Final Report

January 2016

Feasibility study on Regional Manufacturing of Medicines and Health Commodities

Volume 3 (Annexes)

(SADC-SHD&SP/CD/C39/2014)

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1. TERMS OF REFERENCE

1. BACKGROUND

The SADC region has some of the highest rates of morbidity and mortality due to HIV and AIDS, TB and Malaria. Furthermore, these diseases are both the cause and consequence of poverty in the region. To this end, the disease burden in the SADC region is undermining the efforts to eradicate poverty, which is the overarching priority for the regional integration agenda.

SADC Member States have developed different strategies for the control of the three diseases with varying degrees of effectiveness. In addition, SADC has also outlined strategies and activities for the control of the diseases through the Protocol on Health in the Southern African Development Community. These are premised on the principle that a coordinated regional effort is necessary to compliment national strategies.

One of the obstacles affecting the response to these triple disease burdens is limited access to medicines and related commodities for prevention and treatment. Lack of access to essential medicines and related commodities has resulted in millions of people dying in the region. There are a combination of factors that explain the limited access to medicines and related commodities. These include unaffordable prices, inefficient procurement and supply chain systems, weak regulatory and quality assurance mechanisms as well as lack of regional production capacity for medicines and poor or inadequate payment systems.

Costs for medicines are clearly a major obstacle in most of the SADC countries. While medicines represent less than one-fifth of total public and private health spending in most developed countries, in the majority of developing countries including most SADC Member States, it ranges from 25 to 66 per cent. Thus in most Member States medicines constitute the largest public expenditure on health after personnel costs and the largest household health expenditure. Access and affordability to medicines are therefore important determinants for the state of health and poverty for the region and the households.

The SADC region like the rest of Africa heavily depends on imported medicines both patented and generics. As an example, in Africa 37% of ARV medicines are patented products whereas 63% are generics. About 85% of the generic ARV medicines used in the region are imported and 15% are manufactured within the SADC region, the continuity of supply of affordable medicines is increasingly becoming a concern.

The scope for development of pharmaceutical products is very large in SADC and the rest of Africa. The total pharmaceutical market in the SADC region is estimated at US42.2 to US43 billion per year with approximately 24% being local production and the balance being imports.

The SADC Region has committed itself to promoting regional manufacturing of medicines. The SADC Pharmaceutical Business Plan priorities are, among others, the local/regional production of medicines. Similarly, the SADC Industrial Development Policy Framework

focuses on the promotion of regional value chains in SADC as a key industrial policy priority based on the following approaches:

- upgrading of existing manufacturing industries towards more competitiveness (industrial upgrading and modernization);

- fostering backward- and forward linkages and complementarities between sectors and industries, and across the region (industrial deepening) ; and

- diversifying the region's industrial base through new productive activities (industrial diversification).

In an effort to operationalize both the SADC Pharmaceutical Business Plan and the Industrial Policy Framework, the Secretariat seeks to recruit a Firm of Consultants to assess the feasibility of Regional production of Essential Medicines and commodities, especially those related to the three communicable diseases namely HIV and AIDS, TB, and Malaria. The Consultants will also develop modality for operationalizing Regional Production of Medicines and Health commodities.

It is against this background that the SADC Secretariat wishes to hire a Firm to assess the feasibility of regional production of medicines and commodities for the communicable diseases.

2. RATIONALE

The consultancy seeks to assess the feasibility of the production of essential medicines especially those related to the three communicable diseases, namely HIV and AIDS, TB and Malaria as well as the production of health commodities for the three diseases.

The industry component of the trade and economic liberalization intervention area in the RISDP highlights the key challenges, goals and strategies for further industrial development in SADC. During the Summit that was held in Victoria Falls, Zimbabwe, in August 2014, the SADC Heads of State and Government endorsed the following Summit Theme: "*SADC Strategy for Economic Transformation: Leveraging the Region's Diverse Resources for Sustainable Economic and Social Development through Beneficiation and Value Addition*" which placed industrialization at the centre stage of the regional integration agenda.

In deliberating on the Theme, the Summit mandated the Region to develop a strategy and road map for industrialization. Summit also mandated that industrialization should be prioritized in the revised Regional Indicative Strategic Development Plan (RISDP) 2015-2020.

One of the goals of the SADC Industrial Development Policy Framework relates to "*Enhancing the existence and competitiveness of the Pharmaceutical manufacturing plants".* The second goal is "*Diversification of production structures that includes Pharmaceuticals and exports by the year 2015*". The third goal, which relates to poverty reduction, emphasizes enhancement of productive capacity and employment creation.

The consultancy is also premised on the SADC Protocol on Health, particularly article 29 which stressed the need for the region to focus, among others, on the following:

(i) Harmonization of procedures (quality assurance, registration);

(ii) Production, procurement, distribution; and

(iii) Development/strengthening of an Essential Medicines Programme and promotion of rational drug use

2.1 Feasibility Assessment of Regional Production of Essential Medicines

The combination of increasing demand, high costs, and limited access to some of the medicines and over dependency on imported drugs has necessitated SADC to explore the feasibility of regional manufacturing of essential medicines. This is sought in the context of TRIPS flexibilities as reaffirmed by the Doha Declaration.

Also, the continued gap between supply and demand for condoms and malaria related commodities such as bed nets in the context of unaffordable prices has necessitated the exploration for regional production.

Regional production has the added advantages of supply security, building technical capacity for SADC citizens and creating employment which is critical for poverty reduction.

3. OBJECTIVES

The consultancy has two inter-linked objectives:

(i) To assess the feasibility of Regional production of generic essential medicines, especially those related to the three major communicable diseases (HIV and AIDS, Tuberculosis and Malaria) and accompanying/related health commodities such as condoms (HIV and AIDS), Rapid Diagnostic Tests (TB) and long-lasting insecticide-treated nets (Malaria).

(ii) To develop a strategy or modality for operationalizing Regional production of Medicines and Health commodities for the Communicable Diseases.

4. SCOPE OF WORK

To achieve the above objectives the Firm will be expected to carry out the following:

4.1 To conduct feasibility study on production of essential medicines and accompanying/related health commodities for the three communicable diseases – HIV and AIDS, TB and Malaria;

4.2 To propose a strategy/modality to operationalize Regional production of medicines and related/accompanying commodities, including the standards to be adhered to, based on current Good Manufacturing Practices (cGMP); and

4.3 Facilitate dissemination workshops to (1) validate the feasibility study and (2) build consensus on the modality (strategy, mechanisms and standards) for operationalizing production.

Specifically, the Firm will be expected to carry out the following tasks, among others:

4.1.1 Enabling Environment

- To undertake a literature review covering:
    - Documentation of the status of harmonization efforts regarding the regulatory registration and control of medicines in the SADC region;
    - SADC policies concerning medicines for the three communicable diseases;
    - Government policy coherence (e.g. Industry vs. Health vs. Finance);
    - SADC and Member State policies in support of pharmaceuticals manufacturing;

- To ascertain the level of Government support to the pharmaceutical sector through the procurement process (e.g. local preference schemes, price advantage etc);

- To identify current Government incentives to the pharmaceutical manufacturing sector in the SADC region – infant industry protection, tax incentives, duty-free importation (e.g. of raw materials and medicines), grants;

- To assess the extent to which SADC Member States utilize TRIPS flexibilities as reaffirmed by the Doha Declaration in the production of essential medicines;

- To assess the status of the infrastructure needed for systematic quality assurance and quality control (e.g. Laboratories – SNRLs, NRLs);

- To assess the availability of quality medicines in public, private and civil sectors and their inclusion in the national Essential Medicines List (EML);

- To assess the R&D infrastructure (institutions, laboratories, human resources, financing etc) and determine the amount of Government R&D spend for pharmaceuticals development in SADC Member States;

- To assess the availability of required skilled human resources (for production, quality assurance, process maintenance, regulatory compliance, design & packaging & distribution, R&D etc);

- To specify the Certification/Licensing requirements by relevant institutions (e.g. National, Regional and International, WHO prequalification, PIC/S certification, National Drugs Control Authorities;

- To assess the Regulatory landscape with respect to WTO/TRIPS Flexibilities, NMRAs, cGMP and Enforcement through regular inspection (by Regulatory Authorities) of production plants as well as distribution facilities to ensure adherence to Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Warehousing Practices (GWP) and prevent sub-standard and counterfeit products from entering the SADC market; and

- To assess the extent of pharmaceutical industry-academia linkages.

4.1.2 Business case for local production

- To assess the willingness of pharmaceutical companies currently operating in the SADC region to expand, upgrade and/or modernize their operations in order to produce and supply identified pharmaceutical products (i.e. essential medicines and health commodities) to the regional and international market;

- To assess the ability and willingness of key industry players (e.g. Governments, donor-funded procurement agencies, wholesalers, retailers (pharmacists) and consumers) to buy/consume high quality generic essential medicines and accompanying/related health commodities manufactured in the SADC region;

- To identify pharmaceutical and prophylactic products/materials locally produced or imported into the SADC region;

- To determine the size (best estimate) of the market (volume and value; locally produced and imported) for pharmaceutical products (generic essential medicines and accompanying/related commodities, especially for the three communicable diseases) broken down into each category/segment, and indicate the potential for growth;

- To determine the demand and supply distortions in terms of effective operational control of supply chain systems for pharmaceutical manufacturing (e.g. forecasts, inventory status, backlogs, production schedules, supplier delivery schedules, pipeline inventory etc);

- To determine inventory management issues (e.g. associated costs, insurance, taxes, etc);

- To identify possible sources of financing for regional production of essential generic medicines, such as Government, Healthcare Insurance Schemes, company's own funds, Development Finance Institutions (DFIs), foreign direct investments (FDIs), International Government Agencies (e.g. BMZ, GTZ, USAID), local and international NGOs, commercial banks, institutional investors (e.g. pension funds), venture capital firms, Private-Public Partnerships, GFATM, PEPFAR, PMI, Private Health Insurance etc

- To determine the cost (including transport costs, duties, etc) and price/revenue behaviour in the pharmaceuticals industry, and determine the profitability of regional production of the essential medicines and related/accompanying commodities;

- To clearly identify the potential benefits of regional manufacturing of pharmaceutical products to SADC Member States; and

- To determine the level of inclusivity and sustainability of regional production.

4.1.3 Operational issues

- To identify pharmaceutical companies currently manufacturing essential generic medicines in the SADC region, and have the potential for expansion, upgrading and/or modernization of their production to supply the regional and international markets;

- To critically assess the technical and human resource capacities of these existing pharmaceutical manufacturing firms for expansion, upgrading and/or modernization;

- To undertake a critical assessment and profile the SADC pharmaceuticals industry, identifying specific pharmaceutical products (generic essential medicines and accompanying/related health commodities) that could be produced or scaled-up (e.g. APIs, ARVs, anti-TB, anti-malarials, condoms, Rapid Diagnostic Tests, diapers, Intravenous drip set and solutions, cannulas, syringes and needles, swabs, sputum bottles, N95 masks and test kits, audiometry equipment, LLINs, etc);

- To identify the sources of raw materials and other critical inputs (e.g. APIs, High-Density Polyethylene chips and Master Batches, spare parts etc) and assess the availability, reliability and sustainability of supply in the SADC region;

- To assess the level of quality management processes, such as maintaining a Master File for each product; Operational or procedural aspects of Quality Assurance (e.g. quality checks to ensure adherence to current Good Manufacturing Practices (cGMP), Good Distribution Practices (GDP), Good Logistics Practices (GLP) and Good Warehousing Practices (GWP), WHO pre-qualification);

- To assess the level of investments in R&D by local pharmaceutical companies as well as foreign direct investment in R&D in the pharmaceutical sector;

- To assess pertinent production-related issues such as: availability of water of required quality, reliability of supply of electricity, safe disposal of waste etc;

- To undertake a critical assessment of identified linkage opportunities with other Support Industries (e.g. packaging, distribution, repairs and maintenance etc) in the SADC region;

- To make a clear statement regarding the technical and market feasibility and viability of regional production of quality generic essential medicines for HIV and AIDS, TB and Malaria in SADC.

4.2.1 Strategy/Modality (Mechanisms and standards) for regional production

- To develop a strategy/modality for developing the pharmaceutical value chain in the SADC region, with emphasis on generic essential medicines for HIV and AIDS, TB and Malaria, and accompanying/related health commodities;

- The strategy must:
    - Recommend the pharmaceutical products (medicines and accompanying/related commodities for HIV and AIDS, TB and Malaria) that should be produced/up-scaled for regional production;
    - Clearly define the GLP, cGMP, GWP, GDP appropriate for the pharmaceutical manufacturing and distribution processes in the SADC region;
    - Specify the minimum standards to be adhered to in production of the pharmaceutical products identified above;

- Recommend possible partners for collaboration (both regionally and internationally);
- Propose arrangements to facilitate technology transfer in pharmaceutical sector in SADC;
- Propose management and financing mechanisms for regional pharmaceutical production;
- Propose the legal and institutional framework for operationalizing the modality;
- Propose of a coordination mechanism to regional production of the medicines and commodities in SADC.

4.3.1 Workshops for validation and consensus building

To organise two (2) workshops, namely:

(a) A Validation workshop, and

(b) A Consensus-building workshop.

The validation workshop will validate the feasibility study report on Regional production of essential medicines for the three communicable diseases (HIV and AIDS, TB, and Malaria) and accompanying/related health commodities.

The consensus building workshop will be used to obtain consensus of all stakeholders, including Member States, on the strategy/modality for regional production.

5. METHODOLOGY

In undertaking this assignment, the Consultant will be expected to be as rigorous as possible to collect and produce information and make recommendations that are valid and reliable, based on the data analysis. The Consultant will be expected to carry out a comprehensive assessment that includes, but not limited to:

(i) Desk review;

(ii) Interviews;

(iii) Field work through Manufacturing Plant assessments in all SADC Member States;

(iv) Validation workshop and Consensus building workshop

The Consultant must ensure that the methodology and policy options adhere to international norms and standards, and are gender-sensitive.

6. DELIVERABLES AND TIMELINES

6.1 Key Deliverables

The following are the key deliverables for the assignment:

(i) Inception report;

(ii) Draft feasibility study report;

(iii) Proposed strategy (modality) for Regional production of medicines and accompanying/related health commodities;

(iv) Validation and consensus building workshop reports

NB: All the reports, except the Inception Report must be in the three SADC working languages (English, French and Portuguese)

6.2 Timelines for deliverables (deadlines revised May 2015)

Phases	Key Activities	Deliverables	Person Days	Deadlines
1	Planning, literature review, design of data collection tools	Acceptable Inception Report, including draft tools for data collection	49	15 July 2015
2	Finalize the data collection tools, Fieldwork and Report writing	Acceptable Draft Feasibility reports	203	30 Sept 2015
3	Develop proposed Strategy/Modality for Regional production of Medicines and commodities	Acceptable Draft Proposed Strategy/ Modality for Regional production	60	31 Oct 2015
4	(a) Presentation of the Draft Feasibility Study Report at a Validation workshop	Acceptable Validation Workshop report	14	31 Oct 2015
	(b) Presentation of the Strategy/Modality for Regional Production at a Consensus-building workshop	Acceptable Consensus-building Workshop report	14	4 Nov 2015
5	Finalize the Reports, incorporating comments from the workshops	Acceptable final Draft Reports	30	30 Nov 2015
	Total person days		**370**	

Total person days = **370**

7. CONSULTANCY TEAM

The Consultancy will be constituted by a multi-disciplinary team of at least seven (7) core experts. The experts should have demonstrable qualification and work experience in the following fields: Industrial Engineering, Chemical Engineering, Economics, Medicines regulations, Business Administration and Public Health. The Consultancy must demonstrate its capacity to undertake a feasibility study in multi-cultural settings. It is also important to provide evidence that the Consultancy team has the capacity to undertake the assignment within six months.

QUALIFICATIONS AND EXPERIENCE

7.1 The **Team Leader** is required to have required the following qualifications and experience:

Qualifications and Skills

(i) A post-graduate qualification in engineering (preferably in Chemical Engineering), finance, public health, or equivalent;

(ii) Excellent team leadership, communication/networking, writing and organizational, presentation and inter-cultural skills.

Experience

(i) At least 10 years' experience in pharmaceutical formulation and manufacturing plants;

(ii) Demonstrated experience in undertaking feasibility studies in the pharmaceuticals industry;

(iii) Demonstrated experience in project management, strategy development and an in-depth knowledge and understanding of health sector development.

7.2 The Key Staff should include individuals having the following qualifications and experience:

i. Pharmaceutical Production Expert

Qualifications and Skills

(i) At least a Masters' degree in Chemical/Industrial Engineering or equivalent

Experience

(i) At least 10 years' experience in assessment of pharmaceutical manufacturing plants;

(ii) Knowledge of WHO Pre-Qualification Programme and current Good Manufacturing Practice (cGMP) is required.

ii. Public Health Expert/Pharmacist

Qualifications and Skills

(i) At least a Masters' degree in Pharmacy or equivalent

Experience

(i) A minimum of 10 years' experience in the public health sector.

iii. Business/Financial/Market Analyst

Qualifications and Skills

(i) A post-graduate degree in Business Administration or Marketing or Finance or professional accounting qualification (CIMA, ACCA, CPA, CFA, etc), or equivalent

Experience

(i) At least 10 years' experience in business, preferably in the pharmaceutical sector;
(ii) At least 10 years' experience in market analysis, preferably in the pharmaceuticals sector;
(iii) Demonstrated experience in financial analysis.

iv. Economist

Qualifications and Skills

(i) An advanced degree in Economics (with emphasis on Policy Development) or equivalent

Experience

(i) A minimum of 10 years' experience in economic analysis, policy development/analysis as well as development of institutional framework;
(ii) A proven track-record in policy advisory activities, ideally coupled with experience in the initiation, coaching and/or conduct of public-private consultation processes;
(iii) Familiarity with public-private dialogue forums on industrial/economic/public health development would be highly desirable;
(iv) Experience in the pharmaceuticals industry will be a definite advantage.

v. Legal Expert

Qualifications and Skills

(i) At least a Law degree (LLB) with specialization in Intellectual Property

Experience

(i) A good knowledge and understanding of WTO TRIPS flexibilities, including Patents, and how developing countries can utilize them for regional production of essential generic medicines;

(ii) Experience in providing legal advice on regulatory issues relating to the pharmaceuticals sector.

7.2.6 Medicines Regulator

Qualifications and Skills

i) A post graduate degree in pharmacy or related area

Experience

ii) Experience in Good manufacturing Practice among other things;

iii) Experience is regulatory environment in SADC.

iv) At least 12 years' experience as a pharmacist of which at least 5 where on issues of medicine regulation

The consulting firm must have expertise/demonstrated experience in pharmaceutical sector profiling and development of regional value chains (preferably in the pharmaceuticals sector), Medicines Regulation and Inspection, as well as Results-Based Management (RBM).

Experience in undertaking similar assignments in developing countries, especially with donor-funded projects, will be an added advantage.

The Consultancy team must also demonstrate that it has capacity to handle all three working languages of SADC, namely English, French and Portuguese. Language translators and interpreters can be contracted out.

The Consultancy will have to spell out clearly its track record in developing strategies/modalities for production of essential medicines and health commodities for HIV and AIDS, TB, and Malaria. A copy of a product similar to this assignment must be included in its proposal.

8. SUPERVISION AND MONITORING

The Consultant will be engaged by the SADC Secretariat. However, the work will be undertaken in SADC Member States through the Office of the Permanent Secretary/Director General or their delegates.

To ensure linkage between the Member States and the SADC Secretariat, a Technical Review Team will be established to oversee the feasibility study. The purpose of the

Technical Review Team is to: (1) compliment the skills mix in the SADC Secretariat, (2) serve as a quality control forum, and (3) serve as a link between the SADC Secretariat and Member States.

The Technical Review Team will comprise of professionals from various stakeholder organizations, such as: relevant Government Ministries in SADC Member States, UN Agencies (e.g. WHO, UNDP, UNICEF, UNIDO), Professional Associations, Academia and Research Institutions, among others. The proposed composition of the Technical Review Team includes, but not limited to: Pharmacists, Medicines Regulators, Economists, Finance Experts, Procurement Experts, Customs Experts, Engineers, Public Health Experts, Business Administration Practitioners and Legal Experts.

At the SADC Secretariat, the Consultancy will be supervised by the Director of Trade, Industry, Finance and Investment or her delegate.

On the day-to-day interaction, the Consultancy will work under the supervision of the Technical Advisor for the Project (on Technical matters), who will collaborate with the Senior Programme Officers for Health and Pharmaceuticals and for Industry Productive Competitiveness.

9. SUPPORT BY THE SADC SECRETARIAT

The SADC Secretariat will provide all the key documents especially regional policies and frameworks. Letters of introduction of the consultants to the Member States will be facilitated by the SADC Secretariat. Similarly, the SADC Secretariat will be responsible for the logistics of the Validation and Consensus building workshops.

Products to focus on

A. Generic Essential Medicines

APIs, ARVs (HIV and AIDS); anti-TB, anti-malarials

Formulations:

- ARVs (First line treatment; Second line treatment) – tablets, capsules, powders, syrup, vaccines
- African Traditional Medicines

B. Health Commodities

- Condoms
- Rapid Diagnostic Tests
- diapers

- Intravenous drip set and solutions
- cannulas
- syringes and needles
- swabs
- sputum bottles
- N95 masks and test kits
- audiometry equipment
- LLINs
- mosquito repellents
- insect sprays
- insecticides (e.g. DDT)

Criteria for country selection

Analysis of SADC Member States in terms of Market essential generic medicines, Production plants and Referral laboratories for the 3 CDs

	Member State	Market for medicines and related/accompanying commodities for the 3 CDs			Production Plants for (Medicines/Commodities)			Supra-National Reference Laboratories			Regional Centre of Excellence	
		HIV/AIDS	TB	Malaria	HIV/AIDS	TB	Malaria	HIV/AIDS	TB	Malaria	QA	HRD
1	Angola	✓	✓	✓								
2	Botswana	✓	✓	✓	✓			SNRL*	SNRL			
3	DRC	✓	✓	✓	✓		✓					
4	Lesotho	✓	✓	X								
5	Madagascar	✓	✓	✓								
6	Malawi	✓	✓	✓								
7	Mauritius	✓	✓	X								
8	Mozambique	✓	✓	✓								
9	Namibia	✓	✓	✓								
10	Seychelles	✓	✓	X								
11	South Africa	✓	✓	✓	✓	✓	✓	SNRL	SNRL		✓	✓
12	Swaziland	✓	✓	✓								
13	Tanzania	✓	✓	✓	✓		✓				✓	
14	Zambia	✓	✓	✓					SNRL*	SNRL*	✓	
15	Zimbabwe	✓	✓	✓	✓	✓		SNRL*			✓	

Recommendations:

Market: All SADC Member States should be visited

Production plants: Botswana, DRC, South Africa, Tanzania, Zimbabwe have manufacturing plants that should be visited

Reference laboratories: All Member States with Reference Laboratories (SNRL or NRL) should be visited

Centres of Excellence: South Africa, Tanzania, Zambia and Zimbabwe should be visited (To be updated based on the Consultancy on CoE)

2. TERMS OF REFERENCE PER DOCUMENT, LOCATION AND TOOL

	Terms of Reference	In which chapter	Location in report [1]	Tools used
	4.1.1 Enabling Environment			
1.	To undertake a literature review covering:			
	a) Documentation of the status of harmonization efforts regarding the regulatory registration and control of medicines in the SADC region;	- Inception Report - Situational analysis	2.1.1, 2.1.4	- Desk research
	b) SADC policies concerning medicines for the three communicable diseases;	- Inception Report - Situational analysis	2.1.1, 2.1.3	- Desk research
	c) Government policy coherence (e.g. Industry vs. Health vs. Finance)	- Inception Report - Situational analysis	2.1.1, 2.1.2, 2.1.6	- Desk research
	d) SADC and Member State policies in support of pharmaceuticals manufacturing;	- Inception Report - Situational analysis	2.1.1, 2.1.7,	- Desk research
2.	To ascertain the level of Government support to the pharmaceutical sector through the procurement process (e.g. local preference schemes, price advantage etc.);	- Inception Report - Situational analysis	2.1.7, 2.1.8 Vol2:16	- Desk research - Country questionnaire
3.	To identify current Government incentives to the pharmaceutical manufacturing sector in the SADC region – infant industry protection, tax incentives, duty-free importation (e.g. of raw materials and medicines), grants;	- Inception Report - Situational analysis	2.1.7 Vol2:17	- Desk research - Country questionnaire
4.	To assess the extent to which SADC Member States utilize TRIPS flexibilities as reaffirmed by the Doha Declaration in the production of essential medicines;	- Inception Report - Situational analysis	2.1.5 Vol2:30-33	- Desk research - Country questionnaire
5.	To assess the status of the infrastructure needed for systematic quality assurance and quality control (e.g. Laboratories – SNRLs, NRLs);	- Inception Report - Situational analysis	2.1.4 Vol2:12	- Desk research - Country questionnaire - Manufacturer question - SNRL and NMRA interviews
6.	To assess the availability of quality medicines in public, private and civil sectors and their inclusion in the national Essential Medicines List (EML);	- Inception Report - Situational analysis	2.2.1 Vol2:35	- Desk research - Country questionnaire
7.	To assess the R&D infrastructure (institutions, laboratories, human resources, financing etc.) and determine the amount of Government R&D spend for	- Inception Report - Situational analysis	2.1.2, 2.1.7 Vol2:35	- Desk research - Country questionnaire

[1] Locations refer to the section numbers in Volume 1 of the 2nd draft feasibility report; the revised structure of Volume 1 follows the TORs in numbering.

	Terms of Reference	In which chapter	Location in report [1]	Tools used
	pharmaceuticals development in SADC Member States;			
8.	To assess the availability of required skilled human resources (for production, quality assurance, process maintenance, regulatory compliance, design & packaging & distribution, R&D etc.);	- Inception Report - Situational analysis	2.1.9 Vol2:38	- Desk research - Country questionnaire - CoE interviews
9.	To specify the Certification/Licensing requirements by relevant institutions (e.g. National, Regional and International, WHO prequalification, PIC/S certification, National Drugs Control Authorities;	- Inception Report - Situational analysis	2.1.4 Vol2:13	- Desk research - Country questionnaire
10.	To assess the Regulatory landscape with respect to WTO/TRIPS Flexibilities, NMRAs, cGMP and Enforcement through regular inspection (by Regulatory Authorities) of production plants as well as distribution facilities to ensure adherence to Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Warehousing Practices (GWP) and prevent sub-standard and counterfeit products from entering the SADC market; and	- Inception Report - Situational analysis	2.1.4 Vol2:10-14	- Desk research - Country questionnaire - NRMA questionnaire
11.	To assess the extent of pharmaceutical industry-academia linkages.	- Inception Report - Situational analysis	2.1.2, 2.1.9 Vol2:20	- Desk research - Country question
	4.1.2 Business case for local production			
12.	To assess the willingness of pharmaceutical companies currently operating in the SADC region to expand, upgrade and/or modernize their operations in order to produce and supply identified pharmaceutical products (i.e. essential medicines and health commodities) to the regional and international market;	- Situational analysis	2.3, 2.3.5 Vol2:22	- Country questionnaire
13.	To assess the ability and willingness of key industry players (e.g. Governments, donor-funded procurement agencies, wholesalers, retailers (pharmacists) and consumers) to buy/consume high quality generic essential medicines and accompanying/related health commodities manufactured in the SADC region;	- Situational analysis	2.3, 2.3.6 Vol2:23	- Country questionnaire
14.	To identify pharmaceutical and prophylactic products/materials locally produced or imported into the SADC region;	- Situational analysis	2.2.1, 2.3 Vol2:4	- Desk research - Country questionnaire
15.	To determine the size (best estimate) of the market (volume and value; locally produced and imported) for pharmaceutical products (generic essential medicines and accompanying/related commodities, especially for the three communicable diseases) broken down into each category/segment, and indicate the potential for growth;	- Situational analysis	2.2.1, 2.3 Vol2:1-5	- Country questionnaire
16.	To determine the demand and supply distortions in terms of effective operational control of supply chain systems for pharmaceutical manufacturing	- Situational analysis	2.3, 2.3.7 Vol2:24	- Country questionnaire

	Terms of Reference	In which chapter	Location in report [1]	Tools used
	(e.g. forecasts, inventory status, backlogs, production schedules, supplier delivery schedules, pipeline inventory etc.);			
17.	To determine inventory management issues (e.g. associated costs, insurance, taxes, etc.);	- Situational analysis	2.3, 2.3.8 Vol2:25	- Country questionnaire
18.	To identify possible sources of financing for regional production of essential generic medicines, such as Government, Healthcare Insurance Schemes, company's own funds, Development Finance Institutions (DFIs), foreign direct investments (FDIs), International Government Agencies (e.g. BMZ, GTZ, USAID), local and international NGOs, commercial banks, institutional investors (e.g. pension funds), venture capital firms, Private-Public Partnerships, GFATM, PEPFAR, PMI, Private Health Insurance etc.	- Situational analysis	2.3, 2.3.9 Vol2:21, 26	- Country questionnaire
19.	To determine the cost (including transport costs, duties, etc.) and price/revenue behaviour in the pharmaceuticals industry, and determine the profitability of regional production of the essential medicines and related/accompanying commodities;	- Situational analysis	2.3, 2.3.8, 2.3.9, 2.3.10	- Country questionnaire
20.	To clearly identify the potential benefits of regional manufacturing of pharmaceutical products to SADC Member States; and	- Situational analysis	2.3, 2.3.9 Vol2:27	- Analysis
21.	To determine the level of inclusivity and sustainability of regional production.	- Situational analysis	2.3, 2.3.9, 2.3.10	- Analysis
	4.1.3 Operational issues			
22.	To identify pharmaceutical companies currently manufacturing essential generic medicines in the SADC region, and have the potential for expansion, upgrading and/or modernization of their production to supply the regional and international markets;	- Situational analysis	2.4.2 Vol2:4.2	- Desk research - Manufacturer questionnaire
23.	To critically assess the technical and human resource capacities of these existing pharmaceutical manufacturing firms for expansion, upgrading and/or modernization;	- Situational analysis	2.4.7, 2.4.3	- Desk research - Manufacturer questionnaire
24.	To undertake a critical assessment and profile the SADC pharmaceuticals industry, identifying specific pharmaceutical products (generic essential medicines and accompanying/related health commodities) that could be produced or scaled-up (e.g. APIs, ARVs, anti-TB, anti-malarials, condoms, Rapid Diagnostic Tests, diapers, Intravenous drip set and solutions, cannulas,	- Situational analysis	2.4.3, 2.4.9, 2.3.10	- Desk research - Manufacturer questionnaire

	Terms of Reference	In which chapter	Location in report [1]	Tools used
	syringes and needles, swabs, sputum bottles, N95 masks and test kits, audiometry equipment, LLINs, etc.);			
25.	To identify the sources of raw materials and other critical inputs (e.g. APIs, High-Density Polyethylene chips and Master Batches, spare parts etc.) and assess the availability, reliability and sustainability of supply in the SADC region;	- Situational analysis	2.4.4 Vol2:36	- Desk research - Manufacturer questionnaire
26.	To assess the level of quality management processes, such as maintaining a Master File for each product; Operational or procedural aspects of Quality Assurance (e.g. quality checks to ensure adherence to current Good Manufacturing Practices (cGMP), Good Distribution Practices (GDP), Good Logistics Practices (GLP) and Good Warehousing Practices (GWP), WHO pre-qualification);	- Situational analysis	2.4.6 Vol2:37	- Desk research - Manufacturer questionnaire
27.	To assess the level of investments in R&D by local pharmaceutical companies as well as foreign direct investment in R&D in the pharmaceutical sector;	- Situational analysis	2.4.8 Vol2:34	- Desk research - Manufacturer questionnaire
28.	To assess pertinent production-related issues such as: availability of water of required quality, reliability of supply of electricity, safe disposal of waste etc.;	- Situational analysis	2.4.5 Vol2:29	- Desk research - Manufacturer questionnaire
29.	To undertake a critical assessment of identified linkage opportunities with other Support Industries (e.g. packaging, distribution, repairs and maintenance etc.) in the SADC region;	- Situational analysis	2.4.8 Vol2:34	- Desk research - Manufacturer questionnaire
30.	To make a clear statement regarding the technical and market feasibility and viability of regional production of quality generic essential medicines for HIV and AIDS, TB and Malaria in SADC.	- Situational analysis	2.3.10, 2.4.9	- Desk research - Manufacturer questionnaire
	Gap analysis			
	- Stages of the gap analysis: Future state - Stages of the gap analysis: Current situation - Bridge the gap - Conclusions and recommendations for the overall strategy	- Situational analysis	Chapter 3 Vol2:8	- Analysis
	4.2 Strategy/Modality (Mechanisms and standards) for regional production			
31.	To develop a strategy/modality for developing the pharmaceutical value chain in the SADC region, with emphasis on generic essential medicines for HIV and AIDS, TB and Malaria, and accompanying/related health commodities; the	- Strategy	Chapter 4	- Data analysis

	Terms of Reference	In which chapter	Location in report [1]	Tools used
	strategy must:			
32.	Recommend the pharmaceutical products (medicines and accompanying/related commodities for HIV and AIDS, TB and Malaria) that should be produced/up-scaled for regional production;	- Strategy	4.4	- Data analysis
33.	Clearly define the GLP, cGMP, GWP, GDP appropriate for the pharmaceutical manufacturing and distribution processes in the SADC region;	- Strategy	4.5	- Data analysis
34.	Specify the minimum standards to be adhered to in production of the pharmaceutical products identified above;	- Strategy	4.5	- Data analysis
35.	Recommend possible partners for collaboration (both regionally and internationally);	- Strategy	4.6	- Data analysis
36.	Propose arrangements to facilitate technology transfer in pharmaceutical sector in SADC;	- Strategy	4.7	- Data analysis
37.	Propose management and financing mechanisms for regional pharmaceutical production;	- Strategy	4.8	- Data analysis
38.	Propose the legal and institutional framework for operationalizing the modality;	- Strategy	4.9	- Data analysis
39.	Propose of a coordination mechanism to regional production of the medicines and commodities in SADC.	- Strategy	4.10	- Data analysis
	Workshops for validation and consensus building			
40.	To organize a validation workshop; The validation workshop will validate the feasibility study report on Regional production of essential medicines for the three communicable diseases (HIV and AIDS, TB, and Malaria) and accompanying/related health commodities.	- Workshop report	Separate, after the 8-9 Dec workshop	- Workshop
41.	To organize a Consensus-building workshop. The consensus building workshop will be used to obtain consensus of all stakeholders, including Member States, on the strategy/modality for regional production.	- Workshop report	Separate, after the 8-9 Dec workshop	- Workshop
	Final reports			
	Revision of the Situational analysis, Gap analysis, Strategy and Workshop report	- Situational analysis - Gap analysis - Strategy - Workshop report	Will be done 10-11 Dec after workshop	- None

3. THE STUDY TEAM AND PERSONS INTERVIEWED

3.1 Study core team

Core team	
Wilbert Bannenberg	Team Leader, Public Health issues
Marc Van Robays	Co-team Leader, Pharmaceutical Industry issues
Corinne Eisma	Project manager (until 4 November 2015 - maternity leave)
Ingeborg Jille Traas	Project Manager (from 4 Nov), Technical coordinator country data
Leen Jille	Technical coordinator country data, Country consultant Mozambique
Martine Vandermeulen	hera Director

3.2 Contributors

Contributors	
Aarti Patel	Public Health Expert/Pharmacist, QA
Andy Gray	Pharmaceutical Human Resources Expert
Chazile Mavuso	Country consultant Swaziland
David Walwyn	Pharmaceutical production expert, Country consultant South Africa
Ed Vreeke	Economist, Country consultant for Madagascar
Ellen 't Hoen	Medicines Law & Policy adviser
Emmanuel Mujuru	Business/Financial/Market analyst
Geoffrey Ngwira	Country consultant Malawi
George Proctor	Business/Financial/Market analyst, Country consultant Botswana
Gertrude Mothibe	Pharmaceutical production expert, Country consultant Lesotho
Jacques Pilloy	Malaria / artemisinin production expert
Jean Rene Randriasamimanana	Country consultant Madagascar
Jennie Lates	Country consultant Namibia
Léonard Mbusa Mwana	Country consultant DRC
Lino da Costa	Country consultant Angola
Luther Gwaza	Medicines Regulator
Marianne Schürmann	Quality assurance of report
Marlon Burgess	Business/Financial/Market analyst
Miranda Brouwer	Public Health and Tuberculosis Control Specialist
Paulo Nhaducue	Country consultant Mozambique
Rob Verhage	Procurement expert
Romuald Mbwasi	Pharmaceutics expert
Ruth Mudondo	Business/Financial/Market analyst
Shobha Hajarnis	Country consultant Seychelles
Tapiwanashe Kujinga	Legal expert, Country consultant Zimbabwe
Ulrike Zimper	API (raw material) production expert

Violet Kabwe	Country consultant Zambia

3.3 hera review committee members

hera internal Review Meeting 6-8 July 2015	
Wilbert Bannenberg	Team Leader, Public Health issues
Marc Van Robays	Co-team Leader, Pharmaceutical Industry issues
Corinne Eisma	Project manager
David Walwyn	Pharmaceutical production expert
Emmanuel Mujuru	Business/Financial/Market analyst
Gertrude Mothibe	Pharmaceutical production expert
Marlon Burgess	Business/Financial/Market analyst devices, commodities
Romuald Mbwasi	Pharmaceutics expert
Ruth Mudondo	Business/Financial/Market analyst
Marianne Schürmann	Quality assurance of report

hera internal Review Meeting 28-29 September 2015	
Wilbert Bannenberg	Team Leader, Public Health issues
Marc Van Robays	Co-team Leader, Pharmaceutical Industry issues
Corinne Eisma	Project manager
David Walwyn	Pharmaceutical production expert
Emmanuel Mujuru	Business/Financial/Market analyst
George Proctor	Business/Financial/Market analyst
Gertrude Mothibe	Pharmaceutical production expert
Romuald Mbwasi	Pharmaceutics expert
Tapiwanashe Kujinga	Legal expert
Luther Gwaza	Medicines Regulator
Aarti Patel	Quality assurance of report

SADC TRC Meeting 12-13 October 2015	
Wilbert Bannenberg	Team Leader, Public Health issues
George Proctor	Business/Financial/Market analyst

SADC Trade Meeting 12-13 November 2015	
Wilbert Bannenberg	Team Leader, Public Health issues
George Proctor	Business/Financial/Market analyst

SADC Member States Consensus Meeting 8-9 December 2015	
Wilbert Bannenberg	Team Leader, Public Health issues
Marc Van Robays	Co-team Leader, Pharmaceutical Industry issues
Ingeborg Jille Traas	Technical coordinator country data and Project manager
David Walwyn	Pharmaceutical production expert
George Proctor	Business/Financial/Market analyst

	SADC Member States Consensus Meeting 8-9 December 2015
Gertrude Mothibe	Pharmaceutical production expert
Tapiwanashe Kujinga	Legal expert

3.4 SADC Technical review committee members

TRC members	
Mrs. Masello Sello	Legal adviser, Ministry of Health, Lesotho
Mr. Sharma Ramphul	Deputy Director Pharmaceutical Services
Mrs. Rejoice Nkambule	Deputy Director of Health Services
Ms. Mary Mgwatu Masanja	Principal Drug Regulation Officer
Mr. Justus M. Ogando	Regional PEDS Manager – EAC & SADC, CHAI
Dr. Thomas Lapnet-Mustapha	Technical Advisor Medical Products, WHO
Dr. Nelly Mwaka	Gender & HIV Programme Manager, UNDP
Dr. Juergen Reinhardt	Senior Industrial Development Officer, UNIDO
Mr. Shahid Hasan	Consultant, UNIDO
Ms. Keneilwe Lynette Mabote	Regional Advocacy Team Leader, ARASA
Mr. Mulatedzi Makhado	Principal Technical Advisor
Mr. Celestine Kumire	Programme Director, SARPAM

3.5 Manufacturers interviewed

The table below lists all manufacturers that were interviewed by country consultants, and occasionally by members of the core team, in their respective countries.

Country	Organization
Angola	SUAVE
Botswana	Gemi Rubber
Botswana	Strides (re-packaging plant)
DRC	Pharmakina
DRC	Zenufa
Madagascar	BIONEXX
Malawi	Kentam Products Limited
Malawi	Malawi Pharmacies (2005) Limited
Malawi	Pharmanova Malawi Limited
Malawi	SADM Pharmaceuticals
Malawi	Victoria Pharmaceuticals Limited
Mauritius	Ajanta Pharma
Mozambique	Sociedade Moçambicana de Medicamentos
Namibia	Fabupharm
South Africa	Adcock Ingram
South Africa	Aspen
South Africa	Aurobindo
South Africa	Be-Tabs (Ranbaxy)
South Africa	Bio-tech

Country	Organization
South Africa	Cipla-Medpro
South Africa	Fresenius Kabi
South Africa	Medchem
South Africa	Mylan
South Africa	Novartis
South Africa	Sandoz
South Africa	Sanofi
South Africa	Sonke (Ranbaxy JV)
Swaziland	Mtjepa pharmaceuticals
Tanzania	A to Z Mills Ltd.
Tanzania	TPI
Tanzania	Zenufa Laboratories Ltd
Zambia	Baxy Pharmaceuticals Manufacturing Co
Zambia	International Drug Company Ltd
Zambia	NRB Pharmaceuticals
Zambia	Pharmanova
Zambia	Tejay Pharmaceuticals Ltd
Zimbabwe	CAPS
Zimbabwe	PLUS5
Zimbabwe	Varichem Pharmaceuticals

3.6 Other organisations interviewed

The table below lists all organisations that were interviewed by country consultants in their respective countries.

Country	Organization
Angola	National Directorate of Medicines and Equipment
Angola	Elnor Pharma
Angola	Ministry of Finance, Department Tax Procedures, General Tax Administration
Angola	Ministry of Trade, Legal Office
Angola	Ministry of Industry, Institute of Industrial Property
Angola	Ministry of Industry, Institute of Industrial Property, Department of Patents
Angola	General Health Inspection
Angola	Ministry of Health
Angola	Universidade Agostinho Neto
Angola	Instituto Superior de Ciencias da Saude de Luanda
Angola	Instituto Superior Politecnico International de Angola
Angola	Universidade Jean Piaget de Angola de Luanda
Angola	Universidade Privada de Angola
Angola	Universidade de Belas
Angola	Central de Compras e Aprovisionamento de Medicamentos e Meios Médicos (CECOMA) - Central Medical Stores of Angola
Botswana	Allied Health Services and School of Pharmacy, Faculty of Health Sciences, University of Botswana

Country	Organization
Botswana	Biomedical Engineering Department, Ministry of Health
Botswana	Botswana Investment and Trade Center (BITC)
Botswana	Botswana-Harvard HIV Reference Laboratory (BHHRL)
Botswana	Centers for Disease Control and Prevention
Botswana	Central Medical Stores
Botswana	Companies and Intellectual Property Authority (CIPA)
Botswana	Drug Regulatory Unit, Ministry of Health
Botswana	Fine Pharmaceuticals
Botswana	Institute of Health Sciences
Botswana	National TB Ref Laboratory
DRC	3ième Direction of the Ministry of Health (NMRA)
Lesotho	Drug Regulatory Office
Lesotho	Legal Department, Ministry of Health
Lesotho	Lesotho National Development Corporation (LNDC)
Lesotho	Ministry of Finance
Lesotho	Ministry of Trade & Industry
Lesotho	National Drug Service Organisation (NDSO)
Lesotho	Pharmaceutical Sector, Ministry of Health
Lesotho	Pharmacy Department, National University of Lesotho
Lesotho	Tripharm Manufacturing
Lesotho	Pharmaceutical Services, Ministry of Health
Lesotho	Ministry of Health, HIV Disease Control Programme
Madagascar	Agence des Médicaments en Madagascar
Madagascar	Conseil national de l'Ordre des Pharmaciens de Madagascar
Madagascar	Direction de la Pharmacie, des Laboratoires et de la Médicine Traditionnelle
Madagascar	SALAMA (CMS Madagascar)
Malawi	Central Medical Stores Trust
Malawi	College of Medicines, University of Medicine
Malawi	Health Net Limited
Malawi	Health Technical Support Services - Pharmaceuticals, Ministry of Health
Malawi	HIV/AIDS Department, Ministry of Health
Malawi	Malaria Control Programme, Ministry of Health
Malawi	Ministry of Finance
Malawi	Ministry of Industry and Trade
Malawi	National Quality Control Laboratory of Malawi
Malawi	Pharmacy, Medicines and Poisons Board of Malawi (PMPB)
Malawi	TB Programme, Ministry of Health
Mauritius	Clinical Research Regulatory Council
Mauritius	Customs Department, Medicines Regulatory Authority (MRA)
Mauritius	Emerging Sectors and Markets, Board of Investment Mauritius
Mauritius	Ministry of Health
Mauritius	Pharmacy Board
Mauritius	Prime Minister's Office, Ministry of Health
Mauritius	Procurement Unit, Central Medical Stores
Mauritius	University of Mauritius, Faculty of Science

Country	Organization
Mauritius	Wholesale Division (Pharma and Consumer Healthcare), IBL Group
Mozambique	Embassy of Brazil
Mozambique	Essential Drugs and Medicines Programme, WHO
Mozambique	FARMAC
Mozambique	Flanders Cooperation in Mozambique
Mozambique	HIV/AIDS Programme, Ministry of Health
Mozambique	Hoger Instituut voor de Arbeid (HIVA), Faculty of Social Sciences, Catholic University Leuven, Belgium
Mozambique	Human Resources Department, Ministry of Health
Mozambique	Instituto de Gestão das Participações do Estado (IGEPE)
Mozambique	Instituto de Propriedade Intelectual
Mozambique	Legal Department, Ministry of Health
Mozambique	Minister's Office, Ministry of Health
Mozambique	Pharmacy Department, Ministry of Health
Mozambique	Planning and Cooperation Department, Ministry of Health
Mozambique	National Directorate of Industry
Namibia	Science, Technology & Innovation, Multidisciplinary Research Centre
Namibia	Namibia Medicines Regulatory Council (NMRC)
Namibia	National Medicines Policy Coordination Subdivision of Pharmaceutical Services, Ministry of Health
Namibia	University of Namibia
Seychelles	National Institute of Health and Social Studies (NIHSS)
Seychelles	Pharmacy Department, Ministry of Health
Seychelles	Seychelles Revenue Commission, Ministry of Finance and Trade
South Africa	Department of Trade and Industry, Directorate Pharmaceuticals
South Africa	National Institute for Communicable Diseases
South Africa	North West University
South Africa	South African Bureau of Standards (SABS)
South Africa	University of Witwatersrand
Swaziland	Ministry of Health
Swaziland	Swaziland Christian University
Swaziland	National Malaria Programme
Swaziland	National Tuberculosis Programme (TB Centre)
Swaziland	Strategic Information Department
Tanzania	Department of Industrial and Physical Pharmacy, Purdue University
Tanzania	Kilimanjaro School of Pharmacy
Tanzania	Ministry of Health and Social Welfare
Tanzania	Pharmaceutical Manufacturers Association
Tanzania	Pharmacy Council of Tanzania
Tanzania	Tanzania Food and Drugs Authority (TFDA)
Zambia	Department of Pharmacy, University of Zambia
Zambia	Ministry of Justice
Zambia	Pharmaceutical Services, Ministry of Health
Zambia	Zambia Medicines Regulatory Authority (ZAMRA)
Zimbabwe	Medicines Control Authority of Zimbabwe (MCAZ)

Country	Organization
Zimbabwe	National Medicines and Therapeutics Policy Committee
Zimbabwe	NatPharm
Zimbabwe	Pharmaceutical Manufacturers Association
Zimbabwe	Pharmaceutical Wholesalers Association
Zimbabwe	Pharmacy Directorate
Zimbabwe	Stratdigm Consultancy
Zimbabwe	Taxes Department, Ministry of Finance

4. DOCUMENTS CONSULTED (BIBLIOGRAPHY)

4.1 Most essential publications

A review of the 45 most essential publications was done in the inception phase, and is available as an Excel database:
https://www.dropbox.com/s/suece3wx43nibl7/SADC%20Regional%20Production%20Literature%20review%20-%20database.xls?dl=0

For the study, a large number of documents were consulted. All documents have been collected in a Dropbox, sorted per topic:
https://www.dropbox.com/sh/vwlgxy892j75qtp/AAAqNyTPPR0WhzVTaq41-RRva?dl=0

4.2 Literature consulted and referred to in Volume 1

Literature consulted and referred to in Volume 1 of the study report:
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African Innovation Outlook 2010, AU-NEPAD, Pretoria
African Union Commission. 2007. Pharmaceutical manufacturing plan for Africa. African Union (Addis Ababa).
African Union. Pharmaceutical Manufacturing Plan for Africa – Business Plan. Addis Ababa: UNIDO, 2012
API Manufacturing: Facts and Fiction, P. Pollak, Contract Pharma, January/February 2012
AUC – UNIDO. Pharmaceutical Manufacturing Plan for Africa. Addis Ababa. November 2012.
Chen, W., Tang, S., Sun, J., Ross-Degnan, D. & Wagner, A. K. 2010. Availability and use of essential medicines in China: manufacturing, supply, and prescribing in Shandong and Gansu provinces. BMC Health Services Research, 10(1), pp 211.
Department of Trade and Industry (DTI).Human Capital Outlook Implications for Skills Development in the Pharmaceutical Sector: The Adequacy of Higher Education and Training Provision for API and Biotechnology Manufacturing Skills Requirements.
Draft revised regional indicative strategic development plan 2015-2020, SADC Secretariat, April 2015. SADC/EOC/1/2015/3.1B
DTI South Africa, 2014. Adapted from Amsden (2001)
Framework for the harmonized management of tuberculosis in the mining sector, 2014. http://www.health-e.org.za/wp-content/uploads/2014/04/Hamonization-report.pdf
Gwaza, Luther. Review of Operating Procedures Used to Evaluate Medicines Registration Dossiers in SADC Region Draft for stakeholder review. March 2012 (unpublished report)

Literature consulted and referred to in Volume 1 of the study report:
http://www.afdb.org/en/news-and-events/article/revitalizing-africas-pharmaceutical-industry-13289/ Accessed on 19 June 2015
http://www.finance.gov.bw/index.php?option=com_content1&parent_id=334&id=338
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http://www.namibiahc.org.uk/resources/content/manufacturers_exporters_incentives.pdf
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http://www.sadc.int/themes/health/pharmaceuticals/
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http://www.who.int/immunization/research/development/tuberculosis/en/
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International Conference on Local Pharmaceutical Production in Africa, April 2011, Cape Town. Dr Martin Nicholson, consultant UNIDO.
Kaplan 2011, Equinet 2013, WHO 2011, AMASA 2012, Buizert 2007, Consoli (undated). All studies have been collected in a SADC Regional Production Dropbox which will be made available to SADC Secretariat and Member States.
Kaplan, W. 2011. Local production and access to medicines in low-and middle-income countries: a literature review and critical analysis. World Health Organisation (Geneva).
Kenya GMP Roadmap: A Stepwise Approach for the Pharmaceutical Industry to Attain WHO GMP Standards. UNIDO, Kenya, 2014.
Lloyd Matowe. An Overview of Procurement and Supply Management Systems in the Southern Africa Development Community Member States. SADC, September 2015.
Lundvall, B. Å. 2007. National innovation systems—analytical concept and development tool. Industry and innovation, 14(1), pp 95-119.
M Ndomondo-Sigonda and A Ambali. The African Medicines Regulatory Harmonisation Initiative: Rationale and Benefits. Clinical Pharmacology & Therapeutics Volume 89, Issue 2, February 2011, Pages: 176–178.
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Prof Henry Fomundam. Identifying Training and Research Needs and Facilitating the Selection of Centres of Excellence and Centres of Specialisation in Pharmaceutical Training. SADC, August 2015.
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SADC Feasibility study for local production, Zimbabwe country report. 2015
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SADC Pharmaceutical Business Plan 2015-2019, 3rd draft, November 2014. (not yet formally approved by SADC Health Ministers)
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SADC Treaty
SADC. Harmonized Minimum Standards for the Prevention Treatment and Management of TB in SADC. 2012
SADC. Harmonized Minimum Standards for the Prevention, Treatment and Management of Tuberculosis in the SADC Region, 2010.
SADC. Minimum Standards for HIV and AIDS, TB, Hepatitis B and C, and Sexually Transmitted Infections Prevention, Treatment, Care and Support in Prisons in the SADC Region, 2011
SADC. Regional Minimum Standards for the Harmonized Control of HIV and AIDS, Tuberculosis and Malaria in Militaries in the SADC Region, 2010.
SADC/MTF-REI/15/2015/3. SADC Industrialization Strategy & Roadmap 2015-2063. Draft, 26 April 2015.
SAGMA. Analysis of Training Needs in the Generic Medicines Sector in SADC. UNIDO, 2014.
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http://amiif.sarpam.net
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Southern African Development Community. 2014. SPPS Business Case including the Draft SPPS Charter;
Southern African Development Community. 2014. Terms of Reference Pooled Procurement Task Team
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Southern African Development Community. Document available at http://www.sadc.int/files/7614/1898/8449/SADC___Strategy_for_Pooled_Procurement_of_Essential_Medicines_and_Health_Commodities.pdf
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Southern African Development Community. Website http://sadc.int/files/2013/8969/0505/Final_SADC_Industrial_Develeopment_Policy_Framework.pdf
Southern African Development Community. Website http://www.sadc.int/documents-publications/sadc-treaty/
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Southern African Development Community. Website http://www.sadc.int/documents-publications/show/Maseru_Declaration_on_the_fight_against_HIVand_AIDS2003.pdf
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4.3 Key documents consulted for the study

These documents can be obtained in the SADC Dropbox at https://www.dropbox.com/sh/vwlgxy892j75qtp/AAAqNyTPPR0WhzVTaq41-RRva?dl=0

Topic or country	File name
APIs	API study World Bank s17509en.pdf
APIs	Bangladesh feasibility manufacturing GIZ 2007.pdf
APIs	Eloan synthesis of APIs for ARVs combinations critical to access in emerging nations 1-s2.0-S0166354208002908-main.pdf
Botswana	AMIIF-Cadiz ASSIST Health and Medicines Sector Market Assessment in Botswana, Lesotho, Namibia and South Africa.pdf
Botswana	Strides africa_locations.pdf
Centres of Excellence	ANDI_pan_African_Centres_of_Excellence_2015_edition.pdf
Centres of Excellence	CoE.S Selection Criteria.pdf
Centres of Excellence	Gap analysis DraftReport2HFAM06.07.2015A2.docx
China	China-Africa-Health-Collaboration_2015_The-Lancet.pdf
China	China-s-distinctive-engagement-in-global-health_2014_The-Lancet.pdf
condoms_female	Female Condom Generic Specification EN_0.pdf
condoms_female	UNFPA Female Condom Prequalification List.pdf
condoms_female	WHO_RHR_07.18_eng approved one female condom.pdf
condoms_female	WHO_RHR_12_03_eng.pdf
Condoms_male	Male condom English Version updated _April 2013.pdf
Condoms_male	psi_Botswana_Dec5final[smallpdf.com]_1.pdf
Condoms_male	psi_Lesotho_Dec5[smallpdf.com].pdf
Condoms_male	PSI_SouthAfrica_Dec5final[smallpdf.com].pdf
Condoms_male	psi_Swaziland_Dec16final[smallpdf.com].pdf
Condoms_male	RH Interchange Database procurement data.xlsx
Condoms_male	UNFPA External Procurement Support Report 2012.pdf

Topic or country	File name
Condoms_male	UNFPA_MLC Prequalified Factories June 2015.pdf
conference reports LP Africa	2005 GTZ_Addis_Conf_LP_and_AtM
conference reports LP Africa	20060221 WHO AFRO on LP
conference reports LP Africa	20060319 Addis LP and TRIPS
conference reports LP Africa	20071023 Dakar conf LP West Africa
conference reports LP Africa	20091209_WHO Techn Transfer meeting for Africa
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malaria_country profiles	profile_mwi_en.pdf
malaria_country profiles	profile_nam_en.pdf
malaria_country profiles	profile_swz_en.pdf
malaria_country profiles	profile_tz1_en.pdf
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malaria_country profiles	profile_zaf_en.pdf
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pooled procurement	Briefing paper SADC PP Strategy final 14Dec14.docx
pooled procurement	SADC POOLED PROCUREMENT STRATEGY FOR MEDICINES AND HEALTH COMMODITIES(1).pdf
pooled procurement	SADC PPSM Standards draft 21Nov14.pdf
pooled procurement	SADC_Strategy_for_Pooled_Procurement_of_Essential_Medicines_and_Health_Commodities Nov 2012.pdf
pooled procurement	SADC_POOLED_PROCUREMENT situation analysis Sept 2012.pdf
pooled procurement	Situational analysis and feasibility study final 1 Nov 2012.pdf
regulatory	List of RCOREs as per May 2014.xlsx
regulatory	NEPAD AMRH Guide_for_Regional Centres of Regulatory Excellence_RCOREs_September 2014.pdf
regulatory	NEPAD-AMRH -Designated-RCOREs_May-2014-.pdf
reports_not in lit review	Access to Medicines and the transformation of the SA state - Klug - 2011 - La..pdf
reports_not in lit review	AfDB HHA Partners of Harmonization for Health in Africa Discuss Action Plans for High Quality, Affordable Healthcare and Implementation of Tunis Declaration - African Development Bank.pdf
reports_not in lit review	AfDB Value_for_Money_Pharma Ind Africa see page 3 _May_2014.pdf
reports_not in lit review	Bioequivalence feasibility EAC 2009_GIZ AliScheidel.pdf
reports_not in lit review	BMJ Africa could learn from India's burgeoning pharma sector bmj.f4235.full.pdf
reports_not in lit review	BMJ World's poorest countries can increase access through local production says UN

Topic or country	File name
	.d3101.full.pdf
reports_not in lit review	BMZ LP econom feasible 2007 Frank Schmiedchen.ppt
reports_not in lit review	BRICS and South-South Cooperation in Medicine dp177_pap.pdf
reports_not in lit review	BRICS Efforts to secure universal access to HIV_AIDS treatment jebm12081.pdf
reports_not in lit review	EFPIA - The Pharmaceutical industry in figures.pdf
reports_not in lit review	emerging-economies-drive-frugal-innovation.pdf
reports_not in lit review	EU Parliament Magazine - Leveraging Technology Transfer to Improve Access to Medicines - 2015-01-15.pdf
reports_not in lit review	EU-Africa Pharma B2B Forum Final Report.pdf
reports_not in lit review	GIZ- bringing medicines to low income markets 2012.pdf
reports_not in lit review	Global Fund update to IPC_dec2012_Logez_GF.pdf
reports_not in lit review	ICSTD technology-transfer-and-local-production-as-a-means-of-increasing-access-to-vaccines-in-the-developing-world.pdf
reports_not in lit review	IFC_the business of Health in Africa_Final.pdf
reports_not in lit review	IFPMA measuring economic footprint of pharma industry 2013.pdf
reports_not in lit review	Improving Access to Medicines for Neglected Tropical pntd.0001390.pdf
reports_not in lit review	Lancet WHO PQ response to Tide turns in Africa 1-s2.0-S0140673610614511-main.pdf
reports_not in lit review	Liebig DIE-GDI.pdf
reports_not in lit review	NEPAD - Regional Integration Policy Papers- Intra-Regional Trade in Southern Africa- Structure- Performance and Challenges June 2013.pdf
reports_not in lit review	Producing medicines in Africa will only work if they can be distributed properly.pdf
reports_not in lit review	Roger Bate Local Pharmaceutical Production.pdf
reports_not in lit review	Rovira_Domestic Drug Manuf_ solution for Dev C_ in Negotiating Health_2006.PDF
reports_not in lit review	SADC Industrial Development Policy Framework.pdf
reports_not in lit review	SAMED CODE OF BUSINESS PRACTICE Nov 2014 amendments.pdf
reports_not in lit review	SARPAM Business Case FINAL 31 March 2011.docx

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reports_not in lit review	Small and Medium Enterprises and Biopharmaceutical Innovations in Africa_ Challenges and Prospects 2011_10_4_19_Awaritoma.pdf
reports_not in lit review	South-South Cooperation_ Intellectual Property and AIDS Medicines - United Nations University.pdf
reports_not in lit review	STISA2024 Science Technology and Innovation Strategy for Africa.pdf
reports_not in lit review	The road to commercialization in Africa_ lessons from developing the sickle-cell drug Niprisan 1472-698X-10-S1-S11.pdf
reports_not in lit review	Trade-and-Technology-Transfer Africa China 2014.pdf
reports_not in lit review	Treatment for AIDS in 3rd world challenge for manufacturers 2005.pdf
reports_not in lit review	UNAIDS DG on LP s21620en.pdf
reports_not in lit review	UNCTAD unpacking-the-international-technology-transfer-debate-fifty-years-and-beyond 2011.pdf
reports_not in lit review	UNIDO diagrams for factsheet.docx
reports_not in lit review	UNIDO evaluation Strengthening the local production of ess meds 2010.pdf
reports_not in lit review	UNIDO flyer GLO_PR_pharmaceuticals_2011.pdf
reports_not in lit review	UNIDO Flyer Strengthening production Ess Meds in dev c Nov2011.pdf
reports_not in lit review	UNIDO IPC presentation dec2012.pdf
reports_not in lit review	UNIDO PharmaProject Evaluation Report 2010 10 15_final.PDF
reports_not in lit review	UNIDO presentation of its work to IPC 2013-summary.pdf
reports_not in lit review	UNIDO support for LDCs_report 2013.pdf
reports_not in lit review	UNIDO Technology Foresight Manual 2005.pdf
reports_not in lit review	UNIDO TORs Mid-term evaluation 22 Oct 2009.doc
reports_not in lit review	UNIDO_GC15_Lima_Declaration.pdf
reports_not in lit review	UNIDO_industrial_development_south_south_cooperation 2006.pdf
reports_not in lit review	Walwyn Dave_ Patents and profits_ A disparity of manufacturing margins in the tenofovir value chain_16085906.2013.815407.pdf
reports_not in lit review	WHO Draft confidential summary-synthesizing-local-production-studies_v1.3.2.docx

Topic or country	File name
reports_not in lit review	WHO EU ACP FINAL MISSION REPORT PPP EVALUATION_ 24 SEPT 2010.pdf
reports_not in lit review	WHO Global_Strategy_Plan_Action.pdf
reports_not in lit review	WHO Increasing_Access_to_Vaccines_Through_Technology_Transfer.pdf
reports_not in lit review	WHO Zafar Mirza on LP and AtM project 2013.pdf
reports_not in lit review	World Bank Bridging the atlantic africa-brazil-final 2011.pdf
reports_not in lit review	World bank Explaining Africa's (Dis)Advantage 1-s2.0-S0305750X13002234-main.pdf
reports_not in lit review	Yu Access to Medicines, BRICS Alliances, and collective action SSRN-id1088893.pdf
Rwanda	Rwanda legal aspects local production GIZ 2006.pdf
Rwanda	Rwanda, Uganda sign medicine imports deal - News - www.theeastafrican.co.ke.htm
SADC	SADC Assessment_Report_on_the_Statusof_HIV_and_AIDS_Tuberculosis_andMalaria_Surveillance_Systems_in_theSADC_Region.pdf
SADC	SADC Harmonised_Surveillance_Framework_forHIV_and_AIDS_Tuberculosis_and_Malariain_the_SADC_Region.pdf
SADC	SADC___PD_S9___Children_Assessment_Report.pdf
SADC	Regional organisations and SARPAM draft report.doc
SADC	SADC - Final Draft Strategy Roadmap (26.04.2015).doc
SADC	SADC - Situation Analysis on Sustainable Financing in the Region Case Studies.pdf
SADC	SADC - Situational Analysis 'SADC sustainable financing for health and HIV' A4.pdf
SADC	SADC e_platforms Manual v3 10Dec14.pdf
SADC	SADC Final Draft Industrialisation Strategy and Roadmap (26.04.2015).doc
SADC	SADC Functions_and_Minimum_Standards_for_National_Reference_Laboratories_in_the_SADC_Region.pdf
SADC	SADC Handbook on SNRL RCEs 11913FInal.pdf
SADC	SADC Industrial Development Policy Framework (IDPF).pdf

Topic or country	File name
SADC	SADC IUMP Project Document (Approved May 09).doc
SADC	SADC Minimum Standards for Child and adolescent HIV TB malaria.pdf
SADC	SADC official population estimates 1.1.12.xls
SADC	SADC PHARMACEUTICAL BUSINESS PLAN 2007_2013.pdf
SADC	SADC Pharmaceutical Business Plan 2015-2019 -3rd Draft.docx
SADC	SADC Pilot IUMP 23 Feb 2013.pdf
SADC	SADC Secretariat_Procurement_Policy_-_March_2014_Edition.pdf
SADC	SADC Situation Analysis on Sustainable Financing in the Region Case Studies(4).pdf
SADC	SADC situational analysis and feasibility study Pooled Procurement final 1 Nov 2012.pdf
SADC	SADC SUPRANATIONAL REF LABS Minimum Standards 2010 draft.pdf
SADC	SADC TRADE INDUSTRY CONTACT POINTS - February 2012.doc
SADC	SADC_ES_Report_2011-2012_web.pdf
SADC	SADC_Maseru_Declaration_July_2003.pdf
SADC	SADC_protocol_health.pdf
SADC	SADC_RISDP 2011_Summary_en.pdf
SADC	SADC_RISDP 2015-2020 Draft Revised 26.04.2015.docx
SADC	SADC_RISDP_2003_English.pdf
SADC	SADCSTAN Brochure.pdf
SADC	The_New_Partnership_for_Africa's_Development_(NEPAD).pdf
SAGMA	FROST AND SULLIVAN GIL EVENT 25 AUGUST 2011 FINAL - presentation by Chair.pptx
SAGMA	New SAGMA Chairperson shares his view of the opportunities and challenges facing pharmaceutical industry in the SADC Region _ News _ What`s New.htm
senegal mali	Senegal Mali pharmaceutical sector profile final hera Marc Reveillon 2008 English.doc
senegal mali	Senegal Mali pharmaceutical sector profile final hera Marc Reveillon 2008 French.zip
Seychelles	Seychelles 2014 Mid Year Epidemiological Report.pdf
South Africa	20151030 SA single exit prices private sector.xlsx
South Africa	Aarti Patel Drug quality in South Africa perceptions of key players involved in drug distribution

Topic or country	File name
	09526860910975643.pdf
South Africa	AMIIF-Cadiz ASSIST Health and Medicines Sector Market Assessment in Botswana, Lesotho, Namibia and South Africa.pdf
South Africa	Aspen hails decision to boost locally made medicines.pdf
South Africa	DTI Presentation Feb_2013_Andre Kudlinski.pdf
South Africa	IDC ARV study for DTI Feb 2008.pdf
South Africa	Industry Briefing Note on API Investment (June 2008).pdf
South Africa	IPAP2 south africa.pdf
South Africa	KPMG Final Report_2014 02 03.pdf
South Africa	Leveraging the ARV Tender to Expand Local Capabilities.pdf
South Africa	Maintaining manufacturing in South Africa 2008.pdf
South Africa	master_procurement_catalogue_SAF_14april2015_WJB.xls
South Africa	Medical Devices Strategy FINAL.pdf
South Africa	napm-2014-review-16-638 members.jpg
South Africa	pharmaboardroom.com-Interview Colin Sheen Managing Director Adcock Ingram Critical Care nbsp South Africa.pdf
South Africa	pharmaboardroom.com-Interview Kevin Moodaley Head of Operations Hetero Drugs South Africa.pdf
South Africa	pharmaboardroom.com-Interview Vivian Frittelli CEO The National Association of Pharmaceutical Manufacturers NAPM South .pdf
South Africa	pharmaboardroom.com-Interview with Dr Anban Pillay Executive Director Department of Health South Africa.pdf
South Africa	pharmaboardroom.com-Interview with Muhammed Bodhania President NAPM- National Association of Pharmaceutical Manufacturers.pdf
South Africa	pharmaboardroom.com-Interview with Stavros Nicolaou Chairman PHARMISA South Africa.pdf
South Africa	pharmisa 2008 presentation to Portfolio Comm.ppt

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South Africa	Pro-generics policies and the backlog in medicines registration in South Africa_ implications for access to essential and affordable medicines - GaBI Journal.pdf
South Africa	Proposed Government Support for Local ARV API.pdf
South Africa	SA carving out a space niche players 2008.pdf
South Africa	SA condom tender bid list HM012015CNDMVBIDERSRECEIVED.pdf
South Africa	SA Condom tender HM012015CNDM_BidE.pdf
South Africa	SA Draft Point of Care Testing Policy 29 March 2012.pdf
South Africa	SA Industrial Policy Action Plan 2010_2013.pdf
South Africa	SA Preferential Procurement Policy Framework Act 2000.pdf
South Africa	SA The rainbow nation.pdf
South Africa	South Africa creates list of drugs it will buy only if they are made there - FiercePharma Manufacturing.pdf
South Africa	South Africa improving health systems Financing and policies.pdf
South Africa	South Africa Pharma report 2012.pdf
South Africa	The pharmaceuticals segment is facing a number of challenges _ South Africa 2014 _ Oxford Business Group.pdf
South Africa_tender	HM012012CNDM02Contracts condoms up to Mar15.pdf
South Africa_tender	HM012012Contract condoms Dec12 to Nov14.xlsx
South Africa_tender	HM012015CNDM_BidE condoms.pdf
South Africa_tender	HM09-2014RTKCONTRACTCIRCULAR hiv tests april14 to mar17.pdf
South Africa_tender	HP01-2013CoCircular TB aug13 to july15.pdf
South Africa_tender	HP01-2013TB01Contract TB medicines up to Jul15.pdf
South Africa_tender	HP012015TBBid.pdf
South Africa_tender	HP092014SDContract Mal plus Aug14 to Jul16.pdf
South Africa_tender	HP092014SDRESPONSE.xls
South Africa_tender	HP13-2013_2ContrCirc ARV april13 to Mar15.pdf
South Africa_tender	HP132015ARVApril2015toMar2018.pdf

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Tanzania	Govt clears Arusha firm in ARVs scam - National - thecitizen.co.tz.htm
Tanzania	GTZ_Viability of local production in Tanzania.pdf
Tanzania	Reversing Pharmaceutical Manufacturing Decline in Tanzania REPOA_BRIEF_43.pdf
Tanzania	Saint Luke Letter BK22-6-06.pdf
Tanzania	Sustainable Medicine Program in Tanzania.pdf
Tanzania	Tanzania feasibility study local prod GIZ 2007.pdf
Tanzania	Tanzania Indian Generic Companies, ikd-working-paper-37.pdf
Tanzania	Tanzania LOCAL_MANUFACTURERS_paediatric dosage forms report 2010.pdf
Tanzania	Tanzania Mujinja Local Production urban bias 1744-8603-10-12.pdf
Tanzania	Tanzania National Assmnt Rpt on Innovation Access 261213.docx
Tanzania	Tanzania PSAP draft v12 - 31 Apr 14.pdf
Tanzania	The Pharmaceutical Market_ Tanzania.pdf
Tanzania	TZ Eliangiringa Kaale Pharm R and D lab.pdf
Tanzania	TZ Medeor TPI ChristineHaefele2_05-04-11.pdf
Tanzania	TZ Promotion of Domestic Promotion 09 08 12.doc
Tanzania	TZ Situational analysis of the domestic production of medicines in paediatric dosage forms in Tanzania.doc
Tanzania	TZ Strategy for Promotion of Domestic Production 2013-2023.doc
Tanzania	TZ The make or buy debate_ Considering the limitations of domestic production in Tanzania 1744-8603-8-20.pdf
Tanzania	TZ The pharmaceutical industry and LP in TZ DIS83TZN medicines mhamba.pdf
TB	2014.11 Companion.handbook.DR-TB.pdf
TB	Eli Lilly white paper mdr-tb-technology-transfer.pdf
TB	Estimating the market for tuberculosis drugs 2008.pdf
TB	Furin delamanid_QT_access_safety [IJTLD 2015 reaction2].pdf
TB	Future TB treatment lienhardt_c.pdf
TB	GDF presentation on MDR_TB for IPC 2013.pdf

Topic or country	File name
TB	Gupta delamanid_QT_MDR-TB [IJTLD 2015 reaction1].pdf
TB	Harausz QT_prolongation_Rx_MDR-TB [IJTLD].pdf
TB	indicators_african_region WHO Global TB report 2014.pdf
TB	List of TB Supranational Reference Laboratory Network May 2014.pdf
TB	list.documents.developed.docx
TB	MPP-Intervention-in-TB-Trinity-Partners DRAFT for consultation July2015.pdf
TB	MSF_IssueBrief_DRTB_ReadySetSlowdown March 2015.pdf
TB	MSF_TB_Report_UTM3rdEdition-2013.pdf
TB	NixTB_factsheet.pdf
TB	Precarious connections_ Making therapeutic production happen for malaria and TB 1-s2.0-S0277953614004687-main.pdf
TB	RESIST-TB-Clinical-Trials-Progress-Report_20Oct2015.pdf
TB	Rifapentin_Sanofi's Double-Edged Sword _ Treatment Action Group.pdf
TB	Rifapentine registered by FDA for latent TB 37707_20141202_priftin_en.pdf
TB	SADC Assessment_Report_for_theDevelopment_of_Harmonised_MinimumStandards_for_the_PreventionTreatment_and_Management_ofTuberculosis_in_the_SADC_Region.pdf
TB	SADC Framework for harmonized management of TB in the mining sector.pdf
TB	SADC Harmonised_Minimum_Standards_for_the_Prevention_Treatment_and_Management_of_Tuberculosis_2010.pdf
TB	SADC Harmonised_Minimum_Standardsfor_the_Prevention_Treatment_andManagement_of_Tuberculosis_in_theSADC_Region.pdf
TB	SADC TB prevalence mortality incidence 2013 from WHO Global TB report 2014.xlsx
TB	SADC TB report 2013 cover pages.doc
TB	SADC.TB.REPORT.2013.FINAL.DRAFT.September2014.docx

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TB	SADC_TB Minimum_Standards_Report_incl MDR XDR TB 25 Feb2010_Final.pdf
TB	SADC_Tuberculosis_Report_2012.pdf
TB	STAND phase 3 trial TB Alliance in SA.pdf
TB	TB and Patents Article 2014.pdf
TB	tb.data.xlsx
TB	UNITAID_TB_Diagnostics_Landscape_3rd-edition 2014.pdf
TB	UNITAID-TB_Medicines_Landscape-2nd_edition.pdf
TB	WHO Global TB report 2015 9789241565059_eng.pdf
TB	WHO Global_TB_Facts 2015.pdf
TB	WHO Infographics Global TB report2015.jpeg
TORs	ToR - SADC Feasibility study local production - 2015.pdf
TRIPS and legal issues	ECA TRIPS and Public Health What should African countries do paper 49.pdf
TRIPS and legal issues	Felicia Ardenmark Strand Thesis TRIPS_and_medicines.pdf
TRIPS and legal issues	Fred Abbott-presentation trends in health related TT and local production 2010.pdf
TRIPS and legal issues	Lanoszka_The Global Politics of Intellectual Property Rights and drug policies in DCs 2003.pdf
TRIPS and legal issues	Loewenson Options for sustainable access to medicines in Africa_ Moving beyond TRIPs flexibility toward local production capacity Health Diplomacy Monitor Volume 2 Issue 2.pdf
TRIPS and legal issues	Reichmann Procuring Essential Medicines under TRIPS_case for regional Procurement Centres .pdf
TRIPS and legal issues	South Centre RP59_Transition-Period-for-TRIPS-Implementation-for-LDCs_EN.pdf
TRIPS and legal issues	WHO Bulletin Compulsory patent licensing and local drug manufacturing capacity in Africa 13-128413.pdf
Uganda	MeTA-Uganda_Role of local manuf in improving AtM Africa Health 2009.pdf
Uganda	Rwanda, Uganda sign medicine imports deal - News - www.theeastafrican.co.ke.htm
Uganda	Uganda Pharma Sector Profile_TEGLO05015_Ebook_.pdf
Uganda	Uganda Quality Chemical Industries - Pharmaceutical Technology.pdf
Uganda	UNCTAD Development Dimensions of Uganda TT and AtM diaepcb200913overview_en.pdf

Topic or country	File name
UNIDO	UNIDO Outline Country Pharma Scans_july2007.pdf
WHO Local Production CD 2013	Global_Strategy_Plan_Action.pdf
WHO Local Production CD 2013	Increasing_Access_to_Diagnostics_Through_Technology_Transfer.pdf
WHO Local Production CD 2013	Increasing_Access_to_Vaccines_Through_Technology_Transfer.pdf
WHO Local Production CD 2013	Local_Production _Technology_Transfer_Access_Medical_Devices.pdf
WHO Local Production CD 2013	Local_production_and_access_to_medicines.pdf
WHO Local Production CD 2013	Local_Production_Case_Studies.pdf
WHO Local Production CD 2013	Local_Production_Literature_Review.pdf
WHO Local Production CD 2013	Local_Production_Policy_Brief.pdf
WHO Local Production CD 2013	Local_Production_Policy_Framework.pdf
WHO Local Production CD 2013	Trends_in_Local_Production_of_Medicines.pdf
Zambia	ACTwatch HH Report Zambia 2011.pdf
Zambia	ACTwatch_Zambia_OS_ 2011.pdf
Zambia	SCS qualitative report Zambia FINAL 20130117.pdf
Zambia	The Pharmaceutical Market_ Zambia.pdf
Zambia	Zambia_Presentation_SC_2010.pdf
Zambia	Zambia_Report_SC_2009.pdf
Zimbabwe	WHOPIR_Varichem10-14May2010.pdf
Zimbabwe	Zimbabwe Trade Policy Review WTO 2011 s252_sum_e.pdf
Zimbabwe	Zimbabwe_UNIDO_Pharma Sector Profile_032011_Ebook.pdf

5. COUNTRY QUESTIONNAIRE

Enabling Environment

1. Objective of the question:

To ascertain the level of Government support to the pharmaceutical sector through the procurement process (e.g. local preference schemes, price advantage etc.).

Questions to answer:

a. Does the Government have a policy paper with the objective to support the pharmaceutical sector through the procurement process? (yes/no)
    - If yes: obtain electronic copy and add to the answers.
b. Is there an existing domestic preference scheme? (yes/no)
    - If yes: how high is it? How much more expensive can it be to procure locally (in percentages)

Suggested information sources:

The local pharmaceutical industry association, or procurement agency.

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

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2. Objective of the question:

To identify the current Government incentives to the pharmaceutical manufacturing sector in your country.

Question to answer:

a. Is there infant/start-up manufacturing protection? (yes/no)
b. Are there tax incentives? (yes/no)
c. Are duty free importation taxes different between API or FDF? (yes/no)
d. Are there grants? (yes/no) please list.
e. Other incentives for the pharma sector?
f. Is there similar support for raw materials production? (yes/no)

Suggested information sources:

Ministry of Finance/Trade/ Science & Technology; Pharmaceutical Manufacturers Association

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

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3. Objective of the question:

To assess the extent to which your country utilizes TRIPS flexibilities in the production of essential medicines.

Question to answer:

a. Does the government use TRIPS flexibilities to promote access to medicines? (yes/no)

Suggested information sources:

Wilbert can provide a table with this answer from earlier SARPAM report; just check if any TRIPS flexibilities have been used.

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

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4. Objective of the question:

To assess the status of the infrastructure needed for systematic quality assurance and quality control.

Questions to answer:

a. Is there a national medicines regulation authority in your country? (yes/no)
    - If yes, please provide contact details, website email.
b. Does the country have medicines GMP inspectors, which can visit pharmaceutical plants? (yes/no)
    - If yes, please provide contact details, website email.
c. Is there a national quality control lab for medicines? (yes/no)
    - If yes, please provide contact details, website email.

d. Is there another organization involved in control of commodities (condoms, bed nets, diagnostics)? (yes/no)
    - If yes, please provide contact details, website email.

Suggested information sources:

Drug Regulatory Authority or if not existing, Ministry of Health Pharmacy Dept

Details of the information source:
Contact person and function
When spoken to
Means of contact
Contact details

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5. Objective of the question:

To assess the availability of quality medicines in public, private and civil sectors and their inclusion in the national Essential Medicines List (EML).

Questions to answer:

a. Does your country have a national essential medicines list? (yes/no)
b. From which year is the latest EML?
    - Please provide electronic copy
c. Please follow this link to the country medicines and availability database: http://www.haiweb.org/medicineprices/surveys.php
    - Is there a more recent report than listed in the database? (yes/no)
    - If so, please provide reference, preferably in URL.
d. What is the latest % availability of essential medicines in public, private and non-profit sector using the WHO/HAI methodology?

Suggested information sources:
Ministry of Health/Pharmacy Department.

Details of the information source:
Contact person and function
When spoken to
Means of contact
Contact details

Objective of the question:

To assess the R&D infrastructure and determine the amount of Government R&D spend for pharmaceuticals development in your country.

Questions to answer:

a. List the research institutions in your country doing R&D on medicines and health commodities for HIV/AIDS, TB and malaria (universities or industries).
b. List the laboratories in your country that do Research (and Development) in medicines and health commodities for HIV/AIDS, TB and malaria

c. What financing is available in your country or from abroad for researching medicines and health commodities for HIV/AIDS, TB and malaria, and from what sources?

Suggested information sources:
Ministry of Science & Technology or Trade (investment section?) Maybe otherwise Pharm Manufacturers Association or School of Pharmacy (if available)

Details of the information source:
Contact person and function
When spoken to
Means of contact
Contact details

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6. Objective of the question:

To assess the availability of required skilled human resources.

Questions to answer:

a. Are there enough relevant skilled resources available to run at least one GMP compliant manufacturing plant for medicines and/or commodities production in your country? (yes/no)
    - If yes, where are these people trained?
b. Are there enough relevant skilled resources available to run a regulatory authority in your country? (yes/no)
    - If yes, where are these people trained?

Suggested information sources:
School of Pharmacy (Pharmaceutics Department) or Pharmaceutical Manufacturing Association.

Details of the information source:
Contact person and function
When spoken to
Means of contact
Contact details

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7. Objective of the question:

To specify the Certification/Licensing requirements for premises and professionals in API, medicines and/or commodities' production

Questions to answer:

a. Which organisations in your country are involved in certification/licensing premises?
b. Which organisations in your country are involved in certification/licensing professionals (e.g. pharmacists)?

c. Which organisations in your country are involved in registering (market authorisation) for medicines?
d. Which organisations in your country are involved in registering (market authorisation) for medical devices and commodities?
e. Are there any specific rules for export?

Suggested information sources:
Drug Regulatory Authority or Medicines Inspectorate; otherwise MOH Pharmacy Dept; maybe Bureau of Standards for commodities; Pharmacy Council for professionals

Details of the information source:
Contact person and function
When spoken to
Means of contact
Contact details

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8. Objective of the question:

To assess the Regulatory landscape with NMRAs, GMP Enforcement through regular inspection (by Regulatory Authorities) of production plants as well as distribution facilities to ensure adherence to Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and prevent sub-standard and counterfeit products from entering your country.

Questions to ask:
a. Is there a national GMP standard? (yes/no)
    - If yes, please provide the reference.
b. Are manufacturers regularly inspected for GMP? (yes/no)
    - If yes, how often?
c. If so, is the marketing authorisation/registration enforced among all domestic producers? (yes/no)
    - Please explain the situation.
d. Is there a national GDP standard? (yes/no)
    - If yes, please provide the reference.
e. Are the GDPs enforced by the medicines inspectors? (yes/no)
    - Please explain the situation.
f. Is there a pro-active plan or standard to prevent production and/or importation to eliminate substandard and/or counterfeit products on the market? (yes/no)
    - If yes, please provide the reference.

Suggested information sources:
Drug Regulatory Authority or Medicines Inspectorate; otherwise MOH Pharmacy Dept; maybe Bureau of Standards for commodities; Pharmacy Council for professionals

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

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9. Objective of the question:

To assess the extent of pharmaceutical industry-academia linkages in your country.

Questions to answer:

a. Is there a pharmacy educational institution in your country? (yes/no)
    - If yes: please provide contact details
b. Does the school have specific activities or master programme on pharmaceutics? (yes/no)
    - If not, from where do the manufacturers obtain their required professional staff?

Suggested information sources:

Universities (Pharmacy School)

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

Local Production

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10. Objective of the question

To determine the existing local pharmaceutical manufacturing companies and Medical Devices/Diagnostics of HIV/AIDS, TB and malaria.

Questions to answer:

a. Please fill in the matrix below.
   Make a distinction between API manufacturers, Finished Dosage Form (what kind – pills/tablets, syrups/liquids – injectable…) manufacturers or manufacturers of both API and Finished Dosage Forms).

Company	Produces API	Produces tablets	Produces syrups	Produces Injectable	Website or email
[Name]	Yes/no	Yes/no	Yes/no	Yes/no	Provide

b. Which of the above companies produce HIV/AIDS, malaria, TB related products? Provide details of product names.
c. Please list whether the following commodities are locally manufactured.

Company	Yes	Company name	website or email address
Condoms			
Rapid Diagnostic Tests			
Diapers			
Intravenous drip set and solutions			
Cannulas			
Syringes and needles			
Swabs			
Sputum bottles			
N95 masks and test kits			
Audiometry equipment			
LLINs (bednets)			
Mosquito repellents			
Insect sprays			
Insecticides (e.g. DDT)			

Suggested information sources:
Pharmaceutical Manufacturers Association; if not, try individual manufacturers or a bigger wholesaler. Can ask by phone or email.

Details of the information source:
Contact person and function
When spoken to
Means of contact
Contact details

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11. Objective of the question:
To assess the willingness of those pharmaceutical companies currently operating in your country to expand, upgrade and/or modernize their operations in order to produce and supply pharmaceutical products (i.e. essential medicines and health commodities) to the regional and international market.

Questions to answer:
a. Are the companies listed in question 10 willing to expand, upgrade and/or modernise their operations to produce and supply essential medicines and health commodities to the regional and/or international market? (yes/no)

- If yes, is the company prepared to go for WHO pre-qualification?
- If no, provide main barriers.

b. Do any of the manufacturers have a specific plan to upgrade/modernise? (yes/no)
c. Do the manufacturers export their goods indicated in question 10c? (yes/no)
d. Please send contact details of people interviewed or people proposed to be interviewed.

Suggested information sources:
Individual manufacturers. Can ask by phone or email.

Details of the information source:
Contact person and function
When spoken to
Means of contact
Contact details

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12. Objective of the question:

To assess the ability and willingness of key industry players (e.g. Governments, donor-funded procurement agencies, wholesalers, retailers (pharmacists) and consumers) to buy/consume high quality generic essential medicines and accompanying/related health commodities manufactured in the SADC region.

Questions to answer:

a. Does your country import HIV/AIDS, TB, malaria products that are produced in other African countries? (yes/no)
    - If so, from SADC member states? List countries and manufacturers (if possible)
b. Is there any barrier for importing generic essential medicines and/or commodities that are manufactured in other SADC member states? (yes/no)
    - If yes, please describe.

Suggested information sources:
National Procurement Agency or Central Medical Stores. Ministry of Health, and Ministry of Trade/Finance (customs unit)

Details of the information source:
Contact person and function
When spoken to
Means of contact
Contact details

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13. Objective of the question:

To determine the size/best estimate of the market (volume and value; locally produced and imported) for generic essential medicines and accompanying/related commodities, especially for

the three communicable diseases, broken down into each category/segment, and indicate the potential for growth.

Questions to answer:

a. What value (USD, indicate year and exchange rate used, if any) does the country procure for HIV/AIDS, malaria and TB? Provide data for
    - Global Fund (please triangulate data from GF PQR database)
    - PEPFAR (please triangulate data from PEPFAR database)
    - Private sector
    - Government financed
    - Other
b. How many patients are currently under treatment for HIV/AIDS and TB?
c. How many malaria treatments are given per year?
d. How many patients are expected to be needing treatment in 5 years' time for HIV/AIDS, TB or malaria?

Suggested information sources:

- Manufacturers' Association, Ministry of Finance (Customs unit?); HIV/AIDS, TB and malaria programmes (at Ministry of Health or independent)?
- **hera** will supply the country data for GF/PQR and PEPFAR to be verified.
- If you can easily get volume data per product, please collect them and

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

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14. Objective of the question:

To determine the demand and supply distortions in terms of effective operational control of supply chain systems for pharmaceutical manufacturing.

Questions to answer:

a. What are the specific supply chain barriers experienced by domestic pharmaceutical manufacturers to meet the demand. Fill in the matrix and explain if there is a barrier, and fi not why the manufacturer thinks that they were able to overcome/avoid it.

Supply chain barrier	Yes	No	Explain
Forecasts			
Inventory status			
Backlogs			
Production schedules			
Supplier delivery schedules			

Pipeline inventory
Other namely….
…
…

Suggested information sources:

The biggest local manufacturer.

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

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15. Objective of the question:

To determine inventory management issues (e.g. associated costs, insurance, taxes, etc.).

Question to answer:

a. What are inventory management issues experienced by manufacturers?

Suggested information sources:

The biggest local manufacturer

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

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16. Objective of the question:

To identify possible sources of investment financing for setting up (or improving) national or regional production of essential generic medicines.

Question to answer:

a. Have you (the manufacturer) received or applied for financing (fill in the matrix)?

Source of investment financing	Yes	Which institution	Which year	For what	Contact person
Government					
Healthcare Insurance Schemes					
company's own funds					

Development Finance Institutions
Foreign direct investments
International Government Agencies (e.g. BMZ, GTZ, USAID)
local and international NGOs
commercial banks
Institutional investors (e.g. pension funds)
Venture capital firms
Private-Public Partnerships
GFATM
PEPFAR
PMI
Other, namely
….

b. Have you had negotiations with other financing sources (e.g. private or public health insurances (fill in the matrix)?

Institution type	Yes	Which institution	Which year	For what	Contact person

c. Have you received or applied for technical assistance (fill in the matrix)?

Institution type	Yes	Which institution	Which year	For what	Contact person
BMZ					
GIZ					
USAID					
MSH					
Other, namely					

<u>Suggested information sources:</u>
Pharmaceutical manufacturers' Association, or if only one manufacturer just ask them. If more, ask the biggest national manufacturer.

<u>Details of the information source:</u>
Contact person and function
When spoken to

Means of contact
Contact details

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17. Objective of the question:

Firstly to determine the cost (including transport costs, duties, etc.) and price/revenue behaviour in the pharmaceuticals industry, and determine the profitability of regional production of the essential medicines and related/accompanying commodities.

Secondly to examine the difference between basic manufacturing cost and cost to patient.

- As an example, you can start with a Total Manufacturing Cost (= cost of API + excipients + processing to final dosage form + primary and secondary packaging (including package insert if applicable) of for instance of "100" for a product which is locally produced, and build from there the road to public price for the patient.
- You can do the same for products which are imported. The starting point would be less than "100" due to economies of scale etc., but there would be more costs in the Tax/Duty and distribution department.

Question to ask:

a. Find out if there are set margins and, if not, what the generally accepted/used margins are.

COST	NATIONAL PRODUCTION	IMPORTED MEDICINES
Total Manufacturing Cost	100 (see explanation above)	
Tax/import Duty		
Manufacturers margin		
Distribution wholesaler 1		
Distribution regional wholesaler		
Local distribution/pharmacist margin		
Total price to end-user (patient)		

Suggested information sources:

Ministry of Finance (duties, taxes); Pharmaceutical manufacturers Association; biggest wholesaler, pharmacists Association.

Details of the information source:

Contact person and function
When spoken to
Means of contact
Contact details

END

6. MANUFACTURER QUESTIONNAIRE

Manufacturer questionnaire – standard questions – all countries

1) Do you manufacture essential (generic) medicines (API and/or Finished Dosage Forms) or commodities in the field of HIV/AIDS, TB and malaria?

	Yes	No
Active Pharmaceutical Ingredient		
Finished Dosage Form		
Commodity		

2) Please describe the technical installations for production you currently use together with their capacity.

3) Please list products which you produce today.

Product	Pharmaceutical form	WHO-prequalified (Y/N)	National registration (Y/N)

4) Of those products which have WHO prequalification or national registration, which % are exported within and outside the SADC region, please specify.

Product	% exported in SADC	% exported outside SADC

5) If you don't produce products which are WHO prequalified:

   a. Do you have plans to become WHO prequalified for some products in the next 5 years?
   b. If yes, please critically assess the technical and human resource capacities you would need for expansion, upgrading and/or modernization of your plant in order to become

WHO prequalified for some products. What are the hurdles in your opinion to become WHO prequalified?

6) What % of the current capacity is used for production of the listed products.

7) Please describe the level of quality management processes, such as maintaining a Drug Master File for each product, Operational or procedural aspects of Quality Assurance (e.g. quality checks to ensure adherence to GMP, GDP, WHO pre-qualification).

8) Are there any products which you produced since 2010, and for which you stopped production? Please list, and explain why production stopped.

9) Could you describe the level of investments in R&D for your company and describe if relevant, what the incentives are (or should be) from government to support R&D investments in your company.

10) Could you describe the **direct** governmental support to reduce the cost of manufacture: Grants, subsidies, soft loans, provision of land, tax and duty exemptions for imported inputs for local production of essential medical products.

Type of support	Yes/No	Importance (High,Middle,Low)

11) Could you describe the **indirect** governmental support of local production for improving access: Invest in strengthening regulation of national medical products; develop national priority lists of medical products; Improve the financing of health services for expanding the domestic market; facilitate access to foreign markets; facilitate development of regional pooled procurement mechanisms; encourage regulatory harmonization; introduce appropriate pricing policies; facilitate relevant transfer of technology; support incremental innovation and production; develop appropriate intellectual property regimes; develop appropriate investment policies and facilitate joint ventures; facilitate international cooperation for local production.

Type of support	Yes/No	Importance (High, Middle, Low)

12) Could you assess pertinent production-related issues such as: availability of water of required quality, reliability of electricity, safe disposal of waste etc.?

13) Please list the sources of raw materials and other critical inputs, including API's, intermediates, used in the factory.

	Raw material	API	Intermediates	Other input
Source				
Source				
Source				
Source				

14) Please list the suppliers you use for plastics, packaging, distribution, repairs, maintenance etc. from within your country, within SADC and outside the SADC region.

Service	Supplier	In country	Within SADC	Outside SADC

15) Details of the information source.

Contact person and function
When spoken to
Means of contact
Contact details

See below for country specific questions!

Manufacturer questionnaire – South Africa

Manufacturers to visit

- Aspen Pharmacare
- Cipla-Medpro (India).
- Sanofi-Aventis (Pretoria, TB products)

Manufacturers to interview by phone:

- Sonke (Ranbaxy, India),
- Aurobindo (India),
- Mylan (US/India),
- Adcock Ingram (India)
- Be-Tabs (Ranbaxy, India)
- Bio-Tech (51% Africa Biopharma Investments Ltd, 49% JB Chemicals & Pharmaceuticals Ltd (India) – no WHO prequalified products (TB)
- Sandoz
- Fresenius (Germany)
- Novartis
- Mirren (malaria syrup) – not WHO prequalified – export?
- Medchem (capsules – no website found)
- Ketlaphela – planning stage?

Specific questions for Manufacturers Questionnaire:

- Priority visits to Aspen, Cipla, Sanofi
- Questions for Bio-Tech and Mirren: export activities – WHO Prequalification plans.
- Big Pharma (visit Sanofi, others by telephone): Sandoz, Sanofi, Fresenius, Novartis: plans to support local companies to become WHO prequalified and who could export into SADC. Local investment plans.
- Aspen: plans for SADC – priority to become world generic player, less interested in African countries outside SA?
- Ketlaphela: actual situation.
- Indian companies: visit at least 1 to look at their future plans, delocalisation into other SADC countries? (Cipla, Durban)

Manufacturer questionnaire – Namibia

Fabupharm

- Announced to make ARV's
- Claims GMP from Namibian Medicines Regulatory Council: is this comparable with WHO prequalification? If not, plans to become WHO PQ?
- Product list – relevant to the 3 diseases?
- Confirmation of rumours of ARV production (attempt to become WHO PQ?)

Manufacturer questionnaire – Tanzania

1. A to Z Mills Ltd (Arusha):
    - LLIN, only manufacturing company in SADC on WHO list of 11 companies.
    - Visit.
    - Q: export into SADC countries, competitive situation vs. international companies like Baxter, BASF…, plans for expansion, delocalisation into other SADC countries.

2. TPI (Arusha): apparently closed down
    - Check if closed down. Reason?

3. Zenufa (Dar-es-Salaam) + DRC (will be done by Ed)
    - Q: today malaria drugs (quinine, ACT regimens), expansion into HIV/AIDS, TB medicines?
    - Q: what is produced in DRC?
    - WHO Prequalification: plans?
    - Export in which other SADC countries.

Manufacturer questionnaire – Zimbabwe

Varichem pharmaceuticals Ltd (Harare)

- No longer WHO Prequalified
- What support are they getting from UNIDO now (and what support did they get from UNDP $2.1m many years ago?)
- Plans to restart ARV production (ceased in 2012)
- Plans to have WHO prequalified products again? Plans to export to other SADC countries?
- Expansion of product portfolio in HIV/AIDS, TB, malaria?
- Discuss the issue of lack of support from the local market due to import taxes on raw materials, which apparently lead to stop ARV production in 2012.

CAPS Zimbabwe (Harare)

- no longer ARV and TB production
- What is the status of this factory today?

Manufacturer questionnaire – Zambia

NRB Pharmaceuticals

- Indian company
- Q: announced production of anti-malaria drugs and HIV/AIDS ARV's, but website still under construction: what is the stage today? Building completed: assess GMP outline, product range?
- Additional Q: plans for export into SADC
- WHO PQ plans?

MYLAN Laboratories

- has recently also signed up a lease agreement in the Lusaka South Multi-Facility Economic Zone
- Assess plans for production, market, export, WHO PQ
- Interview Geoffrey in Malawi as he worked for Mylan

Manufacturer questionnaire – Madagascar

Artemisinin production

- One or several companies are extracting and producing? Who are they? Controlled by?
- Also chemical modification into artesunate or ACT drugs themselves?
- To which companies/countries they export artemisinin to?
- Possibility to increase farming capacity in Madagascar?
- Possibility to produce rectal artesunate (RAS)?

Manufacturer questionnaire – Lesotho

Lesotho LPV

- Stopped 2006 – lessons learned
- Chances for restart?
- Other small scale production?
- Greenfield?

Manufacturer questionnaire – DRC

Zenufa

- Headquartered in Tanzania: production plant in DRC is producing what? (Quinine? Others?)
- Q: today malaria drugs (quinine, ACT regimens), expansion into HIV/AIDS, TB medicines?
- Q: what is produced in DRC?
- WHO Prequalification: plans?
- Export in which other SADC countries.

PharmaKina

- Pharma Kina (Bukavu) is making malaria products for many decades (based on quinine plantations).
- Quinine production. Other products?
- Pharma Kina also had a local production line for HIV/AIDS supported by EU through Action Medeor (no longer operational?). Pharma Kina developed a production line for ARVs in 2007 (with German and Thai assistance) but they did not have the budget to go for WHO prequalification (then estimated at 300,000 USD – including funds for bio-equivalence studies). Production ceased in 2008.
- No other HIV/AIDS related production known to **hera** in DRC;
- DRC has rubber plantations; assess why they have been unsuccessful in producing latex.

So mainly Pharma Kina (Bukavu), and maybe someone making ARVs or condoms (using national grown latex?)

7. SUPRANATIONAL REFERENCE LABORATORY QUESTIONNAIRE

Definition:

The purpose of the supranational reference laboratory is to complement the deficits in Member States' national reference laboratories. Supranational reference laboratories would have a wide range of competencies and functions.

1) Please state the specialisation of the SNRL (HIV/AIDS – TB – malaria or disease neutral)

2) Which countries besides your own are served by the SNRL?

3) Please give a description of your activities/services
    a. Drug resistance testing
        i. Genotypic testing
        ii. Second-line drug sensitivity testing for TB
        iii. Parasite resistance to anti-malaria drugs and insecticides
    b. Development of quality systems
        i. HIV/AIDS
        ii. TB
        iii. Malaria
    c. Surveillance and epidemic response
    d. Information management, monitoring and evaluation (the SNRL should assist in the development, harmonisation and standardisation of data collection tools)
    e. Training, capacity building, skills transfer and operational research in health
    f. Promotion of health and safety practices
    g. Specimen handling and transportation

4) Please explain how your activities are funded.

5) Please provide the organizational structure, the number of staff working in the SNRL.
    a. How many foreign staff from other SADC countries?
    b. Is it easy to get a work permit for the foreign staff?

6) What is the capacity of the SNRL, and is there room for expansion.
    a. Describe physical infrastructure – does the laboratory meet international design standards – biological safety level 3 (in case of services offered for TB)
    b. Is the current capacity allowing for a rapid turnaround for test samples?
    c. Describe technical equipment

7) Is the SNRL involved in any quality testing of medicines or commodities used in HIV/AIDS, TB or malaria?
    a. If not, who in your country is responsible for that?
8) Is the SNRL accredited by relevant regional or international accreditation bodies?
    a. If not, is there a plan to get accredited?

8. National Medicines Regulatory Authority questionnaire

Questions to the National Medicines Regulatory Authority:

1) Do you issue Market Authorizations for medicines, and if so, how many per year? How many products are currently registered?

2) Do you keep an up-to-date database of medicines circulating in the country? Is this accessible for professional/public? If so, please provide URL.

3) What HIV, TB or malaria medicines or commodities are manufactured in your country? (try to get name of product, generic name and name of manufacturer, and whether this is production of finished product, or repackaging / relabelling from bulk import)

4) Do you have access to a Quality Control Laboratory?

5) Does this lab have the possibility to test the quality of all medicines in the market for HIV/AIDS, TB and malaria produced in your country and/or imported?
    a. What Pharmacopoeial standards are used?
    b. If the national lab cannot test quality of a product, what happens? (Send abroad?)

6) How many pharmaceutical manufacturers have you licensed in your country? How many of those are currently operational? (Try to get a list).

7) Do you inspect pharmaceutical manufacturers? If so,
    a. How many inspections take place per year?
    b. How many inspectors are in place?

8) Which version of GMP do you use to assess pharmaceutical manufacturers? If a national standard: is this compatible with the WHO GMP?

9) How many of the existing manufacturers have been GMP approved by your inspectors? How many have been inspected by foreign inspectors?

10) Is there a National strategy to bring existing manufacturers up to GMP level (and WHO prequalification)? If so, what is the role of the regulator / inspector in this?
11) Are there any plans for new manufacturing plants? If so, will the new factory be GMP? Will the new manufacturer produce medicines or commodities for HIV/AIDS, TB or malaria?

12) Is there a registration procedure for:
    a. Medical devices?
    b. African traditional medicines?

13) Who in the country is controlling the quality of:

a. Bed nets/ LLINs
b. Condoms
c. Chemicals for Indoor Residual Spraying against malaria mosquitos?
d. Diagnostic tests used in HIV/AIDS, TB and malaria

14) How is pharmacovigilance and recall of medicines organized in the country?

15) Is there inspection of Good Clinical Practice organized in the country?

16) Are there initiatives for regional harmonisation?

17) Do you have any mutual recognition agreement with another SADC country?

18) What should happen for SADC to make its own medicines for HIV/AIDS, TB or malaria?

9. CENTRE OF EXCELLENCE QUESTIONNAIRE

Centres of Excellence address areas of laboratory practice in which they have adequate expertise. They are not disease-oriented, but provide essential complementary functions for service delivery. Their mandate should be to address some of the root causes of current deficits which include non-discipline specific considerations, such as human resource development, specialised training, quality management implementation and the establishment and harmonisation of systems of information collection and its management. Centres of excellence should have superior technical expertise, human and material resources, equipment and appropriate facilities.

1) Human resources capacity development
   a) In which disciplines do you offer specialist training? (Diagnostic – Public Health)
   b) How many people are trained on a yearly basis – how many of them are retained within the country where the CoE resides?

2) Describe the development of quality management systems at the CoE

Do you provide quality assurance and proficiency testing at the National Reference Laboratory level?

3) Information management, surveillance and research
   a) Do you establish, standardise and harmonise information management systems and procedures in National Reference Laboratories?
   b) Do you facilitate the implementation of best practices through structured and targeted training programmes?