# Strategy for Regional Manufacturing of Essential Medicines and Health Commodities in SADC (2016-2020)

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

***Final Report***

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This draft strategy follows the feasibility study on Regional Manufacturing of Medicines and Health Commodities performed May-December 2015, and was coordinated by a Core Team consisting of: Wilbert Bannenberg (team leader), Marc van Robays (co-team leader) and Corinne Eisma / Ingeborg Jille-Traas (project managers).

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| | |
|---|---|
| AfDB | African Development Bank |
| API | Active Pharmaceutical Ingredient |
| ARV | Antiretroviral |
| CoS | Centres of Specialization |
| CoE | Centre of Excellence |
| DRC | Democratic Republic of Congo |
| FDF | Finished Dosage Form |
| GCP | Good Clinical Practices |
| GDP | Good Distribution Practices |
| GMP | Good Manufacturing Practices |
| GWP | Good Warehousing Practices (included in GDP) |
| HRD | Human Resource Development |
| ICT | Information and Communication Technology |
| IDPF | Industrial Development Policy Framework (SADC, 2012) |
| IP | Intellectual Property |
| ITN | Insecticide Treated Nets |
| LDC | Least Developed Country |
| LLINs | Long Lasting Insecticide Treated Nets |
| MCC | Medicines Control Council |
| MDR | Multi-Drug Resistant |
| MDR-TB | Multi-Drug Resistant Tuberculosis |
| NMRA | National Medicines Regulatory Authority (or Agency) |
| PBP | Pharmaceutical Business Plan |
| PMPA | (African Union) Pharmaceutical Manufacturing Plan for Africa |
| PPP | Public-Private Partnerships |
| QA | Quality assurance |
| QC | Quality Control |
| R&D | Research and Development |
| RISDP | Regional Indicative Strategic Development Plan |
| SADC | Southern African Development Community (www.sadc.int) |
| SAPMAP | SADC Pharmaceutical Manufacturing Action Plan |
| SHD | Social and Human Development |
| SRA | Stringent Regulatory Authority |
| TB | Tuberculosis |
| TRIPS | Trade Related Aspects of Intellectual Property Rights |
| UHC | Universal Health Coverage |
| WHO | World Health Organization (www.who.int) |
| WHO PQ | WHO prequalification |

# 1. INTRODUCTION / BACKGROUND

The SADC Strategy for Regional Manufacturing of Medicines and Health Commodities provides an overall mechanism for achieving a key priority of both the SADC Industrial Development Policy Framework (IDPF) and the SADC Pharmaceutical Business Plan: ***to produce in SADC a much greater share of the essential medicines and commodities currently used in SADC.***

The SADC region is a global hotspot for HIV, TB and malaria. The SADC Health Ministers have agreed to work towards Universal Health Coverage in 2020. The SADC Trade and Industry Ministers also want to develop a healthy pharmaceutical industry in the region.

Currently only 24% of all essential medicines and 15% of the generic antiretrovirals are produced in SADC. There is only one small factory producing "active pharmaceutical ingredients" (APIs) in SADC. Many of the excipients and packaging materials are also imported.

The SADC Heads of State and Governments in their April 2015 Summit have declared the development of a pharmaceutical industry a priority.

To inform the development of this Strategy, the SADC Secretariat, requested consultants to do a Feasibility Study on Regional Manufacturing of Medicines and Health Commodities for the treatment of the three pandemic diseases. The feasibility study was carried out May-December 2015 with financial support from AfDB, and recommends *inter alia* to strengthen the enabling environment for the whole pharmaceutical manufacturing sector. This would also strengthen the production of other essential medicines, including those necessary to fight the even bigger epidemic of non-communicable diseases.

In addition to information from the feasibility study this Strategy builds on existing regional agreements, policies and plans, such as the:

1. SADC Regional Indicative Strategic Development Plan (RISDP)
2. SADC Protocol on Health
3. SADC Protocol on Trade
4. SADC Industrial Development Policy Framework (IDPF)
5. SADC Industrialization Strategy and Roadmap 2015-2063
6. SADC Industrial Upgrading and Modernization Program (IUMP)
7. SADC Pharmaceutical Business Plan 2015-2019
8. AU's Accelerated Industrial Development of Africa (AIDA)
9. AU's Agenda 2063
10. AU's Pharmaceutical Manufacturing Plan for Africa (PMPA)

A word of caution is needed. The ambitions are high, but the Region should take cognisance of the lessons of the past, where some policies/strategies have not resulted in implementation or outcomes. This Strategy is focussing initially on what is practically achievable in the period 2016-2020. However, the lifespan of some of the interventions will extend beyond 2020, while other longer-term pharmaceutical manufacturing projects come on-stream during phase 2 (i.e. 2021-2030) in accordance with the timelines for the Proposed Action Plan for the SADC Industrialization Strategy and Roadmap 2015-2063.
This strategy can work if it is politically supported, funded and implemented.

## 2. SITUATIONAL ANALYSIS AND SWOT ANALYSIS

The Strategy was preceded by a situational analysis covering all 15 SADC Member States, and interviews with 35 manufacturers, medicines regulators, laboratories and other stakeholders. The results were documented in a feasibility report which also included a gap analysis[1].

The following SWOT analysis of regional production was generated during the process of assessment of the pharmaceutical manufacturing sector:

**Figure 1 – SWOT analysis of the SADC pharmaceutical sector**

| | |
|---|---|
| Strengths<br>1. Political will<br>2. Written, official policies & business plan<br>3. Member States support local production<br>4. Existing production base (15-24%)<br>5. Fast regulatory approvals after joint inspections and dossier analysis (ZaZiBoNa)<br>6. TRIPS flexibilities (8/15 are LDC)<br>7. Centres of Excellence<br>8. Donor interests<br>9. Region contributes to clinical trials | Weaknesses<br>1. Poor Implementation of agreed policies<br>2. Poor policy coherence<br>3. Unevenly spread Human Resources<br>4. Poor Infrastructure<br>5. Financing gap<br>6. Insufficient incentives for local manufacturing<br>7. Unevenly spread production base<br>8. Limited number of regional manufacturers with GMP/WHO prequalification status<br>9. Donor dependency culture |
| Opportunities<br>1. Addressing the public health crisis through mobilising local resources<br>2. New technologies for API production<br>3. Large unmet need<br>4. Growing market, Increasing GDP<br>5. Regional medicines & commodities Regulatory harmonization<br>6. Better professional education<br>7. Increase skilled HR output for pharmaceutical industry<br>8. Reach AU and beyond market<br>9. Developing SADC Pharmaceutical Sector from cost to profit centre<br>10. Increased Development Partners' appetite for health system developments - potential for support in production | Threats<br>1. Cheaper Asian imports<br>2. Price dumping by competitors<br>3. Illegal imports of counterfeit products<br>4. Donor Fund shrinkage<br>5. Corruption, lack of transparency and accountability<br>6. Inadequate supplies of APIs/raw materials<br>7. Single source products (high prices patented meds, supply security)<br>8. Price manipulation of intermediates, APIs<br>9. Vertical integration<br>10. Lack of commitment from some Member States<br>11. Existence of tariff barriers in some Member States |

[1] See SADC Feasibility Study on Regional Manufacturing of Medicines and Health Commodities, Volumes 1 (main report), 2 (country data) and 3 (annexes).

# 3. RATIONALE AND FEASIBILITY

From the situational analysis it is clear that the current SADC pharmaceutical manufacturers would like to get a larger share of the regional market than the 15% generic ARVs, or 24% of all essential medicines currently made in SADC. However, they are facing challenges in non-aligned health, trade, industry, agriculture and finance policies, which often tax raw materials, excipients and packaging material, while the finished products of their mostly Indian competitors enter SADC without taxes.

### Local and regional production targets in SADC

The SADC region faces a big gap in the number of HIV+ people treated. New "test and treat" policies are the best answer to bring the HIV epidemic under control, but will imply a huge expansion in HIV+ people being treated (from the current 6 million to 16 million by 2020). The amount of raw materials needed for production of ARVs to provide for this treatment expansion is massive, and would warrant studying in detail the feasibility of creating a plant for manufacture of related Active Pharmaceutical Ingredients (APIs).

Multiple Drug Resistant (MDR) Tuberculosis is an increasing problem. Current medicines require a very long treatment period, and are relatively unsafe and not always effective in curing MDR-TB patients. Three new medicines are currently being tested that might reduce the treatment period from 20 to 6 months. Ideally, these medicines should be formulated as a fixed-dose combination.

Malaria is effectively treated with combination products made *inter alia* from *Artemisia Annua* plants which can grow in DRC, Tanzania and Madagascar. Currently the raw materials are exported to Europe to be converted into active pharmaceutical ingredients and subsequently medicines. Such conversion could also be done in SADC, and used to make more appropriate dosage forms, e.g. artesunate suppositories to be used at primary care level for children suffering from severe malaria.

### Feasibility

If well planned, and with coherent policies and an enabling environment, it is feasible to produce a larger share of essential medicines and health commodities in SADC.

A push for regional production of the above products will also contribute to developing a healthy pharmaceutical manufacturing capacity in SADC. This could then be used to regionally manufacture more affordable generic versions of new medicines against Hepatitis-C and non-communicable diseases such as cancer, diabetes and cardiovascular diseases.

### Benefits

Benefits of regional production will also include: less dependence on far-away suppliers; more supply security; savings on foreign exchange; more industrialization; more knowledge among companies; more staff employed, etc.

## 4. VALUES AND PRINCIPLES

The Strategy is based on the following values and principles:

1. Health as a human right
2. Transparency and accountability
3. Equity (a fair distribution of manufacturing across SADC region)
4. Gender equality
5. Sustainability
6. Quality and efficiency
7. Principle of subsidiarity
8. Universal health coverage

## 5. VISION

**"A sustainable pharmaceutical manufacturing industry in SADC that contributes to universal health coverage by supplying affordable good quality essential medicines and health commodities for both communicable and non-communicable diseases"**

## 6. PURPOSE

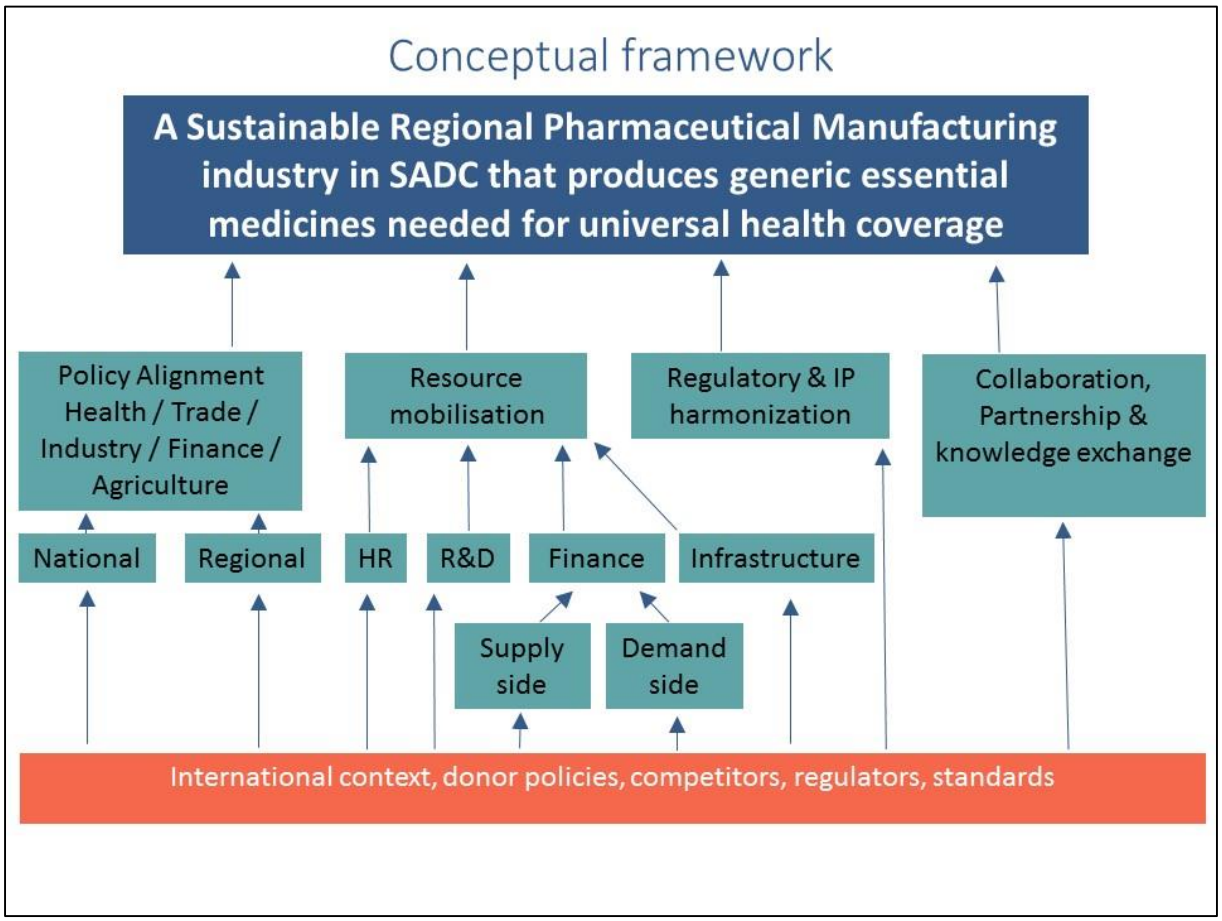
The Strategy has a dual purpose:

1. To develop a sustainable regional pharmaceutical industry that is competitive, reliable, innovative, productive and responsible; and
2. To promote health for all people in SADC through universal health coverage and improved access to essential medicines and health commodities

## 7. CONCEPTUAL FRAMEWORK

The following conceptual framework was developed using the logical framework approach:

**Figure 2 – Conceptual framework for the future pharmaceutical industry in SADC**




The top level box represents the overall goal of the Strategy. It will have specific targets to be achieved by 2020 and beyond, so that the success of the Strategy can be assessed and evaluated. See section 9.4 below.

The next row of 4 blocks are the 4 major focus area outcomes that need to be met in order to achieve the overall goal of the Strategy. For each block one or more Strategic Objectives are listed in section 7.2.

The lower blocks are examples of other focus areas that impact achievement of the major focus areas strategic objectives.

## 7.1 Overall Goal and Targets

Overall goal: a sustainable regional pharmaceutical manufacturing industry in SADC that produces quality assured generic essential medicines and health commodities needed for universal health coverage.

The following targets and related SMART[2] indicators are linked to the overall goal:

1. By 2020, at least 45% of the generic ARVs and 50% of the needed essential medicines are manufactured in SADC as finished dosage forms (by volume)
2. By 2020, at least two new API factories will be established in SADC that produce important raw materials for HIV and malaria medicines
3. By 2020, the SADC region will produce at least 50% of the needed 4 billion male condoms
4. By 2020, the SADC region will produce 40% more long-lasting insecticide treated bed nets than in 2015
5. By 2020, SADC will have an enabling environment with coherent policies between health-trade-industry-finance-agriculture, which supports a shift in industrial structure, manufacturing, production and exports of the pharmaceutical manufacturing industry, while increasing employment in the sector with 50%.

If all inputs and resources for implementation of the action plan are available, these targets have a good chance of being achieved. External risks and assumptions that could interfere with achieving the targets are listed in section 8.

## 7.2 High-level Strategic Objectives

The following high-level strategic objectives are proposed:

1. To align cross-sectoral policies at national and regional level (health-trade-industry-finance-agriculture)
2. To mobilize the necessary resources and inputs (human, knowledge, finance, infrastructure) to facilitate growth in pharmaceutical manufacturing
3. To operationalise harmonized medicines and health commodities regulations in SADC
4. To maximise the presence and use of TRIPS flexibilities in national Intellectual Property laws while mitigating or minimizing TRIPS-plus measures
5. To ensure that all stakeholders collaborate efficiently
6. To ensure efficient and transparent partnerships between industry, universities, academics, and development partners
7. To ensure efficient knowledge exchange among all stakeholders

Each of the strategic objectives is linked to one or more of the specific outcomes that the Strategy aims to achieve. Each outcome is linked to one or more outputs, which the 5 year action plan should be able to achieve.

[2] Specific, Measurable, Achievable, Relevant, Time-bound

## 8. RESULTS FRAMEWORK

| Strategic Objective | | Outcomes | | Outputs | |
|---|---|---|---|---|---|
| **1** | **Align cross-sectoral policies at national and regional level (health-trade-industry-finance-agriculture)** | *1.1* | *Better enabling environment for regional production through coherent cross-sectorial, regional protocols and frameworks* | 1.1.1 | A framework for guiding Member States established |
| | | | | 1.1.2 | A working group setup to analyse existing incoherence and propose solutions |
| | | *1.2* | *National policies aligned with the regional strategy or policies.* | 1.2.1 | Member States supported to align their national policies with the regional strategy. |
| | | *1.3* | *Coherence between ministries of health, trade, industry, finance and agriculture* | 1.3.1 | Integrated operational plans for the relevant ministries |
| **2** | **Mobilize the necessary resources (human, knowledge, finance, infrastructure) to facilitate growth in pharmaceutical manufacturing** | *2.1* | *Sufficient skilled human resources for pharmaceutical manufacturing industry available* | 2.1.1 | Human resources development plans established to cater for all the needs of the regional pharmaceutical industry |
| | | | | 2.1.2 | Institutions established to provide skilled pharmaceutical professionals |
| | | | | 2.1.3 | Mutually recognized qualifications in the region. |
| | | *2.2* | *Research and Development capacity in the region to produce new chemical entities and generics* | 2.2.1 | Centres of Excellence and Centres of Specialisation established |
| | | | | 2.2.2 | Program to exchange R&D knowledge among Member States established |
| | | *2.3* | *Affordable finance mechanisms established* | 2.3.1 | Implemented tariff exemption for imported API's, excipients, packaging |
| | | | | 2.3.2 | Specified % of market designation from regional market for every member state |

| Strategic Objective | | *Outcomes* | | Outputs | |
|---|---|---|---|---|---|
| | | | | 2.3.3 | Donor-SADC funding agreement on preferential procurement established |
| | | | | 2.3.4 | Established local added value in procurement |
| | | | | 2.3.5 | Long term demand plan for priority products developed |
| | | | | 2.3.6 | Finance for investments in new production available |
| | | | | 2.3.7 | Technology transfer mechanism developed |
| | | | | 2.3.8 | Framework agreements for supply established |
| | | *2.4* | *Adequate infrastructure established* | 2.4.1 | Designated special economic zones or industrial parks |
| | | | | 2.4.2 | Stable and affordable electricity supplied |
| | | | | 2.4.3 | Reliable and clean water supplied |
| | | | | 2.4.4 | Suitable pollution free green field locations established |
| | | | | 2.4.5 | ICT |
| | | | | 2.4.6 | Transport networks (road, rail, water) |
| | | | | 2.4.7 | Supportive industries |
| **3** | **Achieve harmonized medicines and health commodities regulation in SADC** | *3.1* | *Well-regulated equitable playing field in place* | 3.1.1 | Establishment of formal NMRA networks & collaboration; regional database of registered medicines, CTs and GMP inspected manufacturing plants; mutual recognition; Bioequivalence centre; MCC to become an SRA; |
| | | *3.2* | *Harmonized standards (GMP, GDP, GLP, GCP) adhered to by relevant stakeholders in all Member States* | 3.2.1 | NMRAs adopt, promote and enforce harmonized GMP standards across SADC; regional GMP training program with work & information sharing; GMP Road maps |
| | | *3.3* | *Access to accredited quality control services* | 3.3.3 | Sufficient Quality Control (QC) laboratories in place with ISO 17025 accreditation |
| | **Maximise the presence and use of TRIPS flexibilities in national Intellectual Property laws while mitigating or minimizing TRIPS-plus measures** | *4.1* | *Effect legislative reforms to incorporate TRIPS flexibilities in all national Intellectual Property laws and mitigate or minimize TRIPS-Plus measures* | 4.1.1 | National IP laws reviewed and amended to fully incorporate TRIPS flexibilities [Potential risk: Implementation of amended legislation stalled and promulgation could take a long time] |

| Strategic Objective | | Outcomes | | Outputs | |
|---|---|---|---|---|---|
| | | *4.2* | *Maximise the use of TRIPS flexibilities in IP laws* | 4.2.1 | TRIPS flexibilities used to improve access to affordable, quality, efficacious and safe medicines *[Potential risk: TRIPS flexibilities may not be applied as a mechanism to improve access]* |
| | | | | 4.2.2 | TRIPS-plus measures mitigated and minimized through national legislative reforms of IP laws *[Potential risk: TRIPS plus may continue due to lack of coherence between Ministries at national level]* |
| | | | | 4.2.3 | Public health outcomes for the three pandemics at national level improved *[Potential risk: Incorporation of TRIPS flexibilities may not guarantee improved public health outcomes for the three pandemics at national level because of other factors (e.g. weak health systems, lack of access to health care facilities etc..)]* |
| **5** | **Ensure that all stakeholders collaborate efficiently** | *5.1* | *A strategic and systematic approach to stakeholder engagement and management* | 5.1.1 | A Stakeholder Engagement Framework/Plan developed |
| | | | | 5.1.2 | Partnership MoUs / agreements developed |
| | | | | 5.1.3 | Round Tables and / or Task Teams on specific topics organized *(Risk: difficulties in management of diverse or competing agendas and interests among stakeholders. Assumption: stakeholders can be persuaded / convinced to work towards common goals / purpose)* |
| **6** | **Ensure efficient and transparent partnerships between industry, universities, academics, and development partners** | *6.1* | *Established framework for partnerships between stakeholders (SADC Secretariat, Member States, industry, academics, development partners)* | 6.1.1 | Developed stronger partnerships between all stakeholders (e.g. Government with industry, academics and development partners) |
| | | | | 6.1.2 | Established and Implemented partnership monitoring and reporting processes |
| | | | | 6.1.3 | Binding agreements in place |
| | | *6.2* | *Developed Information and work sharing mechanisms* | 6.2.1 | Developed accessible platform (database) for information and work-sharing |

| Strategic Objective | | *Outcomes* | | Outputs | |
|---|---|---|---|---|---|
| | | | | 6.2.2 | Strengthened and improved communications and information management for all partnerships areas |
| | | | | 6.2.3 | Developed action plan on information and work sharing mechanisms |
| **7** | **Ensure efficient knowledge exchange among all stakeholders** | *7.1* | *Opportunities and mechanisms to disseminate and translate learning and experiences to relevant audiences provided* | 7.1.1 | Face to face, online courses and webinars made available |
| | | | | 7.1.2 | Yearly workshops and conferences held |
| | | | | 7.1.3 | Centres of Excellence identified and utilised |
| | | | | 7.1.4 | Guidelines and tool kits developed and in place |
| | | | | 7.1.5 | Shared and accessible online repository of guidelines and tool kits, etc. available |
| | | *7.2* | *North-South and South-South learning and knowledge exchange promoted* | 7.2.1 | Partnerships and agreements on learning and knowledge exchange established (incl. exchange visits) |
| | | | | 7.2.2 | Scholarship programmes established |
| | | | | 7.2.3 | Knowledge transfer programmes for special skills put in place |
| | | | | 7.2.4 | Documentation and sharing of best practices instituted |
| | | *7.3* | *Capacity building and skills development of decision-makers to translate evidence into policy, practice and decision-making enhanced.* | 7.3.1 | Skills development for top officials in decision-making positions provided |
| | | | | 7.3.2 | Information-sharing and dissemination mechanisms for decision-makers established |
| | | | | 7.3.3 | Exchange visits and organized tours for top officials in decision-making positions in place |
| | | | | 7.3.4 | Mechanisms for back-to-office reports and briefing to Senior Officials established *(Risks: Uneven knowledge production and sharing between stakeholders in different Member States. Risk2: Inadequate resources for knowledge exchange mechanisms. Assumption: Expertise available to generate information on best practices and extract appropriate lessons learned)* |

# 9. COORDINATION & IMPLEMENTATION

Coordination and implementation of the complex Strategy requires a multi-stakeholder collaboration, whereby the parties meet in structured meetings at regular intervals. The aim of the collaboration is that all parties share their specific knowledge and challenges, learn from each other, build trust and understanding, and that the collective finds solutions for strengthening pharmaceutical production and access to essential medicines and health commodities in the region as well as in all SADC Member States.

It is suggested that the following parties meet regularly to coordinate the implementation of the Strategy:

1. Member State Governments
2. SADC Secretariat
3. Private sector
4. Civil Society
5. Academics

Only if all stakeholders participate, and feel that together they can make a difference, will this ambitious Strategy be implemented. Champions should be sought from key stakeholders. The coordination needs to take place both at regional and national level, and should preferably be supported by a small professional institution or an efficient secretariat.

An ad-hoc, temporary Regional Pharmaceutical Manufacturing Task Team is proposed to coordinate the regional process, while we wait for a more permanent subsidiarity organisation with the proposed name “SADC Pharmaceutical Manufacturing Support Organisation” (SPMSO).

## 9.1 Pharmaceutical Manufacturing Task Team (PMTT)

A SADC Pharmaceutical Manufacturing Task Team (PMTT) should be created as an ad-hoc, multi-stakeholder committee of a manageable size. It should have representatives of relevant key stakeholder groups, independent technical experts and have access to an efficient secretariat.

The task of the PMTT is to fine-tune the SADC Regional Pharmaceutical Manufacturing Strategy and develop the related SADC Pharmaceutical Manufacturing Action Plan.

The PMTT should operate until a more sustainable organisation is formally established.

## 9.2 SADC Pharmaceutical Manufacturing Support Organisation (SPMSO)

While existing SADC structures and decision making processes can be used to approve and monitor the Strategy, it is proposed to task a multi-stakeholder subsidiarity organisation with the implementation and day-to-day coordination of the Action Plan. The reason is that the Strategy and Action Plan can only achieve their objectives, if all parties feel that they form part of the coordinating structure. A business plan, budget and charter will need to be developed.

## 9.3 Action Plan

The high-level objectives, outcomes and outputs proposed in section 7 of this Strategy, will need to be extended into a proper 5-year SADC Pharmaceutical Manufacturing Action Plan (SAPMAP). SAPMAP should incorporate activities from the SADC Industrialization Strategy and Roadmap 2015-2063 (especially the SADC Industrialization Strategy Roadmap Item 6 on Pharmaceuticals production), the SADC Pharmaceutical Business Plan 2015-2019 and the activities proposed in the Feasibility study, related Gap Analysis and Strategy. The Action Plan should also keep links with the overall SADC Industrialization Action Plan, and should include objectives, activities, timelines, responsibilities, SMART indicators and a budget.

## 9.4 Monitoring & evaluation

A standard M&E plan should be set up to cover at least the first phase of the Action Plan (2015-2020). Transparency will be improved through the setting up of a publicly accessible website, publishing Annual Reports and organising an Annual Forum, where all stakeholders can meet, present issues, discuss progress and challenges, and suggest improvements for the action plan and Strategy. If donor resources are used, a Midterm evaluation and a final external evaluation need to be scheduled.

# 10. FINANCING MECHANISMS

The implementation of the Strategy can be financed from a mix of sources:

1. Member States' contributions
2. SADC Regional Development Fund
3. SADC Pharmaceutical Manufacturing Facility
4. A 1-2% quality tax on all medicines imported into the SADC region
5. Development Partners (technical and financial support)
6. Development Banks (Soft loans)
7. Private sector (investment funds)
8. Public-Private Partnerships (PPPs)