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A HealthTech Report

Preliminary Landscape Assessment: The Pharmaceutical Industry in Ethiopia

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Introduction

HealthTech conducted desk research to understand the global pharmaceutical landscape for 4% chlorhexidine (7.1% chlorhexidine gluconate) for umbilical cord care (the CHX Product) in order to facilitate discussions regarding the optimal production strategy for global rollout of this product at a collaborators' meeting held in Washington, DC, on July 19 and 20, 2012. As part of this research, we asked partners and experts to provide information from two selected countries, Ethiopia and Pakistan, to augment existing information.

Prior to engaging in this desk research, we conducted an assessment of potential manufacturers in Nepal (2006) and Bangladesh (2008) and an assessment of the pharmaceutical industry in India (2011). We thought that information from Pakistan would provide a more comprehensive picture of pharmaceutical industries in South Asia, which is a likely place for introduction of the CHX Product in the near future. The national scale-up of the CHX Product is already under way in Nepal and is based on the randomized clinical trial performed in Nepal from 2002 to 2005. Randomized clinical trials on the use of the CHX Product were also performed in Bangladesh from 2007 to 2009 and in Pakistan from 2008 to 2009. Delegates from these two countries as well as from India participated in the dissemination of the clinical trial results in Nepalgunj, Nepal, in 2011 and expressed their interest in initiating dialogues with key stakeholders in their countries in order to move the CHX Product forward. Ethiopia was selected because our conversations with experts revealed that there might be potential interest in use of the CHX Product in that country as well. Unlike Bangladesh, India, and Pakistan, Ethiopia has a relatively weak pharmaceutical industry (based on our desk research), and we felt that interviews with Ethiopian manufacturers could provide additional insight as we consider the optimal manufacturing strategy for global rollout of the CHX Product.

We asked Population Service International (PSI) to interview several pharmaceutical manufacturers in Ethiopia, while we directly interviewed one industry expert in Pakistan who we had met previously through other projects.

In the interest of time, HealthTech created and supplied PSI with an abbreviated questionnaire. PSI then opportunistically selected and interviewed four companies as well as the drug control authority. PSI staff conducted all the interviews in Ethiopia. Due to our time constraint, the number of interviews was limited. Nevertheless, we believe that the interviews in Ethiopia provided valuable information. The interview results compiled by PSI are in Tables 1 and 2 of this report. The key findings and conclusions from the interviews are provided below.

HealthTech intends to compile the information collected through the desk research and interviews and make this information available in the near future in order to guide stakeholders in their decision-making regarding whether and how to introduce the CHX Product in their countries.

Key Findings From Interviews in Ethiopia

The key findings from these interviews are:

- All of the companies import active pharmaceutical ingredients (APIs) from other countries, mostly from China and India.

- The companies interviewed predominantly serve the domestic market. Only one company mentioned that they consign products to South Sudan.
- The majority of their sales (> 60 percent) come from selling their products to the public sector.
- None of the four companies interviewed has a Good Manufacturing Practice (GMP) certificate. Two companies have International Organization for Standardization (ISO) certificates; however, it is unknown which ISO they comply with.
- All of the four companies indicated that they would be interested in manufacturing the CHX Product. However, three out of the four companies said either that they do not know if they can manufacture the CHX Product or that they do not currently have a production line for such a product.
- One company answered that they are capable of manufacturing the CHX Product. This company currently produces chlorhexidine-based disinfectants.
- Three companies said that regulatory approval for the CHX Product would be required. One company, which currently produces chlorhexidine-based disinfectants, believes that no approval is necessary prior to manufacturing and selling and that a notification letter will suffice.
- Two companies believe that having a product similar to the CHX Product would facilitate obtaining market authorization for the CHX Product. Two other companies mentioned that inclusion of the CHX Product into the national essential medicines list would facilitate obtaining regulatory approval.
- A representative from the Food, Medicine, and HealthCare Administration and Control Authority (FMHACA) indicated that the CHX Product might be considered to be a disinfectant rather than a drug; and, if so, its registration process will be easier and shorter.

Conclusions From Interviews in Ethiopia

The interviews conducted in Ethiopia confirm that the pharmaceutical industry in Ethiopia is relatively weak with low adherence to international quality standards such as GMP. APIs are imported from other countries, and the finished pharmaceutical products are sold predominantly in the domestic market, primarily to buyers in the public sector. There is at least one company that currently produces chlorhexidine-based disinfectants. This company might be a good candidate manufacturer for the CHX Product; however, this company's manufacturing capacity and capability is largely unknown. A more expanded and in-depth research will be required in order to better understand the viability of producing a quality CHX Product in Ethiopia.

All the companies that were interviewed, including the one who is currently producing chlorhexidine-based disinfectants, expressed interest; however, their interest does not appear to be based on a clear understanding of the capacity and capability that will be required for manufacturing the CHX Product. Identifying an appropriate manufacturer was not the objective of the interviews. If additional research determines that local production of the CHX Product is a viable option in Ethiopia, we will then need to provide additional information on the CHX Product to potential manufacturers, have discussions with them to gauge their interest, and perform due diligence analysis to select an appropriate manufacturer in the country.

Finally, additional discussions with FMHACA will be required in order to determine whether regulatory approval is required for the CHX Product used on neonates (unlike other chlorhexidine-based hand

sanitizers or surface disinfectants), and, if so, what data/information will be required for the CHX Product.

Table 1 on the following pages contains the interview questions and answers from the interviews with Ethiopian manufacturers. Table 2 contains the contact information of interview participants for each manufacturer.

Table 1. Interview questions and answers from interviews with pharmaceutical manufacturers in Ethiopia.

Questions	Fewus	APF	EPHARM	Asmi
Business				
How long has your company been in business?	9 years.	15 years.	48 years.	15 years.
What is your company's focus area (in therapeutic fields, geographical areas)?	Manufacturing of oral liquid preparations.	Antacids, antispasmodics, analgesics, antitussive/expectorant, antihypertensive, diuretics, bronchodilators, antidepressants, antirheumathoids, anti-infective, antimalarials, antihelmentics, antiulcers, and minerals/vitamins.	Antibiotics, antimalarials, antihelmentics, oral rehydration salt, intravenous fluids, antacids, analgesics, antitussive/expectorant, bronchodilators, and minerals/vitamins.	Hospital medical supplies including bandages, gauze (sterile), disinfectants, and other surgical dressing materials.
Does your company export products to other countries?	No.	Yes, only one consignment to South Sudan.	No.	No.
How much is the current annual revenue? Do you consider your company a large-, middle-, or small-sized company among pharmaceutical companies in your country? What % of your company's revenue comes from sales from the public sector (the government and nongovernmental organizations [NGOs])? What % of your revenue comes from international sales?	US\$555,555. Medium. 60% from the public sector.	US\$12,777,777. Large. 60% from the public sector. Revenue from international sales is negligible.	US\$9,444,444. Large. 65% from the public sector.	US\$500,000.

Questions	Fewus	APF	EPHARM	Asmi
Manufacturing				
Does your company have any international manufacturing certificate? (1) GMP? (2) ISO?	No.	Have an ISO certificate and applied to FMHACA to get GMP certification.	Have an ISO certificate for Quality Management Standards and Environmental Management Systems. Does not have a GMP certificate.	No GMP or ISO certificate but has applied for ISO certification.
Do you manufacture APIs? [If No] From which countries do you mostly import APIs?	No. China (80%) and India (20%).	No. China, Europe, and India.	No. China (65%), Europe (15%, mostly expedients), and India (20%).	No. Germany, India, and the United Kingdom.
Regulatory				
Do you think that the CHX Product (topical antiseptic for umbilical cord care) will require regulatory approval for sales in your country?	Yes.	Yes.	Yes.	Will not need regulatory approval before production and sales.
What will the process be to obtain the regulatory approval for the CHX Product? How long will the process take?	Inclusion of CHX 4% in the national drug list, if not included. Submission of dossier and product sample. It will take 6 months.	Inclusion of CHX 4% in the national drug list. Submission of dossier and product sample. It will take 6 months.	Need to discuss with FMHACA about the process of getting the registration certificate. It will take 1 to 2 years.	Notification with letter. It will take two days.
What data will be required to obtain regulatory approval for the CHX Product? Will the data from clinical trials in Nepal, Bangladesh, and Pakistan be sufficient? Is there a product similar to the CHX Product in your country? [If Yes] Will having a similar product in the market make it easier for the CHX Product to obtain regulatory approval? How so?	Insufficient knowledge of whether clinical data from other countries is a requirement or not for the registration of CHX in Ethiopia.	Insufficient knowledge of whether clinical data from other countries is a requirement or not for the registration of CHX in Ethiopia. Did not know of the existence of a product similar to CHX in the market.	Agreed the clinical trial data from other countries will be sufficient and helpful for the registration of CHX in Ethiopia. Knew of the existence of a similar product to CHX in the market and they believe this will facilitate registration of CHX 4%.	Believe the clinical trial data from other countries are sufficient. There are similar products produced by this company including CHX alone and in combination with another product (Cetrimide), and this will make registration easier since the controlling body has the experience of handling similar issues and requests.

Questions	Fewus	APF	EPHARM	Asmi
Regulatory				
Is pricing of pharmaceuticals regulated? If so, how?	No.	No.	No.	No.
Required Capacity and Interest				
Do you have the interest to produce and market CHX? [If No] What are the reasons?	Yes.	Yes.	Yes.	Yes.
Do you have the required capacity (i.e., facility and equipment) to produce CHX? [If No] If you have the interest to produce and market CHX what measures do you need to take to fulfill the capacity?	Did not know whether they can manufacture it on the existing facility.	Did not know whether they can manufacture it on the existing facility.	No dedicated line for topical liquid preparations but have a topical ointment line. If it is not possible to produce on the existing facility, would consider including it into the new current Good Manufacturing Practice plant.	Yes. Started availing this product with a special request from partner NGOs Jhpiego and University of California, San Diego.
Potential Challenges and Opportunities				
If you were to produce and introduce the CHX Product in your country: What would be the appropriate strategy?	Promote the product to health professional associations, wholesalers, retailers, and the society in different ways such as using flyers and brochures.	Develop CHX 4% mass/volume introduction strategy based on the findings they will generate after doing market assessment.	Wanted to see the market demand, production cost, selling price, and investment required to produce CHX 4% before embarking on its production. Product introduction strategy is through promotion to medical, pharmaceutical, and other health professional associations and to retail outlets.	Promoting the products to health professionals through professional visits and using health professionals' annual conferences and workshops.

Questions	Fewus	APF	EPHARM	Asmi
Potential Challenges and Opportunities				
What challenges and opportunities do you foresee?	<p>Challenges of introducing CHX: The product may not get the required acceptance since the umbilical cord care using CHX is a new indication.</p> <p>Opportunity in producing CHX: The market demand for the product will be high since the infant mortality in Ethiopia is very high.</p>	APF needed more time to assess the challenges and opportunities of producing CHX.	<p>Challenges identified for introducing CHX 4%: Fear of not getting a reliable supplier for raw materials.</p> <p>Opportunities in producing CHX: Product diversification and large population size.</p>	Challenge: The price of the products will be a challenge since it varies with the foreign exchange and demand for the product.
<p>What would be the roles of your company (or manufacturers)?</p> <p>What roles could an NGO like PATH play in order to facilitate product uptake?</p>	<p>Role of Fewus: Preparing and organizing the facility for production and storage.</p> <p>NGO partner's role: Providing financial support, availing raw materials, and promoting the product.</p>	<p>Role of APF: To manufacture the product.</p> <p>Role of NGO partner: Provide product specification and annual market forecast.</p>	<p>Role of EPHARM: Conduct marketing study, product development, and production.</p> <p>Role of NGO partners: Create awareness and financial support.</p>	<p>Role of Asmi: Produce the product to the required standard and to deliver on time.</p> <p>Role of NGO partner: To give a prepayment of 30% at the time of ordering.</p>

PSI also spoke to a representative from FMHACA of Ethiopia who is a team leader on the Local Product Market Authorization Team. He believes that CHX might be considered as a disinfectant rather than a drug; in that case its registration/approval process will be much easier and shorter. He advises including CHX 4% on the national drug list, which will take about three months assuming the advisory committee is back in action (currently not active).

Table 2 List of key personnel interviewed, their responsibility, and contact information.

Date	Manufacturer	Key Personnel		
		Name	Responsibility	Email and Telephone
07/12/2012	Fewus Pharmaceuticals	Wondyifraw Eshete	General Manager	+251911235083 emaisc@ethionet.et
		Birhanu Tadlele	Production Manager	+251911739801
07/12/2012	APF	Shimelis Mamuye	General Manager	+251911212308 shimelispharmacist@yahoo.com
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