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Mann Global Health

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# Landscape Assessment: Leveraging the role of national distributors to increase access to MA combi-packs in Africa

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# Executive Summary

An estimated 56 million abortions occur each year, and more than half of them are unsafe.[1] Medical Abortion (MA) using a combination of mifepristone and misoprostol is a safe and effective alternative to surgical abortion. It is non-invasive, with fewer side effects and fewer provider visits, and, with the ability to be completed at home, is a game changer for women's health. While MA is a low-risk regimen that can be managed by different levels of healthcare providers and patients, few countries in sub-Saharan Africa have made MA combi-packs accessible to women. National commercial distributors are improving access to this important product, and have the potential to do so in a more sustainable way in the future. Market development that enables and fosters commercial distribution is necessary in order to maintain a sustainable and diverse supply of the highest quality MA products so that women have options for safe, effective abortions.

The purpose of this landscape assessment is to provide the Reproductive Health Supplies Coalition (RHSC) with a better understanding of the current challenges and opportunities for engaging nationally-based commercial distributors to introduce, register, and/or distribute medical abortion (MA) combi-packs in select sub-Saharan African countries. Mann Global Health (MGH) was contracted by the RHSC to undertake this assessment in partnership with Marie Stopes International (MSI) and WCG Cares. Based on an initial desk review and discussions with partners, we developed a 10-country list and segmented countries for different levels of assessment: Deep Dive: Burkina Faso, Senegal, Uganda, Zambia; Remote Interviews: Ethiopia, Malawi, Mali, Sierra Leone; Limited Assessment: Zimbabwe and Mozambique.

## Highlights of Key Findings:

- As long as there is demand, albeit at low volumes, commercial distributors are willing to and do stock and sell medical abortion drugs, and the majority of them make a small profit doing so.

- There are commercial actors in all countries that do distribute MA -- either miso, combi-packs or both -- and several more who are potentially willing to enter the market. We did not find any distributors distributing mifepristone outside of combi-packs. The commercial companies currently distributing combi-packs add it to a host of other products they are supplying, so the fact that it is not a big profit maker, with its low volumes and margins relative to the other products they are offering, is not a serious deterrent to them. Their role in supplying MA is a largely passive one, where they make it available but do nothing to push it or grow sales.

- While there are many commercial distributors of misoprostol, we found only two countries -- Zambia and Sierra Leone -- where commercial distributors are distributing combi-packs without involvement of social marketing organizations (SMOs).

**Figure 1**

[1] Barot, S. (2018, March). *The Roadmap to Safe Abortion Worldwide: Lessons from New Global Trends on Incidence, Legality and Safety*. Retrieved from: https://www.guttmacher.org/gpr/2018/03/roadmap-safe-abortion-worldwide-lessons-new-global-trends-incidence-legality-and-safety

- Converting potential demand into actual consumer demand is a critical part of market development efforts. Yet commercial distributors we interviewed are not willing to invest in demand creation for MA because it is not profitable enough, compared to their other products. Instead they look to the SMOs for this support. Every commercial distributor we interviewed cited product detailing and promotion for MA products as absolutely necessary.

- Ex-manufacturer price was not thought to be a major issue in improving the MA market. MA is not purchased for routine or frequent use, and is only purchased when needed. Combi-pack prices, for most markets, compare favorably to other abortion options – surgical, MVA, or even traditional methods. (Note that more information on pricing and willingness to pay will be needed in intervention markets.)

- One of the obstacles to greater commercial market activity in MA is the cost of market entry. Commercial distributors view the time required for new product registration as an important barrier to introducing MA; registration costs were cited but are seen as less of a barrier. The major risk cited is the level of minimal orders and the high possibility of expiring stock in a context of relatively low demand.

- SMOs have made good headway in some MA markets, in getting products registered, detailing and training providers and retailers, and advocating for wider access to MA for women. It is this work that induced various commercial companies to start selling MA and continue to distribute it (see country reports, in Annex I). But there remains a question as to whether commercial actors need to continue to rely on SMOs as "middle men" when markets are maturing and a high level of demand has been created. Given the wide distribution channels for pharmaceutical products that commercial distributors develop and maintain, adding one or more MA products – bought and imported from the source – is feasible, if regulatory and entry barriers are reduced.

## Key Recommended Interventions

This landscape assessment should be viewed as a starting point in thinking through potential interventions. Given the limited time for the assessment, and particularly the limited time on the ground in only four of the ten countries, the landscape provides initial information on the state of the MA markets (mostly for combi-packs), general findings of strengths and weaknesses, and very preliminary recommendations for further exploration. **For a summary of country-level recommendations, please see Annex II.**

### A Note on Total Market Stewardship

As an overarching recommendation, we urge RHSC to consider supporting a stewardship role in MA markets in any country where it plans other interventions.

None of the markets we assessed had a guiding **vision** or **strategy** for how the MA market should evolve. All market actors "do their own thing" without regard to the health of the *market*, vs. the success of their own programs. With no vision of total market success for medical abortion, interventions might have unintended, negative consequences.

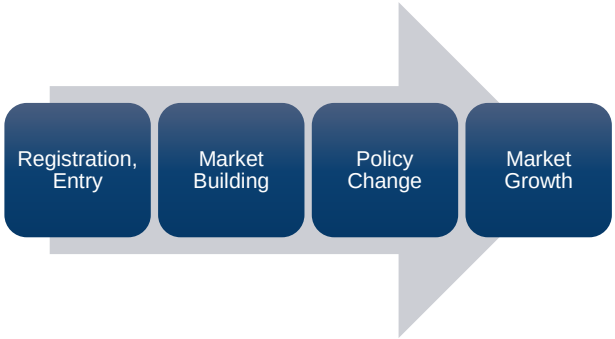
Furthermore, in none of the markets we examined was there sufficient coordination of market actors. Governments did not take the lead in stewarding the different MA implementers, and these actors were frequently unaware of what others in the same space were doing around MA. There is need for improved communications in these countries, to reduce duplication of effort, unnecessary competition, and other practices that prevent market development.

Interventions to help one type of market player (e.g., a commercial distributor) can succeed in building sustainability if that player's actions are planned and positioned within a broader, total market context.

RHSC is well placed to convene the different market actors in any given country – public sector, SMOs, NGOs, and commercial entities – and plan for steps that will improve the total market. Good total market interventions are ones that look to ensure equity, while also building sustainability. Working primarily with one type of market actor on specific market functions can potentially yield great results, as long as that work accounts for the work of other actors and other market functions.

The below interventions follow the spectrum of market development.

**Figure 2:** Spectrum of Market Development




## Registration/Market Entry

### i) Register new commercial combi-pack products.

***Where there are no combi-packs, but there is commercial capacity:*** In Malawi and possibly Zimbabwe, where there are no combi-pack products available, donors should work with commercial actors to register combi-pack products that meet international quality guidelines (such as International Conference on Harmonisation (ICH); WHO pre-qualified; Stringent Regulatory Authority-approved) at the lowest possible prices. WHO's Collaborative Procedures for Accelerated Registration should be considered if the product is WHO pre-qualified. Donors should cover the registration costs -these costs aren't significant to large commercial actors, but they do expect them to be covered.

***Where there are no combi-packs, but there is NGO or SMO capacity***: In Mali and Senegal, donors should work with NGOs or social marketing organizations (SMOs) on new combi-pack registrations, as the SMOs in these francophone countries are thought to have a higher chance of getting products registered, versus commercial registration. (Though technically, both SMOs and commercial entities can make registrations as long as they comply with the requirements (i.e.: pharmaceutical license, in-house pharmacist, etc.).) Commercial entities could then distribute the new products.

***Where SMO-registered combi-packs are available, and there is additional commercial capacity for increased sales***: Even in countries that have SMO combi-packs available, donors should work with commercial actors to register new *commercial* brands. They should prioritize countries such as in Sierra Leone, Uganda and Mozambique, and coordinate with others such as Concept Foundation (which may also be launching new brands).

**ii) Negotiate gradual release of orders in sync with demand, to mitigate major risk to commercial distributors of expired stock; Pool procurement across countries.** Donors could help provide the capital for minimum orders from manufacturers and negotiate graduated releases of stock to avoid expiry. Currently, some minimum order requirements are considered large and expiry dates relatively short, so that businesses fear being left with unsold stock, in a context of low demand.

Donors could also consider pooled procurement across countries. Manufacturers such as Naari can do one run of an order then produce different packaging for different countries. The amount of coordination and planning time for this needs careful consideration. Working across countries may also present the option of getting an "access" price, a discounted price for donor projects.

## Market Building

**iii) Donors should pick one or more locally based commercial companies and incentivize them to perform different market functions that do not currently work well.** Where regulatory rules are part of the problem in a market, various companies have the capability to handle registration as the local agent, to import and to distribute. These companies can eliminate the transaction costs of working with multiple smaller players. In other cases, it may be necessary and feasible to split registration, importation and distribution functions among different companies, and even assign some of these responsibilities to high functioning SMOs in a way that opens up commercial opportunities for market growth.

**iv) Fund SMOs with a view to supporting commercial growth and sustainability.** Donors should consider moving away from funding the long-term sales, distribution, and overhead costs of SMOs in some markets, especially where demand has risen and there are established brands. There can be hybrid coverage between SMOs or social enterprises and commercial distributors, with a planned transition to full commercial distribution, particularly in urban areas. In places where SMOs are thought to crowd out commercial players (an example mentioned was Ethiopia), there is a need to create more space for commercial activity, for competition to drive growth and quality improvements.

Donors should continue funding NGOs and SMOs for market functions where they add value, such as in product detailing, sensitizing and educating providers and pharmacists, awareness-raising at the community level, and advocacy at different levels to eliminate barriers to access. Getting providers to switch from misoprostol to combi-packs requires additional training and support.

In addition, SMOs and NGOs are best placed to reach equity goals in countries, where they help meet the needs of vulnerable populations who are not served by the commercial sector (e.g., in rural areas).

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising through local grassroot networks, so that women know about the combi-pack and where to access it, and how to get follow up support.
- Do Fund: SMO medical detailing *OR* medical detailing in-house in commercial companies *OR* a combination of the two, where SMOs second detailers to commercial companies.
- Don't Fund: SMO urban sales and distribution and their associated overhead, beyond the short/medium-term, depending on the status of the MA market in each country.

- Do Fund: SMOs to reach rural and vulnerable populations – a requirement for achieving equity in MA markets. Donor subsidy will likely be required for reaching these populations for the long term, given that the cost of more targeted outreach is high and is therefore not practical for commercial companies.

## Policy Change

**v) Fund advocacy to liberalize laws and remove barriers to improve access to safe abortion.** Donors should continue to fund advocacy efforts to liberalize laws and remove barriers such as requirements for prescriptions that hamper access to safe abortion services. Especially in restricted countries, these efforts must be rooted in nationally led efforts that can garner community level support. Where law change is not an option, donors could support revision of guidelines for task-shifting and getting combi-pack products onto essential medicines lists, which can improve availability and accessibility of abortion services.

## Market Growth

**vi) Expand rural access and redirect subsidies to underserved populations.** Donors should fund more work for provider promotion and behavior change in rural areas, and awareness-raising in the community through local networks. Social marketing organizations and NGOs are traditionally the best placed to do this kind of work. Reaching vulnerable populations is critical for equity, as currently the promotion and distribution of MA is focused almost exclusively on urban areas. In rural areas, demand generation with women and communities should be paired with detailing of providers to enlist them as supporters of MA. At the same time, supply chains may need to be established and maintained.

# I. Introduction

The purpose of this landscape assessment is to understand better the current challenges and opportunities for engaging nationally-based commercial distributors to introduce, register, and/or distribute medical abortion (MA) combi-packs in select sub-Saharan African countries. Mann Global Health (MGH) was hired by RHSC to conduct this assessment, in partnership with Marie Stopes International (MSI) and WCG Cares. Other partners who contributed to the assessment were DKT, PSI, Ipas, and CHAI. A list of stakeholders interviewed is in Annex III.

This landscape assessment focused on questions in three main categories: Enabling Environment, Market Dynamics, and Perspectives of Commercial Actors.

**Enabling Environment:** We considered the legal status of abortion; current policies and regulations affecting abortion provision; and the status of registrations for MA products. We explored levels of commitment and attitudes towards abortion, and practical implications of existing policies and regulations.

**Market Dynamics:** We assessed the current availability of MA products and what might be in the pipeline. We looked at social marketing organizations, the public sector, and commercial players.

**Perspectives of Commercial Actors:** We explored the views of commercial actors (importers, wholesalers/distributors, pharmacists), including both those currently involved in medical abortion and those who are not. We sought to understand the barriers they face when it comes to medical abortion registration, introduction, and distribution. Further, we discussed with them a range of possible market interventions to gauge their interest and willingness to engage in market opportunities. See Annex III for a list of all interviewees.

Based on an initial desk review and discussions with partners, we developed a 10-country list and segmented countries for different levels of assessment. The following countries are covered in this landscape analysis:

**Deep Dive Countries**, where we visited and did more extensive interviewing:
1.) Burkina Faso, 2.) Senegal, 3.) Uganda, 4.) Zambia
**Remote Interview Countries**, where we interviewed key stakeholders:
5.) Ethiopia, 6.) Mali, 7.) Malawi, 8.) Sierra Leone
**Limited Investigation Countries**, where we conducted desk reviews:
9.) Mozambique, and 10.) Zimbabwe.

We selected these countries based on consideration of factors in the table below.

| Country Selection Criteria |
|---|
| Legality of abortion |
| Environment for abortion |
| Current registration and availability status of all MA products |
| Potential for scale / Ease of doing business |
| Availability of national abortion data / research |
| Contacts or relationships with commercial distributors |
| Potential for regional representation |

**Applying a Market Development Approach**

Throughout this landscape report, we have noted findings and made recommendations that go beyond the scope of this current RHSC project, to orient the reader to the state of a country's MA market in more comprehensive terms. The reason for providing this broader lens

is that any planned intervention in a country's market will need to accommodate all the different market actors, and to account for how and where different market functions are failing or succeeding.

As such, we have made recommendations that go beyond the RHSC project scope but that may nevertheless be helpful to donors who are considering funding activities to improve MA markets. If taken together, the work that RHSC does with commercial partners will be amplified by additional interventions by donors and their partners to fix other failing market functions. As an example, commercial distribution of combi-packs in Zambia will be greatly improved if national regulations no longer require three clinicians to sign off on MA prescriptions. With fewer restrictions that handcuff retailers and create stigma among providers, commercial sales can increase.

Additionally, as discussed in the executive summary above, we believe that there is an important role that RHSC can play in coordinating across market actors, and supporting greater market stewardship. Orienting planned interventions within the total market context, and communicating within a country to see how best to develop the total MA market, will be the keys to creating projects that improve long-term access to safe abortion products.

# II. Key Findings

The following findings and recommendations for combi-pack markets are expressed in typical market development / total market approach language and stages, to help understand where there are challenges and opportunities in these markets. Note that we were not able to look at *total markets for abortion* – including surgical, MVA, misoprostol, combi-pack, and unsafe traditional methods.

Given limitations of resources and time for the landscape, we were likewise unable to examine all market actors in any particular market, nor go in-depth on all market functions. In the below findings we include the information readily available per function, and note in other places that the information was not available but should be obtained and understood before market intervention strategies are designed.

The findings below highlight what we learned about the 10 countries, in terms of the following:

1. **Market actors**.
   Who are the different actors in combi-pack markets? What are their roles?
2. **The 4 Ps of Marketing**.
   What do we know about the combi-pack **product** (including quality)? **Price** at various points throughout the value chain? **Place** – whether clinics or pharmacies? **Promotion** – including promotion to providers and awareness-raising among potential consumers?
3. **Other Market Functions**.
   What role does the regulatory environment play in the market? How do policies and laws affect the market? To what extent do different market actors coordinate and collaborate effectively? Are there issues around financing that are important to the market?

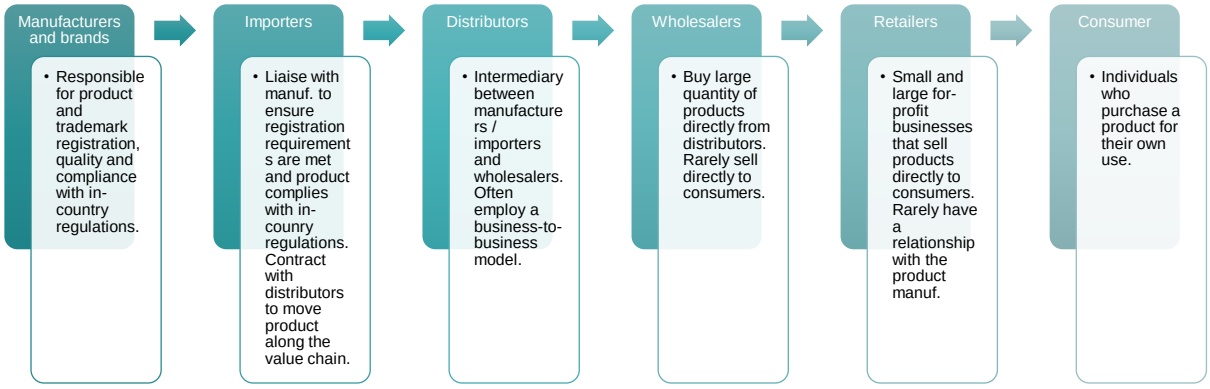
## 1. Market actors

The market actors that are important to the MA combi-pack value chain include the below. In some countries, importers also play the role of one-stop shops, where they distribute to their own retailers, for example. Many of the commercial actors we met with performed multiple functions; importing, acting as wholesalers, and distributing. **For ease of understanding**

**throughout this report, we will refer to "Distributors" to describe actors that distribute products, regardless of whether they do active sales (which is rare) or are actually wholesalers who passively fulfil orders.**

In all countries examined, the manufacturers were foreign, so that product had to be imported.

**Figure 3:** MA Combi-pack Value Chain

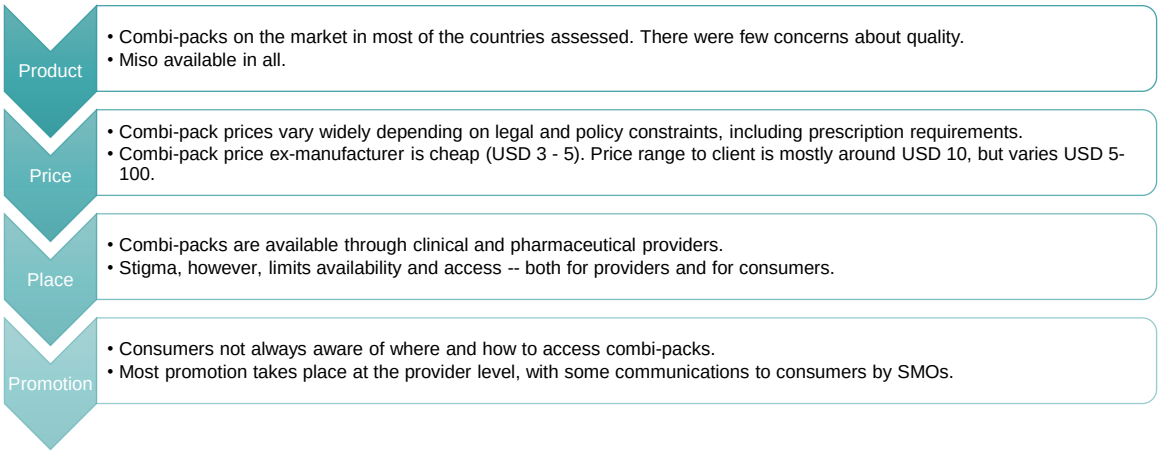



In the country summaries contained in Annex I we have listed most of the major distributors in each country for MA. In some cases, these are SMOs, or a combination of SMOs and commercial organizations. Retailers of combi-packs include clinicians and pharmacists, depending on local laws and policies. Where information was available, we have noted distinctions between public sector, SMO, and commercial provision of MA products.

## 2. The 4 Ps of Marketing

In the most basic marketing terms, combi-pack markets were assessed according to the below functions.

**Figure 4:** 4 Ps of Marketing




**a) Product**: While misoprostol was available in all countries, and from multiple providers/retailers, combi-packs were far less common, seen in only six of the ten countries assessed. Five countries had more than one brand of combi-packs on the market. We did not find any distributors distributing mifepristone outside of combi-packs.

All combi-pack products are sourced from foreign manufacturers and imported already packaged and branded. Zambia and Sierra Leone are the only countries reporting unregistered combi-pack products on the market.[2]

*Availability*: Misoprostol was frequently found to be available -- legal, registered, of quality (reputable brands, though black market products were cited), supported by ministries of health, stocked in clinics and pharmacies, with multiple brands on the market. This was not true for combi-packs, which were registered in very few of the landscaped countries.

*Accessibility*: All MA drugs, on the other hand, (misoprostol and combi-packs) were far less accessible – free from stigma (for providers as well as clients), *perceived* as legal, easily located by customers locally, priced affordably, able to be purchased without a prescription, etc. We found that while prescriptions are required for both misoprostol and combi-packs in most countries, it's easier to get misoprostol over the counter without one than it is for combi-packs.

**"***Quality***"** was seldom raised by stakeholders as a current barrier to market growth (noting, however, that our assessment focused only on reputable distributors). Most of the misoprostol drugs on the markets we assessed were registered and brought in by large companies following international quality standards. The combi-packs available are also to these standards. In Senegal, there are reports of counterfeit drugs coming over the border, and in Sierra Leone unregistered products are coming in from Liberia. No quality issues were identified with these, however, nor with the unregistered products found in Zambia (although these are not likely to be reported).

| Medical Abortion Product Regimen | Description |
|---|---|
| Mifepristone + Misoprostol | A mifepristone and misoprostol combination regimen, wherever mifepristone is legally available and accessible, is the recommended first-line regimen for medical abortion. Mifepristone 200 mg is taken and followed by misoprostol 800 mcg buccally, vaginally, or sublingually 24 to 48 hours later. |
| Misoprostol-Only | Misoprostol-only is a second-line regimen recommended by the WHO only in cases when mifepristone is not available, as this method is less effective. |
| "Combi-pack" | A "combi-pack" includes both mifepristone and misoprostol in one package with 1 tablet of 200 mg mifepristone and 4 tablets of 200 mcg misoprostol. The combination pack is a more convenient means of distributing both products. |

**b) Price**: The ex-factory price of a single combi-pack was roughly USD$3 – 5. Given that women typically pay for one or two abortions over the course of their lives,[3] a consumer cost that includes typical (not black market) pharmaceutical margins is affordable for most women.

As long as there is demand, albeit at low volume, commercial distributors are willing to and do stock and distribute medical abortion drugs, and the majority of them make a small profit doing so (though most that were not working with SMOs were not willing to tell us how much). If the pharmacists, retail outlets, and clinics that the distributors are supplying request MA, the distributors stock and supply it. Some wholesalers with their own retail outlets said that they did not want to disappoint their customers, even if it was just one client every few days asking for MA.

[2] Please see Annex IV Country Matrix showing legal status; product registration/indications; and inclusion in guidelines information for each country.

[3] Singh, S. et al. (2018, March). *Abortion Worldwide 2017: Uneven Progress and Unequal Access*. Retrieved from: https://www.guttmacher.org/report/abortion-worldwide-2017

Distributors want to secure business with pharmacists by providing the products that they are requesting. In general, we found amongst the distributors of combi-packs that were sourced from SMOs that they make profit margins of around 20-30%, with retailers making additional variable margins. A distributor purchasing directly from a manufacturer without SMO involvement, as in the example below in Zambia, is also making a profit margin of 30%.

**The critical point is that margins need to be added at each point in the supply chain for any product to be financially viable.** Further, the Zambia example shows that offering the combi-pack without SMO involvement does not have to mean higher prices to the client. In Zambia, Yash Pharmaceuticals is selling Medabon, which goes for USD 9 to the client at the lower end, with prescription, which is the same price that clients in Sierra Leone pay for Mariprist, which passes from MSI to a commercial distributor. It's only a bit higher than what clients at the lower end pay for DKT's combi-pack in Ethiopia.

In fact, given the low ex-factory cost of combi-packs, it's possible that commercial distributors could offer combi-packs even cheaper than what they do through SMOs. Realistically this will play out differently in different markets depending on what prices the market can bear. Commercial distributors we interviewed recognized that there will be limits to the prices they can charge clients with such a high proportion of people who are poor in these countries. But many distributors accept that their profit margins will remain low for a combi-pack product; what they need is volume growth, which is why they want to see product detailing and promotion and community education and awareness.

**Examples of Profit Margins for Combi-Packs and Miso**

| Combi Manufacturer/ Partner | Ex-Factory Price in USD (Profit Margin) | Price to Wholesaler/ Distributor in USD (Profit Margin) | Price to Retailer USD (Profit Margin) | Price Range to Client in USD | Comments |
|---|---|---|---|---|---|
| **ACME (India)/MSI Sierra Leone Mariprist combi-pack** | 3.5 (42%) | 6 (20%) | 7.5 (17-38%) | 9-12 | |
| **Naari (India)/DKT Ethiopia SafetyKit combi-pack** | 2.45 | N/A | Not known | 5-100 | Upper end is for high-end private clinics; the majority of the volume is at the lower end. |
| **SUN (India)/Yash Pharmaceuticals (Zambia) Medabon combi-pack** | 4.00 (33%) | N/A | 6 (33-94%) | 9-100 | Yash sells both commercially and to Ipas; upper end client price is without a prescription. |
| **Naari (India) / DKT Burkina Faso** | 2.45 (32%) | 3.6 (31%) | 5.2 (25%) | 6.9 | |

| Misoprostol Manufacturer/ Partner | Ex-Factory Price in USD (Profit Margin) | Price to Wholesaler in USD (Profit Margin) | Price to Retailer in USD (Profit Margin) | Price Range to Client in USD | Comments |
|---|---|---|---|---|---|
| **ACME (India) / MSI Senegal Misoclear box of 3 tablets** | 0.2 (78%) | 0.92 (23%) | 1.2 (31%) | 1.75 | Mark up by wholesaler is restricted |

Even though MA prices charged to clients vary widely, demand remains relatively inelastic as MA is by its nature a product that women only seek out when they really need it. Many studies have shown the high prices clients pay for *unsafe* abortions,[4] but according to pharmacists we met in Zambia, for example, clients are also willing to pay very high prices (up to USD$100) in pharmacies that will sell MA to them off-book, without a prescription.

Clients are at times willing to pay more for MA from a pharmacy because it is more convenient and discreet.[5] In Uganda, we found combi-packs mostly selling for USD$10. In francophone countries, where pharmacy boards regulate pricing throughout the value chain, there is little variation in consumer price, but unofficially, prices do vary.

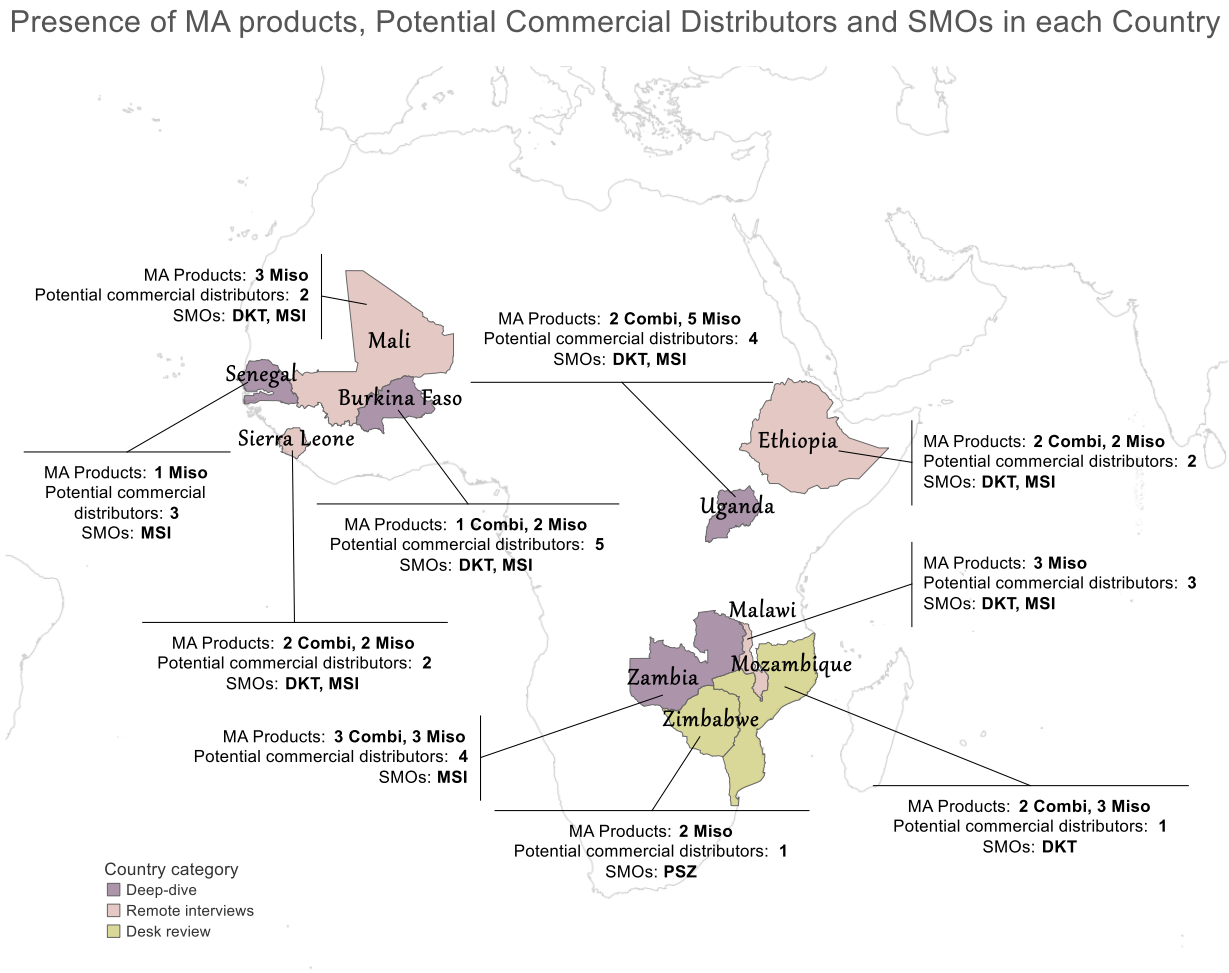
In all countries, there are commercial actors who didn't agree with abortion and wouldn't supply MA. On the other hand, we found commercial actors in all countries who do distribute MA -- either miso, combi-packs or both -- and several more who are potentially willing to enter the market. The commercial companies currently distributing combi-packs add it to a host of other products they are supplying, so the fact that it is not a big profit maker, with its relatively low volumes and margins compared to the other products they are distributing, is not a serious deterrent to them. Their role in supplying MA is a largely passive one, where they make it available but do nothing to push it or grow sales.

In francophone countries, for some distributors socially marketed misoprostol is considered promising in terms of volumes and turnover, with a few commercial distributors commenting that this is an important product for them. In Senegal, MSI's Misoclear ranks 48 out of 3,000 plus products for Laborex in terms of volumes/margins. One important consideration is that because misoprostol has other indications, it provides "cover" to distributors in restricted settings.

[4] Leone T et al., The individual level cost of pregnancy termination in Zambia: a comparison of safe and unsafe abortion, *Health Policy and Planning,* 2016, 31(7):825–833, http://dx.doi.org/10.1093/heapol/czv138.

[5] Katharine F. et al. 2018. Medical Abortion Provision by Pharmacies and Drug Sellers in Low- and Middle-Income Countries: A Systematic Review. Studies in Family Planning 49(1):57-70. DOI: 10.1111/sifp.12049.

**Figure 5:** Presence of MA products, Potential Commercial Distributors and SMOs in each Country




c) Place (providers: clinics and pharmacies): Combi-packs are available from service providers and outlet providers, with much greater access in urban areas than in rural ones. In some countries, we heard that providers and pharmacists do not stock combi-packs because they fear being stigmatized by their communities, or because they themselves are opposed to abortion. Unsurprisingly, MA is a product seen as controversial by a number of providers, resulting in barriers to availability.

Often these providers are not fully aware of the laws around provision of abortion and MA, and therefore decline to provide abortions out of fear of legal repercussions. Most doctors in Ugandan public health facilities, for example, are not providing abortions (at least not in those facilities; many have their own private facilities). In Senegal, Misoclear (misoprostol) is sold in packs of 3 tablets; prescriptions for multiple packs at once raise suspicion that the product will be used for abortion, making pharmacists nervous.

The result of these provider barriers is that abortion may be available in a country, and still not accessible. In such a case, commercial distributors experience low demand for MA from their clients – those same providers – and therefore classify that market as unpromising.

> ***"Some providers don't know that they can provide these drugs, and others are afraid to do so."***

*-- Commercial Distributor in Uganda*

**d) Promotion**: As a pharmaceutical product, most of the promotion around combi-packs is at the provider level. MA brand promotion occurs below-the-line, and through medical detailing – mostly done by SMOs. SMOs promote MA products to providers, who then purchase from the SMOs and/or their commercial distribution partners. **Most SMOs in our assessment are already working in partnership with commercial distributors to help expand their sales coverage.** They have their own sales people and also work through the commercial distributor. Commercial distributors report that they benefit from the medical detailing and provider demand work done by the SMOs. Unlike the SMOs, these distributors are not active product promoters but rather suppliers who respond to demand from their provider/retailer clients. In addition, some of them do not want to promote abortion or to be seen doing so. The distributors in some cases say that the education provided by the SMOs to pharmacists and providers is good protection for them, as it decreases the likelihood of selling MA to women who are beyond the recommended gestation, and helps these women better manage side effects and complications.

Commercial distributors report that clients (providers, retailers) are not brand sensitive, so that new brands are at no disadvantage. Pharmacists in Zambia and Uganda reported that clients usually don't ask for any specific brands but use local terms to explain what they need. Some commercial distributors have preferred SMO brands that they know or even have exclusive relationships with: they have developed trust in these brands, and have good relationships with the SMO, and therefore don't switch brands easily. The key point is ensuring availability to customers though, so they will switch if they have to in order to avoid stock-outs. If those brands were not available, according to two of the distributors we met in Zambia, they would just order a different brand if it were comparably priced. In Zambia, when we asked a commercial distributor "What do you do if MSI's combi-pack product is out of stock?" the response was, "we order Medabon or Antipreg from Yash (Pharmaceuticals)."

However, it is only in Zambia and Sierra Leone, that there is an option to switch to combi-pack brands that are not tied to SMOs. In other countries, some distributors will switch over from one SMO brand to another to get a better price or to ensure stock, and many sell multiple SMO brands. Once combi-packs start selling, even at low volumes, distributors want to maintain stock. If there were registered commercial brands at a similar price point, they would also buy these. The vast majority of their clients, they say, will buy whichever brand is cheaper, if given a choice. Consumer product preference is primarily driven by the providers and what they have been detailed on.

The result of this indifference around brands is that, unlike fast-moving consumer goods such as condoms, MA products feature very little brand equity. Any brand that is registered and of high (or similar) quality, is correctly priced, and can be imported easily is a brand that distributors are willing and able to sell.

Converting potential demand into actual consumer demand is a critical part of market development efforts. This function is best performed by a provider (outlet provider, or pharmacy; and service provider, or clinic). Detailing must involve training, not just order taking. Getting providers to switch from misoprostol to combi-packs requires additional training and support. To get providers where they want them, pharmaceutical companies typically work with them to improve their abilities in sales and client support, as they do for their products such as hypertension, diabetes, oncology, etc. Yet commercial distributors we interviewed are

not willing to do this for MA because *currently* it is not profitable enough. Instead they look to the SMOs for this support.

> ***"Where we really need them (the SMOs) is talking directly to the providers. They are the ones who can persuade them to use the products and teach them how they work."***
>
> ***-- Commercial Distributor in Sierra Leone***

> ***"Marie Stopes people give detailed education to the pharmacists so they know how to assess clients, so this decreases the risk of anything going wrong, like some kind of complication."***
>
> ***-- Commercial Distributor in Zambia***

## 3. Other Market Functions

In addition to the 4 Ps of marketing, other market functions play important roles in combi-pack markets. The market functions most frequently highlighted as not working well were around legal and policy issues, as well as coordination.

a) **Regulatory Environment**. One of the obstacles to greater commercial market activity in MA is the cost of market entry. Commercial distributors view new product registration costs and the time required as barriers to introducing MA. Product registrations can cost up to USD$5,000, but this can be paid by the manufacturer. What's a much more significant barrier is the significant personnel time needed to complete the necessary documentation and follow up, often requiring repeated efforts to push the process along. SMOs have reported waits for registration approval of up to three years, with much of that time spent providing additional paperwork, or lobbying different government offices.

In francophone countries, commercial importers are not willing to take the time to work through the extremely slow and delicate process of registration. SMOs, and the donors behind them, are viewed as holding greater sway with all the relevant government bodies, so that they can make more progress even when there are many levels of opposition to abortion products.

In addition, the roles of different commercial companies are at times more regulated in francophone Africa. A company has to already have the license to import to be allowed to register a product. An even bigger barrier is the fact that once the first product in its category is launched, the pharmacy board sets a price limit for all future products in that category. The MOH Pharmacy boards give little or no room for negotiation. In Burkina Faso, a slightly higher price can get accepted for the second or following products; in Senegal, the MOH pushes for a 30% reduction for the second product and a 15% reduction for all subsequent products of the same category. For a commercial company that expects to add margins through the value chain, this could be a major deterrent.

b) **Policy Environment**

Even in places where MA is less restricted and more available, women cannot easily access these products. In all ten countries that we assessed, despite the variations in abortion laws and environments, interviewees consistently reported that women lack awareness about the specifics of the law and where they can access safe, affordable abortion services. These women also face various hurdles to obtaining MA, such as onerous requirements for prescriptions or for multiple clinicians to sign off.

Commercial entities working in MA in the countries we covered spoke of the value of and need for NGO support for awareness-raising work at the community level. When NGOs work on community sensitization, more women know of combi-packs and where to find them.

### c) Coordination and Collaboration of Market Actors

At the **global level**, several donors and organizations working on safe abortion are currently doing assessments of MA products. Findings from these different assessments are not yet coordinated or synthesized. They are summarized below.

| Organization | Focus | Countries | Comments |
|---|---|---|---|
| Concept Foundation | MA | Zambia, Zimbabwe, Botswana, Namibia, Central Asia | Ongoing |
| CHAI | MA and MVA in public sector | Zambia, Sierra Leone, Uganda, Liberia, Nigeria, South Africa | Ongoing |
| Ipas | MA and MVA supply chain | Cote d'Ivoire, Cameroon | Starting in February 2019 |
| PSI Social Enterprise | Contraception/MA products | All Southern African countries; will expand to East/West Africa | Has been ongoing for 2 years. |

At the **regional and national levels**, there are examples of successful coordination among market actors, as well as stories of poor coordination and collaboration.

An example of combi-pack coordination is Lucky Pharmaceuticals, which is a distributor that supplies Marie Stopes Sierra Leone's (MSSL) combi-pack, Mariprist, across the country and in Liberia, distributing it alongside a large basket of other pharmaceutical and medical products. In this case and in others, commercial distributors source their combi-pack MA products via SMOs as they are the only source. They say that they would not have introduced combi-packs nor be selling it if the SMO had not facilitated registration and importation, financed the minimum order, and in some cases, provided the warehouse space.

On the other hand, in countries such as Ethiopia, in-country commercial distributors report being crowded out by SMOs, saying, "DKT has everything covered." There is actually room for market expansion, considering that the estimated total number of abortions in Ethiopia is more than 620,000, and that DKT is projecting 500,000 in SafetyKit combi-pack sales this year.[6] Yet these commercial distributors don't see enough room and express a concern that to enter the Ethiopia market in the context makes no sense, when the combi-pack is subsidized by donors.

Although there is price variation, as discussed above, if a commercial distributor is trying to enter the market where the only combi-pack product being sold to private clinics and pharmacists is $5-6, it will be very difficult to sell a combi-pack priced much higher. The same complaint was raised in Malawi, where for many years free and cheap contraceptives have been on the market, and where one major distributor said that commercial companies would be more willing to enter the market for contraceptives and MA, if not for NGO activity that made it impossible for them to charge prices that would yield a profit. SMOs play an important role in creating new business for MA, but there is also a need for healthy competition to drive quality and offer more choices for women.

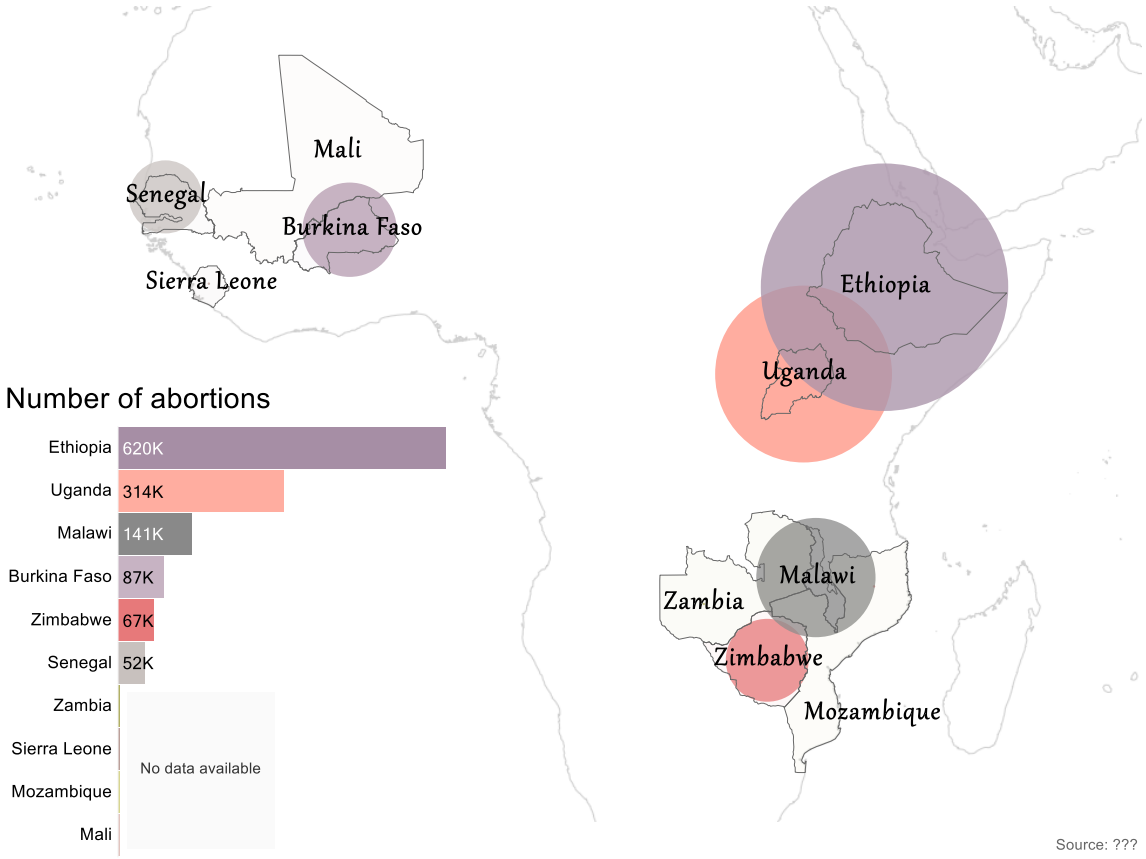
[6] Guttmacher Institute (2017, January). *Induced Abortion and Postabortion Care in Ethiopia, Fact Sheet.* Retrieved from: https://www.guttmacher.org/fact-sheet/induced-abortion-ethiopia

One of the issues driving these distortions in the market is the question of incentives. Commercial actors are incentivized by profit, while SMOs are frequently incentivized by their donors for increasing sales numbers or couple years of protection (CYPs). A profit incentive means that commercial distributors need a healthy combination of volume and margin. A CYP incentive means that SMOs push highly subsidized sales to increase health impact. For the most part, neither actor is incentivized for growing a balanced MA total market that is both more sustainable and more equitable.

SMOs, for the most part, are not on a path to sustainability, where they could continue their MA distribution and related activities with no more donor support to sales and related administrative costs. Instead, too much subsidy is at times flowing through markets where there are examples of women's willingness to pay a more sustainable price.

SMOs have made good headway in some MA markets, in getting products registered, detailing and training providers and retailers, and advocating for wider access to MA for women. It is this work that induced various commercial companies to start distributing MA and to continue to distribute it. Though SMO sales in the assessment countries have been increasing, this is at a low level everywhere apart from Ethiopia, so there is market potential.

Market size: number of abortions in each country




But there remains a question as to whether commercial actors need to continue to rely on SMOs as "middle men" as markets are maturing, and when they could potentially, in most of the countries we assessed, run a small but profitable MA business independent of SMOs. Given the wide distribution channels for pharmaceutical products that commercial distributors develop and maintain, adding one or more MA products – bought and imported from the

source – is feasible, if regulatory and entry barriers are reduced. However, if commercial distributors are to continue selling MA, there has to be demand.

This commercial success depends on where a country is in terms of market development. If the demand has been generated at volume with adequate margins, the commercial distributors will have incentive to drive the MA business. For countries like Ethiopia or Zambia, combi-packs are better known and demand is growing so as to support commercial distribution if there is space, which may require the SMOs to get out of the way. The same is not true in a place like Burkina Faso, where the market needs more priming. Even in markets that are more developed, there is a need to activate demand.

The only places where we found or heard of commercially-branded combi-packs were Zambia and Sierra Leone. In Sierra Leone, there was a combi-pack product by Abeer Pharmaceuticals in the market that was coming from Liberia, but is no longer found. In Zambia, Yash Pharmaceuticals imports from Indian manufacturers and distributes combi-pack products Antipreg and Medabon. Yash began distributing these combi-packs as part of a DFID tender for Ipas, and now distributes both for the donor contract, and on a commercial basis to private clinics and pharmacies, without any NGO/SMO involvement.

### d) Financing requirements

There are a number of issues around financing that affect commercial interest and ability to play a greater role in combi-pack distribution.

Minimum orders from manufacturers for most combi-packs are 20-30,000 combi-packs, a sizable volume for a new market entrant. In places like Ethiopia, rules around foreign currency inhibit commercial actors from purchasing these large volumes from abroad.

In addition, we heard reports of combi-pack products expiring in Zambia and Uganda, so that commercial companies worry about the risk of not being able to sell the entire stock, even if capital can be raised to purchase. Commercial distributors are concerned that the initial capital outlay, coupled with the risk of large quantities of expired stock, will leave them exposed in a market that is still nascent or undeveloped.

## III. Preliminary Recommendations

The limited scope and duration of this landscape assessment mean that the following recommendations should be viewed as preliminary. The first rule of any market intervention is “know your market,” followed closely by “do no harm to the market.” Before any project is designed, initial landscape findings must be fleshed out on the ground in a country, with full consideration of the potential impact of any activities on the total market, across all market players and functions. The recommendations proposed here are meant as a starting point, to help select priority markets, and to outline areas that have emerged as promising but require further exploration. For a summary of country-level recommendations, please see Annex II.

Given the higher effectiveness of combi-pack products, an environment where countries graduate from a less effective/potentially less safe miso-only regime – and, critically, from all unsafe abortion methods -- to a safe, highly effective combi-pack regime is good public health. Advocacy should drive support among policy-makers, as well as awareness-raising amongst providers and communities. Market development in all the countries assessed will be necessary in order to develop or maintain a sustainable and diverse supply of quality combi-packs.

None of the combi-pack markets we examined were mature. Some, such as in Senegal or Mali, were non-existent, and the most advanced, such as Zambia, were nevertheless still developing markets.

In terms of combi-pack market development, it is useful to consider the following market stages:

1. **Non-Existent:** Where combi-packs are currently not allowed nor present, usually in highly restrictive settings such as Senegal;
2. **Nascent:** Where combi-packs are starting to be registered, with limited support by the clinical and commercial community and low demand;
3. **Developing:** Where combi-pack products have been registered and are available but are still not supported by significant portions of the clinical and commercial community, and sales remain moderate to low, such as in Uganda or Zambia; OR where there is wider availability but the market is skewed toward one distributor, such as in Ethiopia;
4. **Mature:** Where there is wide acceptance, support and distribution of multiple, high quality combi-pack products.

| Stage of Market Development | Non-Existent | Nascent | Developing | Mature |
|---|---|---|---|---|
| Conditions | Combi-pack not allowed/not present | Combi-pack starting to be registered, with limited support and low demand | Several comb-packs registered, with growing support and demand but low sales OR Support and demand, but limited product choice | Wide combi-pack availability and acceptance, healthy competition |
| | Highly restricted environment | Moderately restricted environment | Moderately liberal/liberal environment | Liberal environment |
| Assessment Countries | Senegal<br>Mali<br>Malawi<br>Zimbabwe | Burkina Faso | Zambia<br>Uganda<br>Sierra Leone<br>Ethiopia<br>Mozambique | N/A |

To achieve sustainability, an open market, healthy competition, and appropriate pricing are required. Multiple manufacturers and brands by different importers are needed in a market for women to have options. To grow that market, different kinds of investments for different stages of development should be targeted carefully.

Our proposed recommended interventions follow the spectrum of market development for MA: registration/entry; market building; policy change; and market growth. Donors could boost commercial distribution of combi-pack products by investing in product registration and by facilitating the management of various market functions. These activities can open up the market and ease entry, while crowding in commercial players and supporting an enabling environment.

See Annexes I and II for detailed recommendations for individual countries.

| Key Market Development Functions | Registration/Entry | Market Building -Initial Introduction to Trade | Policy Change | Market Growth |
|---|---|---|---|---|
| Barriers Faced | High cost and time for new product registration<br><br>Risk of expiry as minimal orders are too large<br><br>Foreign currency limitations affect ability to purchase from abroad | Lack of awareness of providers about the law, the product and how to use it; Stigma<br><br>Lack of awareness by women about the law and where to access safe abortion services and products | Restrictions in abortion law and requirements that block access<br><br>Guidelines and essential medicines lists not conducive to safe abortion | Demand takes time to build to level to achieve high volumes and value<br><br>Equity needs to be addressed |
| Recommended Intervention | Facilitate registration of new commercial combi-pack products<br><br>Negotiate gradual release of stock | Support commercial distribution<br><br>Transition SMOs to areas of added value away from urban distribution<br><br>Fund product detailing<br><br>Fund demand generation with providers | Fund advocacy to liberalize laws<br><br>Coordinate with other safe abortion donors to change policy guidelines (e.g., around prescriptions) | Support move from urban to rural areas<br><br>Redirect subsidies to underserved populations<br><br>Fund innovation to further improve quality, safety and client experience |
| | Senegal, Mali, Malawi, Zimbabwe, Sierra Leone, Uganda, Mozambique | All, for specifics on countries, see Annexes I and II | All, for specifics on countries, see Annexes I and II | Start some elements in Zambia, Uganda |

## Registration/Entry

### i) Register new commercial combi-pack products.

- ***Where there are no combi-packs, but there is commercial capacity:*** In Malawi and possibly Zimbabwe, where there are no combi-pack products available, donors should work with commercial actors to register combi-pack products that meet international quality guidelines (such as WHO pre-qualified; Stringent Regulatory Authority-approved) at the lowest possible prices. WHO's Collaborative Procedures for Accelerated Registration should be considered. Donors should cover the registration costs -these costs aren't significant to large commercial actors, but they do expect them to be covered.

- ***Where there are no combi-packs, but there is NGO capacity***: In Mali and Senegal, donors should work with NGOs on new combi-pack registrations as these likely have a higher chance of succeeding, versus commercial registration (though technically, both SMOs and commercial entities can make registrations as long as they comply with the requirements – e.g., pharmaceutical license, in-house pharmacist, etc.) Negotiations with SMOs and commercial actors should focus on the support role SMOs can play in building commercial capacity and sustainability.

- ***Where SMO-registered combi-packs are available, but there is commercial capacity for increased sales***: Even in countries that have combi-packs available, donors should work with commercial actors to register new brands. They should prioritize countries that do not have a registered *commercial* combi-pack brand, such as in Sierra Leone, Uganda and Mozambique, and in coordination with others such as Concept Foundation, which may also be launching new brands.

**ii) Negotiate gradual release of order in sync with demand to mitigate major risk to commercial distributors of expired stock.**

Donors could help provide the capital for minimum orders from manufacturers and negotiate graduated releases of stock to avoid expiry. Lower batch size may be feasible but is likely more expensive. One critical consideration is that batch size needs to be in line with actual demand.

Donors could also consider pooled procurement across countries. Manufacturers such as Naari can do one run of an order then produce different packaging for different countries (USD 3.00-3.50/combi-pack). The amount of coordination and planning time for this needs careful consideration. Working across countries may also present the option of getting an “access” price, a discounted price for donor projects.

## Market Building

**iii) Donors need to pick commercial partners to incentivize, and these will be different in every country.** Some commercial companies have the capability to handle registration as the local agent, as well as to import and distribute. These companies can eliminate the transaction costs of working with multiple smaller players, and make it easier for RHSC to intervene across multiple market functions with a single partner. For instance, in francophone countries with restricted pharmaceutical channels, it might be easier to work with an international supplier, such as Planet Pharma or Continental, that is based in France and that supplies pharmaceutical products to many countries in West and Central Africa.

In other countries it will be necessary to split registration, importation and distribution functions among different companies, with more partners and more need for RHSC to play a collaboration and stewardship role. In all such countries except for Zambia, a large part of the challenge will be to find a path that accounts for the role of SMOs and how they should evolve, as well as the roles of the different partners responsible for the main value chain functions.

In all countries that are in the market building stage, there is a need for marketing and demand generation, which can be done by SMOs or by the commercial companies themselves, or in tandem.

**iv) Fund SMOs with a view to supporting commercial growth in sustainable ways.** Donors should consider moving away from funding the sales, distribution, and overhead costs

of SMOs in some markets, especially where demand has risen and there are established brands. There can be hybrid coverage between SMOs or social enterprises and commercial distributors, then transition to full commercial distribution in urban areas. In places where SMOs crowd out commercial players, there is a need to create more space for commercial activity, for competition to drive growth and quality improvements.

Donors should continue funding NGOs and SMOs for market functions where they add value, such as in product detailing, sensitizing and educating providers and pharmacists, awareness-raising at the community level, and advocacy at different levels to eliminate barriers to access.

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising through local grassroots networks, so that women know about the combi-pack and where to access it, and how to get follow up support.
- Do Fund: SMO medical detailing *OR* medical detailing in-house in commercial companies *OR* a combination of the two, where SMOs second detailers to commercial companies. Detailing has to involve training, not just taking orders.
- Don't Fund: SMO urban sales and distribution and their associated overhead, beyond the short/medium-term, depending on the status of the MA market in each country.
- Do Fund: SMOs to reach rural populations – a requirement for achieving equity in MA markets. Donor subsidy will likely be required for reaching these vulnerable populations for the long term, given that the cost of rural outreach is too high for commercial actors to make a profit.

**vi) Coordinate between donors and NGOs working on MA.** Donors and organizations working on safe abortion should better coordinate and share findings from their various assessments on MA products. This could perhaps be facilitated by the RHSC Safe Abortion Supplies Workstream.

## Policy Change

**vii) Fund advocacy to liberalize laws and remove barriers, to improve access to safe abortion**. Donors should continue to fund advocacy efforts to liberalize laws and remove barriers such as requirements for prescriptions and multiple doctor signatures, in order not to hamper accessibility of safe abortion services. Especially in restricted countries, these efforts must be rooted in nationally led efforts that can garner community level support. Where law change is not an option, donors could support revision of guidelines -- such as what is happening in Senegal and Malawi, for example -- and getting MA products onto essential medicines lists, which can improve availability and accessibility of abortion services.

## Market Growth

**viii) Expand rural access and redirect subsidies to underserved populations.** Donors should fund more work for provider promotion and behavior change in rural areas, and awareness-raising in the community through local networks. Social marketing organizations and NGOs are traditionally the best placed to do this kind of work. Reaching vulnerable populations is critical for equity, as currently the promotion and distribution of MA is focused almost exclusively on urban area. In rural areas, demand generation with women and communities should be paired with detailing of providers to enlist them as supporters of MA. At the same time, supply chains may need to be established and maintained.

# ANNEX I: Country Discussions

**Deep Dive Countries**

## Burkina Faso

### A. Overview

Burkina Faso permits abortion to save the life of a woman or preserve her physical health, as well as in the case of rape, incest, or fetal anomaly. Abortions are only permitted for pregnancies under 10 weeks. There is low knowledge of the legal status of abortion among women, with only one third reporting that they are aware of the scenarios for which abortion is legal. Abortion incidence data are scarce; however, a study in 2011 estimated that there were 87,200 abortions performed that year.[7] Unsafe abortion contributes to a substantial proportion of maternal deaths at 28.3%.[8] Women who have abortions are typically young, living in urban areas, and unmarried with no previous children. There remains a high level of stigma around abortion, with many women selecting clandestine and unsafe procedures.[9]

In May 2018, Burkina Faso made some progress towards liberalization of abortion law. The new law has removed the requirement that two doctors authorize an abortion in cases where the woman's health is at risk. In addition, the timeframe for abortions provided to survivors of rape and incest has been increased from ten to fourteen weeks. Finally, the government has removed the requirement that survivors of rape or incest must prove their particular experience.[10]

***Misoprostol*** is registered under the brand name Misoclear by MSI and is approved for incomplete abortion and miscarriage but not for induced abortion. Cytotec is also available although has frequent stock-outs. Misoprostol is included in the EML list; mifepristone is not.

DKT submitted request in 2018 for registration of two Misoprostol brands (Misodia and Miso-fem). Misodia has been registered and can be supplied to the public sector distribution channel CAMEG in case of any tenders. Miso-fem's registration is pending, contingent upon final decisions that are expected in early 2019.

***Combi-packs***: DKT also submitted registration for 2 MA combi-packs (Mifepack and Mifedia). Both Mifepack and Mifedia are indicated for abortion. Registration for Mifepack was recently granted. Registration of Mifedia, which will be eligible in case of public sector tenders, is still in process.

IPPF/ABBEF (national affiliate) is still working on the registration of Medabon after doing a five-year pilot study with the MOH.

MSI submitted a registration request for combi-pack in 2018; decision of the MOH Pharmacy Board is expected in early 2019.

### B. Key Findings

[7] Sedgh, G.et al., 2011. Estimating abortion incidence in Burkina Faso using two methodologies.. *Studies in Family Planning,* 42(3), pp. 147-54.
[8] Ipas, 2016. Comprehensive abortion care needs and opportunities in francophone West Africa: Situational Assessment Results.
[9] Ibid
[10] MSI. Abortion Advocacy Across the World. 2018. https://www.mariestopes-us.org/2018/abortion-advocacy-across-world/

## 1. Market Actors

**a) Commercial Actor Involvement in MA Distribution.** There are five "private pharmaceutical wholesaler / distributors" that import, wholesale and distribute: Laborex, UbiPharm (the biggest), Tedis, DPBF and SRP. These five supply the private sector of around 350 pharmacies that provide products to an estimated 500 to 1000[11] depot pharmacies in rural and peri-urban sites. The public sector distributor (CAMEG) is in charge of supplying generic drugs (Essential Medicines) to all public health care facilities; they also sell and deliver certain generic products approved by the MOH to private pharmacies.

All five companies are willing to sell combi-pack products. So far, only one of the five, UbiPharm, sells DKT's combi-pack, while the other 4 have ordered it (their internal processes to order took more time). For these companies, any new registered product will be examined by their pharmacists and if they see a business need to include the product into their portfolio (that consists generally of 3,000 or more different products), then they will order and distribute it to the pharmacies. For them, misoprostol is important as demand from pharmacists is high. Compared to other products they sell, Misoclear is in the top tier of highest selling products, and they anticipate that combi-pack sales will be good.

### b) The Role SMOs.

DKT has recently entered the MA market with a strategy to supply both the private market (pharmacies and private clinics) and the public sector with misoprostol and combi-packs. Sales for its combi-pack for the private sector started strong (see Product below) and this is expected to cut into MSI's sales eventually if MSI is not able to register its combi-pack. DKT's misoprostol product for the public sector will also affect MSI's sales to the public sector (which were 80,000 tablets in 2018) since it has been registered as a preferred product in CAMEG. If DKT's misoprostol product for the private sector gets approved as expected, this will have a more immediate impact on MSI sales.

***Misoprostol***: MSI is working mainly through the private pharmaceutical distribution channel in order to sell their Misoclear. This has allowed MSI to greatly expand its reach, and will do so for DKT.

MSI's Misoclear is imported by Laborex on MSI's behalf, as MSI does not have an import license. Misoclear is not available in the preferred international distribution platforms (such as Planet Pharma or Continental) where the wholesaler/distributors usually procure/import their products, so sales are managed locally by MSI. Only 2 of the 5 commercial wholesaler/distributors purchase locally from MSI, which limits the availability of the product in pharmacies. MSI regional office in Dakar confirmed that they are working on the inclusion of Misoclear onto the international distribution platform. Until this happens, DKT will have an advantage if its miso product for the private sector gets approved as it will be available through Planet Pharma.

***Combi-pack***: DKT's combi-pack is available through Planet Pharma. For DKT, this platform has been very helpful in streamlining multiple product orders across the region, but it also requires DKT to oversee the process, as their basket of products is considered relatively low volume and low profit by Planet Pharma.

Lack of regulatory oversight has meant that SMOs have been able to set up models of distribution despite not having formal authorizations. Oversight is tightening, however, and for any new combi-pack products to come into the market, formal authorizations must be in place.

[11] Identification of these depot pharmacies is ongoing by MOH/Pharmacy board

| Commercial Actors in Burkina Faso involved in MA | Functions | Current SMO Partner | Market Authorization Holder (MAH) | Current MA Products Sold (Price to consumer) | MA Sales/ Geographic coverage/ Populations Served | MA Manufacturer | History/Planned Work/Potential |
|---|---|---|---|---|---|---|---|
| **Laborex** | Importer Wholesaler Distributor | MSI-BF | MSI-BF | Misoclear (USD 9.50 for pack of 20 tablets) | 28,000 tablets/ month Nationwide | ACME | Will sell DKT's combi-pack |
| **UbiPharm** | Importer Wholesaler Distributor | DKT | DKT | Mifepack (USD 6.81) | c. 3,000 combi-packs/ month to UbiPharm | Naari | Sales recently started in October 2018. |
| **Tedis** | Importer Wholesaler Distributor | N/A | N/A | N/A | N/A | N/A | Will sell DKT's combi-pack |
| **DPBF** | Importer Wholesaler Distributor | MSI-BF | MSI-BF | Misoclear (USD 9.50 for pack of 20 tablets) | 6,000 tablets/ month Nationwide | ACME | Will sell DKT's combi-pack |
| **SRP** | Importer Wholesaler Distributor | N/A | N/A | N/A | N/A | N/A | Will sell DKT's combi-pack |

## 2. The 4 Ps of Marketing

### a) Product

MSI reported sales of ***misoprostol*** of 467,912 tablets in 2017.

MSI sold 401, 232 misoprostol tablets from January to October 2018. Misoclear sales are considerably higher than Cytotec, which has irregular supply and frequent stock-outs. The relatively strong sales of Misoclear bode well for potential combi-pack sales.

DKT sold 6,120 ***combi-packs*** during October-November 2018.

### b) Price

*Misoprostol*: MSI's Misoclear price to wholesalers is USD 6.25 for a pack of 20 tablets; USD 9.50 to the consumer.

DKT plans to sell its miso product for the private sector to the wholesaler for USD 0.82/pack of 4 tablets, with a consumer price of USD 1.5. If so, then DKT's miso brand will be 21% cheaper than MSI's brand to the client. The cheaper price to the wholesaler and being on the international platform will be an advantage for DKT. But if pharmacists have the option of recommending to the client either DKT or MSI's products (usually they don't as when the provider prescribes, they specify brand) then MSI's products may have an advantage since pharmacists want to sell the most expensive product because markups are by law a fixed percentage.

*Combi-pack*: DKT's price of its combi-pack to the trade on the international platform is USD 3.60; consumer price is USD 6.81.

A significant potential barrier for commercial actors to start selling combi-packs is that price is the determining factor when approving the registration of alternative products of the same category: the first product price (PGHT - Prix Grossiste Hors Taxes, or the wholesale price of the product without importation taxes) serves as a reference, and additional products are expected to be cheaper. Negotiations can at times get a slightly increased price (+5-7%) accepted. This means that commercial companies will have limits on what prices they can set. This is particularly important if SMOs have registered the first product at a low price point, which is true for DKT in Burkina.

### c) Place

Misoprostol products and DKT's combi-packs are sold in pharmacies via prescription, and also in some private clinics. MSI also sells Misoclear to CAMEG, which supplies public health centers. Health care providers are key, as they prescribe to the clients; they need to be aware of the available products and brands, their compositions and prices.

### d) Promotion

Because the product category requires a medical prescription (for misoprostol as well as combi-pack), brand promotion is limited to health professionals and outlets such as clinics and pharmacies. No mass media promotion is allowed. MSI is not allowed to put its contact center (call center) number on the Misoclear pack. For the end consumer, brand awareness and loyalty play a less important role, as these products require medical prescriptions, and the prescriber is the one promoting a particular product and brand.

MSI has been providing sensitization and product detailing for Misoclear since its introduction. Medical detailing is a key strategy to inform health care providers and pharmacist agents about the product and its correct use, and to promote the brand. Detailing is seen by commercial

distributors as essential to increase brand awareness at the level of medical prescribers and dispensers, and to grow the market. It's too early to tell if there are any issues with providers switching to combi-packs. DKT has a team of medical representatives and clinical trainers working on this as they expect providers will need a lot of support.

### 3. Other Market Functions

#### a) Regulatory Environment

The Pharmacy Board of the MOH was reorganized and a new entity was recently created (ANRP, Autorité Nationale de Reglémentation Pharmaceutique). Regulations are expected be more strictly enforced in the future. Sales of pharmaceutical products are restricted to either public sector or private sector distribution channels.

Burkina is representative of other francophone African countries that have similar French "inherited" laws and regulations in the health and pharmaceutical sector and that have a legal indication for abortion. Several countries (8 or 10) are planning to have a regional registration process (Autorisation de mise sur le marché AMM - authorization process) for pharmaceutical products, similar to the EU regulations. Burkina was selected to manage the regional process for the other countries. This could expedite future product registration and importation in the region: once a product is registered regionally, it could be put on the market in all the other countries. This initiative, however, has been discussed for many years, and there has been little progress.

#### b) Policy Environment

The new Minister of Health is trying to liberalize abortion without making it legal. However, most stakeholders interviewed think that major changes are unlikely in the next few years. Recently, following a delegation of donors highlighting unsafe abortion, civil society and religious groups have been heavily protesting against MOH efforts to liberalize access to abortion, and, more broadly, against the involvement of foreign organizations in national matters.

#### c) Coordination and Collaboration of Market Actors

In Burkina, as well as in Senegal and Mali, the SMOs have to work with the private pharmaceutical wholesalers to sell their MA products since SMOs are not allowed to do sales. This way of working is very beneficial to DKT and MSI who have been able to expand their sales as a result.

The SMOs focus on product detailing and promotion, and both MSI and DKT are experienced in this. There are two other NGOs in Burkina that are not selling MA but could potentially get involved in IEC/BCC and medical detailing: the national SMO PROMACO and the IPPF affiliate which is planning to increase MA interventions.

#### d) Financing Requirements

Registration of a product costs USD 530 for the first product of a category, and USD 2,600 for all following, so this could be a barrier for some companies. Also private pharmaceutical wholesalers can't do product registrations, so another entity is required to do this. Registrations can be done by a representative of the manufacturer based in Burkina; this can be an NGO, or a private sector pharmaceutical promotion agency such as Eurotech.

## C. Recommended Interventions

### Registration/Entry

**i. Register new combi-pack product through the regional registration process.** Donors should consider registering a new combi-pack product through the regional system. This

needs more detailed exploration but could be a more efficient way of getting a new combi-pack product into not only Burkina Faso but also other countries in the region such as Senegal and Mali. This is especially important given the difficulties expected for new combi-pack product registration in Senegal and Mali (see discussion on Senegal and Mali below.)

- Commercial actor to take on registration. Donors to cover all registration costs, including staff time to liaise with manufacturer, do application and follow up.
- Consider paying bonus for achieving registration.
- As an important potential barrier to commercial actors is the price limitation, donors could advocate at the MOH Pharmacy Board for acceptance of different rules and regulations for full commercial products (versus SMO products), which would allow a waiver to register a higher priced commercial brand.

**ii. Facilitate purchase and importation of combi-pack order.**

- Negotiate gradual release of stock from manufacturer in line with expected sales.
- Consider providing capital for initial stock purchase (soft loan).

**Market Building**

**iii. Collaborate with commercial distributors to distribute new combi-pack product.**

- Cover costs of product detailing and promotion

**iv. Fund SMOs with a view towards supporting commercial growth in sustainable ways**. While donors work on registration of a new combi-pack product, which may take some time, they should continue funding SMOs to distribute misoprostol and combi-packs and help prime the market for additional products.

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising through social mobilization interventions with women's associations and networks so that women know about the law, the combi-pack and where to access it.
- Do Fund: SMO/NGO medical detailing *OR* medical detailing in-house in commercial companies to sensitize providers and get them confident in the provision of combi-packs.

**Policy Change**

**v. Fund targeted advocacy interventions to create a less hostile environment for abortion provision and remove barriers to access such as punishments for those who don't report abortions that occur outside the legal provisions.** These efforts must be rooted in nationally led efforts that can garner community level support, critical in a restrictive environment.

# Senegal

## A. Overview

Senegal's abortion laws are highly restrictive and unclear. The criminal code prohibits any form of abortion, even in case of rape and incest; however, medical ethics codes allow for abortion if three doctors attest to the necessity of the procedure to save the pregnant woman's life. There are differing views as to whether there is reason to be hopeful for change. An abortion task force comprised of Ipas, Gynuity, MSI, other NGOs and the MOH (Director of Maternal Health) and cabinet members are reflecting on the option of registering a "missed period pill" (like menstrual regulation in Bangladesh). No one expects any changes until after the presidential election in February 2019. Gynuity is very active in medical abortion, holding workshops with key partners to see how they can introduce it; what is the best approach with authorities, how to develop appropriate messages; and how to explore acceptability and demand.

Clandestine abortion is common, with an estimated 51,500 abortions performed in 2012. The rate of abortion of 17 per 1,000 women is lower than the regional rate in West Africa, at 28 per 1,000 women. However, the majority of these procedures were clandestine and unsafe. Women face strict penalties for seeking abortions, and an estimated 38% of incarcerated women are in jail for pregnancy-related crimes including abortion, miscarriage, and infanticide.[12] Abortions are more common in the capital city of Dakar than in other regions, as urban women generally prefer smaller family sizes and many women from rural areas travel to the main city to obtain abortions and post-abortion care.

An estimated two-thirds of abortions in Senegal are high-risk and performed by untrained individuals, with 38% performed by traditional healers and 21% performed by women themselves. Trained providers must work in clandestine environments due to the strict nature of the law. While provision of post abortion care is legal, women who seek care for unsafe abortions are often reported to law enforcement.[13] DKT has to report every doctor they sell MVA to, the only place where they are asked to do this.

***Misoprostol*** is available by prescription under the brand name Misoclear (MSI's product). Cytotec was previously available but is no longer found at scale; only few pharmacies continue selling it. Misoprostol is included in the EML list, approved for incomplete abortion and miscarriage, missed abortion in the 1st trimester, and intrauterine fetal death, but not for induced abortion.[14] [15]

The MOH procures misoprostol but on an irregular basis, and only 1% of public sector health providers reported use of misoprostol in 2013.[16] The public sector supply chain launches tenders to procure misoprostol; the last one was in 2016. A 2014 study found that a large proportion of pharmacists had heard of misoprostol (72%), yet there was low availability of the

[12] Hefez, J. When Abortion is a Crime: Women Behind Bars in Senegal. Medium. 2017. https://medium.com/@ppglobal/when-abortion-is-a-crime-women-behind-bars-in-senegal-1662ae6e36b8

[13] Sedgh, G., 2015. Estimates of the incidence of induced abortion and consequences of unsafe abortion in Senegal. *International Perspectives on Sexual and Reproductive Health,* Volume 41(1), pp. 11-19.

[14] Venture Strategies. Misoprostol registrations July 2013 https://www.k4health.org/sites/default/files/Global%20Misoprostol%20Registration%20by%20Indication%20detailed%20spreadsheet_0.pdf

[16] Population Council. Senegal: the impact of a study on misoprostol knowledge and use amongst pharmacists. 2016. https://www.popcouncil.org/uploads/pdfs/2016STEPUP_SenegalMisoPharmacies.pdf

product (34% of pharmacies). The majority of misoprostol sales were indicated for gastric ulcers (70%) with a limited amount of product sold for post abortion care (3.7%).[17]

No ***combi-pack*** is available yet. MSI has submitted combi-pack registration; DKT's registrations for a miso product and for combi-pack are pending. Since mife is clearly linked to abortion, there is no mife registered or available yet. Stakeholders from the Abortion Task Force don't think that DKT and MSI's combi-pack registrations will be approved given the restricted environment.

## B. Key Findings

### 1. Market Actors

**a) Commercial Actor Involvement in MA Distribution:** There are six private sector pharmaceutical wholesalers. The three major ones are Laborex, UbiPharm and Sodipharm. As in other francophone countries, wholesalers can't register pharmaceutical products; they import and distribute them to the pharmacies. There are 1,000 private pharmacies in Senegal.

**b) The Role of SMOs:** MSI began distribution of Misoclear in 2016, selling exclusively through one pharmaceutical wholesaler, Laborex, which procures the product from the France-based distributor Continental Pharmaceutique. Laborex, UbiPharm, and Sodipharm are potential candidates to sell a new combi-pack product.

MSI also distributes Misoclear through its informal network of providers, both qualified providers and unqualified ones who they train on the product use and side effects.

In Francophone Africa, sales of pharmaceutical products such as misoprostol and combi-pack have to be through either private commercial pharmaceutical wholesalers that have rights to handle drugs, or through the public sector supply chain system.[18] So MSI can't do its own distribution, and working through Laborex allows for much greater sales reach. In Senegal, organizations that are not registered as a pharmaceutical enterprise can't do marketing and product promotion of pharmaceutical products,[19] so MSI pays a marketing agency to do this. This means that MSI has effectively outsourced both the distribution and the marketing and promotion of its miso product to commercial companies.

[17] Ndao, R. et al. Knowledge and provision practices of misoprostol among pharmacies in Senegal. Population Council 2014. StepUp Research Report. https://www.popcouncil.org/uploads/pdfs/2014STEPUP_MisoPharmaciesReport.pdf

[18] Licenses from MOH to operate as pharmaceutical agency and for the pharmacist in charge of the agency

[19] Such as hormonal contraceptives and misoprostol that require a VISA (AAM autorisation de mise sur le marché) – whereas condoms can be sold by any commercial entity without restrictions

| Commercial Actors in Senegal involved in MA | Functions | Current SMO Partner | Market Authorization Holder (MAH) | Current MA Products Sold (Price to consumer) | MA Sales/ Geographic coverage/ Populations Served | MA Manufacturer | History/Planned Work/Potential |
|---|---|---|---|---|---|---|---|
| **Laborex** | Importer<br>Wholesaler<br>Distributor | MSI-Senegal | MSI-Senegal | Misoclear | c. 20,000 tablets of Misoclear/month<br><br>Nationwide | ACME | Candidate for selling combi-packs |
| **UbiPharm** | Wholesaler<br>Distributor | N/A | | | | | Candidate for selling combi-packs |
| **Sodipharm** | Wholesaler<br>Distributor | N/A | | | | | Candidate for selling combi-packs |

## 2. The 4 Ps of Marketing

### a) Product

In 2017, MSI sold 308,400 tablets of Misoclear, and has sold 206,400 this year (as of October 2018). Though it's hard to assess what % of the Misoclear sales are for abortion, these sales do indicate a strong private market for MA. Cytotec was formerly available through pharmacies at scale, but availability has considerably decreased.

Stakeholders indicated that an important black market of pharmaceutical products is organized through a network of powerful "Islamic brotherhoods". They sell products leaking from the public and private sectors, as well as fake drugs imported illegally from other countries. There have been no reports of adverse incidents related to these fake drugs, however, it is safe to assume that there are quality concerns here.

### b) Price

MSI's price to Laborex is USD 0.92 per pack of 3. Price to the consumer is USD 1.75.

### c) Place

Misoprostol is mostly available through private sector pharmacies, as well as through some private clinics and through the black market as above.

### d) Promotion

Similar to Burkina, the MA product category requires a medical prescription for misoprostol, so brand promotion is limited to health professionals and outlets such as clinics and pharmacies. No mass media promotion is allowed, and it is the providers who recommend products to clients.

Marketing is done by dedicated agencies, such as Green Pharma, Les Laboratoires Didy or Valdafrique, which are in charge of promoting medical products and training health care providers and pharmacy personnel on behalf of SMOs such as MSI and ADEMAS. As these agencies are paid regardless of the quality of the training given to the healthcare provider, the SMOs manage the process to ensure that product introduction and promotion are done well.

## 3. Other Market Functions

### a) Regulatory Environment

Different stakeholders mentioned that in the Senegalese context it is easier for a project that has external donor support to get a new product registered, compared to a commercial entity. Examples were ARVs funded by donors who could get the products registered quickly, given the "public health pressure." Some stakeholders also questioned whether a pure commercial entity could register a MA product in Senegal, as the MOH tends to be less likely to give Market Authorization for commercial agents. This means that it may be better for a SMO to do the registration, but SMOs would not have the incentive to do so for a commercial brand.

### b) Policy Environment

MSI's Misoclear product was introduced at first as a pack of 10 tablets. Then when MSI registered the pack of 3, the MOH withdrew the authorization of the pack of 10 tablets to reduce the risk of using the product for MA (for which a total of 12 tablets are needed). This illustrates the very restrictive environment in Senegal. In this context it seems quite unlikely that a combi-pack with the single indication of medical abortion can get registered. Alternative solutions could be to try registering a combi-pack for post-abortion care instead. Or, to register - like in Bangladesh- a product for menstrual regulation as a "missed period pill."

Many pharmacists are scared and either do not want misoprostol on their shelves, or are very restrictive in checking on the prescriptions and limit the staff who can actually sell the product. A stakeholder reported that a pharmacist was condemned to prison last year because he had sold misoprostol to a nurse with a fake prescription, who had given the product to a patient who then died. This fear would likely be more of an issue with a combi-pack product even if indicated for post-abortion care.

### c) Coordination and Collaboration of Market Actors

SMOs must work through private pharmaceutical wholesalers in Senegal. MSI currently works through Laborex, and if a combi-pack product were to be registered by any of the SMOs, they would work through these companies as well. Further, SMOs use dedicated marketing agencies for product detailing and promotion, so they are actually outsourcing most of the functions required to distribute MA products. The SMO manages the different functions and works to ensure quality in the detailing process.

The national SMO ADEMAS, not currently selling MA, could potentially get involved in IEC/BCC, but would need a marketing license to carry out medical detailing efforts. This is also true of the IPPF affiliate.

### d) Financing Requirements

Though the cost of registration of new products is not high at USD 763, product registration can take a very long time: some requests to register products from 2015 are still in process.

## C. Recommended Interventions

### Registration/Entry

As registration by a commercial company without SMO involvement is, according to stakeholders of the Abortion Task Force, very likely to get rejected for combi-pack in Senegal, as are DKT and MSI submissions for registration for combi-pack for MA only, because of the above mentioned legal context. Some stakeholders suggested that donors could fund a SMO to register a new combi-pack for post-abortion care, not just limited to MA. If such a strategy were practical, it might help get the combi-pack product approved, drawing on references to studies showing the higher effectiveness of combi-pack for post-abortion care.[20]

**i. Register new commercial combi-pack product with indication for PAC (not abortion).** Consider which organization is best placed to handle such a registration, whether an NGO, SMO, or commercial company. While an SMO or NGO may have a better chance of securing registration, they will have little incentive to do so if the brand will not be owned by them.

This process could run simultaneously as donors tried to register a combi-pack product through the regional product registration system in Burkina to increase the chances of a new combi-product being registered.

### Market Building

**ii. Collaborate with commercial distributors to distribute new combi-pack product.** Cover costs of product detailing and promotion.

**iii. Fund SMOs with a view to support commercial growth and sustainability**. Given the fact that SMOs have to outsource essential functions such as distribution and

[20] Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss, Courtney A. Schreiber, M.D., M.P.H., Mitchell D. Creinin, M.D., Jessica Atrio, M.D., Sarita Sonalkar, M.D., M.P.H., Sarah J. Ratcliffe, Ph.D., and Kurt T. Barnhart, M.D., M.S.C.E. N Engl J Med 2018; 378:2161-2170 . DOI: 10.1056/NEJMoa1715726

marketing/promotion but are better placed to register MA products, Senegal could be a good test case of having a partnership between an SMO/NGO and a commercial company for a *commercial* brand. The SMO could be funded to carry out a limited set of functions, akin to a management/technical support role.

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising through social mobilization interventions with women's associations and networks so that women know about the law, the combi-pack and where to access it.

- Do Fund: medical detailing, critical for new product like combi-pack, especially in such a highly restrictive environment. In the meantime, fund detailing for misoprostol to increase knowledge and use amongst providers, which will help them get ready for combi-pack introduction. Either marketing agencies or SMOs/NGOs could get marketing licenses or embed their own sales teams in existing marketing agencies.

**Policy Change**

**iii. Fund advocacy interventions.** Work through the existing Abortion Task Force targeting professional bodies (medical and pharmaceutical boards, jurists) and influential stakeholders (MOH staff, parliamentarians, political and religious leaders) to move the abortion agenda forward and advocate for a change of the current abortion law, rules and regulations; including advocacy for a "missed period pill.'

# Uganda

## A. Overview

Uganda has a high rate of maternal mortality at 343 deaths per 100,000 births, an estimated 8% of which are due to unsafe abortion.[21] Under Ugandan law abortion is explicitly permitted to save a woman's life, and in the 2006 National Policy Guidelines and Service Standards for Sexual and Reproductive Health and Rights, circumstances were expanded to include the case of fetal anomaly, rape, incest, or if the woman is HIV-positive.[22] The penal code lays out jail sentences for women and providers, but in practice, there are very few actual prosecutions.

The 2006 guidelines suggest that medical and surgical abortion may be undertaken by medical officers, OB/GYNs, and surgeons, while treatment of incomplete abortion may be performed by nurses and midwives. The 2006 guidelines were expected to be updated in 2017; however, a new revision is not yet in place. National standards and guidelines to reduce morbidity and mortality from unsafe abortion were published in April 2015, but was subsequently suspended due to lack of political will.[23]

The rate of abortion varies by geographic area, with higher proportions of abortions taking place in urban areas, particularly in the capital city of Kampala. An estimated 314,300 abortions took place in Uganda in 2013, which translates to a rate of 39 per 1,000 women of reproductive age.[24]

***Misoprostol*** has been registered in Uganda since 2008, and is available as Cytotech, Kontrac, Misoclear, Isovent and Misopro. It is registered for gastric ulcers, treatment of postpartum hemorrhage, and other gynecological indications.[25] ***Mifepristone*** was registered in 2013, and both DKT and MSI registered mife products, but they are no longer selling these since they have both recently registered ***combi-pack products***, indicated for abortion. Misoprostol is on the EML but mifepristone is not.

## B. Key Findings

### 1. Market actors

**a) Commercial Actor Involvement in MA Distribution:** Uganda has numerous large commercial pharmaceutical companies operating sophisticated, nationwide distribution networks. Some of these companies, including Laborex, SurgiPharm, Cipla/Quality Chemicals, and Royal Pharma, to name a few, sell MA products. Commercial actors often partner with other companies to import thousands of products, which they then distribute. Many companies operate comprehensively as importers, wholesalers, distributors, and retailers.

There are 1,810 licensed outlets which sell pharmaceutical products. In Kampala, many importer/wholesaler/distributors operate in the same area of the city alongside many pharmacies, and there is fluid trade of products. Retail branches often buy from various wholesalers, even when they are supposed to buy from their associated one. We saw one

[21] Uganda Ministry of Health, *Health Sector Strategic Plan III: 2010/11-2014/15*, Kampala, Uganda: Ministry of Health, 2010.
[22] Center for Reproductive Rights (CRR), 10 key points about Uganda's laws and policies on termination of pregnancy, Fact Sheet, New York: CRR, 2011.
[23] Guttmacher Institute. Fact Sheet: Abortion in Africa. 2017. https://www.guttmacher.org/fact-sheet/abortion-africa
[24] Guttmacher Institute. Fact Sheet: Abortion and post abortion care in Uganda. 2018. https://www.guttmacher.org/fact-sheet/abortion-and-postabortion-care-uganda#4
[25] Uganda. Essential Medicines Supply List. 2016. http://srhr.org/abortion-policies/documents/countries/05-Uganda-Essential-Medicines-and-Health-Supplies-List-2016.pdf#page=84

pharmacy in Kampala, for example, which had a nurse who could write prescriptions for combi-packs, and she was regularly sourcing another brand of combi-pack from a wholesaler down the road when her pharmacy was out of stock from its regular supplier.

**b) The Role of SMOs:** The SMOs are tapping into commercial distributors' existing distribution networks in order to deepen MA coverage.

- DKT works through SurgiPharm and has its team embedded in their operations. SurgiPharm has over 1,000 products and nationwide coverage.
- MSU works with several large importer/wholesaler/distributors with nationwide coverage, such as Royal Pharma, Medvin, and Escorts Pharmacy, with whom they have an exclusive relationship. They also previously worked with Abacus, another large importer/wholesaler/distributor, but stopped when Abacus started having management issues and underwent a reorganization.
- Some commercial actors now selling combi-packs were already selling contraceptive products or miso. Those not yet selling combi but who are selling miso could be good candidates to sell combi-packs in the future, as they are already familiar with the issues surrounding MA.

| Commercial Actors in Uganda | Functions | Current SMO Partner | Market Authorization Holder (MAH) | MA Products Sold (Consumer Price) | MA Sales/ Geographic coverage/ Populations Served | Manufact-urer | History/Planned Work/Potential |
|---|---|---|---|---|---|---|---|
| **SurgiPharm** | Importer<br>Wholesaler<br>Distributor | DKT | DKT | MA-KARE combi (USD 6)<br>Miso-KARE | Nationwide | Naari (India) | Contract with DKT for basket of MA and contraceptive goods |
| **Royal Pharma** | Importer<br>Wholesaler<br>Distributor | MSU | MSU | Mariprist combi (USD 7-8)<br>Misoclear | MSI sells c. 928 combi-packs/month and c. 177,872 Misoclear tablets/month across all distributors.<br><br>Nationwide - 20 branches | ACME | Candidate for distributing combi without SMO |
| **Medvin** | Importer<br>Wholesaler<br>Distributor | MSU | MSU | Mariprist combi<br>Misoclear | Sales as above<br><br>Nationwide -12 outlets | ACME | Candidate for distributing combi without SMO |
| **Escorts Pharmacy** | Importer<br>Wholesaler<br>Distributor<br>Retailer | MSU | MSU | Mariprist combi<br>Misoclear | Sales as above<br><br>Nationwide -14 outlets | ACME | Exclusive contract with MSU for Mariprist |
| **Laborex Uganda** | Importer<br>Wholesaler<br>Distributor | N/A | Laborex | Miso product<br>Cytotec | 1,000 miso / month<br>Nationwide | Pfizer | Potentially interested in distributing combi |
| **Delmaw Enterprises** | Importer<br>Wholesaler<br>Distributor | N/A | Delmaw | Miso product<br>Kontract | Nationwide | Fourrts India Ltd | Potentially interested in distributing combi |
| **Cipla/Qual-ity Chemicals Industries** | Manufacturer<br>Importer<br>Wholesaler | N/A | Cipla/Quality Chemicals Industries | Misoprost (USD .20/tablet) | About 54% of total sales of all drugs are to Ugandan | Cipla Ltd India | Have manufacturing plant in Uganda for |

| | | | | |
|---|---|---|---|---|
| | Distributor | | government; rest to other African countries directly or via Global Fund. | ARVs, anti-malarials, hepatitis drugs. Did not interview but worth following. |
| **ZiZhu Pharma** | Manufacturer | | Self | Looking for a distributor in Uganda for combi product; awaiting WHO PQ. Plans to export to Kenya & TZ. |

## 2. The 4 Ps of Marketing

### a) Product

*Two combi-packs are registered and on the market*: DKT's MA-KARE and MSI's Mariprist, both of which are new this year. MSI has sold 6,499 of Mariprist from April to October 2018. MSI sold 1,778,779 miso tablets from January to October 2018. Coverage is good in Kampala and major towns across Uganda.

*Misoprostol* does require a prescription but it is widely available over-the-counter. No quality issues with drugs arose in our assessment, but pharmacists expressed preference for combi-packs as they were more effective than miso alone.

### b) Price

All companies we interviewed explained that because clients were asking for medical abortion drugs, albeit at low volume, they wanted to offer it. One Managing Director explained that he sees it as the company's duty to offer all the products clients may want, and he sees the public health benefit of medical abortion, while others explained that this was simply good business to have a wide product offering. For SurgiPharm, combi-packs were a gap in their offering and a way to reach the bottom of the pyramid, to which they hope they can sell other products. For their part, the commercial companies work with the SMOs in order to expand their product offering; it's less about making a profit (although some do make a small one), and more about keeping their clients happy.

DKT sells its combi-packs to SurgiPharm with a 15% margin; SurgiPharm also adds a margin of 15%, then it is sold to the client for about USD 6. SurgiPharm said it is probably making a small loss if warehouse rental is factored in, but they expect to make this up as sales increase. Some pharmacists we met had switched to DKT's product because it was cheaper.

MSI sells its combi-pack to its distributors for USD 6; the price to the client is USD 7-10. MSI's distributors say that they are covering costs and making a small profit. We didn't hear concerns about the level of pricing to the client in Kampala, but MSU sales representatives reported that consumers in rural areas complained about the combi-pack price being too high.

Since there isn't much brand awareness, clients will go for the cheaper product if they are given a choice. The price of combi-pack probably does vary outside the USD 10 range for provision without a prescription, but none of the pharmacists we interviewed admitted to this, as they did in Zambia.

As long as commercial distributors could get the same price or similar from the manufacturer, they should be able to provide the product at a reasonable price to the client. In fact, they may be able to add an adequate mark up and still offer an affordable price to the client by cutting out the SMO margins.

### c) Place (providers: clinics and pharmacies):

- Providers working in public facilities will not provide MA, but some will do so in their private clinics.
- Providers in large private hospitals tend not to order combi-packs, according to DKT, and most of their sales come from smaller clinics.
- Apart from private clinics, women purchase MA products from pharmacies and require a prescription.
- Rural providers are thought to prefer MVA so they can get the job done as soon as possible with a lower risk of being found out. DKT conducted a recent survey showing

that abortions in rural areas where they are working are 80% MVA; by contrast, MSI reported 80% MA out of all its services.

**d) Promotion**

Stigma around abortion remains pervasive in Uganda and inhibits availability, as many providers are unwilling to provide the service. Providers also lack full awareness of the law and the 2006 guidelines, and still think abortions, and therefore combi-packs, are illegal. Since promotion of MA products can't be done directly to women, it's up to providers to promote the product.

*Combi-packs:* The commercial distributors we interviewed all remarked that combi-packs needed to be supported by promotion and medical detailing amongst the providers. These companies would not assign sales and marketing personnel for combi-packs, as a currently low margin / low volume product, but they saw the need for sales and detailing people to promote sales, especially at this early stage of product awareness.

Some companies anticipate that combi-pack sales will increase over time as awareness of the product grows. Others, however, say that they expect them to remain a low margin, low volume product for the short-term, and view this as acceptable since they are piggy-backing this product onto their existing distribution. (SurgiPharm predicts that combi-packs will be high volume in the future, while Delmaw saw that there could be opportunities for tenders for bigger volumes in the future.)

Laborex, which sells Cytotec and is not yet selling combi-packs, said that they would expect marketing support if they were to add combi-pack to their products. They also said that they would appreciate post-market surveillance to get information about outcomes and any adverse events.

SurgiPharm said that a critical factor in working with DKT was that DKT would provide sales people who would promote the product.

Various models for product detailing could work for these companies: having a separate organization or company do this work (such as an SMO), or having dedicated staff embedded in their team and paid for by another party, or cost-sharing staff time. This latter option is less desirable as it could lead to staff spending more time on more profitable products at the expense of combi-packs.

*Misoprostol*: Misoprostol is seen by Laborex as a fast moving product, with current sales of 1,000 per month. Note, however, that this number was 5,000 per month previously, before prescriptions were enforced.

Delmaw described Kontrac, its misoprostol product, as a "big mover for the business" because they distribute it through tenders for NGOs. MA products represent less than 1% for companies such as Medevin who sell 2,500-3000 different products. They would like to see demand generation done so that sales will increase in future.

Women do ask for MSI's product Misoclear by name, as the product has been in the market for several years, but women rarely ask for the combi-pack products by brand name, which is not surprising as they are new to the market.

**3. Other Market Functions**

a) **Regulatory Environment**.

All five companies interviewed said that they could handle the registration and importation of a new product but would expect reimbursement for the registration fees, as these were a

significant cost. The National Drug Authority is not seen as political or having anti-choice biases, with decisions based on public health need and science.

SMOs talk about converting buyers from misoprostol to combi-packs, but others noted that keeping misoprostol products on the market is a good risk mitigation strategy in case combi sales are ever suspended or shut down. MSU reports a recent tightening of oversight on their clinics, and an increase of mystery clients coming to clinics and calling their call center.

### b) Policy Environment.

We heard from many interviewees that women lack awareness about the abortion law and where they can access safe, affordable abortion services. Commercial actors we interviewed spoke of the value of and need for NGO support for awareness-raising work at the community level. Although the conditions for abortion have been expanded, there is still a climate of fear around abortion, amongst women and providers. The president's wife is anti-choice and has significant influence over the MOH, though her activities against abortion ebb and flow (currently they are getting stronger). DKT, like MSI, reports that they have experienced closer scrutiny of their work.

The requirement to get a prescription is also a barrier for women. Some pharmacists we interviewed reported that most women don't come with a prescription, but others said most did. All said that if women didn't have a prescription, they sent them to get one before they would sell them combi-packs, although in reality this is probably not the case. However, they said that they have regularly sold miso to women without prescriptions, because it could be used for other indications so they weren't as worried. Authorities do come and check pharmacies to see if prescriptions have been given but this is for all products.

### c) Coordination and Collaboration of Market Actors.

In Uganda, with such limited provision of MA in the public sector, the private sector is playing a critical role in making these services available. SMOs and commercial actors are collaborating so that on the one hand, SMOs can introduce MA products and deepen their sales coverage, and on the other, commercial distributors can widen their product offering. SMOs are also distributing other products through the commercial distribution partners, such as contraception, emergency contraception and condoms.

When products are new and require promotion and sensitization amongst providers, this kind of partnership makes sense. But for the longer-term, the question arises as to what extent the SMOs are necessary for ongoing sales and distribution. The need for product detailing and promotion is clear, but that function doesn't necessarily have to be done by SMOs.

If commercial distributors are to enter the market, then they will need to see a place for themselves in that market. Delmaw's Head of Marketing, for example, said that he was aware that DKT was selling a combi-pack product, so they would need to be convinced that there was room in the market for them to enter.

### d) Financing requirements.

A major risk commercial actors see is expiry of products. Recently DKT had to donate products that were near expiry, which is something that the commercial partners don't want to see as it erodes willingness to pay in the market. Commercial distributors need to be confident that they can sell what they take on, so it's important to consider minimum order levels, if stock can be released gradually according to demand, and ensuring that demand continues and rises. As an example, Delmaw expressed concern about minimum orders, which could be 30,000 boxes, and said they would need to see a strong business case before agreeing to take on that much risk.

## C. Recommended Interventions

Uganda is a developing combi-pack market: combi-pack products have been registered and are available but there is still limited support by the clinical and commercial community. This requires interventions across the spectrum of market development.

### Registration/Entry

**i) Register a New Combi Product.** While availability of combi-packs has greatly improved in Uganda, with the SMOs working with commercial distributors who have nationwide coverage, the fact that there are no strictly commercial brands on the market means that this availability is dependent on SMOs and their donor funds – a precarious and unsustainable position. Donors could facilitate the registration of a new combi-pack product by covering the registration fees and staff time. A company like Laborex is an excellent candidate for this.

**ii) Negotiate Gradual Stock Release from Manufacturers** to mitigate risks of unsold stock. Donors could negotiate a gradual release of stock as stock expiry is a major risk for companies. Donors could also consider covering the costs of warehouse space in the short term, as an added incentive.

### Market Building

**iii) Donors should pick one or more commercial partners to incentivize.** The five companies we interviewed have the capability to handle registration as the local agent, as well as to import and distribute. Laborex and Melcome showed interest in taking on the registration, importation and distribution of combi-pack products and can do so in a viable way by piggy backing onto their existing distribution systems. Donors should also consider working with companies that have their own *retail* branches, in which they have recommended price ranges for their products. This level of visibility into retailer pricing can help keep combi-pack prices affordable for women.

**iv) Fund SMOs with a view to support commercial growth sustainability**. As conversations with stakeholders in Uganda demonstrated, there are good roles that SMOs should play as the market develops, and roles that they should phase out of. If donors want to help the market develop, then they will need to consider the functions for which they are funding the SMOs.

- Do Fund: SMOs and NGOS to conduct community education and awareness-raising so that women know about the combi-pack and where to access it.
- Do Fund: SMO medical detailing/provider promotion *OR* medical detailing/provider promotion in-house in commercial distributors.
- Don't Fund: Phase out funding of SMOs' sales and distribution to urban areas where commercial companies can prosper.
- Do Fund: SMOs *OR* private companies to conduct post-market surveillance, collecting data on outcomes, adverse events etc. Good data are valuable to commercial companies, yet they don't want to collect them themselves.

### Policy Change

**v) Fund advocacy to improve policy guidelines to enable better access to safe abortion**. While market development is supported through the introduction of new combi-pack products, donors should also continue funding advocacy efforts such as getting the 2006 National Policy Guidelines and Service Standards for Sexual and Reproductive Health and Rights and those on reducing morbidity and mortality from unsafe abortion, revised and implemented to embrace MA and specifically combi-packs; and for getting mifepristone on the Essential Medicines List.

## Market Growth

**vi) Expand access by redirecting subsidies to underserved populations such as rural areas.** To grow the market in Uganda in the longer term, donors should redirect subsidy to rural areas, where there is a particularly strong need to raise awareness among women about the law and about where they can access safe abortion products and services. A similar education and behavior change effort should be prioritized among providers who serve rural populations. Currently SMOs are covering some of the same ground in Kampala and big towns, visiting the same distributors and retailers, and fighting for market share. Some of these efforts should be moved to rural areas not well covered.

# Zambia

## A. Overview

Zambia has one of the most liberal abortion laws in sub-Saharan Africa, allowing for termination of pregnancy on health and socioeconomic grounds.[26] However, the numerous requirements that must be met for women to receive a safe abortion mean that many women lack *access* to these services. In particular, the law requires that the abortion be performed in a facility by a physician with the consent of three registered medical professionals. In an emergency, the consent of only one doctor is required, but what constitutes an emergency hasn't been tested.

There were new safe abortion guidelines signed in April 2018, but there is a lack of political will to launch them. Ipas is pushing guidelines on Safe Motherhood and Nutrition which include safe abortion, and hope that they can get these implemented.

Women who attempt to induce their own abortion face prison sentences of up to 14 years.[27] Abortion may be performed in both public and private sector facilities. Zambia has been declared a "Christian nation," and conservative religious views prevail. In addition to structural and cultural barriers, the high out-of-pocket cost of abortion services leads many women to seek unsafe alternatives.[28] The rate of maternal mortality in Zambia is estimated to be 224 deaths per 100,000 births, with an estimated 30% of those deaths resulting from unsafe abortions.[29] Data on the characteristics of women seeking abortion are scarce. However, small studies from hospitals throughout the country suggest that younger women in urban areas make up the majority of abortion patients.

**Misoprostol** is registered on the EML and is available by prescription under the brand names Misoclear, Misopro, and Cytotec[30]. It is approved for treatment of incomplete abortion and miscarriage, missed abortion in the first trimester, and intrauterine fetal death.[31]

**Mifepristone** is not on the EML but both misoprostol and mifepristone are in the national guidelines.

The **combi-pack products** registered and on the market are:

- Marie Stopes Zambia's (MSZ) Mariprist, Medabon, and Antipreg, all registered for induced abortion.
- There was also another combi-pack product, Divabo, on the market which was not registered and came in through a special import licence, but the last stock expired this year.
- DKT is in the process of registering a combi-pack product.

[26] Guttmacher Institute. Unsafe Abortion in Zambia. 2009. https://www.guttmacher.org/sites/default/files/report_pdf/ib-unsafe-abortion-zambia.pdf
[27] Mubita-Ngoma, C. Abortion Policy in Zambia: Implementation Challenges. 2017. https://www.researchgate.net/publication/321910700_Abortion_Policy_in_Zambia_Implementation_Challenges
[28] Leone T et al., The individual level cost of pregnancy termination in Zambia: a comparison of safe and unsafe abortion, *Health Policy and Planning,* 2016, 31(7):825–833, http://dx.doi.org/10.1093/heapol/czv138.
[29] Mubita-Ngoma, C. Abortion Policy in Zambia: Implementation Challenges. 2017. https://www.researchgate.net/publication/321910700_Abortion_Policy_in_Zambia_Implementation_Challenges
[30] Zambia Register for Marketing Authorization. 2015. http://srhr.org/abortion-policies/documents/countries/09-Zambia-Register-for-Marketing-Authorisations-Medicines-Regulatory-Authority-2015.pdf#page=2
[31] Venture Strategies. Misoprostol registrations July 2013 https://www.k4health.org/sites/default/files/Global%20Misoprostol%20Registration%20by%20Indication%20detailed%20spreadsheet_0.pdf

- Zizhu Pharmaceuticals has registered non-pre-qualified separate packing of generic mifepristone and misoprostol but hasn't received any orders recently.

## B. Key Findings

### 1. Market actors

**a) Commercial Actor Involvement in MA Distribution:** None of the global pharmaceutical giants are in Zambia, but there are many companies selling pharmaceutical products. Commercial wholesaler/distributors in Zambia are often not highly specialized and sell a myriad of products with the goal of quick profit, so fast moving goods are the priority. Most commercial 'distributors' in Zambia don't have active sales teams and operate more like wholesalers.

However, there are several commercial wholesaler/distributors that do distribute MA products. We met with several companies that import, wholesale and distribute pharmaceutical products such as Westgate Pharmaceuticals, Pharmaplus, Life Pharmaceuticals, and Lusaka Pharmaceuticals, who sell MSZ's Mariprist combi-pack product and also MSI's Misoclear and/or other miso products. These companies sell to private clinics and pharmacies. There are 214 licenced pharmacies in Zambia.

We also met with 2 other very large companies with nationwide reach that import, wholesale and distribute: Sterelin and Melcome, which are not yet selling combi-packs. Melcome previously sold misoprostol but pulled it from the market over fear of 'abuse' and checks from the authorities. Sterelin has been selling miso and now has a deal with PSI's social enterprise to register, import and distribute a basket of goods including contraceptive products and misoprostol, with plans to include a combi product. (See Yash Pharmaceuticals below.)

**b) SMOs and NGOs:** MSZ, which has two sales representatives, increasingly works through commercial wholesaler/distributors to deepen their sales coverage. Some of these wholesalers/distributors focus on particular geographical areas while others are nationwide, and they range in size. For all of them, MA is a very small part of their business, less than 1%.

Yash Pharmaceuticals previously distributed Mariprist for MSZ, and has plans to distribute for DKT once they register a combi-pack product (in the process of registering one currently). Yash won a tender to supply Ipas with Medabon, and now supplies them with Medabon and Antipreg. Yash also distributes Medabon and Antipreg on a purely commercial basis, meaning no subsidies and no SMO/NGO involvement. About 50% of Yash's Medabon sales are through Ipas and the other half is to private clinics and pharmacies. 90% of Yash's Antipreg sales are through Ipas and 10% goes to the private market.

| Commercial Actors in Uganda | Functions | Current SMO Partner | Market Authorization Holder (MAH) | MA Products Sold (Consumer Price) | MA Sales/ Geographic coverage/ Populations Served | Manufacturer | History/Planned Work/Potential |
|---|---|---|---|---|---|---|---|
| **Westgate Pharmaceuticals** | Importer<br>Wholesaler<br>Distributor<br>Retailer | MSZ | MSZ | Mariprist combi (USD 12-15)<br>Misoclear | Sells c. 200 Mariprist/ month<br><br>Lusaka/Eastern Zambia: 4 retail branches | ACME | Limited regional scope |
| **Pharmaplus** | Importer<br>Wholesaler<br>Distributor | MSZ | MSZ | Mariprist combi (USD 12-15)<br>Misoclear | Sells c. 200 Mariprist/ month<br><br>Nationwide | ACME | Candidate for distributing combi without SMO |
| **Life Pharmaceuticals** | Importer<br>Wholesaler<br>Distributor<br>Retailer | MSZ | MSZ | Mariprist combi (USD 12-15)<br>Misoclear | Sells c. 150 Mariprist/ month<br><br>2 retail branches; will open 3rd | ACME | Limited regional scope |
| **Lusaka Pharmaceuticals** | Importer<br>Wholesaler<br>Distributor<br>Retailer | MSZ | MSZ | Mariprist combi (USD 12-15)<br>Misoclear | Sells 500 Mariprist/ month<br><br>Nationwide 6 retail branches, 2 of which are in Lusaka | ACME | Candidate for distributing combi without SMO |
| **Yash Pharmaceuticals** | Importer<br>Wholesaler<br>Distributor | N/A | Yash | Medabon (USD 12-15)<br>Antipreg (USD 12-15) | Sells 1,000-1,500 Medabon/month to private clinics and pharmacies; same amount monthly to Ipas.<br><br>Sells c. 160 Antipreg/month to private clinics and pharmacies; c. | SUN (Medabon)<br>Intas (Antipreg) | Sells Medabon and Antipreg to Ipas and also on commercial basis. Will partner with DKT when their combi-pack is registered. Potentially interested in selling other combi-pack brands. |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | 2,080/month to Ipas. Nationwide | | |
| **Sterelin** | Importer Wholesaler Distributor | PSI | PSI | Forthcoming | Nationwide | | Working with PSI's social enterprise whose basket of goods is under registration, will probably include a combi-pack product. |
| **Melcome** | Importer Wholesaler Distributor | N/A | N/A | N/A | Nationwide | N/A | Potentially interested in distributing combi; used to sell miso |
| | | | | | | | |

| Other Manufacturers with plans for MA combi-pack | Country | Status |
|---|---|---|
| ZiZhu Pharmaceuticals | China | V.L. Healthcare will be local agent once ZiZhu's generic combi-pack gets WHO PQ. Could not reach for interview. |

## 2. The 4 Ps of Marketing

**a) Product**:

- PSI distributed misoprostol sporadically in previous years, including 108,290 units in 2011 and 119,988 units in 2013.
- MSZ sold 3,585 tablets of Misoclear in 2017 and has sold 5,190 tablets of Misoclear as of October 2018.
- MSZ has sold 16,630 combi-packs this year as of October 2018, against 19,845 in 2017. MSZ's view is that sales are low compared to the potential market, and they are trying to increase distribution in more remote areas.
- Yash sells approximately 2,000 combi-packs of Antipreg and 12,000-18,000 of Medabon a year to private clinics and pharmacies; and 25,000 combi-packs of Antipreg and 12,000-18,000 of Medabon a year to Ipas.

**b) Price**: Medabon is USD6 to the wholesaler/distributor, while Mariprist is USD9. The price to the client for both products, as well as Antipreg, is USD12-15 with a prescription, but this can rocket to USD50-100 without one, for all brands. According to MSZ, pharmacies selling at high volumes are doing so without prescriptions.

While one wholesaler/distributor stated that it would not stock MA if it were not the MSZ brand, two others said they would just order another brand from Yash. Some wholesaler/distributors said they feel they are getting a good price from MSZ, and are able to add margins of 20-30%, but they are not making big profits because the volumes are too low. The reason that they are content to continue distributing MA is that they are able to add MA products to the hundreds of other products they sell.

**c) Place (providers: clinics and pharmacies)**: Despite the liberal law, medical abortion drugs are largely not available in the public sector, as the government does not buy them. Women can see a doctor and get a prescription, but then have to go to a pharmacy to fill it. In public facilities, Ipas works to change attitudes of doctors through advocacy and VCAT. Once Ipas stops working in a facility, however, despite sustainability plans, the MOH doesn't order the drugs. CHAI has similar experience in the facilities where they are working.

**d) Promotion**: All wholesalers talked about the need to educate communities about unsafe abortion and where to access services. With restrictions around marketing and public advertising of any drugs, awareness-raising has to be done more at the community level so women know where to go for a safe service. There is also a low level of awareness of the law amongst wholesalers, pharmacists and doctors, affecting their willingness to provide the product. MSZ recently conducted a study on self-use of MA and had trouble recruiting pharmacists, as they didn't want to be involved in anything to do with abortion.

The larger commercial companies say that marketing support and promotion are required to sensitize and create demand amongst providers and pharmacists. This kind of detailing is the model that they use for their more lucrative brands, supported by dedicated sales people. A couple of the smaller companies (such as Westgate) said that they didn't get any detailing

from MSZ and didn't require it for combi-pack, as their pharmacist clients were familiar with the product.

Others expressed appreciation for the work done by MSZ to activate demand amongst providers and pharmacies through sensitization, training, awareness-raising on the law, and call contact center. Pharmacists expressed interest in getting more education and detailing on the combi product, and there's an expectation that new products should come with some initial detailing to ensure demand from their clients.

According to the pharmacists we spoke with, women rarely ask for particular brands; they just ask for help with termination. Occasionally they ask for the miso product Cytotec. According to Yash, women are starting to ask for Antipreg's "pink packs," but they don't know the brand names and just want a solution regardless of brand. Sales of emergency contraception far exceed sales of MA: pharmacists reported selling 1-2 packs of Mariprist per day compared to 40 doses of EC.

### 3. Other Market Functions

**a) Regulatory Environment.** ZAMRA keeps a close eye on which companies are distributing which drugs, particularly in Lusaka, and they are getting stricter. They tend to carry out audits in waves (when they have funding). They have up to date records on all companies that hold the marketing authorizations for each drug; licensed wholesalers; and registered retail pharmacies. Before pharmacies were selling freely, but now ZAMRA is asking to see doctors' signatures, making pharmacies nervous. Inspections by regulatory authorities occur every year and licences are revoked when there is no evidence of prescriptions by three doctor for each order of combi-pack.

**b) Policy Environment.** The conservative socio-cultural environment in Zambia, in addition to personal beliefs, affect what pharmacists are willing to sell. According to MSZ, some outlets purchase combi-packs, some only miso, and some (the ones that are anti-abortion) only pregnancy test kits. Providers are currently seen as obstacles to market growth, so that commercial companies want greater efforts to sensitize and educate providers and pharmacists. This would come with product detailing but also requires changes in the policy and socio-cultural environment to decrease stigma around abortion.

**c) Coordination and Collaboration of Market Actors.** Zambia is the only country in our assessment besides Sierra Leone where we found combi-packs being sold on a commercial basis without SMO involvement, and shows that this can be done. There is room in the market both for MSZ and a commercial distributor, Yash. While Yash initially sold combi-packs through MSZ, they now do so on their own commercially, as well as supplying Ipas. Yash switched to importing and selling Medabon in 2016 because they felt too much pressure to promote and sell MSZ's product. Yash does not want to be seen to be promoting abortion but believes the combi-pack is an important product to have in its offering for health reasons. Yash says that they will continue to sell combi-packs in the future regardless of donor funding or tenders, and that they would not increase the price of the products even if they were no longer supplying Ipas. They are also interested in working with donors on new programs to expand access.

An interesting example of SMO collaboration with the commercial sector is PSI's regional social enterprise based in South Africa. The aim is to offer a basket of affordable, high quality family planning and MA products either through a global brand or through partnerships to boost existing commercial brands. In Zambia, PSI is partnering with Sterelin to register a number of new products. What is different about the social enterprise approach, as opposed to how SMOs are working with commercial distributors in many countries, is that it is designed to lead to less donor dependence over time and commercially viable products.

**d) Financing requirements.** Importing products into Zambia is not difficult, but registration costs (USD 4,00) and time are barriers for products that don't make large profits. Annual renewals of licences at USD 800 are also required. If any of the companies we met with were to take on registration for a combi product, they would want the registration and license fees to be covered.

Minimum orders are also an issue: Yash found it difficult to import and sell 40-50,000 combi-packs previously, so they have lowered their annual order to 30,000 and negotiated a gradual release of stock.

## C. Recommended Interventions

Zambia is a developing combi-pack market: three combi-pack products have been registered and are available but there is still limited support by the clinical and commercial community. Zambia presents an interesting case as one of only two countries assessed where there are commercial combi-pack products available. In this scenario where there are two brands on the market available on a commercial basis, Antipreg and Medabon, plus PSI's social enterprise product and DKT's combi pack likely to be forthcoming, it's less of a priority to register a new commercial brand, but other interventions could help develop the market.

### Registration/Entry

**i) Facilitate purchase and importation of combi-pack order to help commercial actors scale up.**
-Consider providing capital for larger stock purchase (soft loan).
-Negotiate for gradual release of stock in line with expected sales.

For example, while Yash Pharmaceuticals is already selling combi-packs commercially, they could expand their sales if they had support for making larger stock purchases- while still graduating shipments – and had more support for product detailing and promotion, as below.

### Market Building

**ii) Donors could collaborate with commercial distributors to boost sales of existing commercial combi-pack products.**
Donors could consider covering costs of product detailing and promotion for a limited time to enable expansion to new areas. This could be done through Yash and also working with additional commercial distributors.

**iii) Fund SMOs with a view towards supporting commercial growth in sustainable ways**.
As in Uganda, there are good roles that SMOs could play in Zambia as the market develops, and roles that they should phase out of. If donors want to help the commercial market develop, then they will need to consider the functions for which they are funding the SMOs. Zambia represents an opportunity to fund social marketing programs in such a way as to increase sustainability via the private sector.

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising so that women know about the combi-pack and where to access it.
- Do Fund: SMO medical detailing/provider promotion and VCAT activities. *OR* medical detailing/provider promotion in-house in commercial distributors. *OR* a hybrid of the two, where SMOs second detailers to the commercial distributors for a discrete period of time, to boost provider buy-in.

- Don't Fund: Long-term SMOs sales and distribution and their associated overhead, unless they can quickly become commercially viable (as in, for example, a fully cost recoverable DKT or MSI product, or PSI social enterprise product).

**Policy Change**

**iv) Fund advocacy to improve policy guidelines to enable better access to safe abortion**. To increase longer-term availability of medical abortion, donors should continue funding advocacy efforts for:

- persuading the MOH to finance and supply its facilities with combi packs;
- introducing guidelines to allow mid-level providers to provide abortion; and
- lifting requirements for prescriptions – especially the requirement for three providers' signatures.

**Market Growth**

**v) Expand access and equity by redirecting donor subsidies to underserved populations such as rural areas.** In order to meet equity goals, where women in areas beyond large urban centers are able to access MA, donors could bring new attention to rural areas, where there is a particularly strong need to raise awareness about the law and about where women can access safe abortion products and services. The main activities to increase equity in rural populations are to:

- detail providers that service rural populations with family planning products and services, so that they commit to stocking combi packs;
- increase awareness of laws and regulations among women in these areas, so that they know their rights to safe abortion;
- increase women's knowledge of where to obtain combi packs;
- facilitate a stable supply chain, where extra funding may be required to reach low volume, far flung outlets.

**Remote Interview Countries**

# Ethiopia

## A. Overview

Ethiopia's abortion law is relatively liberal compared to those in neighboring countries. After a reform in 2005, the law now permits abortion in the case of rape, incest, fetal impairment, if the mother's life or physical health is in danger, if the mother has physical or mental disabilities, or if the mother is a minor who is mentally or physically unprepared for childbirth.[32] Shortly after the 2005 legal reform, national guidelines were expanded to permit medical abortion in accordance with WHO clinical recommendations on safe abortion.[33] Ethiopia's MOH at the national level is committed to safe abortion, but this is not necessarily the case at the sub-national levels or the provider level.

In 2014, an estimated 620,300 abortions were performed. Women seeking abortion services are primarily young, married, and have had at least one previous pregnancy.

Misoprostol is registered for PPH and medical abortion under the brand names Misoprost, Cytotec, Ace Miso and Miso-fem. Mifepristone is registered for medical abortion. Three combi-packs are registered in Ethiopia: DKT's SafetyKit; MSI's MariSafe; and Elpis Pharmaceuticals' Ace Kit which was just registered in January 2019. Concept Foundation facilitated the registration of Medabon which since lapsed, and now Medtech (SUN's local agent)is awaiting renewal for Medabon.

MVA and misoprostol used with mifepristone or used without are on the EML and in the national guidelines. The technical guidelines state that a doctor or mid-level provider has to provide MA and it should be done in a health facility, while training guidelines allow the second dose to be taken at home. By mandate all public facilities offer MA per the guidelines. Ipas, EngenderHealth, FGAE and MSI all provide training to the government on safe abortion.

## B. Key Findings

### 1. Market actors

**Commercial Actor Involvement in MA Distribution:** The global giant pharmaceutical companies do not operate in Ethiopia, but there are several large companies selling pharmaceutical products, as well as smaller distributors that are very fragmented and not specialised. Some of the larger companies relevant to MA include Eyasu Pharmaceuticals, Life Care Pharmaceuticals Trading, AfroGerman Chemicals, Beker Business Pharmaceuticals, Zaf Pharmaceuticals, Caroga Pharma, Elpis Pharma, Medtech, and Micro Pharma. As in other countries, many companies operate comprehensively as importers, wholesalers, distributors and retailers, so that they have the capacity to both bring in combi-packs and distribute them.

Currently three of these companies are selling miso, Elpis Pharma, Caroga Pharma and Micro Pharma. Elpis just got its combi-pack Ace Kit registered in January 2019. AfroGerman Chemicals previously worked with Concept Foundation to register Medabon, but a mistake

[32] Ethiopia Ministry of Health, Health Sector Development Program IV in Line with GTP, 2010/11–2014/15, Addis Ababa, Ethiopia: Federal Democratic Republic of Ethiopia, 2010.
[33] Ibid.

with labeling left DKT's name (who were previously Concept's partner) on the pack and resulted in all the products being recalled and destroyed. This experience has made AfroGerman skeptical of being involved in MA. They say that DKT has the market totally covered and they have no plans to get back into the MA business. Medtech has applied to renew Medabon, but we weren't able to learn their plans. Eyasu used to distribute MVA kits but stopped working with NGOs when they restructured their business. We spoke with two companies-Beker Business Pharmaceuticals and Zaf Pharmaceuticals- which haven't been involved in selling MA before but would be willing to consider selling combi-packs if there was a business case and significant barriers, such as foreign currency limits, could be overcome.

**b. The Role of SMOs.** DKT is the main distributor of combi-packs in Ethiopia and does its own distribution of its combi-pack product SafetyKit. MSI distributes its combi-pack product, MariSafe, to its own clinics and franchisees.

| Commercial Actors in Ethiopia involved in MA | Functions | Current SMO Partner | Market Authorization Holder (MAH) | Current MA Products Sold (Price to consumer) | MA Sales/ Geo coverage/ Pops Served | MA Manufacturer | History/ Planned Work/ Potential |
|---|---|---|---|---|---|---|---|
| **N/A** | N/A | DKT | DKT | SafetyKit (combi)<br>Misofem (miso) | Large and secondary urban areas | Naari<br>Naari | |
| **N/A** | N/A | MSI | MSI | MariSafe (combi) | | Naari | |
| **Eyasu Pharma** | Importer<br>Wholesaler<br>Distributor | N/A | N/A | N/A | | N/A | Previous supplier of MVA kits to NGOs; no longer works with NGOs. Willing to consider selling combi-packs. |
| **Life Care Pharma Trading** | Importer<br>Wholesaler<br>Distributor | N/A | N/A | N/A | | ZiZhu | Will be distributor for ZiZhu's WHO pre-qualified combi product if it gets registered, not yet submitted. Will be sold commercially. Also will sell miso and EC. |
| **AfroGerman Chemicals** | Importer<br>Wholesaler<br>Distributor | N/A | N/A | N/A | N/A | N/A | Concept worked with AfroGerman Chemicals to register Medabon. No plans to sell MA; say DKT now has market covered. |
| **Beker Business** | Importer<br>Wholesaler<br>Distributor | N/A | N/A | N/A | N/A | N/A | No previous MA sales but potential. |
| **Medtech** | Importer<br>Wholesaler<br>Distributor | N/A | | Medabon | Covers almost all regions | SUN | Medtech is SUN's local agent. Has recently applied to renew Medabon. Discovered late in landscape assessment process so did not interview. |
| **Elpis Pharmaceuticals Import** | Importer<br>Wholesaler<br>Distributor | N/A | | Ace Kit combi-pack<br>Ace Miso | | ACME<br>ACME | Combi-pack just registered in January 2019. Discovered late in landscape assessment so did not interview. |
| **Zaf Pharma** | Importer<br>Wholesaler<br>Distributor | N/A | N/A | N/A | Covers 7 regions | N/A | Potential interest in selling combi-pack if could see space for private market. |
| **Caroga Pharma** | Importer<br>Wholesaler<br>Distributor | N/A | | Cytotec | | Piramal Health | Did not interview. |

| | | | | | |
|---|---|---|---|---|---|
| **Micro Pharma** | Importer<br>Wholesaler<br>Distributor | N/A | Misoprost | Cipla Ltd | Did not interview. |

## 2. The 4 Ps of Marketing

### a. Product

*Misoprostol*: DKT has distributed a high volume of misoprostol since 2011, ranging from 245,000 to 343,000 units per year.

*Combi*: DKT sold 565,291 of its combi product SafetyKit in 2017, and is projecting 500,00 for 2018, a drop mainly due to a temporary supply disruption.[34]

MSI sold 29,253 MariSafe combi-packs in 2017 and 32,503 in 2018 as of October.

### b. Price

DKT's combi-pack ranges from USD 5 to USD 100 to the client, depending on where it is sold. The lower range is for very rudimentary Lower Clinics while the upper range is for specialist MCH Centers serving a relatively affluent urban elite.

MSI's combi-pack ranges from USD 12 to USD 28 to the client, including the services and depending on where they are offered. The lower range is for MSI's private franchisees while the upper range is for MSI's public franchisees.

MSI receives donor funds for the costs of MariSafe for its clinics and franchise, but it operates a revolving fund under its business wing which is able to cover the cost of the MariSafe (just the products themselves) sold to its informal network.

DKT's combi products are funded by its donors -- LAD, DFID, the Dutch and the Irish. They recover some costs in-country but cannot repatriate these funds and use them to buy drugs (See Financing below). DKT Ethiopia is independent, so they do not have the option of having a headquarters office purchase drugs for them.

### c. Place

DKT supplies free SafetKit combi-packs to public facilities and to NGOs partners nationwide. Public sector distribution takes place in large and secondary urban areas. Free combi-pack distribution to the public sector represents 23% of DKT's total distribution of combi-packs; 25% goes to NGO partners and 52% goes to the private sector (pharmacies, private clinics and hospitals). Women go to private clinics and pharmacies and pay for combi-packs due to the better service and shorter waiting times compared to the public sector.

MSI combi-pack product distribution is only directed towards its own clinics and franchisees.

### d. Promotion

The combi-pack is seen as a specialized product that requires medical detailing and promotion. Women need a prescription to obtain medical abortion and cannot get it over the counter, so providers are the point of contact for women. DKT has a team of qualified nurses who go to private sector clinics to do product demonstrations and arrange training for providers. Given the stigma around abortion, many women are unwilling to seek prescriptions, while women especially in rural areas are not aware of the law and where to go for a safe abortion. Commercial actors such as Zaf Pharmaceuticals explained that they would expect comprehensive product detailing and promotion with providers for combi-pack introduction, coupled with launch events for stakeholders and opinion leaders.

[34] DKT International. *DKT Social Marketing Contraceptive Sales Database 1990-2017*. Retrieved from: https://www.dktinternational.org/contraceptive-social-marketing-statistics/

## 3. Other Market Functions

### a. Regulatory Environment

Advocates such as Ipas want to see the requirement for prescriptions lifted, so that pharmacists can provide combi-packs. But some stakeholders disagree that there's a pressing issue to allow pharmacists to provide combi-packs, because women can get them for free at public facilities or at private clinics. The private clinics are staffed by doctors and mid-level providers who can provide MA.

Pharmacies are mostly located around clinics and hospitals, and comprise only about 10-15% of the total market for combi MA sales and distribution. One MOH official explained that there was certainly some movement of combi-packs out of public facilities to pharmacies because the supply figures didn't always match the clients seen.

Ethiopia has highly developed regulation and oversight, with clinics frequently visited and audited. Recently reforms of processes and procedures have been enacted to make it more efficient to get quality assured drugs into Ethiopia. It's too early to tell any impact from this yet.

### b. Policy Environment

Despite the liberal law, stigma still exists, with many pharmacists unwilling to provide MA, even with a prescription, and not aware of the law. Especially given the high degree of regulation, pharmacists don't want to take the risk of any complications. Pharmacists require more orientation on the law, and on side effects and complications of MA, and the assurance of having a network of clinics and hospitals for easy referrals.

### c. Coordination and Collaboration of Market Actors

Given DKT's extensive coverage - selling 525K combi in 2017 compared with an estimated market size of 620K according to Guttmacher – a number of commercial distributors say that they feel crowded out of the market. Several commercial sector interviewees, as well as MOH staff, remarked that 'DKT covers everything' so there was no point trying to get involved in combi-packs.

Life Care Pharmaceuticals is planning to distribute ZiZhu's combi-pack product once it is registered, but do not expect big sales given DKT's coverage, though they are hoping they can apply for government tenders in future for miso and combi-packs.

Eyasu says that they would be willing to sell combi-packs *only* if DKT were not in the picture distributing "subsidized" products, as they were "monopolizing."

(Discovered late in the assessment process so there wasn't time to interview them) Medtech has applied to renew Medabon's license, and Elpis applied to register a combi-kit called Ace-kit. Neither company seems to be involved with an SMO. Presumably these companies see a business case for entering the market, or are looking to position themselves for the future.

### d. Financing requirements

Ethiopia is somewhat unique among the countries we assessed, as it has highly restrictive rules about foreign currency that make it difficult to purchase drugs from outside the country. These rules have created obstacles for growing a commercial market for combi-packs, and have also constrained how the SMOs can operate in the combi-pack market. Every interviewee raised the foreign currency limit as a major issue.

Eyasu Pharmaceuticals explained that costs of registration aren't expensive (USD 924 fee per product plus USD 350 for inspection costs), but companies have to apply to banks to access foreign currency to purchase drugs for importation, and then wait their turn. Therefore, these companies prioritize their highest profit makers for import, rather than MA drugs. There is

some hope with the new Prime Minister that there will be improvements in economic policy and that the foreign exchange rules will be loosened, yet this will take time.

There is a move for local production of combi-packs and other drugs, featuring a pharmaceutical zone where global companies are producing some drugs locally. Humanwell, a Chinese company, has opened a factory outside Addis and expects to be producing combi-packs and EC within 2 years. Organisations/businesses working on safe abortion would be able to purchase supplies inside Ethiopia and not have to import.

When asked about this new development, commercial distributors said that, yes, it would get around the obstacle of foreign exchange controls by allowing them to purchase locally, however, the companies manufacturing in the pharmaceutical zone would also be doing their own distribution, or would likely fix a limit on price which would curb potential profits of distributors.

## C. Recommended Interventions

### Registration/Entry

### Market Building

i) **Fund SMOs to help move the market towards greater sustainability.** More so than in any other country we assessed, in Ethiopia donors should consider encouraging their SMO partners to move to greater financial sustainability, in order to allow the commercial sector space to enter the market. DKT and MSI are providing increasing access to combi-packs for women in ways that are critical to women's health and development. But while the Ethiopian MA market is performing well in terms of equity, it is lagging in terms of sustainability.

Combi-pack sustainability, in plain terms, happens when there is no or little reliance on external donor funding to meet the growing MA needs of women in Ethiopia. It can, for the most part, be achieved by one of three paths, or a combination of the three:

- The SMOs raise prices so that they can self-fund their combi-pack work in urban areas and compete with any private sector company *on a level playing field*;
- The SMOs create space for and support the entry of private sector players into the combi-pack market;
- The government of Ethiopia, with its own resources, commits to making combi-packs available to women in the long-term.

A healthier, more balanced Ethiopian market would see commercial companies launching their own brands; social marketers covering their own urban program costs through product sales; and donors subsidizing product distribution to the poor and to vulnerable populations in rural areas, for example, in many cases via the SMOs. SMOs have done an excellent job of seeding the market and growing demand, and should begin to transition to more targeted activities while facilitating private sector entry.

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising especially in rural areas so that women know about the combi-pack and where to access it.
- Don't Fund: products and overheads for SMOs to distribute in large urban areas, beyond the short-term, unless there is no alternative for combi-pack supply in the public sector.
- Do Fund: SMOs to extend coverage to vulnerable and hard-to-reach communities with donor subsidy as needed.

- Do Fund: detailing and training of providers, data collection on combi-pack use and other market information.

ii) **Foreign currency controls:** Local production of combi-packs could be a long-term solution to overcome foreign currency barriers, and could potentially be a positive development for Ethiopia and the region. This needs further assessment, but potentially donor funding could help ensure that local product manufacturing meets international quality standards.

**Policy Change**

iii) **Eliminating the requirement for prescriptions:** Despite the fact that women can access services in the public sector and private clinics, they often prefer to seek abortions at pharmacies or drug stores for convenience and discretion. Donors should continue funding advocacy for eliminating prescription requirements, and generating more evidence that women can self-administer, such as Ipas is piloting.

# Malawi

## A. Overview

An estimated 141,000 abortions were performed in Malawi in 2015, suggesting an annual rate of abortions of 38 abortions per 1,000 women.[35] Unsafe abortion accounts for up to 18% of maternal mortality in Malawi.[36] The current law prohibits induced abortion in Malawi, except for the case of surgical abortion if a woman's life is in danger. Legal ramifications for providing abortion services are severe, with up to 14 years imprisonment for the person administering abortion services and up to 7 years imprisonment for the pregnant woman. Recently, the "Termination of Pregnancy" bill was under consideration to liberalize the abortion law to allow abortion in cases of rape, incest and pregnancies that threaten a woman's mental and physical health.[37] It's now on hold until after elections in May 2019.

Urban, non-poor women are more likely than rural and poor women to obtain abortions from medical professionals. For rural women, self-induced abortion and use of traditional healers is more common than for their urban counterparts.[38] An estimated 38% of induced abortions in 2015 were treated at a health facility; however, this proportion of induced abortions varies by region, with higher rates of facility-based abortions in the Southwest rather than other regions.[39]

**Misoprostol** is available under the brand names Misoprost, Kontrac, and Misoclear (Banja La Mtsogolo (BLM)'s product; BLM is MSI in Malawi). It is approved for PPH, incomplete abortion and miscarriage, missed abortion in 1st trimester, intrauterine fetal death, cervical ripening, but not for induced abortion. Cytotec is used in public facilities for PPH and PAC, purchased through the Central Medical Stores. Only MVA and misoprostol are in the post-abortion care guidelines. Miso is on the essential medicines list for PPH and incomplete abortion. Mifepristone is not registered in Malawi.

No **combi-pack** is currently available, though DKT is trying to register one. BLM unsuccessfully attempted to register a combi-pack last year, and was told combi-packs were 'illegal'.

The MOH uses the Jhpiego curriculum on PAC and trains its providers on this. BLM trains its own providers on PAC, MVA and MA. Cytotec training is part of government training for PPH and PAC.

## B. Key Findings

### 1. Market actors

**a) Commercial Actor Involvement in MA Distribution:** There are several large pharmaceutical companies in Malawi such as Worldwide, PharmaVet, PharmaChem, PharmaMed, Galaxy, Artemis, Intermed and Yash Pharmaceuticals. These companies function comprehensively as importers, wholesalers and distributors and are capable of nationwide distribution.

[35] Polis, C. et al., 2017. Incidence of induced abortion in Malawi, 2015. *PLOSone.*
[36] Global Health Now. Rewriting Malawi's Abortion Law. 2018. Johns Hopkins Bloomberg School of Public Health. https://www.globalhealthnow.org/2018-10/rewriting-malawis-abortion-law
[37] http://www.smdmalawi.com/media/com_acymailing/upload/termination_of_pregnancy_bill_1.pdf?utm_source=Global+Health+NOW+Main+List&utm_campaign=dcd1a2958d-EMAIL_CAMPAIGN_2018_10_01_05_01&utm_medium=email&utm_term=0_8d0d062dbd-dcd1a2958d-2890801
[38] Polis, C. et al., 2017. Incidence of induced abortion in Malawi, 2015. *PLOSone.*
[39] Ibid.

Some of these companies, such as Worldwide, are selling misoprostol and other reproductive health products. Intermed is working with DKT to register a combi-pack and other products, but we could not find out more details as they are under a confidentiality agreement.

**b) The Role of SMOs:**

**Misoprostol:** BLM sells Misoclear to over 100 pharmacies across Malawi and supplies its own clinics. BLM hasn't been able to find a commercial distributor for Misoclear as the large ones are already selling miso which they are accessing at cheaper prices.

Distributors of misoprostol make only small margins on misoprostol, and as a relatively low volume product, this only works because they have lots of other products. Worldview for example sells over 500 products and its medical equipment and lab divisions are the big profit makers.

BLM met with Intermed last year and presented a proposal for them to take on distribution of Misoclear. Intermed was already selling the miso brand Kontract so didn't want to take on Misoclear because it was twice the price. Intermed recognized that some demand was there, and likely to grow, but they needed a lower-priced product, saying that they can't charge high prices in a poor country like Malawi or the product won't sell.

**Combi-pack**: Intermed is now partnering with DKT and they have a combi-pack under registration, and while details aren't public yet, it's assumed that DKT was able to offer a low enough price for its combi-pack product with room for a small margin for Intermed and still enable an affordable price to the client.

| Commercial Actors in Malawi | Functions | Current SMO Partner | Market Authorization Holder (MAH) | MA Products Sold (Consumer Price) | MA Sales/ Geographic coverage/ Populations Served | Manufact-urer | History/Planned Work/Potential |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| **Intermed** | Importer Wholesaler Distributor | DKT N/A | DKT | DKT combi Kontract miso | Nationwide | Naari Fourrts | Combi-pack registration pending |
| **N/A** | N/A | BLM | BLM | Misoclear (USD 1.00) | BLM sells c. 1,700 Misoclear tablets/month<br><br>100 pharmacies Nationwide | ACME | BLM does its own distribution. |
| **Artemis** | Importer Wholesaler Distributor | N/A | N/A | N/A | Nationwide | N/A | Very interested in selling miso; candidate for selling combi |
| **Worldwide** | Importer Wholesaler Distributor | N/A | | Miso | Nationwide | | Candidate for selling combi |
| | | | | | | | |
| **Yash Pharma** | Importer Wholesaler Distributor | N/A | N/A | N/A | | N/A | Zambian company. See Zambia section. Ready to try to register and sell Antipreg and Medabon. |

## 2. The 4 Ps of Marketing

### a) Product
BLM sold 8,370 tablets of Misoclear in 2017, and as of October 2018 has sold 17,055 tablets.

### b) Price
BLM buys Misoclear for USD 0.53 and sells it to the client for USD 1.00.

### c) Place
Misoprostol is widely available in pharmacies and over-the-counter in Malawi, while there is no mifepristone available.

### d) Promotion
Demand is steady, and expected to grow, for misoprostol. Worldwide noted that there was an increase in the number of gynecologists graduating now, and therefore demand for gynecological products would increase.

Given levels of stigma on abortion, there is expected to be more reluctance to stock and sell a combi-pack product versus misoprostol, so provider education and detailing will be critical. It will take time to build up awareness of the product, and confidence in using it.

To introduce a combi-pack product, Artemis said that they would expect to be provided with promotional materials and initial training to their marketing team, or potentially have someone who is dedicated to the product be embedded in their marketing team. Once they have integrated a new product into their portfolio, their team could manage the day to day marketing/detailing. Other companies also said that they would require product detailing and promotion.

## 3. Other Market Functions

### a) Regulatory Environment
The main concern of interviewees from a regulatory perspective was that selling combi-pack products would invite more regulation and scrutiny from authorities. As in other restricted environments, it would make sense to keep misoprostol on the market even if a combi-pack product gets registered, in case such a new product ever gets blocked.

### b) Policy Environment
BLM thought it was a good time to try to register a combi-pack when it did last year as the abortion bill had just been tabled. In retrospect, they think that the attention on the issue, and strong opposition from religious groups, made it the wrong time. Now that things have quieted down, there may be a better chance to get a combi-pack approved.

While the abortion bill is on hold, Ipas, the MOH Reproductive Health division and other NGOs are working to change the definition of ‘danger’ in the post-abortion (PAC) guidelines to expand the circumstances when abortion is permitted. The redefinition of ‘danger’ will be in reference to comprehensive abortion care which will be a small part of the guidelines. Ipas believes that this will help get the guidelines passed, as most of the content is about PAC. They aim to finalize the guidelines by February 2019 and submit these for approval in the MOH. Ipas is hopeful that these will be accepted.

The MOH Director for Reproductive Health noted that consultations on abortion showed a 50%-50% split pro-choice/anti-choice so it was hard to predict what will happen in future on the abortion bill.

### c) Coordination and Collaboration of Market Actors

Some of the large commercial distributors express a concern that to enter the market makes no sense if products will be given away for free or heavily subsidized as contraceptives have been. A recent assessment looking at the market for contraception concluded that Malawi's private sector was "ready, willing and able to provide contraceptive products when they saw that a strong market need is evident"; and a great example of this is how the private sector steps in to sell emergency contraception, as it is often not available in the public sector.[40]

One major distributor, Worldview, said that if there were a true gap in the market for combi-pack products, commercial companies would be willing to enter, but only if the NGOs did not provide these for free or heavily subsidized, as this would make it impossible for them to charge prices that rendered a profit. They already sell miso and lots of other reproductive health products so they see the potential benefits of a combi-pack product.

Commercial companies do not think that MA is a big profit-making opportunity at present, even if the SMOs were not in the picture, because of the current low margins and low volume of the product. Rather, unless these companies are helped to overcome barriers while the market is small and still immature, and see that there will be space in the market, they won't bother to enter.

Artemis is very interested in selling misoprostol and have been looking for a supplier. They think that there is demand for misoprostol and the market is still not well covered by the products available. They haven't given the combi-pack market much thought but are willing to consider it and have offered to do a market survey on both combi-packs and misoprostol.

Given the restricted environment in Malawi for the foreseeable future, the public sector will only be providing abortion when a woman's life is in danger, and will not be using combi-packs. Thus far, it is only DKT entering the combi market. This means that there is potential space in the market for commercial players. However, there will be limits to what these companies can charge in Malawi given the high level of poverty.

The Zambian company, Yash Pharmaceuticals, which sell combi-pack products Antipreg and Medabon commercially in Zambia, are interested to register these products in Malawi. They would be interested in getting an "access," donor-negotiated discount price, as this would mean that they would still have room to make a profit margin while keeping the price for women affordable.

### d) Financing requirements

Commercial companies expect that combi-pack product registration costs would be covered. Artemis also said that they could not commit to large volumes initially, and others are similralry concerned about expiry of products.

## C. Recommended Interventions

Malawi is a Non-Existent combi-pack market with no combi-pack products available, and DKT's combi-pack pending registration.

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[40] Bare, Andrea and Erika Beidelman, "The Donor Funded Dilemma: What's Stopping Emerging Countries from Developing Private Markets for Contraceptives?" NB Healthcare, netbillion.net

## Registration/Entry

**i) Register a New Combi Product.** With no combi-pack products in the market and only DKT's combi-product under registration, donors could considering registering a new product through a commercial company such as Yash Pharmaceuticals, Artemis or Worldwide. There will need to be inducements and risk mitigation mechanisms put in place to get them to register and import a combi-pack product. They will also need to be convinced of the gap in the market.

**ii) Negotiate Gradual Stock Release from Manufacturers** to mitigate risks of unsold stock. Donors could negotiate a gradual release of stock as stock expiry is a major risk for companies. Yash Pharmaceuticals is able to bring combi orders gradually into Zambia rather than the whole order at once, and they/others may be able to do the same in Malawi. Donors could also consider covering the costs of warehouse space in the short term, as an added incentive.

**iii) Negotiate "Access" Prices from Manufacturers**. In a country as poor as Malawi, starting out with as low as possible prices from the manufacturer is an important first step in keeping the products affordable to women. Donors could negotiate discounted prices for combi-packs. Usually commercial companies are precluded from obtaining such "access" prices, but donors may be able to work out an arrangement with manufacturers on this, by ensuring that while commercial companies can make profit margins, their prices to consumers are reasonable.

## Market Building

**iii) Donors should pick one or more commercial partners to incentivize.** Yash Pharmaceuticals, Artemis or Worldwide are all potentially interesting in selling combi-packs in Malawi.

**iv) Fund SMOs with a view to support commercial growth and sustainability**.

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising so that women know about the combi-pack and where to access it.
- Do Fund: SMO medical detailing/provider promotion *OR* medical detailing/provider promotion in-house in commercial distributors. Promotion of the combi-pack and sensitization for providers will be critical to get providers to switch from misoprostol or start using MA.
- Don't Fund: additional SMOs to enter the market unless commercial players aren't stepping in.

## Policy Change

**v) Advocate to liberalize laws**. Post-elections and hopefully after having the PAC guidelines revised with an expanded definition of danger, donors could consider funding efforts to get the TOP bill passed, but this must be done very carefully and be seen to be coming from Malawian organizations, stakeholders and public.

# Mali

## A. Overview

Mali's abortion law is restrictive. Abortion is legal only to save a woman's life and in cases of rape and incest. Women who perform a self-termination or receive abortion services outside of the legal limits are subject to up to five years in prison. Providers face up to three years in prison and potential loss of their medical license. Given the clandestine nature of abortion services, there is very little data on the incidence of either safe or unsafe abortion. However, it is estimated that abortion is the fifth leading cause of maternal death, contributing to Mali's high maternal mortality rate of 368 deaths per 100,000 births.[41]

Given the burden of unsafe abortion that results in complications, the government integrated guidelines for provision of post-abortion care in reproductive health guideline updates in 2009 and 2013. Therapeutic abortions are typically practiced in hospitals; however, data on type and volume of abortion services are not generally collected at facility level. There are very little data on the demographics of women seeking abortion services, but a 2018 report commissioned by FIGO suggests that the mix of women who received abortion services was varied and included women of all reproductive ages, both married and unmarried, with and without previous children, and at varying levels of educational attainment.[42] MSI established a technical committee under the "Amplify change" project in October 2018. The purpose of this committee comprised of 18 different organizations (including SMOs, INGOs, national NGOs, representatives of Government institutions) is to collect evidence on unsafe abortion.

Abortion services (through misoprostol and MVA) are permitted at referral health centers through public hospitals and can be administered by surgeons, OB/GYNs, and midwives per the 2009 abortion care standards.[43] Post-abortion care services are approved at all levels of the health system.[44] While post-abortion care is required to be free of charge, there are reports that provider stigma results in charges to the woman.[45]

***Misoprostol*** is available under the brand names Cytotec, Misoclear (MSI's product) which was approved for treatment of incomplete abortion and miscarriage and PPH, but not for PAC or MA, in 2008, and Misofem (DKTs product).[46,47]

Misoprostol is in the Essential Medicines List.

PSI submitted the request to register their misoprostol brand Avertisso (pack of 4 misoprostol, from ACME) and expects to receive the Market Authorization to distribute the product in early 2019. DKT received their Market Authorization and just started to sell misoprostol in a pack of 4 tablets.

***Combi-pack:*** No combi-pack is available in Mali. MSI has the intention to register a combi-pack product, Mariprist. PSI does not plan on registering a combi-pack. DKT's application to

[41] Traoré, L., Bulthuis, S.. Mali Country Report: Needs Assessment on Safe Abortion Advocacy. 2018. SOMAGO. https://www.figo.org/sites/default/files/uploads/Mali%20Country%20Report_Rapport%20SOMAGO%20English%20translation.pdf
[42] Ibid.
[43] Direction nationale de la santé. (2009). Normes et protocoles des soins d'avortements. Bamako: DNS
[44] Direction nationale de la santé. (2013). Politiques, normes et procédures en santé de la reproduction. Bamako: DNS.
[45] Direction nationale de la santé. (2009). Normes et protocoles des soins d'avortements. Bamako: DNS
[46] Venture Strategies. Misoprostol registrations July 2013 https://www.k4health.org/sites/default/files/Global%20Misoprostol%20Registration%20by%20Indication%20detailed%20spreadsheet_0.pdf
[47] World Health Organization. Global Abortion Policies Database. Country Profile: Mali. http://srhr.org/abortion-policies/country/mali/

register a combi-pack product has very recently been approved but they have been asked to lower the price so this is being negotiated.

## B. Key Findings

### 1. Market Actors

**a) Commercial Actor Involvement in MA Distribution:** There are over 60 private pharmaceutical wholesalers. Some of the major ones also operating in other Francophone countries operate in Mali, such as Laborex, UbiPharm, and Sodipharm.

**b) The role of SMOs**

SMOs distribute their miso products through the major private pharmaceutical wholesaler/distributors: MSI distributes Misoclear through Laborex to pharmacies and through its informal network of providers; DKT is working through the international pharmaceutical wholesaler platform Planet Pharma in France, where UbiPharm imports products internationally. PSI is distributing free misoprostol through the ProFam clinical network and also to public sector health facilities with whom they collaborate. The public sector distributor (PPM Pharmacie Populaire du Mali) is also distributing misoprostol to the health facilities and regional depots; private pharmacies also purchase products from these regional depots.

Both Laborex and UbiPharm are potential candidates to sell combi-packs.

| Commercial Actors in Mali involved in MA | Functions | Current SMO Partner | Market Authorization Holder (MAH) | Current MA Products Sold (Price to consumer) | MA Sales/ Geographic coverage/ Populations Served | MA Manufacturer | History/Planned Work/Potential |
|---|---|---|---|---|---|---|---|
| **Laborex** | Importer Wholesaler Distributor | MSI | MSI | Misoclear (USD 1.75 for packet of 3) | Sales of c. 57,000 Misoclear tablets/ month Nationwide | ACME | Potential for selling combi-packs. Will sell PSI's miso product Avertisso. |
| **UbiPharm** | Importer Wholesaler Distributor | DKT MSI | DKT MSI | Misodia Misoclear (USD 1.75 for packet of 3) | DKT sold 135,360 tablets in October 2018 to Ubipharm, not directly to consumer<br><br>Nationwide | ACME | Potential for selling combi-packs. Will sell PSI's miso product Avertisso. |
| **Sodipharm** | Importer Wholesaler Distributor | | | | Nationwide | | Potential for selling combi-packs. Will sell PSI's miso product Avertisso. |

## 2. The 4 Ps of Marketing

### a) Product

MSI sold 474,507 Misoclear tablets in 2017 and sold 567,233 Misoclear tablets as of October 2018.

PSI has recently done a market estimation survey for misoprostol; total market volume is estimated to be 2 million tablets annually. Cytotec has 30% of market share, MSI's Misoclear 60%; and others including public sector 10%.

PSI expects that it can capture part of the market by Cytotec since questions are being raised about its authorization. PSI's sales projection for 2019 is 12,500 boxes/4.

DKT recently started selling its misoprostol product and sold 135,360 tablets to Ubipharm in October.

Mali has a black market of pharmaceutical drugs, and according to key informants, pharmacies sell Cytotec without prescription. Cytotec seems to be imported without having the official VISA/AMM; wholesalers and pharmacists seem to bypass formal regulations.

### b) Price

MSI is selling Misoclear in packs of 3 tablets to pharmaceutical wholesalers at USD 0.92, who sell at USD 1.2 to pharmacies and private providers with a recommended consumer price of USD 1.75. The actual price, however, can be 3 or more times higher in cases of stock out or at special periods of the year such as after the year end holiday season. These increases are also a result of a general lack of respect for recommended pricing schedules, with prices fluctuating depending on the situation, customer, and time of day.

PSI's projected price to consumers is USD 1.14 for a pack of 4 tablets thus considerably cheaper than MSI.

### c) Place

Misoprostol is sold through pharmacies, informal provider networks, private clinics and public facilities.

### d) Promotion

Similar to Burkina Faso and Senegal, promotion of misoprostol is limited to health professionals and outlets such as clinics and pharmacies, since it requires a prescription. No mass media promotion is allowed, and therefore promotion efforts must be directed to providers. Product detailing is seen as very important to introduce and promote MA products. Stakeholders indicated that many health care providers lack in-depth knowledge on correct use of misoprostol. There is a need for training of providers to increase their technical capacities to correctly prescribe and manage side effects of the product.

DKT has a team of 3 sales people and 1 clinical trainer embedded within a local marketing agency.

MSI Mali is shifting from managing promotion of Misoclear by their own detailing team, to using the pharmaceutical promotion agency Societé Promotion Medicale's (SPM) sales and promotion

agents. This move is meant to save human resource costs and because they think that it will increase sales through greater reach.

### 3. Other Market Functions

#### a) Regulatory Environment

As in Senegal, NGOs in Mali may have advantages over commercial actors in getting products such as misoprostol registered with informal support from the MOH, and by using consultants well connected to the Pharmacy Board to assist with the registration process. The registration process of MSI's combi-pack is being managed by the pharmaceutical promotion agency SPM on MSI's behalf.

#### b) Policy Environment

Abortion is a highly sensitive matter and faces high resistance from many government officials, but at the MOH there is informal assistance and support. Officials do not want to be directly linked to the abortion agenda.

#### c) Coordination and Collaboration of Market Actors

As in Burkina and Senegal, there is a natural division of labor in Mali, where the SMOs can't sell products themselves, but work through the private pharmaceutical wholesalers.

During this assessment, it became clear that the SMOs were not aware of each other's plans for new products. This lack of communication is one of the hallmarks of poor in-country stewardship of a product market. With SMOs launching similar products, they should coordinate better so as not to duplicate product detailing and promotion efforts.

#### d) Financing Requirements

Official registration costs are USD 526, but the process may necessitate hiring a consultant, which can add another USD 2,000 to the total cost.

## C. Recommended Interventions

### Registration/Entry

Registration in Mali faces similar challenges as those in Senegal, where registration by a commercial company without SMO involvement is very likely to get rejected for combi, as are DKT and MSI submissions for combi-pack for MA only. Donors should consider the feasibility of funding a SMO to register a new combi-pack for post-abortion care, not just limited to MA. It could help get the combi-pack product approved to make reference to studies showing the higher effectiveness of combi-pack for post-abortion care.[48]

#### i. Register new commercial combi-pack product with indication for PAC (not abortion).

Consider whether this is best done through an NGO or SMO, or through a commercial company. While an SMO or NGO may have a better chance of securing registration, they will have little incentive to do so if the brand will not be owned by them.

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[48] Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss, Courtney A. Schreiber, M.D., M.P.H., Mitchell D. Creinin, M.D., Jessica Atrio, M.D., Sarita Sonalkar, M.D., M.P.H., Sarah J. Ratcliffe, Ph.D., and Kurt T. Barnhart, M.D., M.S.C.E. N Engl J Med 2018; 378:2161-2170 . DOI: 10.1056/NEJMoa1715726

This process could run simultaneously as donors tried to register a combi-pack product through the regional VISA system in Burkina to increase the chances of a new combi-product being registered.

## Market Building

**ii. Collaborate with commercial distributors to distribute new combi-pack product.**
Cover costs of product detailing and promotion.

**iii. Fund SMOs to support commercial growth and sustainability**.
SMOs in Mali have to outsource essential functions such as distribution and sometimes marketing/promotion, but are better placed to register MA products. Mali could be a good test case of a partnership between an SMO/NGO and a commercial company for a commercial brand. The SMO could be funded to carry out a limited set of functions, akin to a management/technical support role. There could even be a transition of the brand, starting as an SMO brand, but eventually transferring it to the commercial company.

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising through social mobilization interventions with women's associations and networks so that women know about the law, the combi-pack and where to access it.

- Do Fund: medical detailing, critical for new product like combi-pack, especially in such a highly restrictive environment. In the meantime, fund detailing for misoprostol to increase knowledge and use amongst providers, which will help them get ready for combi-pack introduction. Either marketing agencies or SMOs/NGOs could get marketing licenses or embed their own sales teams in existing marketing agencies.

## Policy Change

**iv. Fund advocacy interventions through the Amplify Change umbrella targeting professional bodies (medical and pharmaceutical boards, jurists) and influential stakeholders (MOH staff, parliamentarians, political and religious leaders) to further liberalize the abortion law, remove barriers to access, and increase financing for post-abortion care and safe abortion.**

# Sierra Leone

## A. Overview

Sierra Leone has the world's highest rate of maternal mortality at 1,360 deaths per 100,000 births in 2016, with unsafe abortion accounting for an estimated 10% of these deaths. Current law allows abortion to save the life of the woman or to preserve physical/mental health. A major effort in 2015 to liberalize abortion laws resulted in the passing of the "Safe Abortion Law, 2015" by Parliament. However, the reform was ultimately blocked by the president after pressure from religious lobbyists. The proposed law would have allowed women to terminate a pregnancy in any circumstance up to 12 weeks, and up to 24 weeks in cases of incest, rape and fetal impairment. Advocacy work is continuing at the grassroots level, and the bill has been revised to be a broader SRHR bill to increase the chances of getting it passed.

MVA, misoprostol, and mifepristone are included on the national Essential Medicines List (EML).[49] MSI has a misoprostol product registered under the brand name Misoclear which is approved for treatment of incomplete abortion and miscarriage, missed abortion in the 1st trimester, and intrauterine fetal death.[50] Mifepristone is registered for PAC. The miso product Cytotec is also registered.

Two **combi-packs** are registered: MSI's Mariprist and more recently DKT's MisoMife-Fem. Other combi-products are found on the market such as PSI's Pro-Fem and a commercial brand by Bunty Pharmaceuticals, both which come in through Liberia. A combi-product from Abeer, also from Liberia, was available until early this year but has now expired.

## B. Key Findings

### 1. Market actors

#### a) Commercial Actor Involvement in MA Distribution:

In Sierra Leone, there are 76 licensed importers but only a handful are sizeable and also doing distribution. The largest pharmaceutical company is People's Pharmacy. Lucky Pharmaceuticals, one of the largest companies that imports and is a wholesaler/distributor, sells over 150 products and medical equipment, devices and supplies throughout Sierra Leone and Liberia. Another wholesaler/distributor company, West Care, distributes over 200 medical products.

#### b) The Role of SMOs:

MSI works through Lucky Pharmaceuticals, which allows them to have nationwide coverage in both Sierra Leone and Liberia. MSI employs one salesperson with a team of CBDs in each country, leveraging Lucky's existing distribution network.

DKT will be doing its own distribution.

With Mariprist being sold in Liberia, and PSI's Pro-Fem and commercial brands coming through from Liberia, there seems to be a dynamic, growing market joining the two countries.

[49] Government of Sierra Leone Basic Package of Essential Health Services for Sierra Leone Ministry of Health and Sanitation. 2010. http://srhr.org/abortion-policies/documents/countries/02-Sierra-Leone-Essential-Medicines-List-2010.pdf#page=1

[50] Venture Strategies. Misoprostol registrations July 2013 https://www.k4health.org/sites/default/files/Global%20Misoprostol%20Registration%20by%20Indication%20detailed%20spreadsheet_0.pdf

Mariprist represents only about USD 65-70K of Lucky's USD 8 million business. Lucky is not making big profits on selling combi-packs, nor are they making losses. The company's Managing Director is socially minded, but emphasised that they operate on a fully commercial basis. It works for him to sell Mariprist as he is also selling hundreds of other products.

| Commercial Actors in Sierra Leone | Type of Commercial Actor | Current SMO Partner | Market Authorization Holder (MAH) | MA Products Sold (Consumer Price) | MA Sales/ Geographic coverage/ Populations Served | Manufact-urer | History/Planned Work/Potential |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | Importer / Wholesaler/ Distributor | MSSL | MSSL | Mariprist (USD 9-12)<br>Misoclear | Total MSSL Mariprist sales c. 570/month<br>Total MSSL sales 7,600 Misoclear tablets/month<br><br>Nationwide/Liberia | ACME | MSSL's distributor in Sierra Leone and Liberia; exclusive contract so MSSL's products must be bought through them and they buy only Mariprist. Potential for selling combi-packs without SMO if can break exclusivity. |
| **N/A** | | DKT | DKT | MisoMife-Fem (will change to MM Combi Kit) | Nationwide | Naari | DKT will do its own distribution. |
| **Artemis** | Importer/Wholesaler/ Distributor/ Retailer] Westcare | MSSL | MSSL | Mariprist (USD 9-12)<br><br>Misoclear | Nationwide/Liberia | ACME | Previous distributor for MSSL; now purchases through Lucky. Potential for selling combi-packs without SMO. |
| **Worldwide** | Wholesaler/ Distributor We Yone Side Enterprises | MSSL | MSSL | Mariprist (USD 9-12)<br>Misoclear | Nationwide/Liberia | ACME | Purchases through Lucky. Very local, Port-Loko only. |

## 2. The 4 Ps of Marketing

### a) Product

**Misoprostol**: MSI sold 128,200 Misoclear units in 2017 in Sierra Leone and 56,400 in Liberia. As of October 2018, MSI has sold for the year 76,500 units of Misoclear in Sierra Leone, and 104,000 in Liberia.

**Combi-pack**: MSI sold 4,885 combi-packs in Sierra Leone and 900 in Liberia in 2017, and have sold 5,690 in Sierra Leone and 7,230 in Liberia this year as of October in 2018.

### b) Price

Lucky buys Mariprist for USD6 from MSSL, who get it from ACME at USD3.50, and sells it on for USD7.50, then it retails for between USD9-12. The owner feels that USD3 would be much more reasonable for clients given how poor the country is. At USD 9-12 for combi, he says that it remains an expensive product out of reach or requiring time to save for most consumers. He has repeatedly requested MSSL to drop the price.

DKT's products tend to be cheaper so this may have some impact on the market once their sales get going.

### c) Place (providers: clinics and pharmacies)

Women don't need a prescription and can get combi-pack products over the counter. There were no issues reported around selling from pharmacies and drug stores. This makes the product much more accessible, as drug stores and CBDs are able to purchase combi-pack for distribution and get further reach, especially out of towns where there are fewer pharmacies. Combi is not found in the public sector, and the government doesn't buy miso either.

### d) Promotion

**Misoprostol**: We Yone Side Enterprises, a smaller distributer working in Port Loko, says that they are stocking both Misoclear (misoprostol) and Mariprist (combi-pack) as women know Misoclear and ask for it. He'll stock both while customers get to know more about Mariprist. He sees a need for more community sensitization but hasn't had promotion support from MSI, so he does this himself as a trained Community Health Assistant.

In Sierra Leone, Misoclear sales are decreasing while they are increasing in Liberia despite increases in combi-pack sales.

**Combi-pack**: According to the bigger companies, clients and providers are slowing getting to know the Mariprist brand, though sales are increasing.

DKT's product is just coming on the market, and is expected to be sold in many of the same places.

Lucky only sells Mariprist as the Managing Director "believes in good quality products and sees that this is helping a major social issue, teen pregnancy".

According to Lucky, if MSI didn't do the marketing they do, they could easily do it with their own marketing people. Where they really see the value of SMOs is doing education of the community and providers, which should include pharmacists and community drug sellers, since this is where women go first.

West Care says that the two-day training done by MSI was very helpful for the pharmacists so they know how to use the product. One of the concerns for pharmacists is assessing the gestational age, which they see as a bit risky, so medical detailing helps them and the wholesalers feel more confident.

### 3. Other Market Functions:

#### a) Regulatory Environment

Registration of new products can take six months to a year, and applicants can be asked for bribes. The drug authority is getting stronger, and DKT expects that they will continue to do so as the MA market develops as happened in Ghana.

#### b) Policy Environment

Most people still believe abortion is illegal and stigma is pervasive. Although the law has liberalized, pharmacy guidelines still cite abortion as illegal.

#### c) Coordination and Collaboration of Market Actors

West Care previously distributed MSSL's products. MSI asked them to be the national distributors, but they declined, as they thought the price for combi was too high, and wouldn't support the 30% mark-up they estimated they needed to add, plus it wasn't selling fast enough.

In fact MSI's previous order expired before everything was sold. West Care now buys combi-packs from Lucky Pharmaceuticals when its retail outlets demand it, with a mark-up of 10%, but this is done in small quantities so they don't have to pay much up front or for warehousing. Lucky is in a stronger financial position and is able to place advance orders, pay cash, and hold all the stock.

#### d) Financing requirements

Purchasing minimal orders is seen as a barrier as cited by a regulation expert. Foreign exchange losses are common and companies can lose a lot of money if they have to wait to get paid back for initial outlays. It may be 4-8 weeks before a company is paid for its product sales and by that time, rates have changed and there are potential significant losses.

## C. Recommended Interventions

Sierra Leone is a developing combi-pack market: there are 2 registered SMO combi-pack products, with DKT's product just coming out. There are commercial products from Liberia also available at times.

#### Registration/Entry

**i) Register a New Combi Product.** There isn't a commercial brand registered in Sierra Leone and the commercial products available from Liberia aren't reliable, so donors could consider registering a new combi-pack product. Putting the capital upfront would be an important inducement for some companies.

**ii) Negotiate Gradual Stock Release from Manufacturers** to mitigate risks of unsold stock. Donors could negotiate a gradual release of stock as stock expiry is a major risk for companies. Donors could also consider covering the costs of warehouse space in the short term, as an added incentive.

## Market Building

**iii) Donors should pick one or more commercial partners to incentivize.** Both Lucky Pharmaceuticals and West Care are potentially interested in registering a combi-pack product although Lucky currently has an exclusive deal with MSSL.

**iv) Fund SMOs with a view to support commercial growth and sustainability**. Before the market is shaped by the SMOs, there is an opportunity in Sierra Leone to increase sustainability via the private sector. Donors could facilitate the coordination of SMO operations to expand the market, rather than encouraging branch switching. If the SMOs concentrate efforts in the same space, this will potentially crowd out the private sector.

- Do Fund: SMOs and NGOs to conduct community education and awareness-raising so that women know about the combi-pack and where to access it.
- Do Fund: SMO medical detailing/provider promotion *OR* medical detailing/provider promotion in-house in commercial distributors.
- Don't Fund: Phase out funding of SMOs' sales and distribution to urban areas where commercial companies can prosper.
- Don't Fund: SMOs' sales and distribution and their associated overhead, beyond the short-term. Commercial companies are already doing distribution and doing it well.

## Policy Change

**v) Advocate to liberalize laws**. Donors should continue funding advocacy efforts for further liberalizing the law in Sierra Leone. These efforts are in conjunction with grassroots organizations and therefore can be linked well to community education and awareness raising on safe abortion services and products.

With Mariprist being sold in Liberia, and PSI's Pro-Fem and commercial brands coming through from Liberia, there seems to be a dynamic, growing market joining the two countries.

Mariprist represents only about USD 65-70K of Lucky's USD 8 million business. Lucky is not making big profits on selling combi-packs, nor are they making losses. The company's Managing Director is socially minded, but emphasised that they operate on a fully commercial basis. It works for him to sell Mariprist as he is also selling hundreds of other products.

# Mozambique

## A. Overview

Mozambique liberalized its abortion law in 2014 to allow women to electively terminate pregnancy during the first 12 weeks upon request, during the first 16 weeks in the case of incest or rape, and during the first 24 weeks if the mother's physical or mental health is in danger or in the case of fetal anomaly.[51] The law was passed in an effort to curb Mozambique's high rate of maternal mortality at 490 deaths per 100,000 births.[52] Despite the expansion of the abortion law, many women still face challenges in obtaining abortion services. A 2018 study found that women of all ages suffer from low levels of autonomy, limited health facility access and a lack of patient-centered care that deters them from seeking facility-based services[53].

Despite the liberalization of the law as well as updated clinical guidelines on abortion and post abortion care, Mozambique still faces challenges in implementing the new policy.[54] In addition to surgical methods, combination mifepristone/misoprostol is approved under the 2017 guidelines.[55] Since 2007, misoprostol has been allowed for distribution by prescription at pharmacies and drug stores.[56] Providers have the legal right to conscientious objection; however, in the case of medical necessity, providers are not given the right to object.[57] According to Ipas, who are doing VCAT, the government is very open when discussing abortion, and the MOH moved quickly to write standards and guidelines for safe abortion once the law changed. The MOH has a very dynamic focal point for the National Technical Working Group who is an obstetrician/gynecologist, and the MOH is very supportive of safe abortion trainings and TOT, often participating.

## *B. Key Findings*

- Misoprostol (Cytotec) is available in the public system and sold at pharmacies with a prescription, although in reality prescriptions are required.
- ZiZhu exports misoprostol to Mozambique via UNFPA. There is no data on use but it's assumed that most women are asking for misoprostol for PPH then using it or selling it for abortion.
- DKT sold 289,230 miso tablets in 2017.

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[51] International Business Times. Mozambique Legalizes Abortion: President Signs Law Seeking To Curb High Maternal Mortality Rate. December 2014. https://www.ibtimes.com/mozambique-legalizes-abortion-president-signs-law-seeking-curb-high-maternal-1763486

[52] Mozambique Penal Code. 2013. http://srhr.org/abortion-policies/documents/countries/01-Mozambique-Penal-Code-2013.pdf#page=21

[53] Federico, M. et al. Factors Influencing Abortion Decision-Making Processes among Young Women. International Journal of Environmental Research and Public Health. 2018. 15, 329; doi:10.3390/ijerph15020329.

[54] Mozambique. Clinical Guidelines on Abortion and Post Abortion Care. 2017. http://srhr.org/abortion-policies/documents/countries/07-Mozambique-Clinical-guidelines-on-abortion-and-post-abortion-care-2017.pdf#page=1120

[55] Mozambique. Clinical Guidelines on Abortion and Post Abortion Care. 2017. http://srhr.org/abortion-policies/documents/countries/07-Mozambique-Clinical-guidelines-on-abortion-and-post-abortion-care-2017.pdf#page=1120

[56] http://srhr.org/abortion-policies/documents/countries/02-Mozambique-National-Medicines-Form-2007.pdf#page=64

[57] Mozambique Ministerial Decree on Abortion. 2017. http://srhr.org/abortion-policies/documents/countries/06-Mozambique-Ministerial-Decree-on-abortion-2017.pdf#page=1111

- DKT's combi-pack product, Seguru (Safe), is available for USD 3.90-USD 4.00 (recommended price) to the client and is sold to pharmacies, private clinics (including DKT clinics which are situated inside larger clinics) and NGO partners. Coverage is throughout the country though the north is not as well covered as the south.
- DKT sold 100,135 combi-packs in 2017. DKT says combi-packs are one of their fastest growing commodities.
- Medabon was registered by Concept Foundation but is no longer available. We didn't hear back from Concept about why this is the case.
- With support from Ipas and other partners, such as Pathfinder, DKT and PSI, public health facilities offer DKT's combi-pack for free. Ipas works in 40 facilities as a pilot; Women can access the combi-pack at public counters in public facilities, though there isn't always doctor availability. The standards and guidelines address what can be done if there's no doctor, so this isn't a big problem. Outside the public system, women do need a prescription for combi-packs, though this is not needed in practice.
- No mass media is allowed for MA; promotion has to be done through providers.
- There aren't issues with stock-outs of combi-pack or miso. Combi-pack supplies are adequate through 2019.
- According to Ipas, demand still needs to be created: especially in rural areas, there is low awareness the law change.
- A big challenge is data on abortion: the data available doesn't reflect reality. Most abortion wasn't recorded until the law changed. Ipas cites several surveys that show the impact of unsafe abortion.

| Commercial Actors in Mozambique involved in MA | Functions | Current SMO Partner | Market Authorization Holder (MAH) | Current MA Products Sold (Price to consumer) | MA Sales/ Geographic coverage/ Populations Served | MA Manufacturer | History/Planned Work/Potential |
|---|---|---|---|---|---|---|---|
| **Currently Selling Combi-pack** | | | | | | | |
| **N/A** | N/A | DKT | DKT | Segura (USD 6) | Nationwide | | DKT does its own distribution |
| | | N/A | | Cytotec | | Pfizer | |
| **N/A** | N/A | N/A | | Generic miso | | ZiZhu | Imported by UNFPA |
| **Suggested Commercial Actors to Contact** | | | | | | | |
| **MEDIS** | | N/A | N/A | N/A | N/A | N/A | Mr Leite (aleite@medis.co.mz) (http://www.grupoazevedos.com/actividade/internacional). Suggested by Triggerise Foundation as main pharma company. |

# Zimbabwe

## A. Overview

Zimbabwe's abortion law permits termination of pregnancy in the case of rape, incest, to save the woman's life, or in the case of serious fetal anomaly up to 22 weeks of gestation.[58] Women who violate this law face up to five years' imprisonment. An estimated 66,800 abortions were performed in 2016, translating to 18 abortions per 1,000 women of reproductive age. This is one of the lowest rates in sub-Saharan Africa, likely due to high rates of contraceptive use, and yet the majority of abortions are clandestine and unsafe.[59] Of those who received a clandestine abortion in 2016, 60% resulted in complications that required medical treatment.[60]

Misoprostol, indicated for PAC, was added to the national EML in 2011 and is distributed by pharmacies and drug stores by prescription.[61] A revision to national guidelines in 2014 attempted to make post abortion care services available at a broader range of facilities, however the guidelines have not been implemented effectively.[62] Despite the legal status of misoprostol as well as national guidelines supporting expansion of PAC services, a study reviewing 2016 census data found that only 20% of facilities have the basic capability to provide PAC.[63] There are current efforts underway in 2018 to liberalize Zimbabwe's abortion laws.[64]

## B. Key Findings

- Population Services Zimbabwe (PSZ, PSI in Zimbabwe) is selling Misoclear. PSZ sold 34,980 Misoclear tablets in 2018 as of October. Volume is low and PSZ is only selling to pharmacies and clinics.
- There is no combi-pack available since it is not yet registered. PSZ applied in January for accelerated registration and this is still in process, expected to take 2 years as it did with Misoclear. The process has been very slow with the authorities continually saying they don't have all required information and asking for more, but PSZ believes that they can get registration next year. PSI is also trying combi-pack registration.
- PSZ has a distribution company, HealthMed, which is one of the largest distributors in the country. PSZ also had its own sales team but stopped distribution since they couldn't get a distribution license. They need a standard warehouse and appropriate staffing to be able to do so and so far they have hired the personnel, a pharmacy technician, and a marketing person, but are still looking for a suitable warehouse.
- There is a lot of advocacy on abortion being done by different organizations including PSZ working with some of members of parliament and the Zimbabwe Women's Lawyer Association.

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[58] Zimbabwe Termination of Pregnancy Law. http://srhr.org/abortion-policies/documents/countries/01-Zimbabwe-Abortion-Law-1977.pdf#page=2

[59] Sully EA, , et al. (2018) Abortion in Zimbabwe: A national study of the incidence of induced abortion, unintended pregnancy and post-abortion care in 2016. PLoS ONE 13(10): e0205239. https://doi.org/10.1371/journal.pone.0205239

[60] Madziyire, M. et al. Severity and Management of Postabortion Complications Among Women in Zimbabwe, 2016: A Cross-Sectional Study. BMJ Open. 2018. https://doi.org/10.1136/bmjopen-2017-019658

[61] Zimbabwe Register for Approved Human Medicines. 2015. http://srhr.org/abortion-policies/documents/countries/04-Zimbabwe-Register-for-Approved-Human-Medicines-2015.pdf#page=25

[62] Zimbabwe Ministry of Health and Child Care, Chipato T. National Guidelines for Comprehensive Abortion Care in Zimbabwe, 2nd edition. 2014

[63] Riley, T. et al. Evaluation of the capacity and quality of post-abortion care in Zimbabwe: a health systems, signal function approach using a health facility census. 2018 PAA Presentation. https://paa.confex.com/paa/2018/mediafile/ExtendedAbstract/Paper21097/Zimbabwe%20PAC%20Signal%20Functions%20PAA.pdf

[64] Phiri, M. As Teenagers Die, Zimbabwean Lawmakers Call for Abortion Reform. Reuters. 2018. https://www.reuters.com/article/us-zimbabwe-abortion-law/as-teenagers-die-zimbabwean-lawmakers-call-for-abortion-reform-idUSKBN1IA00J

| Commercial Actors in Zimbabwe | Functions | Current SMO Partner | Market Authorization Holder (MAH) | MA Products Sold (Consumer Price) | MA Sales/ Geographic coverage/ Populations Served | Manufacturer |
|---|---|---|---|---|---|---|
| **HealthMed** | Importer<br>Wholesaler<br>Distributor | PSZ | PSZ | Combi-pack under registration; Misoclear | Nationwide | ACME |
| | | PSI | PSI | Combi-pack under registration | | |
| **Pharmaceutical and Chemical Distributor (PCD)**<br>**New Avacahs Greenwood wholesaler and distributor**<br>**Vary springs** | | | | | | These companies are suppliers of PSZ. Another one they use is Pulse Med but they are known to be anti-choice. |

# ANNEX II: Country-level Recommendations

**Recommended Interventions Overall and by Country:**

**Suggested Timeline**
S-Short-term: early in Year 1 of project
M-Medium-term: Years 1-3 of project
L-Long-term: Beyond project
O-Ongoing, not necessarily part of this project

| Country/Combi-pack Market Stage of Development | MA Products Registered and Reported Available | Registration/ Market Entry | Market Building | Policy Change | Market Growth | Pros | Cons/Risks |
|---|---|---|---|---|---|---|---|
| **Across Countries** | N/A | **If registering new combi-pack products in several countries, consider negotiating an "access" price (discount price for donor projects) and pooled procurement.** (S)<br><br>Potential manufacturers:<br><br>1. Naari<br>2. ACME<br>3. ZiZhu (generic) | N/A | N/A | N/A | Better chance of getting access price with bigger order across countries than only one.<br><br>Pooling procurement enables smaller orders per country to minimize risk of expired stock. | Can be complex and time consuming to coordinate pooled procurement across countries.<br><br>Different packaging for batches may drive up the price. |
| **Deep Dive Countries** | | | | | | | |
| **Burkina Faso/Nascent** | 1 combi-pack: Mifepack (Manufacturer: Naari; MAH: DKT)<br><br>2 miso products: | **Register new combi-pack product through the regional registration process.** (S)<br>-Commercial actor to take on registration. Donors to cover all | **Collaborate with commercial distributors to distribute new combi-pack product.** (S-M)<br>-Cover costs of product detailing and promotion | **Fund targeted advocacy interventions to create a less hostile environment for abortion provision and** | N/A | Regional registration could cut costs and time of separate registrations in each country. | Regional registration process may take a long time to start functioning, then it may not function well. |

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|---|---|---|---|---|---|---|---|
| | Misoclear (Manufacturer: ACME; MAH: MSI)<br><br>Cytotec (Pfizer) | registration costs, including staff time to liaise with manufacturer, do application and follow up.<br>-Consider paying bonus for achieving registration.<br>-Advocate for acceptance of different rules and regulations for full commercial products which would allow a waiver to register a higher priced commercial brand.<br><br>**Facilitate purchase and importation of combi-pack order.** (S)<br>-Negotiate gradual release of stock from manufacturer in line with expected sales.<br><br>-Consider providing capital for initial stock purchase (soft loan). | **Fund SMOs with a view towards supporting commercial growth in sustainable ways**.<br><br>Do Fund: SMOs and NGOs to conduct community education and awareness-raising through social mobilization interventions with women's associations and networks (O)<br><br>Do Fund: SMO/NGO medical detailing *OR* medical detailing in-house in commercial companies. (S-M)<br><br>Potential commercial actors for distribution:<br><br>1. Laborex,<br>2. UbiPharm<br>3. Tedis<br>4. DPBF<br>5. SRP | **remove barriers to access such as punishments for those who don't report abortions that occur outside the legal provisions.** (O) | | | Commercial brand will likely cannibalize the sales of the SMOs. This will compromise their ability to build their businesses and expand reach.<br><br>More brands available may will result in more visibility and potentially more scrutiny. |
| **Senegal/Non-Existent** | 2 miso products: Misoclear (Manufacturer: ACME; MAH: MSI)<br><br>Cytotec | **Register new commercial combi-pack product with indication for PAC (not abortion).** (S)<br>-Consider which organization is best placed to handle such a registration, whether an | **Collaborate with commercial distributors to distribute new combi-pack product.** (S-M)<br>-Cover costs of product detailing and promotion.<br><br>**Fund SMOs with a view to support** | **Fund advocacy interventions.** Work through the existing Abortion Task Force targeting professional bodies (medical and pharmaceutical | N/A | No combi-packs are currently registered, so registering one will make a big impact.<br><br>This process could run | While SMOs may have a better chance of securing registration, SMOs have no incentive to do so as they are trying to register their |

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| | | NGO, SMO, or commercial company. | **commercial growth and sustainability**. Senegal could be a good test case of having a partnership between an SMO/NGO and a commercial company for a *commercial* brand. it to the commercial company.<br><br>Do Fund: SMOs and NGOs to conduct community education and awareness-raising through social mobilization interventions with women's associations and networks so that women know about the law, the combi-pack and where to access it. (O)<br><br>Do Fund: medical detailing, critical for new product like combi-pack, especially in such a highly restrictive environment. (S-M) Fund detailing for misoprostol to ready for combi-pack introduction. (O)<br><br>Potential commercial actors for distribution:<br>1. Laborex<br>2. UbiPharm<br>3. Sodipharm | boards, jurists) and influential stakeholders (MOH staff, parliamentarians, political and religious leaders) to move the abortion agenda forward and advocate for a change of the current abortion law, rules and regulations; including advocacy for a "missed period pill.' (O) | | simultaneously as donors tried to register a combi-pack product through the regional VISA system in Burkina to increase the chances of a new combi-product being registered | own combi-pack products. There may be other NGOs who could do so such as ADEMAS.<br><br>Commercial brand will likely cannibalize the sales of the SMOs. This will compromise their ability to build their businesses and expand reach. |

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| | | | Potential commercial actors for marketing/product detailing:<br>1. Green Pharma<br>2. Les Laboratoires Didy<br>3. Valdafrique | | | | |
| **Uganda/Developing** | 2 combi-pack products: Mariprist (Manufacturer: Acme; MAH: MSI; special import license) MA-KARE (Manufacturer: Naari; MAH DKT)<br><br>6 miso products: Kontrac (Manufacturer: Fourrts India; MAH: Delmaw) Misoclear (Manufacturer: ACME; MAH: MSI) Miso-KARE (Manufacturer: Naari; MAH: DKT) Cytotec (Manufacturer: | **Register a New Combi Product.** (S)<br><br>**Negotiate Gradual Stock Release from Manufacturers** to mitigate risks of unsold stock. (S)<br>-Donors could also consider covering the costs of warehouse space in the short term.<br><br>Potential commercial actors for registration and importation:<br>1. Laborex<br>2. Delmaw<br>3. Royal Pharma<br>4. Medvin | **Donors should pick one or more commercial partners to incentivize.** (S)<br><br>**Fund SMOs with a view to support commercial growth sustainability**.<br><br>Do Fund: SMOs and NGOS to conduct community education and awareness-raising (O)<br>Do Fund: SMO medical detailing/provider promotion *OR* medical detailing/provider promotion in-house in commercial distributors. (S-M)<br>Don't Fund: Phase out funding of SMOs' sales and distribution to urban areas where commercial companies can prosper. (S-M) | **Fund advocacy** for getting the 2006 National Policy Guidelines and Service Standards for SRHR and those on reducing morbidity and mortality from unsafe abortion revised and implemented to embrace combi-packs; and for getting mifepristone on the Essential Medicines List. (O) | **Expand access by redirecting subsidies to underserved populations such as rural areas.** (M-L) | With 2 combi-pack products already registered or with special import license, chances are good for registering another combi-pack product.<br><br>There are several options for commercial actors who could handle registration, importation and distribution. | Once a new combi-pack product is registered, it may take time to get sales going as by that time DKT and MSI's products would have been in the market for over a year. Ensuring product promotion and detailing is critical.<br><br>Commercial brand will likely cannibalize the sales of the SMOs. This will compromise their ability to |

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| | Pfizer; MAH: Laborex); Misopro (Manufacturer: Naari; MAH: DKT); Misoprost (Manufacturer: Cipla India; MAH: Cipla/Quality Chemicals Industries) | | Do Fund: SMOs *OR* private companies to conduct post-market surveillance, collecting data on outcomes, adverse events etc. (M) | | | | build their businesses and expand reach.<br><br>Funding for SMO distribution and sales shouldn't be phased out until the new commercial brand is available in order to ensure there is combi-pack availability.<br><br>More brands available may will result in more visibility and potentially more scrutiny. |
| **Zambia/Developing** | 3 combi-packs: Medabon (Manufacturer: Sun Pharmaceutical Industries Ltd; MAH: Yash) Mariprist (Manufacturer: ACME; MAH: MSI) Antipreg (Manufacturer: | Not priority to register new combi-pack products.<br><br>**Facilitate purchase and importation of combi-pack order to help commercial actors scale up.** (S)<br>-Consider providing capital for larger stock purchase (soft loan).<br>-Assist negotiations for gradual release of stock | **Collaborate with commercial distributors to boost sales of existing commercial combi-pack products.** (S)<br>-Cover costs of product detailing and promotion for a limited time to enable expansion to new areas.<br><br>Potential commercial actors for distribution: | **Fund advocacy** for persuading the MOH to finance and supply its facilities; introducing guidelines for mid-level providers; and lifting requirements for prescriptions – especially the requirement for 3 | **Expand access and equity by redirecting donor subsidies to underserved populations such as rural areas.** (M-L) | Zambia presents the only opportunity within these 10 countries where combi-packs are already registered and being sold on a commercial basis. This project can | Boosting the existing commercial brands may lead to cannibalization of SMO sales.<br><br>Less impact intervening in Zambia compared to a market where there are no |

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| | Intas India; MAH: Yash);<br><br>3 miso products:<br>Misoclear (ACME; MSI)<br>Cytotec (Pfizer)<br>Misopro (Naari)<br>Misoprostol (Zizhu Pharma)<br><br>1 mife product:<br>Mifepristone (Zizhu Pharma) | in line with expected sales.<br><br>Potential commercial actors for importation:<br>1. Yash Pharmaceuticals | 1. Yash Pharmaceuticals<br>2. Melcome<br>3. Pharmaplus<br>4. Lusaka Pharmaceuticals<br><br>**Fund SMOs with a view towards supporting commercial growth in sustainable ways**.<br><br>Do Fund: SMOs and NGOs to conduct community education and awareness-raising (O)<br>Do Fund: SMO medical detailing/provider promotion and VCAT activities. *OR* medical detailing/provider promotion in-house in commercial distributors. *OR* a hybrid of the two. (S-M)<br>Don't Fund: Long-term SMOs sales and distribution and their associated overhead, unless they can quickly become commercially viable. (M-L) | providers' signatures. (O) | | move straight to testing interventions around distribution. | commercial brands. |
| **<u>Remote Access Countries</u>** | | | | | | | |
| **Ethiopia/Developing** | 2 combi-packs:<br>MariSafe (Manufacturer: | N/A | **Fund SMOs to help move the market** | Fund advocacy for eliminating the | N/A | A healthier market could be created | Decreasing funds for SMOs alone |

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| | Naari; MAH: MSI)<br>SafeTkit (Manufacturer: Naari; MAH: DKT)<br><br>4 miso products:<br>Miso-Fem (Manufacturer: Naari; MAH: DKT)<br>Misoprost<br>Ace Miso<br>Cytotec | | **towards greater sustainability** (S-M)<br>Do Fund: SMOs and NGOs to conduct community education and awareness-raising especially in rural areas (O)<br>Don't Fund: products and overheads for SMOs to distribute in large urban areas, beyond the short-term, unless there is no alternative for combi-pack supply in the public sector.<br>Do Fund: SMOs to extend coverage to vulnerable and hard-to-reach communities with donor subsidy as needed.<br>Do Fund: detailing and training of providers, data collection on combi-pack use and other market information.<br><br>**Collaborate with**<br>1. Zaf Pharmaceuticals<br>2. Beker Pharmaceuticals<br>3. Eyasu<br>4. Life Care<br><br>Donors could help ensure that local product | requirement for prescriptions. (O) | | with more competition to drive growth and quality improvements. | won't be enough to incentivize commercial entry.<br><br>If SMOs lose coverage ability, and no commercial company steps in, then access to combi-packs will be restricted.<br>DKT is serving a sizeable number of women so this will have a big impact. |

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| | | | manufacturing meets international quality standards. | | | | |
| **Malawi/Non-Existent** | 3 miso products: Misoclear (Acme Formulations, Cipla; MSI) Misoprost (**Cipla**) – Kontrac (Fourrts India Ltd) | **Register a New Combi Product.** Donors could consider registering a new product through a commercial company. (S)<br><br>**Negotiate Gradual Stock Release from Manufacturers** to mitigate risks of unsold stock. (S) Donors could also consider covering the costs of warehouse space in the short term, as an added incentive.<br><br>Negotiate "Access" Prices from Manufacturers. (S) | **Donors should pick one or more commercial partners to incentivize.** (S)<br><br>Potential commercial actors for distribution:<br>1. Yash Pharmaceuticals<br>2. Worldwide Pharmaceuticals<br>3. Artemis<br><br>**Fund SMOs with a view to support commercial growth and sustainability**.<br><br>Do Fund: SMOs and NGOs to conduct community education and awareness-raising. (O)<br>Do Fund: SMO medical detailing/provider promotion *OR* medical detailing/provider promotion in-house in commercial distributors. Promotion of the combi-pack and sensitization for providers will be critical to get providers to switch from misoprostol or start using MA. (S-M) | Fund advocacy to liberalize abortion laws. (O) | N/A | No combi-packs are currently registered, so registering one will make a big impact. | Commercial brand will likely cannibalize the sales of the SMOs if they are successful registering combi-packs. This will compromise their ability to build their businesses and expand reach. |

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| | | | Don't Fund: additional SMOs to enter the market unless commercial players aren't stepping in. (S) | | | | |
| **Mali/Non-Existent** | 3 miso products:<br>Cytotec (Pfizer) – miso<br>Misoclear (Manufacturer: Acme; MAH: MSI)<br>DKT miso | **Register new commercial combi-pack product with indication for PAC (not abortion).** (S)<br>Consider whether this is best done through an NGO or SMO, or through a commercial company. | **Collaborate with commercial distributors to distribute new combi-pack product.** (S-M)<br>Cover costs of product detailing and promotion.<br><br>Potential commercial actors for distribution:<br>1. Laborex<br>2. UbiPharm<br>3. Sodipharm<br><br>**Fund SMOs to support commercial growth and sustainability**.<br>Test partnership between an SMO/NGO and a commercial company for a commercial brand.<br><br>Do Fund: SMOs and NGOs to conduct community education and awareness-raising through social mobilization interventions with women's associations and networks so that women know about the | **Fund advocacy interventions through the Amplify Change umbrella targeting professional bodies (medical and pharmaceutical boards, jurists) and influential stakeholders (MOH staff, parliamentarians, political and religious leaders) to further liberalize the abortion law, remove barriers to access, and increase financing for post-abortion care and safe abortion.** (O) | N/A | No combi-packs are currently registered, so registering one will make a big impact.<br><br>This process could run simultaneously as donors tried to register a combi-pack product through the regional VISA system in Burkina to increase the chances of a new combi-product being registered. | While an SMO or NGO may have a better chance of securing registration, they will have little incentive to do so if the brand will not be owned by them. |

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| | | | law, the combi-pack and where to access it. (O)<br><br>Do Fund: medical detailing, critical for new product like combi-pack. (S-M) In the meantime, fund detailing for misoprostol to get ready for combi-pack introduction. (O) | | | | |
| **Sierra Leone/Developing** | 2 combi products: Mariprist (Manufacturer: Acme; MAH: MSI)<br>MisoMife-Fem Combo (Manufacturer: Naari; MAH: DKT);<br>2 miso products: Misoclear (Manufacturer: ACME; MAH: MSI)<br>Cytotec (Pfizer) | **Register a New Combi Product.** (S)<br>-Consider providing capital for purchase of initial stock.<br><br>**Negotiate Gradual Stock Release from Manufacturers** to mitigate risks of unsold stock. Donors could also consider covering the costs of warehouse space in the short term, as an added incentive. (S) | **Donors should pick one or more commercial partners to incentivize.**<br><br>Potential commercial actors for distribution:<br>1. Westcare<br>2. Lucky<br><br>**Fund SMOs with a view to support commercial growth and sustainability**.<br><br>Do Fund: SMOs and NGOs to conduct community education and awareness-raising so that women know about the combi-pack and where to access it. (O)<br><br>Do Fund: SMO medical detailing/provider promotion *OR* medical detailing/provider promotion in-house in | **Fund advocacy to liberalize laws**. These efforts are in conjunction with grassroots organizations and therefore can be linked well to community education and awareness raising on safe abortion services and products. (O) | N/A | Combi-packs already registered paving the way for further registrations. | Commercial entry into the market may compromise the ability of SMOs to expand their reach.<br><br>More brands available may will result in more visibility and potentially more scrutiny. |

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| | | | commercial distributors. (S-M)<br><br>Don't Fund: Phase out funding of SMOs' sales and distribution to urban areas where commercial companies can prosper. (M)<br>Don't Fund: SMOs' sales and distribution and their associated overhead, beyond the short-term. Commercial companies are already doing distribution and doing it well. (M) | | | | |
| **<u>Countries for Limited Assessment</u>** | | | | | | | |
| **Zimbabwe/Non-Existent** | Misoclear (Manufacturer: ACME; MAH: MSI) | **Consider registering new commercial combi-pack product.** (S)<br><br>**Coordinate with Concept Foundation upcoming assessment.** (S) | **Explore options to support commercial distributors to distribute new combi-pack product.**<br><br>Potential commercial actors for distribution:<br><br>1. Pharmaceutical and Chemical Distributor<br>2. New Avacahs<br>3. Greenwood<br>4. Vary Springs | Not assessed | N/A | Similar to Malawi | Similar to Malawi |
| **Mozambique/Developing** | Seguro (Manufacturer: | **Consider registering new commercial** | **Explore options to support commercial distributors to** | Not assessed | Not assessed | Similar to Ethiopia | Similar to Ethiopia |

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| | ACME; MAH: DKT)<br><br>Miso products: DKT miso Cytotec | **combi-pack product.** (S)<br><br>**Coordinate with Ipas upcoming assessment.** (S) | **distribute new combi-pack product.**<br><br>Potential commercial actors for distribution:<br><br>1. Medis | | | | |

# ANNEX III: Stakeholders Interviewed

| Interviewee Name | Country | Position | Organization |
|---|---|---|---|
| **Abebayehu, Chernet** | Ethiopia | Technical Manager and Regulatory Affairs | Afro German Chemicals |
| **Abdulber, Sufyan** | Ethiopia | | Plan, Monitoring and Evaluatuation Directorate (PMED) |
| **Adama, Nambaloum Oumard** | Burkina Faso | Representative Regulations | EUROTECH |
| **Atwine, Lily** | Uganda | Regulatory Officer | National Drug Authority |
| **Baig, R. Sameeullah** | Zambia | Managing Director | Melcome Pharmaceuticals Limited |
| **Banda, Gwen K.** | Zambia | Director Marketing & Operations | Sterelin Medical & Diagnostics |
| **Baptista, Julio** | Mozambique | Country Director | DKT |
| **Baratal, Ivania** | Mozambique | Health Systems Advisor | Ipas |
| **Bare, Andrea** | USA | Senior Advisor, Healthcare | William Davidson Institute |
| **Bareto, Manohar** | Zambia | Senior Pharmacist | Cairo Pharmacy |
| **Beye, Cheick Sida El Khair** | Senegal | Administrateur | Green Pharma |
| **Blackholly, Helen** | UK | Head of Technical Services | MSI |

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| **Boustred, Richard** | Senegal | Regional and Country Director | DKT |
| **Brett, Tracey** | South Africa | Consultant | |
| **Brown, Alex** | Mali | Country Rep | PSI |
| **Brown, Heidi** | Burkina Faso | Operations Director | Marie Stopes International Burkina Faso |
| **Chhadat, Riyaad** | Zambia | Director | Westgate Pharmaceuticals Limited |
| **Cisse, Salimata** | Senegal | Marketing Manager | MSI |
| **Cook, Marcie** | USA | VP, Social Enterprise | PSI |
| **Coulibaly, Georges** | Burkina Faso | Country Director | MSI |
| **Dehinsilu, Kunle** | Sierra Leone | Integrated Marketing Director | Marie Stopes Sierra Leone |
| **Dharmalingam, Raju** | Zambia | Manager | Link Pharmacies |
| **Dia, Dr.** | Senegal | Pharmacist Responsible | Duopharma |
| **Diarra, Dr.** | Mali | General Director | Ubipharm |
| **Diawara, Fatoumata** | Mali | WHP Quality Assurance Officer | PSI |
| **Diop, Adama Yamouna Faye** | Senegal | Executive Director (entering) | ADEMAS |
| **Diop, Ayisha** | Senegal | Technical Advisor | Gynuity |

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| **Erb, Florence** | Switzerland | Program Officer | Concept Foundation |
| **Eyasu, Mr.** | Ethiopia | Managing Director | Eyasu Drugs and Medical Supplies |
| **Flores Alvarez,, Mario** | Sierra Leone | Regional and Country Director | DKT |
| **Formson, Kwesi** | Zambia | Country Director | Marie Stopes Zambia |
| **Francesa, Mary** | Zambia | Pharmacist | Pearly Waters Chemist |
| **Fu, Ryan** | USA | | CHAI |
| **Gade, Nils** | Ethiopia | Regional Director | MSI |
| **Gadi, Sankalp** | Uganda | Finance Manager | Medvin Pharma Limited |
| **Gning, Sanou** | Senegal | Country Director | Marie Stopes Senegal |
| **Gupta, Rajul** | India | Assistant General Manager-Business Development | Naari |
| **Hamon, Chris** | USA | Senior Advisor, Supply Chain Management | Ipas |
| **Harrington, Rory** | Ethiopia | Country Director | DKT |
| **Hassan, Muhammad** | Malawi | Managing Director | Intermed Pharmaceuticals |
| **Herlemont, Antoine** | Senegal | Deputy Director | Laborex |
| **Hess, Risha** | Ethiopia | Country Director | Marie Stopes International Ethiopia |
| **Holland, Sue** | UK | Regional Director | MSI |
| **Janese** | Uganda | Pharmacist | Astra Pharmacy |
| **Jassy and Patel** | Uganda | Pharmacist | Prudent Pharmacy |

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| **Jhannani, Shankar** | Sierra Leone | Owner | Lucky Pharmaceuticals |
| **Jhannani, Shankar** | Sierra Leone | Director | Lucky Pharmaceuticals |
| **Joan** | Uganda | Pharmacist | Aaron Pharmacy |
| **Johnson, Wiltshire** | Sierra Leone | Regulatory Advisor | Pharmacy Board of Sierra Leone |
| **Kachale, Fannie** | Malawi | Director of Reproductive Health | MOH Malawi |
| **Kam, Pascale** | Burkina Faso | Marketing Officer | MSI |
| **Kamanga, Brenda** | Malawi | | Ipas |
| **Kamara, Alhaji Saidu** | Sierra Leone | Managing Director | We Yone Side Enterprises |
| **Kamuhangire, Moses** | Malawi | Corporate Services Director | Banja La Mtsogolo (MSI) |
| **Kassaw, Jemal** | Ethiopia | Country Director | EngenderHealth |
| **Katewu, George** | Sierra Leone | Managing Director | West Care |
| **Kawanu, Patrick** | Zambia | Social Marketing Manager | Marie Stopes Zambia |
| **Kidanemariam, Saba** | Ethiopia | Country Director | Ipas |
| **Kigozi, Frank** | Uganda | Marketing Representative-Merck | Laborex Uganda Ltd |
| **Kiryowa, Uthuman** | Uganda | Deputy Company Pharmacist | Laborex Uganda Ltd |
| **Kone, Fatimata Pouye** | Senegal | Regional Products Manager | MSI |
| **Krishnan, Kalyan** | Zambia | Director | Life Pharmacy |
| **Kumar, J. Siva** | Malawi | Technical Director, Pharmacist | Worldwide Pharmaceuticals |

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| **Lemi, Paul** | Uganda | Social Marketing Manager | Marie Stopes Uganda |
| **Luembe, Ntindah** | Zambia | Regional Social Marketing Manager | Marie Stopes Zambia |
| **Lyoko, Nyambe** | Zambia | Assistant Director | ZAMRA |
| **Madan, Yasmin** | USA | Private Sector Lead | ThinkWell |
| **Malmqvist, Alison** | South Africa | Country Director | PSI |
| **Mhango, Waza** | Zambia | | CHAI |
| **Mwalubunju, Chance** | Malawi | | Ipas |
| **Mwebaze, Festo** | Uganda | Head of Marketing | Delmaw Enterprises Ltd |
| **Nataguia, Flaure** | Mali | Head of Procurement | Ubipharm |
| **Nayar, Kinny** | Uganda | Managing Director | SurgiPharm |
| **Nazir and Nakabuye** | Uganda | Pharmacist | Life Pharmacy |
| **Ndiaye, Papa Amadou** | Senegal | Pharmacist Responsible | Les Laboratoires Didy |
| **Okello, Bob** | Uganda | National Sales Director | DKT |
| **Okoya, Beauty** | Zambia | Pharmacist | M-Care Pharmacy |
| **Onesmus, Mr.** | Zambia | Pharmacist | Happy Pill Pharmacy |
| **Ouedraogo, Boureihiman** | Burkina Faso | Exective Director | ABBEF-IPPF |
| **Pasha, Mohammed Saleem** | Uganda | Operations Director | Escorts Pharmaceuticals Ltd |
| **Patel, Hitesh** | Zambia | Director | Pharmaplus |
| **Patel, Mikin** | Zambia | Managing Director | Lusaka Pharmacy LTD |

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| **Phiri, Naomi** | Zambia | | Ipas |
| **Renaud, Benoit** | Netherlands | CEO & Co-Founder | Triggerise |
| **Robles, Wilberto** | USA | Senior Director of Regulatory Affairs | WCG Cares |
| **Saleem** | Uganda | Pharmacist | Multiple Pharmacy |
| **Sarr, Cheikh Saad Bou** | Senegal | Exective Director (departing) | ADEMAS |
| **Screawn, Paul** | UK | Head of Social Marketing | MSI |
| **Sekimpi, Carol** | Uganda | Country Director | Marie Stopes Uganda |
| **Shabuddin, Saleem** | Uganda | Director | Royal Pharma 2011 Ltd |
| **Shankar, Shiva N.** | Zambia/Malawi | General Manager - Ethical Formulations | Yash Pharmaceuticals Ltd. |
| **Shewin, Noti** | Zambia | Pharmacist | SM Health Pharmacy |
| **Shibru, Abebe** | Zimbabwe | Country Director | Population Services Zimbabwe |
| **Sidibe, Bakary** | Mali | Country Director | Marie Stopes International Mali |
| **Silesh, Asmamaw** | Ethiopia | | Life Care Pharmaceuticals |
| **Solomon, Negussie** | Ethiopia | Manager | Zaf Pharmaceuticals |
| **Tesefaye, Mr.** | Ethiopia | Manager | Beker Pharmaceuticals |
| **Theophile, Aohui** | Burkina Faso | Pharmacist Responsible | Laborex |
| **Thomas, Ajeesh** | Malawi | Business Head-Malawi | Artemis |
| **Toe, Simplice** | Burkina Faso | Executive Director | PROMACO |
| **Tony** | Uganda | Sales Representative | Marie Stopes Uganda |

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| **Traore, Ibrahim** | | Service Homologation | ANRP Agence National de Regulation (MOH Pharmacy Board) |
| **VanDeReep, Maarten** | Malawi | Country Director | Banja La Mtsogolo (MSI) |
| **Vemer, Hans** | Switzerland | CEO | Concept Foundation |
| **Wu, Marissa** | Sierra Leone | | CHAI |
| **Yilbetal, Abeje** | Ethiopia | Acting Director | FMHACA |
| **Zhu, Orrin** | China | | China Resourcers ZiZhu Pharmaceutical Co. Ltd. |
| **Zolowere, Davie** | Malawi | Clinical Quality Director | Banja La Mtsogolo (MSI) |
| **Zulu, Wanazi** | Zambia | Regulatory Affairs Coordinator | Sterelin Medical & Diagnostics |

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