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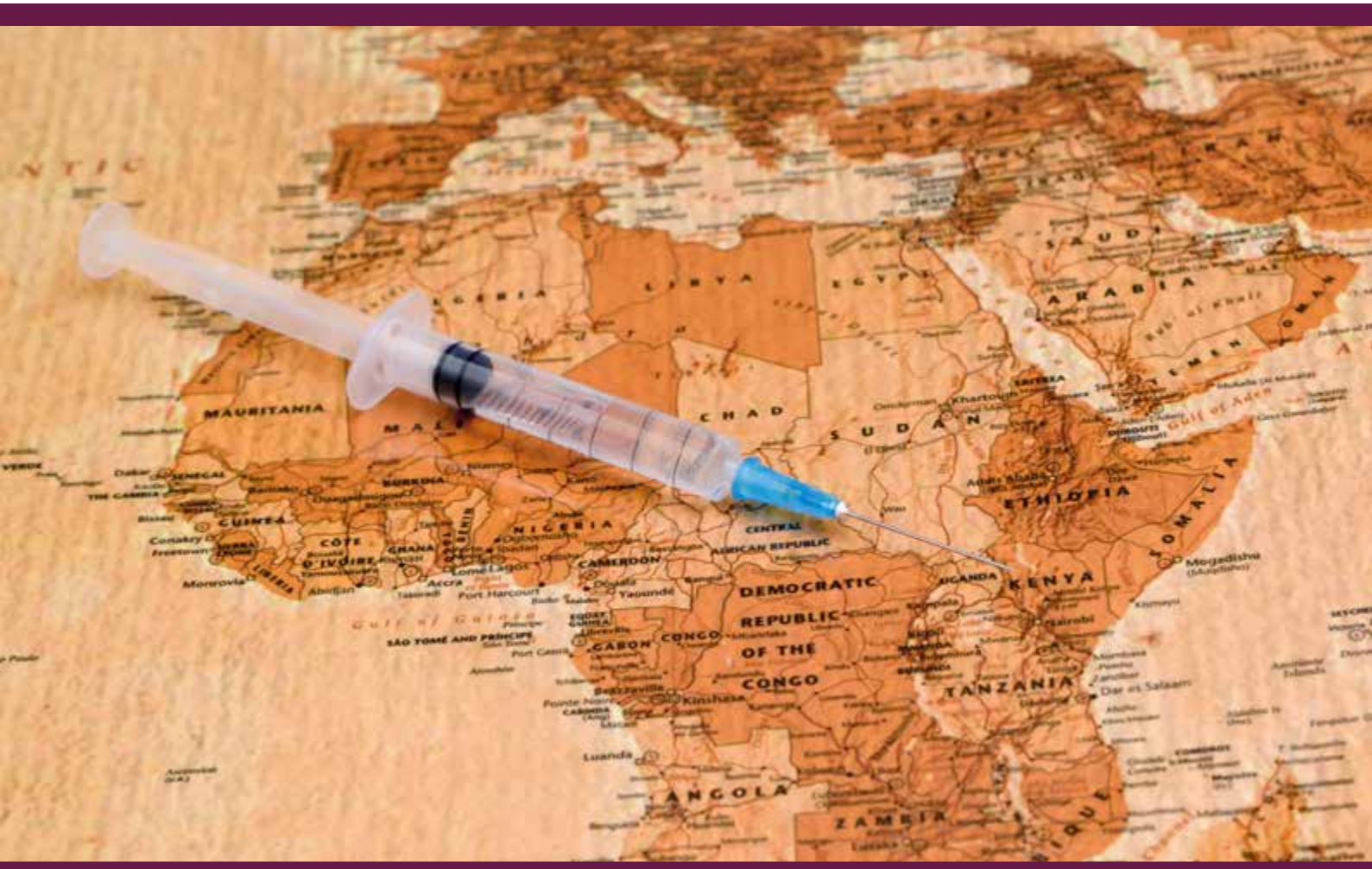

WHITE PAPER

Commercialising vaccines: A methodology to identify potential market opportunities and conduct outline assessments

Case study: South Africa

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Case study: South Africa

Global UNIDO Project:
Strengthening the local production
of essential medicines in developing countries
through advisory and capacity building support

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This document has been prepared by Kris Howard, Pharmaceutical Manufacturing Expert, UNIDO, and Martin Nicholson, International Pharmaceutical Expert, UNIDO. It forms part of UNIDO's global project "Strengthening the local production of essential medicines in developing countries through advisory and capacity building support", which is led by Juergen Reinhardt, Senior Industrial Development Officer and Project Manager, assisted by Alastair West, Pharmaceutical Manufacturing Plan for Africa Business Plan Coordinator.

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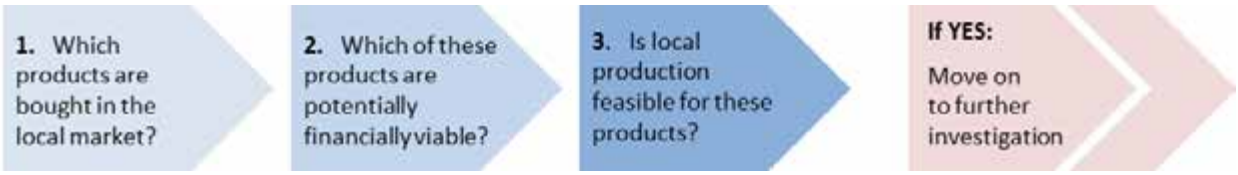
Executive Summary

This paper describes a methodology to perform an initial evaluation to decide which vaccines, if any, may be worth manufacturing for a particular market. These methods do not constitute a comprehensive market analysis but instead form part of an initial concept level business case analysis.

This stepwise approach is demonstrated using a real life example, South Africa, as a country case study.

The evaluation is carried out in three steps:



The document outlines each of these three stepwise phases which collectively comprise the methodology, and also details the next steps that would need to be taken to validate a business case.

Publicly available information on the existing South African vaccine manufacturer indicate that the conclusions drawn by this document relating to the South African market do in fact identify the key market opportunities there. This indicates that the methodology has delivered a valid assessment result in this particular case study, thus endorsing the approach taken. The results of the analysis may even provide insight as to why certain strategic decisions were made by the existing South African manufacturer, however further discussion on this point is beyond the remit and focus of this study.

The document supports and expands upon the white paper "Establishing Manufacturing Capabilities for Human Vaccines"[1] published in 2017 and assumes the reader is familiar with the concepts introduced therein. This white paper was designed to give a basic overview of the vaccines industry and summarize key cost drivers and factors to consider when planning the establishment of a vaccine production facility.

The objective of the current paper is to demonstrate how a person endowed with knowledge of the vaccine industry and basic market data can determine the high level feasibility of potential commercial vaccine opportunities in a market.

[1] https://www.unido.org/sites/default/files/files/2017-12/Establishing-Manufacturing-Capabilities-for-Human-Vaccines-ebook.pdf

Introduction

This paper introduces a high level methodology that can be used to identify potential commercial opportunities in the vaccines market and to systematically pare them down to the opportunities with the highest potential. It then seeks to determine if, from this list of opportunities, either the entirety or a sub-set of it constitute a financially viable opportunity to produce vaccines locally for a given market or region. The methodology follows three steps:

1. **Understand the local market for vaccines** – determine which vaccines are currently being supplied to the market, who purchases them (private citizens or insurance schemes, NGOs or the government), the basic procurement information for these vaccines (manufacturer, quantity purchased, purchase price) and how all of these details may change over the coming years.
2. **Identify financially viable candidates for local production** – determine if a compelling case can be made for these local purchasers to buy from a newly proposed organization. In many cases, the largest purchasers will be NGOs or the local governments so an opportunity to support local industry or generate procurement or forex savings may feature highly on their list of priorities.
3. **Assess feasibility of local production** – determine if local production of certain high potential vaccines presents a commercially attractive proposition for a new entity, local market purchasers and a technology transfer partner who currently makes these or similar vaccines. Issues such as facility operating and investment costs and the ability to achieve a certain facility capacity utilization will begin to factor into this decision.

This methodology should not be seen simply as a recipe for evaluating these types of scenarios around the world. Market data availability and format as well as local conditions will vary widely from market to market and must be evaluated on a case by case basis. So, whilst the basic approach depicted here is still a valid one, it may require experts with specific knowledge of the local market and the inner workings of the pharmaceutical industry to complete a similar assessment in other markets. Furthermore, it should be noted that the output from such a methodology should be considered as an initial high level analysis that needs to be further developed and expanded prior to making any investment decisions.

Lastly, this methodology has made one very large assumption, namely that the localization of vaccine production will occur via a technology transfer from another company. Whilst development of a novel and unique vaccine by a firm that is new to the vaccines industry is certainly possible (in other words, developing a product from scratch in a new company), the results of doing so vary widely in terms of duration, cost and probability of a successful product development program, and thus have not been accounted for here. The technology transfer-based route is consequently the predominant industry approach in the majority of cases like this, since it is more predictable in terms of duration, cost and probability of success.

Local market for the case study: South Africa

For the purposes of demonstrating the application of the methodology, South Africa was chosen as a suitable case study because of the relative ease with which data could be accessed. South Africa self-procures (i.e. is not GAVI supported) a substantial amount of vaccines every year for its EPI (Expanded Program on Immunization) through a local vaccines company, Biovac.

This analysis treats the South African market as a hypothetical example for the purposes of demonstrating the methodology. Importantly, it considers the country as if it were a 'clean slate', i.e. without consideration of the current manufacturing capacity present there. Whilst this is not actually the case in this country, given the presence of one local vaccine manufacturer, the analytical methods demonstrated can be used to assess feasibility for any market.

First Phase: Understanding the local market for vaccines

The South African EPI immunizes approximately 90% of the targeted EPI population (i.e. children under 12 years of age) free of charge, making the South African government the largest purchaser of vaccines in the country by far. Due to this, the analysis is focused on the public EPI vaccines market rather than the smaller, more fragmented private market. When discussing the local production of vaccines, the largest commercial opportunities for new market entrants are almost exclusively found within the public market. South Africa is not a GAVI eligible country and actually donates to the GAVI fund. It is important to note that:

- **GAVI eligible countries have their vaccines bought by UNICEF at what can be assumed to be close to COGs (Cost Of Goods) prices** - typically making the commercial potential of these markets lower than Non-GAVI funded countries**.**
- **Not all GAVI eligible countries should be discounted as places where local production is not viable.** In some circumstances, countries that will soon graduate from GAVI support can be good candidates for local production.

South Africa purchases all of its vaccines on the open market, including EPI products and those purchased for other uses by the government (vaccination of armed forces, healthcare workers, and so on). The vaccines bought by the SA government and the prices paid can be seen by examining publicly available tender data. This does not include operational and administrative costs. See the Appendix for more information on this.

By comparing the purchasing data from the tenders with the PAHO/UNICEF data, the following information can be extracted:

Table 1: Overview of South Africa Vaccine Purchase 2014-2016

Generic Vaccine Product Description	Part of EPI? (y/n)	Brand	Manufacturer	SA Price/ dose (ZAR)	SA Price/ dose (USD)	Quantity	Total Cost (USD)	% Budget
Hepatitis B	n	HEBERBIOVAC B AMD	CGEB *	29.50	2.22	264,477	587,461	0.2%
Rotavirus	y	ROTARIX	GSK	82.09	6.18	4,555,587	28,158,131	8.4%
BCG Intradermal	y	BCG SSI ID	SSI**	2.26	0.17	721,301	2,459,191	0.7%
BCG Intradermal	y	BCG Cipla/SII	Cipla	2.54	0.19	721,301	2,756,270	0.8%
Diphtheria Tetanus	y	DIFTAVAX	Sanofi Aventis	11.41	0.86	455,559	3,914,837	1.2%
Diptheria, Pertussis,Tetanus, Polio, HIB, HepB	y	HEXAXIM ***	Sanofi Pasteur	228.44	17.20	-	-	0.0%
Diptheria, Pertussis,Tetanus, Polio, Haemophilus	y	PENTAXIM	Sanofi Pasteur	186.35	14.03	9,111,175	127,841,839	38.1%
Hepatitis B	y	HEBERBIOVAC B PMD	CGEB *	7.99	0.60	927,387	5,577,869	1.7%
Human Papilloma	y	CERVARIX	GSK	108.60	8.18	2,000,000	16,354,190	4.9%
Influenza	n	Vaxigrip 2013	Sanofi Pasteur	55.94	4.21	3,000,000	12,636,097	3.8%
Measles	y	ROUVAX	Sanofi Pasteur	8.82	0.66	961,735	6,383,325	1.9%
Measles	y	Measbio	Biofarma Indonesia	11.11	0.84	961,735	8,045,959	2.4%
Meningococcal Meningitis A and C Single Dose	n	Menomune	Sanofi Pasteur	109.43	8.24	27,400	225,765	0.1%
Pneumococcal	y	PREVENAR	Pfizer	184.90	13.92	6,833,381	95,135,317	28.3%
Pneumococcal, Polyvalent	n	Pneumovax	MSD	101.85	7.67	24,200	185,586	0.1%
Polio Oral Trivalent	y	POLIORAL	Sanofi Pasteur	2.62	0.20	400,000	1,576,387	0.5%
Polio Oral Trivalent	y	POLIORAL	Sanofi Pasteur	3.45	0.26	865,562	2,247,163	0.7%
Rabies (embryo cells cultured)	n	Rabipor	Novartis	165.62	12.47	660,000	8,230,495	2.4%
Rabies (vero cell cultured)	n	Verorab	Sanofi Pasteur	158.83	11.96	660,000	7,893,065	2.3%
Tetanus Toxoid	y	TETAVAX	Sanofi Pasteur	8.42	0.63	865,562	5,486,259	1.6%
Yellow Fever	n	Stamaril	Sanofi Pasteur	216.21	16.28	15,100	245,823	0.1%
						Total	**335.9**	**USD ($ M)**
							4,461.6	**Rand (ZAR M)**

* Center for Genetic Engineering and Biotechnology

** Statens Serum Institute

*** South Africa is transitioning from a combination of Pentaxim + Hep B vaccine to Hexaxim, which is an all in one covering the same six antigens - this is why Hexaxim is currently shown at 0% of the budget.

Second Phase: Identifying financially viable candidates for local production

When identifying potential candidates for local production, the question to answer is “Can a compelling case be made for the local government to buy from you?”. Of course, things such as the safety and efficacy of the product will factor into the government’s decision to buy from a new supplier, but here we will begin with a financial assessment. Below are the guidelines used to carry out a quick and relatively straight forward assessment of the financial viability of local production for the products SA is purchasing:

- **UNICEF/PAHO prices**

  As discussed in the previous white paper, the UNICEF price is generally the lowest price for which a vaccine will be sold, and for many products is at or close to the cost of goods and