Feasbility assessment for production of 7.1% chlorhexidine digluconate for umbilical cord care in Pakistan

March 2014

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This project is made possible by the generous support of the United Nations Children's Fund (UNICEF) as part of the UN Commission on Life Saving Technologies for Women's and Children's Health. The contents are the responsibility of PATH and do not necessarily reflect the views of UNICEF or The UN.

Contents

Introduction

Under the implementation plan for the UN Commission on Life-Saving Commodities, the Chlorhexidine Working Group (CWG) has been working to establish local production of 7.1% chlorhexidine digluconate (delivering 4% chlorhexidine) for umbilical cord care (the chlorhexidine product) in selected countries in order to increase the availability of good-quality product at an affordable price.

Local production is defined as production in low- and middle-income countries (LMICs) by locally owned companies or subsidiaries of multinational companies. The potential benefits of local production include improvement in reliability of supply, realization of foreign import savings, development of further innovation capacity, creation of enhanced export capacity, and development of human capital. Local production of high-quality medicines could also lead to cost savings and improvement in product quality, depending on the product to be produced and regular surveillance of LMICs' quality control capacity.[i] Furthermore, local production may allow for better adaptation to local cultural preferences.

The profile of chlorhexidine for umbilical cord care is appropriate for local production because:

- The chlorhexidine product does not require proprietary active pharmaceutical ingredients (APIs), equipment, or processes for manufacturing.
- Pharmaceutical companies in many LMICs are capable of secondary production (i.e., the production of finished product forms from raw materials and excipients) for topical medicines. Thirty-four countries in Africa, for example, indicated that they have secondary-level production.[ii]
- The API used to make 7.1% chlorhexidine digluconate for umbilical cord care—20% chlorhexidine digluconate—is manufactured in multiple countries and is readily available for purchase and import.
- The costs of raw materials are not significantly high for the chlorhexidine product, but costs associated with shipment and import duties will likely constitute a large portion of the total cost and will, therefore, significantly affect pricing of the finished chlorhexidine product.

However, local production of the chlorhexidine product is not feasible in every LMIC. Numerous factors need to be in place in order to make local production feasible. In preparation for a stakeholder meeting on the chlorhexidine product in Pakistan, PATH was tasked to perform a feasibility assessment for local production of the chlorhexidine product in that country.

Methodology

In order to assess the feasibility of local production of the chlorhexidine product, we performed a landscape analysis using secondary data. We also hired a local consultant to interview a select number of pharmaceutical manufacturers in Pakistan and to gain additional information specific to that country. The results of secondary data analysis and interviews are described in the following sections. The results were subsequently evaluated against the "Checklist for production decision-making" (Appendix 1) developed

by the CWG to identify whether local production of the chlorhexidine product is feasible in Pakistan and to define the necessary next steps.

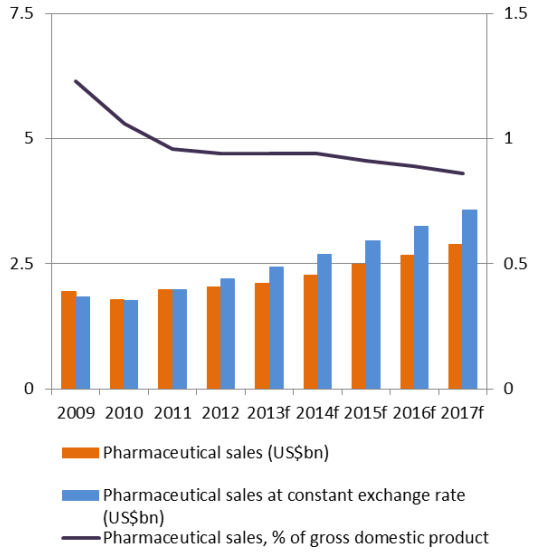
Overview of the Pakistani pharmaceutical manufacturing industry

Pharmaceutical market

The pharmaceutical market in Pakistan was estimated to be PKR 189.2 billion (or US$2.03 billion) in 2012 and is expected to grow to PKR 308.75 billion (or US$2.88 billion) by 2017 (see Figure 1). This growth can be attributed primarily to growth of its large and aging population.[iii]

Pakistan has 177 million inhabitants, approximately 4.8 million annual crude births.[iv] About 400 pharmaceutical manufacturers are registered in the country, 25 of which are multinationals. The majority of pharmaceutical companies in the country follow Good Manufacturing Practices (GMP).[v,vi]

Figure 1: Pharmaceutical market forecast (f): 2009-2017[iii]



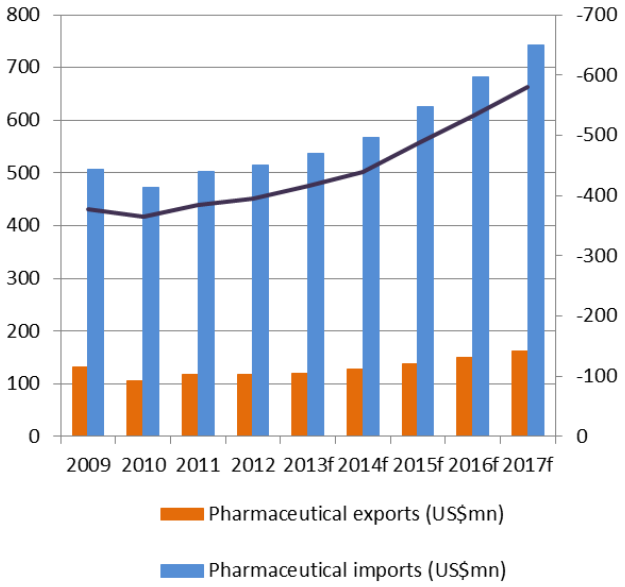
Local manufacturers, including the 25 multinationals, meet approximately 70 percent of the local demand for finished medicines.[vii] Pakistani national companies hold approximately 57.3 percent of the market share while multinationals hold the remaining market share, and the top 15 companies (both Pakistani and multinational companies) hold approximately 56.8 percent of the market share.[v] The leading top ten suppliers of finished drugs are multinationals, and GlaxoSmithKline is the largest pharmaceutical supplier in Pakistan in terms of sales.[iv] These data indicate that the market is highly concentrated and that multinationals hold relatively strong positions in that market.

The pharmaceutical industry in Pakistan produces various pharmaceutical product forms, including tablets, capsules, syrups, suspensions, drops, creams, gels, ointments, ophthalmic/optic drops, infusions, insulin, suppositories, vaccines, liquid and power injections, inhalers, vitamin sachets, disposable enemas, and modified-release dosages.[vi] Currently, 78,000 pharmaceutical products are registered in the country.[viii] The industry is focused on basic generic medicines. However, larger domestic companies are looking to move up the value chain.[iv] Considering the process and equipment required for the chlorhexidine product, and regardless of whether it is produced in gel or liquid form, pharmaceutical companies in Pakistan are not expected to encounter significant technical constraints in producing the product.

There are only a few small-scale manufacturers of APIs in Pakistan. As a result, the majority of pharmaceutical companies import APIs and other raw materials from European, Japanese, Korean, South American, and Southeast Asian countries and have little control over the cost of APIs.[vi] If the chlorhexidine product were to be manufactured in Pakistan, the API (20% chlorhexidine digluconate) would have to be imported from other countries, which might impact the end price of the product.

In 2012, exports were valued at around US$118.39 million (see Figure 2). Pharmaceutical companies in Pakistan export their products to less-developed Central Asian, Southeast Asian, and African countries, with a focus on Sri Lanka, the Philippines, and Vietnam.[iv] These countries could be potential markets for pharmaceutical companies in Pakistan if they decide to manufacture the chlorhexidine product. However, the viability of gaining sufficient market share in the global market is a concern considering that there already are pharmaceutical companies that produce the chlorhexidine product in Nepal and India. Lomus Pharmaceuticals Pvt. Ltd. in Nepal has been supplying its gel chlorhexidine product to African countries for research and pilot introduction purposes. Galentic Pharma Pvt. Ltd. in India provides its liquid chlorhexidine product to the United Nations Children's Fund (UNICEF). In addition, Bangladesh aims to establish local production, and establishment of local production in Nigeria is already under way. Under these circumstances, the number of export markets pharmaceutical companies in Pakistan might be able to gain is a concern.

Figure 2: Pharmaceutical Trade Forecast (f): 2009-2017[iii]



Regulatory environment

Medicines marketed in Pakistan are required to be registered under Section 7 of the Drug Act of 1976. Pakistan has experienced devolution of services related to the public sectors, including the health sector, with passage of the 18th amendment to its constitution, which became effective June 28, 2011. The Federal Ministry of Health was dissolved, and overall responsibility for health services, policy direction, and planning devolved to the provinces. However, all regulatory bodies were exempted from devolution, and the new Ministry of Regulation was created. This new ministry is expected to enhance the regulation and accreditation of human resources for health.[ix] Provincial health departments gave their consent for the formation of the Drugs Regulatory Authority of Pakistan (DRAP) at the federal level to keep a uniform policy of drug regulations and pricing throughout Pakistan. As a result, DRAP is responsible for issuing manufacturing licenses, registering products, monitoring and implementing GMP, and all other related matters.

The registration process for medicines typically takes 6 to 12 months from the date when regulatory dossiers are submitted. The registration processes for prescribed medicines and over-the-counter medicines are not different. If finished pharmaceuticals are imported, foreign manufacturers of these medicines are subject to GMP inspection.

The chlorhexidine product for umbilical cord care will need DRAP registration, whether manufactured locally or imported. One of the basic requirements for registration is the availability of safety and efficacy data, preferably from developed countries; however, documented proof of safety and efficacy from any source is accepted. Community-based randomized controlled trials were conducted in Pakistan, Nepal, and Bangladesh in order to prove the safety and efficacy of the chlorhexidine product. These trial results, together with World Health Organization (WHO) recommendation of the chlorhexidine product for umbilical cord care, would be useful for product registration in Pakistan.

Drug Policy

Pakistan's National Drug Policy of 2003 states that, "Policy will be geared to increase share of essential drugs in local production and to make such drugs available at affordable prices where-ever needed" to encourage manufacturing of drugs within the country.[x] To this extent, full import tariffs are exempted to UNICEF and on AIDS medicines to achieve affordability of those medicines.[xi]

Drug prices are regulated under Section 10 of the Drug Act of 1976 which gave the Ministry of Health complete control over drug pricing. About 800 drugs, which include lifesaving drugs (e.g., medicines used for cardiovascular diseases, diabetes, cancer and other chronic diseases) are considered essential and the Ministry of Health has controlled their prices. The chlorhexidine product, which is listed on the WHO Model List for Essential Medicines for Children, is likely to be considered as an essential medicine in Pakistan and to be subject to price control. A transparent system of price revision has been developed that allows periodic across-the-board price increases based on changes in inflation rate, the exchange rate of the rupee, etc. However, no periodic across-the-board price increase has been initiated since 2001.[xi] The Pakistan Pharmaceutical Manufacturers Association has proposed to the government to link drug prices with the Consumer Price Index or State Bank inflation statistics. [xii]

Pharmaceuticals containing chlorhexidine digluconate

Many pharmaceuticals containing chlorhexidine digluconate are currently registered in Pakistan. Some pharmaceuticals contain chlorhexidine digluconate as the only active ingredient while others contain multiple active ingredients including chlorhexidine digluconate. However, only six companies are continuing to sell their products, including five companies that make products containing chlorhexidine digluconate only; the other one makes a product that contains chlorhexidine digluconate as well as other APIs. Most companies that once registered pharmaceuticals containing chlorhexidine digluconate either have never manufactured their products or have withdrawn their products from the market (see Appendix 2).

PATH's consultant interviewed three companies: Platinum Pharmaceuticals (Pvt.) Ltd., Nexus Pharma (Pvt.) Ltd., and Sante (Pvt.) Ltd. Only Platinum Pharmaceuticals currently sells stomatologicals containing chlorhexidine digluconate (e.g., mouthwash). The other two companies have discontinued their chlorhexidine digluconate-containing products. The profiles of these three companies are described in Appendix 3. The owners of Platinum Pharmaceuticals particularly expressed interest in producing the chlorhexidine product, provided that the product is recommended by international organizations such as UNICEF and WHO.

Conclusions and recommendation for next steps

The results of the secondary data analysis and interviews were evaluated against the "Checklist for production decision-making" (Appendix 1) developed by the CWG to indicate whether local production of the chlorhexidine product is feasible.

Four out of six criteria were checked in the category of "Capability and capacity of pharmaceutical companies," which suggests that the capability or capacity to produce the chlorhexidine product potentially exists among pharmaceutical companies in Pakistan. There are a sufficient number of companies that have GMP certificates issued by the local authority. A few of these companies produce pharmaceuticals that contain chlorhexidine digluconate. These companies are importing the API from other countries, which indicates that they are already aware of foreign sources for the API required for the chlorhexidine product. At least one company, Platinum Pharmaceuticals, which currently produces stomatologicals containing chlorhexidine digluconate, expressed initial interest in producing the chlorhexidine product, although widening the search for committed and interested pharmaceutical companies will be required if local production of the product is determined to be feasible. The chlorhexidine product requires regulatory approval; however, results from community-based randomized controlled trials from three countries could be used for regulatory approval, thus decreasing the time to market for the product. In order to ensure that pharmaceutical manufacturers in Pakistan truly have the technical capability and capacity and are committed to producing the chlorhexidine product, a full GMP audit by expert auditors as well as a business due diligence evaluation study will be required.

It would be difficult for Pakistani pharmaceutical companies to capture the competitive export market. However, Pakistan's crude birth rate of 4.8 million babies—which represents the potential total market size for the country—could be sufficient to entice Pakistani pharmaceutical companies. Whether or not local production of the chlorhexidine product for the domestic market alone can lead to sustained production and affordable pricing will require further investigation.

However, it is questionable whether the domestic market size alone would lead to sufficient reduction in production cost to achieve a price that is lower than a maximum price that the Ministry of Health would likely establish for the product since it is considered to be an essential medicine. It may be difficult for pharmaceutical companies in Pakistan to gain sufficient share of the global market to increase their production quantity enough to further reduce production costs. Lomus Pharmaceuticals in Nepal already

produces and distributes the chlorhexidine product, and Galentic in India also produces the product for UNICEF's Supply Division. In Africa, some countries are interested in establishing local production capacity for the chlorhexidine product, and Nigeria especially has been making good progress in this regard.

As a result, we recommend the following activities as next steps in order to determine if locally producing the chlorhexidine product in Pakistan is feasible, provided that current policy and guidelines already define the application regimen (duration of use), product form (gel or liquid), and location of use (facility and/or community).

1. Develop an introduction and scale-up plan (with cost estimate) that includes how use of the chlorhexidine product can be expanded geographically within Pakistan and which distribution channels will primarily be used. The introduction and scale-up plan should be supported by both government and international organizations.
2. Estimate the demand size within Pakistan based on the introduction and scale-up plan. Simultaneously perform a cost analysis to compare the estimated price of the chlorhexidine product depending on whether it is imported or produced locally.
3. Canvas pharmaceutical companies in Pakistan and identify interested and committed manufacturers.
4. Conduct full GMP audits of those pharmaceutical companies that were identified in order to ascertain their capability and capacity to produce the chlorhexidine product in good quality. Concurrently perform business due diligence to confirm their interest and the viability of their business.

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[vii] Pakistan Pharmaceutical Manufacturers' Association website, available at http://www.ppma.org.pk/PPMAIndustry.aspx. Accessed February 7, 2014.

[viii] Latest figures obtained from DRAP July 2013.

[ix] WHO Global Health Work Force Alliance. Pakistan. Available at http://www.who.int/workforcealliance/countries/pak/en/. Accessed February 7, 2014.

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Appendix 1: Checklist for production decision-making

Questions	Column A Landscape (Yes/No)	Column B Remark
Capability and capacity of pharmaceutical companies		
Are there any pharmaceutical manufacturers in your country that have a GMP [Good Manufacturing Practices] certificate issued by the local regulatory authority and have a manufacturing license for their current products?	☒ **Yes** ☐ No	
Are there any pharmaceutical manufacturers in your country that already produce topical medicines in liquid or gel form?	☒ **Yes** ☐ No	
Is the existing capability of pharmaceutical manufacturers adequate for manufacturing 7.1% chlorhexidine digluconate for cord care? *[Note: The adequacy of manufacturing capability should be assessed by trained GMP auditors.]*	☐ Yes ☐ No	Needs further evaluation
Are pharmaceutical manufacturers knowledgeable about where to obtain quality API [active pharmaceutical ingredients], excipients, and other raw materials?	☒ **Yes** ☐ No	
Do these pharmaceutical manufacturers have a good record of financial stability over time? *[Note: Financial statements over the past 3 to 5 years could be used as verification.]*	☐ Yes ☐ No	Needs further evaluation
Given the domestic market size for 7.1% chlorhexidine digluconate, are there pharmaceutical companies willing to sell the product to public-sector purchasers at affordable prices?	☒ **Yes** ☐ No	
Affordability		
Given the domestic market size for 7.1% chlorhexidine digluconate for cord care, can the API, excipients, and other materials be obtained from quality sources at reasonable costs?	☐ Yes ☐ No	Needs further evaluation
[If the API is imported] Do the tax and import duties for the API significantly affect the price of the finished product?	☐ Yes ☐ No	Needs further evaluation
Can 7.1% chlorhexidine digluconate for cord care be produced more inexpensively locally than importing a 7.1% chlorhexidine digluconate product? *[Note: Price and cost associated with importing a product from Lomus or purchasing from the United Nations Children's Fund Supply Division Catalogue can be used as a bench mark.]*	☐ Yes ☐ No	Needs further evaluation
Sustainability		
Are pharmaceutical manufacturers able to sustain the supply of 7.1% chlorhexidine digluconate, given the domestic market size, product pricing, and cost of production of the product?	☐ Yes ☐ No	Needs further evaluation
If the domestic market size is too small to sustain the supply:		
Are there viable markets in neighboring countries into which the 7.1% chlorhexidine digluconate could be exported?	☐ Yes ☒ **No**	
Are there any trade zones or regulations that could facilitate the export of 7.1% chlorhexidine digluconate for cord care while maintaining affordable end-user pricing?	☐ Yes ☒ **No**	
Are pharmaceutical manufacturers in your country able to meet any larger regional demand?	☐ Yes ☐ No	Needs further evaluation
Are pharmaceutical companies in your country capable of exporting and marketing medicines to neighboring countries?	☒ **Yes** ☐ No	

Appendix 2: Pharmaceuticals registered in Pakistan

A. Containing chlorhexidine digluconate only as the active pharmaceutical ingredient (API)

No	Brand Name	Manufacturer	Form	API/Strength	Pack Size
1	CHLORO-4	MEDIPAK LIMITED	Solution	Chlorhexidine digluconate 4% w/v	60 ml
					500 ml
					1,000 ml
2	HEXIRUB	PHARMAWISE LABS	Solution	Chlorhexidine digluconate 5 % w/v	500 ml
3	LOREXINE	PHARMAWISE LABS	Solution	Chlorhexidine digluconate 1.5% w/v	1,000 ml
4	CHLORO SOL	MEDISEARCH PHARMACAL	Solution	Chlorhexidine digluconate 1.5% w/v	1,000 ml
5	HEXALON	POLYFINE CHEMPHARMA	Solution	Chlorhexidine digluconate 1.5% w/v	1,000 ml
6	SMYLE	ALBRO PHARMA	Solution	Chlorhexidine digluconate 1.5% w/v	120 ml
7	LIPI SCRUB	LAHORE PHARMA	Liquid	Chlorhexidine digluconate 0.1% w/v	500 ml
8	CLINICA	PLATINUM PHARMACEUTICALS	Mouthwash	Chlorhexidine digluconate 0.2% w/v	150 ml
			Mouthwash	Chlorhexidine digluconate 0.2% w/v	300 ml
			Gel	Chlorhexidine digluconate 0.2% w/w	40 g
			Paste	Chlorhexidine digluconate 0.2% w/w	100 g
			Paste	Chlorhexidine digluconate 0.2% w/w	40 g
9	CODENT	NEUTRO PHARMA (PVT) LTD.	Mouthwash	Chlorhexidine digluconate 0.2% w/v	120 ml
10	MOUTH CARE	ENGLISH PHARMACEUTICALS	Mouthwash	Chlorhexidine digluconate 0.2% w/v	120 ml
11	ORAHEX	ZANCTOK PHARMACEUTICALS	Mouthwash	Chlorhexidine digluconate 0.2% w/v	150 ml
			Gel	Chlorhexidine digluconate 0.2% w/w	40 gm
12	MEXX	NEO NEXUS PAKISTAN	Mouthwash	Chlorhexidine digluconate 0.12% w/v	150 ml
			Paste	Chlorhexidine digluconate 0.12% w/v	50 g
13	LACER	HIMONT PHARMACEUTICALS	Gel	Chlorhexidine digluconate 0.2% w/w	30 ml

Products currently available in the market.

B. Containing chlorhexidine digluconate and other APIs

No	Brand Name	Manufacturer	Form	API/Strength	Pack Size
1	BEPANTHEN PLUS	BAYER PAKISTAN	Cream	Chlorhexidine digluconate 0.5% w/w D-Pantothenol 5% w/w	15 g
2	GRAMEX PLUS	PLATINUM PHARMACEUTICALS	Gel	Chlorhexidine digluconate 0.25% w/w Metronidazole 1% w/w	40 gm
3	REVOMET PLUS	ZANCTOK PHARMACEUTICALS	Gel	Chlorhexidine digluconate 0.25% w/w Metronidazole 1% w/w	40 gm
4	PLITOL	PLIVA PAKISTAN	Solution	Chlorhexidine digluconate 0.3% w/v Cetrimide 3%w/v	1,000 ml
5	SAVTOL	PHARMAWISE LABS	Solution	Chlorhexidine digluconate 0.3% w/v Cetrimide 3%w/v	1,000 ml
6	LP-LON	LAHORE PHARMA	Liquid	Chlorhexidine digluconate 1.5% w/v Cetrimide15% w/v	1,000 ml 112 ml
7	SEP-GARD	ZAFA PHARMACEUTICAL	Liquid	Chlorhexidine digluconate 1.5% w/v Cetrimide 15% w/v	1,000 ml 50 ml
8	BIO-SEPT	ARDIN PHARMACEUTICALS	Liquid	Chlorhexidine digluconate 7.5% w/v Cetrimide 15% w/v	1,000 ml
9	BENZYCLOR	ZANCTOK PHARMACEUTICALS	Mouthwash	Chlorhexidine digluconate 0.2% w/v Benzydamine 0.15% w/v	150 ml
10	BENZYCOL	EVEREST PHARMACEUTICALS	Mouthwash	Chlorhexidine digluconate 0.2%w/v Benzydamine 0.15% w/v	140 ml
11	ENZICLOR	PLATINUM PHARMACEUTICALS	Mouthwash	Chlorhexidine digluconate 0.2%w/v Benzydamine 0.15% w/v	150 ml 300 ml
12	HEXA COOL	PHARMEVO	Mouthwash	Chlorhexidine 0.2%w/v Sodium Fluoride 0.025%w/v	NA
13	OCCTTAL	HELICON PHARMACEUTEK	Mouthwash	Chlorhexidine digluconate 0.2% w/v Benzydamine 0.15% w/v	120 ml 300 ml
14	ZYDINE	SANTE (PVT) LIMITED	Mouthwash	Chlorhexidine digluconate 0.2% w/v Benzydamine 0.15% w/v	250 ml
15	LASOGEN	HIMONT PHARMACEUTICALS	Paste	Chlorhexidine digluconate 0.2%w/v Benzydamine 0.15% w/v	100 g 150 ml
16	LACER	HIMONT PHARMACEUTICALS	Mouthwash	Xylitol 1%w/v Chlorhexidine digluconate 0.12%w/v	200 ml

Products currently available in the market.

Appendix 3: Profiles of a few pharmaceutical companies

Platinum Pharmaceuticals (Pvt.) Ltd. (Mid-sized company)

Overview

The company started its business as a retail pharmacy and expanded its business to manufacturing pharmaceuticals in 1996. It has ISO 9002, 14001, and 17025 certifications and complies with local Good Manufacturing Practices (GMP). They focus on producing antibiotics, analgesics, and cardiology products in a variety of dosage forms, including oral solid and liquid medicines (i.e., tablets, capsules, and syrups), topical ointments, and stomatologicals (i.e., mouthwash and toothpastes). They currently produce stomatologicals containing chlorhexidine digluconate. Active pharmaceutical ingredients (APIs) of pharmaceuticals they manufacture are imported from European countries, China, and India while primary containers are sourced locally.

Revenue structure

It has an annual review of PKR 1.75 billion. Ten percent of the revenue is generated by exporting products to Sri Lanka, the Philippines, Myanmar, and Thailand. Five percent of the revenue comes from sales to public institutions. Platinum Pharmaceuticals has a product that contains chlorhexidine digluconate, CLINICA brand. The sales of the brand are shown below.

Product	Quantity	Sales Value (PKR)	Sales Value (US$)	Growth Over Last Year (%)
Total sales of CLINICA brand	452,500	19,828,000	245,000	---
Mouthwash 150 ml	167,000	7,666,000	79,000	-2
Mouthwash 300 ml	35,600	2,857,000	29,000	-17
Gel 40 g	81,100	448,000	46,000	-3
Toothpaste 40 g	95,600	3,932,000	40,000	1
Paste 100 g	73,200	4,925,000	51,000	4

Level of interest

The owners are willing to get the product registered and manufacture it in Pakistan provided that the product is included in United Nations Children's Fund or World Health Organization recommended protocols for maternal, neonatal, and child health.

Nexus Pharma (Pvt.) Ltd. (Small-sized company)	
Overview	The previous company, Neo Nexus, was a pharmaceutical distributor. It started pharmaceutical manufacturing in 2002. Their manufacturing started with stomatologicals (i.e., mouthwash and a gel preparation for oro-dental care); however, they discontinued manufacturing these products in 2007 and switched to manufacturing systemic oral solid and liquid product forms with a focus on antibiotics, analgesics, and other general pharmaceutical preparations. Their website states that their manufacturing facility complies with ISO standards and current GMP.
Revenue structure	The total revenue of the company is unknown, but their website claims that their sales have grown at an average rate of 20 percent over the past five years.
Level of interest	N/A

Sante (Pvt.) Ltd. (Small-sized company)	
Overview	The company was established in 1996. The core business of Sante was ophthalmic products, but it has expended its business by adding dermatological preparations and ear, nose, throat products. Sante has a manufacturing facility for sterile eye/ear preparations (i.e., drops and ointments), skin cream/ointment and gel forms, and systemic oral solids and liquids with APIs from China. The website states that the company has ISO 9001:2000 certification. The company use to manufacture a mouthwash containing chlorhexidine digluconate, but it discontinued manufacturing the product 3–4 years ago since the product did not generate sufficient profit margins.
Revenue structure	The total revenue of the company is PKR 700 million annually.
Level of interest	N/A