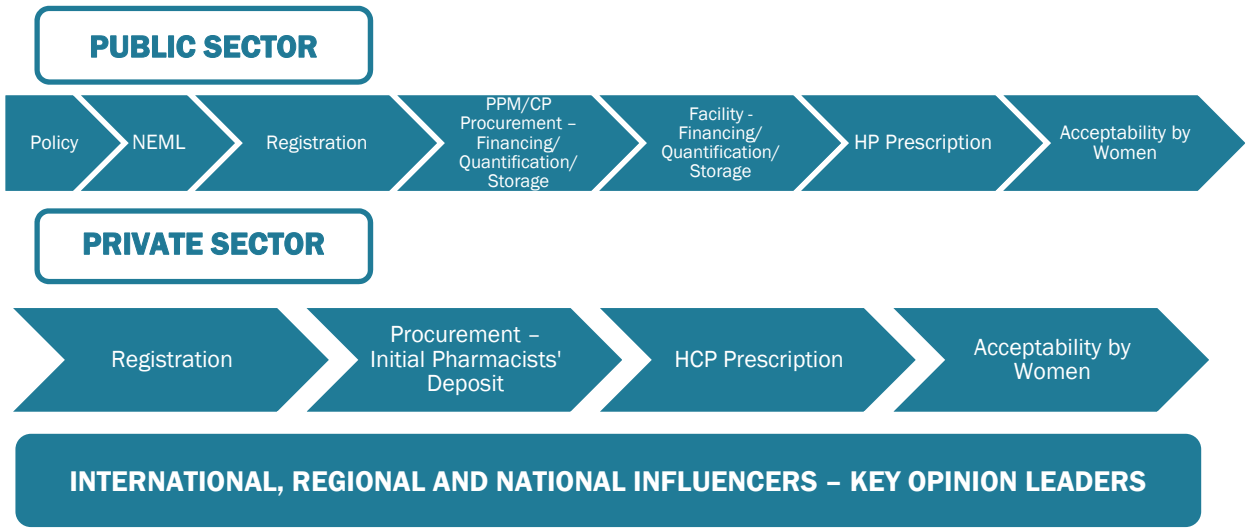
OiU's unique administration system allows oxytocin administration where it would not be possible without the Uniject® device, and may therefore be a key tool to decrease maternal death related to PPH by increasing uterotonic protection either as part of AMTSL or as part of management of the third stage of labor without CCT, and increasing access to oxytocin for treatment of PPH when prevention has failed.

Because of the potential to increase impact on maternal health and improve sustainability of the product with larger volumes and lower costs, a parallel introduction at the regional level is highly recommended.

ACCESS FLOWCHART

Figure 1 summarizes OiU access requirements in Mali and in the region.

Figure 1. Public and Private Sector Requirements for OiU Access



RECOMMENDATIONS FOR OIU INTRODUCTION IN MALI

Dr. Alfred Dembélé, CADG, appears to have all of the qualifications necessary to facilitate the commercialization of OiU in Mali, particularly in the public sector. In addition, he comes highly recommended by several partners including PSI and IntraHealth International, and seems interested in the project. The following steps describe the activities required to facilitate OiU introduction in Mali, which will take some time. Given the current political instability in Mali, moving forward to register and distribute OiU will depend on authorization of the USAID Mission in Mali. It may be possible to move forward immediately with certain activities in spite of the political problems. If so, this would facilitate introduction of OiU when a new government is in place.

1. **Register the product.** Mr. Sékou Dembélé, head of the DPM registration division, and Mr. Drissa Traoré, delegated by the DPM, are expecting the OiU dossier to begin the registration process. Dr. Alfred Dembélé, CADG, the recommended agent, has facilitated more than 30 product registrations over the years in Mali.

2. **Facilitate procurement by the PPM and private sector distribution: availability in both sectors is important to increase access and decrease the risk of stock-out.** Dr. Dembélé has been working closely with the PPM for many years with his social marketing

company. Direct mutual agreement would be best with OiU as it is a unique product, with a different price compared to that of oxytocin in ampoules. With regard to private sector distribution, CADG appears to have all of the necessary licenses to import and either distribute or sub-contract with international distributors when relevant.

3. **Provide scientific information to contribute to creating demand.** Providing scientific information to HCPs about this new product is critical to creating demand and a market for the product. Most HCPs work in both the public and private sectors, hence there are strong linkages between both sectors and it is key to have the product available in both. In addition, for HCPs, community health workers or *matrones* to use OiU in a CSCom, the product has to be ordered by the manager and approved by the "Association de Santé Communautaires" (ASACO). It is therefore essential to also inform health committee members about this new product. CADG seems well positioned to do that, given Dr. Dembélé's past experience working with HCPs in reproductive health through his social marketing firm, and currently with emergency contraception and other drugs in CADG's portfolio targeted at obstetrician/gynecologists and midwives.

4. **Facilitate the following key activities:** *Although not within the scope of this work that is focused on registration and distribution, the following activities are key and should be facilitated:*
   - **Advocate both at national and regional levels:** OiU's unique presentation allows oxytocin administration where it may otherwise not be possible without Uniject® and the addition of the TTI assures quality of the product. It may therefore be a key tool to decrease maternal death related to PPH by increasing uterotonic protection during third stage of labor and access to oxytocin for immediate treatment of PPH. It is therefore important to continue advocating to the MOH and all stakeholders influencing policy to promote use of uterotonic drugs by **trained** community health TBAs or *matrones*. Moreover, training and sensitization about the value of OiU for increasing access to uterotonic drugs for the prevention and treatment of PPH should involve all public, private for- and not-for profit structures and HCPs.
   - **Determine who will finance the product and its introduction activities:** USAID and UNFPA have been the key partners, but other bilateral donor agencies may also be interested in procuring OiU for their districts.
   - **Strengthen the existing uterotonic drug supply chain management** and monitoring.
   - **Revise the NEML** during a technical consensus meeting to reconcile it with current policies and practices. The specification of a pre-filled injection device for oxytocin administration would be best, although it is not essential.

5. **Although it is possible to differentiate the product into a branded product and a generic product, with different prices, it may be best to have a single name to increase brand recognition and thus facilitate market creation;** that strategy should be tested. Sanofi Aventis, for instance, differentiated Artesunate Amodiaquine as ASAQ Winthrop®, generic in the public sector, and Coarsucam®, the branded product in the private sector, with significantly different prices. However, patients are not aware that it is the same product and that may contribute to Coarsucam® sales being relatively limited in the private sector despite this artemisinin combination therapy being a WHO-recommended, quality-assured anti-malarial available in pediatric formulation and dosage.

RECOMMENDATIONS FOR OIU REGIONAL INTRODUCTION

For the reasons mentioned above (i.e., increased impact on maternal health and better sustainability of the product), a regional introduction is highly recommended. To complement work by Dr. Alfred Dembélé to introduce OiU in Mali, the IDA Foundation, for instance, may be an excellent partner for a regional introduction outside of Mali, complemented by a marketing firm such as Ethica/Propharmed. At the regional level, the following activities are recommended:

1. Review current studies and gaps for scaled oxytocin use in other countries in the region, and evaluate where birth attendants not considered "skilled" are currently or could potentially be authorized to administer oxytocin for prevention and/or treatment of PPH and could therefore potentially use OiU. Work with the MOH, obstetrician/gynecologists, midwives and other stakeholders to understand the context, scope of work of birth attendants not considered "skilled," and in particular, current policies regarding which cadres are authorized to inject oxytocin and at which points of care.

2. In those countries where OiU may be used, evaluate the interest and, as relevant, engage the MOH reproductive health department representatives to plan for OiU introduction. Beyond Mali, those countries may be Benin, Burkina Faso, Niger, Senegal and/or Togo.

3. Conduct a regional workshop with the MOHs/reproductive health department representatives, midwives, obstetrician/gynecologists and other HCP associations, as well as other important national and international stakeholders, to share best practices with regard to use of oxytocin for prevention and treatment of PPH, and the role of OiU in increasing access to oxytocin. The West and Central African Confederation of Midwives, and their Secretary General, Mrs. Fall, may be a key partner to facilitate OiU introduction in the region.

4. If relevant, set up or strengthen an existing regional working group to facilitate OiU introduction in the context of PPH prevention in the community and/or the most peripheral health care facilities.

5. If/when ready to work at the regional level, facilitate country-by-country registration and public sector procurement, possibly through the IDA Foundation, which will subcontract with another organization for private sector distribution. Registration is necessary in each individual country, and the product may be launched in the private sector once approved by a handful of countries. For public sector procurement, direct mutual agreement between national central pharmacies and BIOL may be feasible because OiU is a unique, pre-filled syringe system.

6. Demand needs to be stimulated because the product is new and insufficiently known: Assess various options to communicate to HCPs, and simultaneously develop the private sector market either through a marketing firm such as Ethica/Propharmed, or a social marketing firm such as PSI. As in Mali, there may be a strong potential demand for the product in the private sector, and developing it is critical, given the strong links between the public and private sectors and the fact that many providers work in both sectors. Indeed, supplying to both public and private sectors is important to increase access and decrease the risk of stock-out.

7. It will be essential to develop a solid business case demonstrating the positive aspects of such a venture for the private sector partner, with a clear demand forecast.

8. With partners, sensitize and advocate at national, regional and global levels to facilitate a positive environment for oxytocin use for the prevention of PPH and the role of OiU in increasing access to oxytocin. Nationally, contribute to information, education and sensitization of health professionals and communities, possibly through women's associations. In addition, engage regional political leaders and health professional associations using existing networks, as a means of communicating the message to country governments. Internationally, it would be relevant to engage the UN Commission on Life-Saving Commodities[22] to include OiU along with oxytocin in ampoules in their portfolio. Catharine Taylor from PATH is the co-chair of the innovation working group and is therefore well-positioned to bring the focus onto OiU. This commission aims to "advocate at the highest levels to catalyze change in the way essential but under-used commodities for women's and children's health are produced, distributed and used."

9. **Evaluate and engage other potential partners as relevant:**
   - **Other regional policymakers/influencer organizations, with a lead role for WHO. OOAS** appeared supportive and may contribute with advocacy, policy work or pooled procurement.
   - The regional association of central pharmacies (Association des Centrales d'Achats Africaines de Médicaments Essentiels - ACAME) as well as pharmacists who are active in their professional associations.
   - Procurement and funding agencies committed to maternal health and willing to support these efforts: UNFPA, USAID, and other bilaterals. UNICEF may support demonstration projects to show evidence of OiU use by non-skilled birth attendants as well as facilitate use by SBAs and inclusion of OiU on the list of commodities being assessed by the UN Commission on lifesaving commodities.

10. WHO Pre-Qualification, although not compulsory, would certainly be favorable, facilitating procurement by international buyers.

In addition, PATH may want to conduct the same analysis in Asian countries such as Bangladesh or Nepal, where birth attendants not considered "skilled" are providing advanced maternal care and may potentially use OiU.

[22] http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities accessed on 4/30/12; "As part of the *Every Woman Every Child* movement and efforts to meet the health-related Millennium Development Goals, the Commission will champion efforts to reduce barriers that block access to essential health commodities."

Conclusion and Next Steps

OiU has some unique characteristics that would allow extending oxytocin use for prevention and treatment of PPH where it is otherwise not possible, thus contributing to the reduction of postpartum hemorrhage and, consequently, maternal death. The overall context is favorable for introduction of OiU in Mali. If the USAID Mission in Mali approves, given the current political instability, it may be relevant to hire an agent and start the OiU commercialization activities now in order to be ready to introduce the product when a new government is in place. The agent selected will file for registration and start working with the MOH and the PPM to facilitate public sector procurement, if possible by mutual agreement. In parallel, the agent will develop a strategy to inform HCPs and develop the private sector market.

In addition, given the increased potential impact on maternal health, the economies of scale and better sustainability with a regional OiU introduction, it would be relevant to complement this preliminary analysis with an evaluation of the regional market readiness and commercialization options. Such an analysis should include a review of current studies and gaps for scaled use, of the national interest in selected key countries and of the commercialization options. One commercialization scenario may involve the IDA Foundation facilitating registration and public sector procurement, complemented by a (social) marketing firm to develop the private sector market.

According to B. Waning,[23] two elements were instrumental in improving the availability of new pediatric ARV formulations and reducing prices: **sensitization/advocacy** and **positive business case/financials** with clarity on demand. She stressed that dialogue was critical: with countries to decrease barriers such as policy barriers, with manufacturers to increase their willingness to develop products that meet local needs, with donors and partners to provide support. Whether OiU is introduced in Mali or in the region, **product awareness and favorable policies are critical to a sustainable demand, which is in and of itself essential to OiU success. Engaging the UN Commission on Life-Saving Commodities to include OiU in their portfolio would be highly relevant.**

Facilitating a dual public and private sector market is important to increase access and decrease the risk of stock-out. For the public sector, focus will be on OiU use where oxytocin ampoules cannot be used—for prevention in the community by authorized and **trained** TBAs or *matrones*, and, in facilities, in situations where BAs are alone when attending a birth, in emergencies or when there is a stock-out of oxytocin in ampoules. The support of the Maternal and Child Health Integrated Program (MCHIP) and partners to advocate for and sensitize key stakeholders about the importance of oxytocin and the role OiU can play to increase access to oxytocin to prevent PPH will be paramount to OiU's introduction and success.

[23] B. Waning, 2010, Evidence from the ARV field accessed on 15/2/12 at: http://www.mmv.org/sites/default/files/uploads/docs/events/ASTMH2010/2_Brenda_Waning.pdf.

Interviewees – Contacts

MALI

Institution	Contact	Title	Contact information
CNOP[24]	Dr. Doumbia Abdou	President	pharmacielassin@yahoo.fr
CoPharma	Dr. Adama Asonogo	Procurement Head	asanogo@copharma.com.ml
DPM	Pr. Ousmane Doumbia	Director	dpm@dirpharma.org
	Dr. Sékou Dembélé	Head, Regulatory Division	dembele_sekou@yahoo.fr
	Dr. D Touré	RH focal person	segatoure@yahoo.fr
	Mr. Drissa Traoré	Focal person for OiU registration	drissatraore53@yahoo.fr
Hal Point G	Pr. Dolo	Head, Ob/Gyn Department – Pdt Ob/Gyn Association	(223) 66 75 02 95
IntraHealth International	Dr. Cheick Touré	Country Director	ctoure@intrahealth.org
Malian Midwives' Association	Ms. Dicko Fatimata Maïga	President	sdicko@yahoo.fr
MOH	Dr. Binta Keita	Chief Division of Reproductive Health, DOH, MOH	bintakeita11@yahoo.fr
MSH	Dr. Fatoumata Diallo	Senior Technical Advisor	fdiallo@msh.org
	Dr. Sangare Abdoul	Manager	asangare@msh.org
PPM	Dr. Aicha Guindo	Director	(223) 20 22 50 59
	Dr. Adama Dembélé	Procurement Head	docdembele@hotmail.com
PSI	Dr. Rodio Diallo	Country Representative	rdiallo@psimali.org
Save the children	Dr. Houleymata Diarra	USAID /MCHIP Mali Chief of Party	hdiarra@savechildren.org
WHO	Dr. M. Maiga	EMP NPO	maigam@ml.afro.who.int
WHO - RH	Dr. Fatouma Tessougué	MPS NPO	tessouguef@ml.afro.who.int

Potential agents' contact information is provided in Appendices C-H.

REGIONAL AND GLOBAL CONTACTS

Institution	Contact	Title	Contact information
Ethica	Mr. Charly Kourouma	Africa Regional Manager	charly@orange.sn
IDA Foundation	Mr. Nicolas Bablon	Africa Regional Manager	nbablon@idafoundation.org
ANFES – Senegal Midwives Association	Ms. Marième Fall	President	mariemefallsr@hotmail.fr
OOAS	Dr. Aicha ADO – BOUWAYE	Head, Maternal Health Division	abouwaye@wahooas.org

[24] National Pharmacists Association.

Institution	Contact	Title	Contact information
UNICEF	Mr. Francisco Blanco, Ms. Caroline Damour, Ms. Kim Dickson, Ms. Helene Moller	Supply and Maternal & Child Health divisions	fblanco@unicef.org cdamour@unicef.org kdickson@unicef.org hmoller@unicef.org
UNFPA[25]	Dr. Luc de Bernis	Senior Maternal Health Advisor	debernis@unfpa.org

[25] The local Mali UNFPA person could not be contacted during this mission.

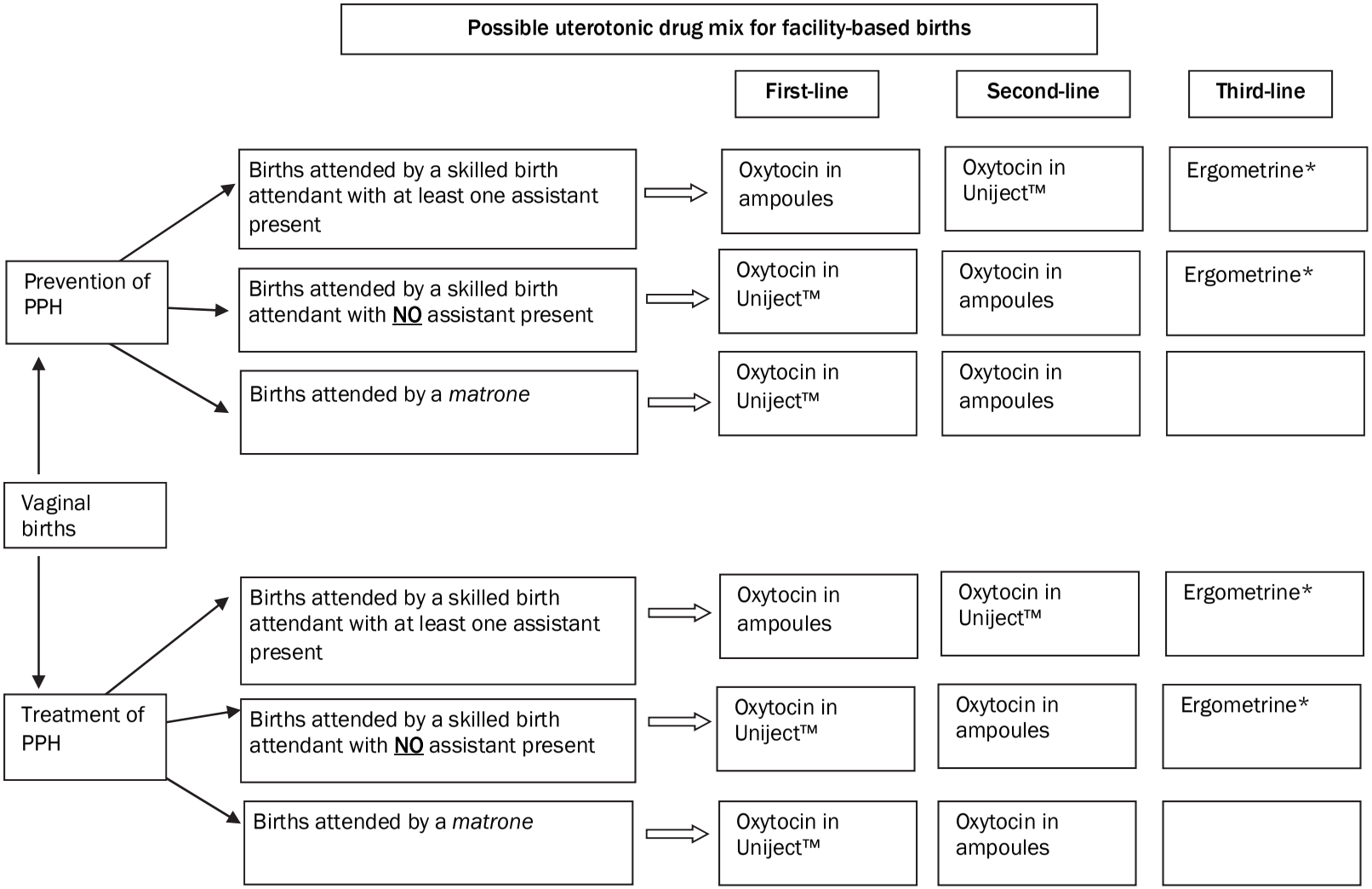
Appendices

APPENDIX A. REFERENCE DOCUMENTS

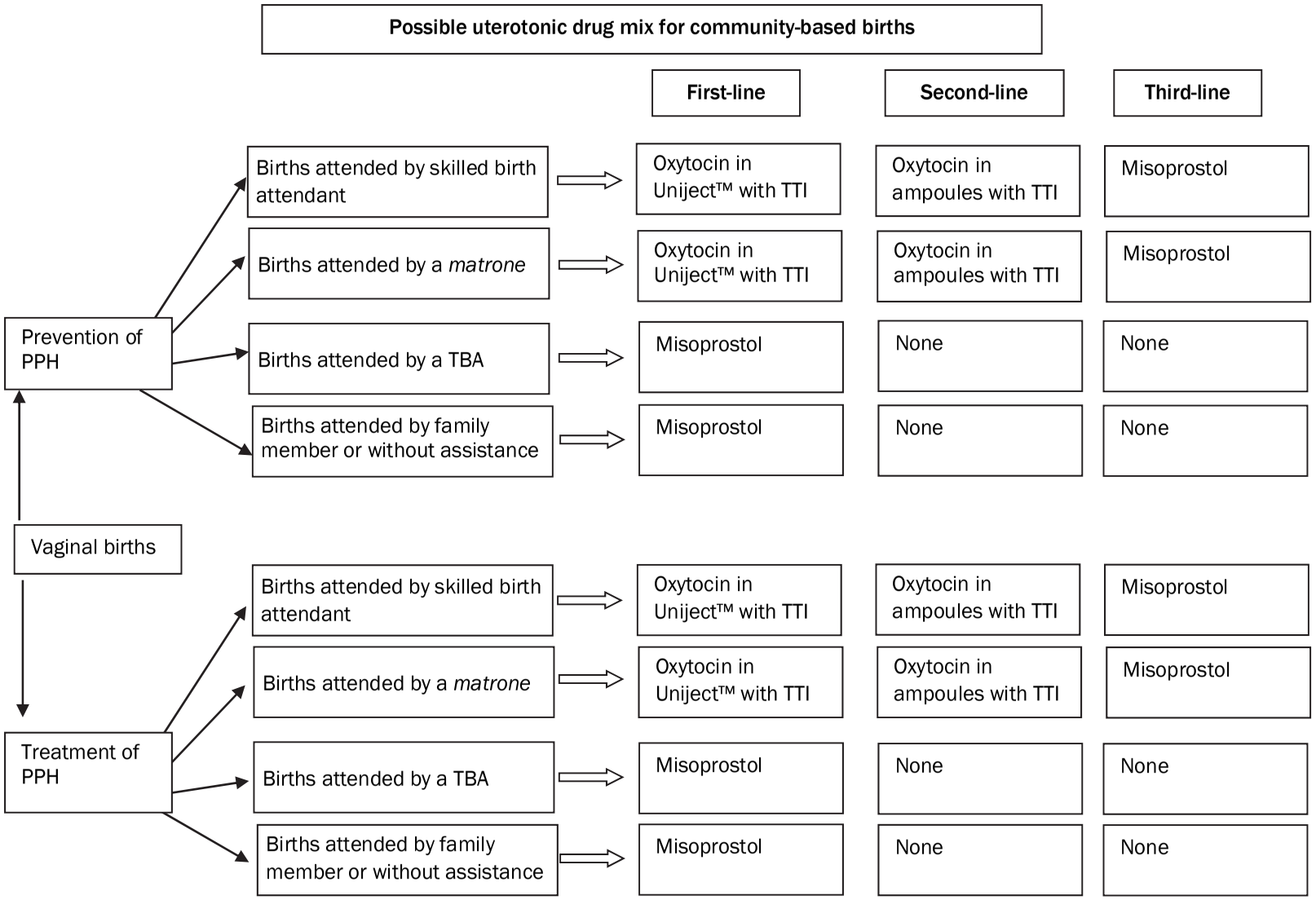
1. Manuel de procédures pour l'enregistrement des médicaments multi sources (Guide for registering medications in Mali with reference to the MOH "Arrêté interministeriel 05-2203" from 20/9/05):
   http://www.who.int/medicines/areas/coordination/mali_registration_multisource.pdf

2. Common Technical Dossiers proposed for UEMOA countries
   http://www.uemoa.int/Documents/Actes/Reg_06_2010_CM_UEMOA.pdf /
   http://www.uemoa.int/Documents/Actes/Dec_08_2010_CM_UEMOA.pdf /

APPENDIX B. POSSIBLE UTEROTONIC DRUG MIX FOR FACILITY- AND COMMUNITY-BASED BIRTHS



*Ergometrine is contraindicated in women with hypertension.


Possible uterotonic drug mix for community-based births
First-line
Second-line
Third-line
Prevention of PPH
Births attended by skilled birth attendant
Oxytocin in Uniject™ with TTI
Oxytocin in ampoules with TTI
Misoprostol
Births attended by a matrone
Oxytocin in Uniject™ with TTI
Oxytocin in ampoules with TTI
Misoprostol
Births attended by a TBA
Misoprostol
None
None
Births attended by family member or without assistance
Misoprostol
None
None
Vaginal births
Treatment of PPH
Births attended by skilled birth attendant
Oxytocin in Uniject™ with TTI
Oxytocin in ampoules with TTI
Misoprostol
Births attended by a matrone
Oxytocin in Uniject™ with TTI
Oxytocin in ampoules with TTI
Misoprostol
Births attended by a TBA
Misoprostol
None
None
Births attended by family member or without assistance
Misoprostol
None
None

APPENDIX C. CADG – DR. ALFRED DEMBELE

Institution Name	CADG (Centrale d'Achat des Génériques)
Contact	**Dr. Alfred Dembélé**
Good reputation	Very good
Sensitization to "social" products	Social marketing firm previously; dissolution in progress
Recommended by	Ms. Rodio Diallo, PSI; Dr. Dembélé, head registration at DPM; Dr. Touré, IntraHealth. Network is key in Mali; CADG is very well recognized
Created	2010
2011 Turn Over (million FrCFA)	50
No. of Employees	10 sales reps, organized by area, as Mali is vast
Experience with registration	Registered 30 products for IPCA, MSR Lab, PSI Mali + special import authorizations for PSI Mali
Registration strategy	CADG has their name as the Mali contact
License to import	Yes
Successfully works with PPM	In the past, not with new company. He wants to do it, fulfills all criteria to respond to tenders. PM would then purchase directly from BIOL
Strategy to work with PPM	Tenders
Will develop the private market	Will inform obstetrician/gynecologists, midwives, nurses, *matrones* and place sales reps; will need some support for documents, initial stock and communication
Has cold storage	800 m^2storage, including cold room that needs to be equipped; currently uses fridges for cold; agreement with Laborex-UbiPharm. CADG does storage, stock management, etc.
Transport /cold transport	Works with Laborex–Ubipharm, main international distributors, for the transport, i.e., agreement to use their infrastructure. Otherwise ice boxes, no cold truck currently
Has other RH products	Protec emergency contraception and Ferravit; worked in that area with social marketing firm; provided training to GAPTA. No uterotonic in his portfolio
Will develop into other African countries	Did a lot of social marketing in Burkina Faso and Senegal, could easily develop the project there with contacts; easy to do as there are regional agreements, but requires sales force and needs to focus on Mali as he is starting
List of products managed	MSR Lab products = Ferravit sp (Vit B12+Zinc); Croiscard (Ca +Vit D3); Protec (emergency contraception pill); Lumate forte (AL); Palmather (artemether)
Phone	223 66 72 16 06
E mail	alfreddembele@yahoo.fr

APPENDIX D. WASULU PHARMA – MR. SOUMAILA DIALLO

Institution Name	Wasulu Pharma
Contact	**Mr. Soumaila Diallo**
Good reputation	Probably yes
Sensitization to "social" products	± provides anti TB to the PPM
Recommended by	Dr. Sanogo UbiPharm; Dr. Fatoumata Diallo, MSH
Created	2005
2011 turnover	600 million FrCFA
No. of employees	11 sales reps, exclusive by pharma company
Experience with registration	Registered 40 products over the years
Registration strategy	Suggests a temporary authorization while waiting for the market approval
License to import	No, filed for authorizations, only imports "para pharmacy"
Sucessfully works with PPM	Yes, since 2005; provided anti TB drugs to PPM in 2011–12; Responds to tenders and then PPM orders directly to pharma company (McLeods – Phyto Riker generics from Ghana)
Strategy to work with PPM	Tenders
Will develop the private market	**Since his sales reps are exclusive per company, he would promote OiU himself.** Would start with larger private health centers. Initial DPAV (Supplies are not paid for until after they are sold, and unsold inventories are the property of the manufacturer)
Has cold storage	NA
Transport/cold transport	NA
Communicates with RH providers	Already visits the RH providers for magnesium sulfate; no uterotonic in his portfolio
Will develop into other African countries	Wants to, that is his main driver for this project; however, he has not started yet
List of products managed	Represents McLeods, Planete Pharma, Cooper France, Tablets India Ltd.
Fees	Either % of sales + expenses reimbursement, or fixed fees
Phone	(223) 20280160
E mail	wasulu_pharma@yahoo.fr

APPENDIX E. HINANE SANTE – DR. AMADOU CISSÉ

Institution Name	Hinane Santé
Contact	**Dr. Amadou Cisse**
Good reputation	Yes
Sensitization to "social" products	2 common projects with PSI
Recommended by	PSI Rodio Diallo
Created	1995 in that pharmaceutical field, 2010 for this organization
2011 turnover (FrCFA)	Information not available
No. of employees	Four sales reps
Experience with registration	No, only took products already authorized; registered Exphar products previously
Registration strategy	
License to import	No
Successfully works with PPM	Previously, long time ago, not with current company
Strategy to work with PPM	Respond to tenders and PPM to procure directly from BIOL
Will develop the private market	Yes, will start with large symposium, Initial DPAV.
Has cold storage	No,- distributors do
Transport/cold transport	No, distributors do
Communicates with RH providers	AB, oflox, rocythromycine, clomifène, and ovules in the past; no uterotonic in his portfolio
Will develop into other African countries	Theoretical interest, one country at a time, but it is too early as he is starting his company
List of products managed	Antimalarials ASAQ, QUININE ASP; antibiotics; antihypertensive; gynec (did not want to mention the companies); for PSI: Plan B and Confiance®
Fees	Not discussed
Phone	(223) 66 79 55 64
E mail	hinanesante@yahoo.fr

APPENDIX F. ETHICA – MR. DJINGUINTA CAMARA

Institution Name	Ethica
Contact	**Mr. Djinguinta Camara**
Good reputation	Yes
Sensitization to "social" products	± as he provides antibiotics and ARVs to the PPM
Recommended by	MMV
Created	>20 years ago
2011 Turn Over (FrCFA)	
# employees	32 sales reps in Mali + country director
Experience with registration	40 products per year; is at DPM 2 times/week
Registration strategy	
License to import	No, a distributor would, Laborex in the same group
Successfully works with PPM	Yes, example: antibiotics, ARVs, Perfalgan
Strategy to work with PPM	Responds to tenders, follows orders; PPM imports directly
Will develop the private market: comm	Yes, Promotion with both public + private sector providers
Has cold storage	No, distributor
Transport/cold transport	No, distributor
Has other RH products	Multiple for Bayer, Pfizer, others; no uterotonic
Will develop into other African countries	14 countries in the western and central Africa region
List of products managed	Multiple
Phone	(223) 76 21 51 04
E mail	djiguintaca@yahoo.fr

APPENDIX G. IDA FOUNDATION – MR. NICOLAS BABLON

Institution Name	IDA
Contact	**Mr. Nicolas Bablon**
Recommended by	Most NGOs, multilateral organizations are clients
Created	1972 (HQ)
2011 Turn Over (FrCFA)	210M US$ (global)
# employees	155 (worldwide)
Experience with registration	Yes
Registration strategy	Assists BIOL or registers a product as own product
License to import	Yes
Successfully works with PPM	They "guide through every step of the supply chain" – Work with MOH directly
Strategy to work with PPM	Recommends mutual agreement rather than tenders
Will develop the private market	No, another organization is necessary
Has cold storage	NA – would subcontract distribution
Transport/cold transport	NA – would subcontract distribution
Has other RH products	Yes – no conflict of interest
Will develop into other African countries	100 countries worldwide, 63% of business in Africa, regional office in Nigeria; may do a supply agreement for several countries
List of products managed	3000 products
Phone	(31) 20 403 71 44
E mail	nbablon@idafoundation.org

http://www.idafoundation.org/fileadmin/user_upload/Documenten/PDF/Product_Library/IdaFoundation_EN_DEF.pdf

APPENDIX H. ETHICA/PROPHARMED – MR. CHARLY KOUROUMA

Institution Name	Ethica/Propharmed (Eurapharma Group)
Contact	**Mr. Charly Kourouma**
Activities	▪ Communication/marketing with HCP ▪ Can also facilitate as needed: ▪ Registration ▪ Public sector procurement ▪ And/or private sector distribution via the Laborex affiliate
Good reputation	Represents large pharmas such as Novartis, Pfizer, Bayer, Merck on an exclusive basis in addition to smaller firms "multi cards"(> 15 labs)
Sensitization to "social" products	Facilitate public sector procurement of ARVs and works with public sector HCPs, for instance with ob/gyn products
Recommended by	MMV
Many years in the business	>20 years – Parent company: Eurapharma includes Laborex group: 50% of pharmaceutical wholesale market in Africa and marketing services via Ethica/Propharmed
Experience with registration	1,000 products per year
Successfully works with central pharmacies	Facilitate public sector procurement of ARVs and antibiotics
Will develop the private market	Yes, in 14 francophone Africa countries
Communicates with RH providers	Yes, OiU would be grouped with other small pharma gynecological products, e.g., Utrogestan®, Progestogel®
Licenses to import	Via Laborex, affiliate of Eurapharma group
Has cold storage/transport	Yes, Laborex
Large coverage in the region	14 countries – 350 to 400 sales reps
E mail	charly@orange.sn