



*Final report*  
*January 2016*

Feasibility study on Regional Manufacturing of  
Medicines and Health Commodities

**Volume 2A**  
**(Country summaries - infographics)**

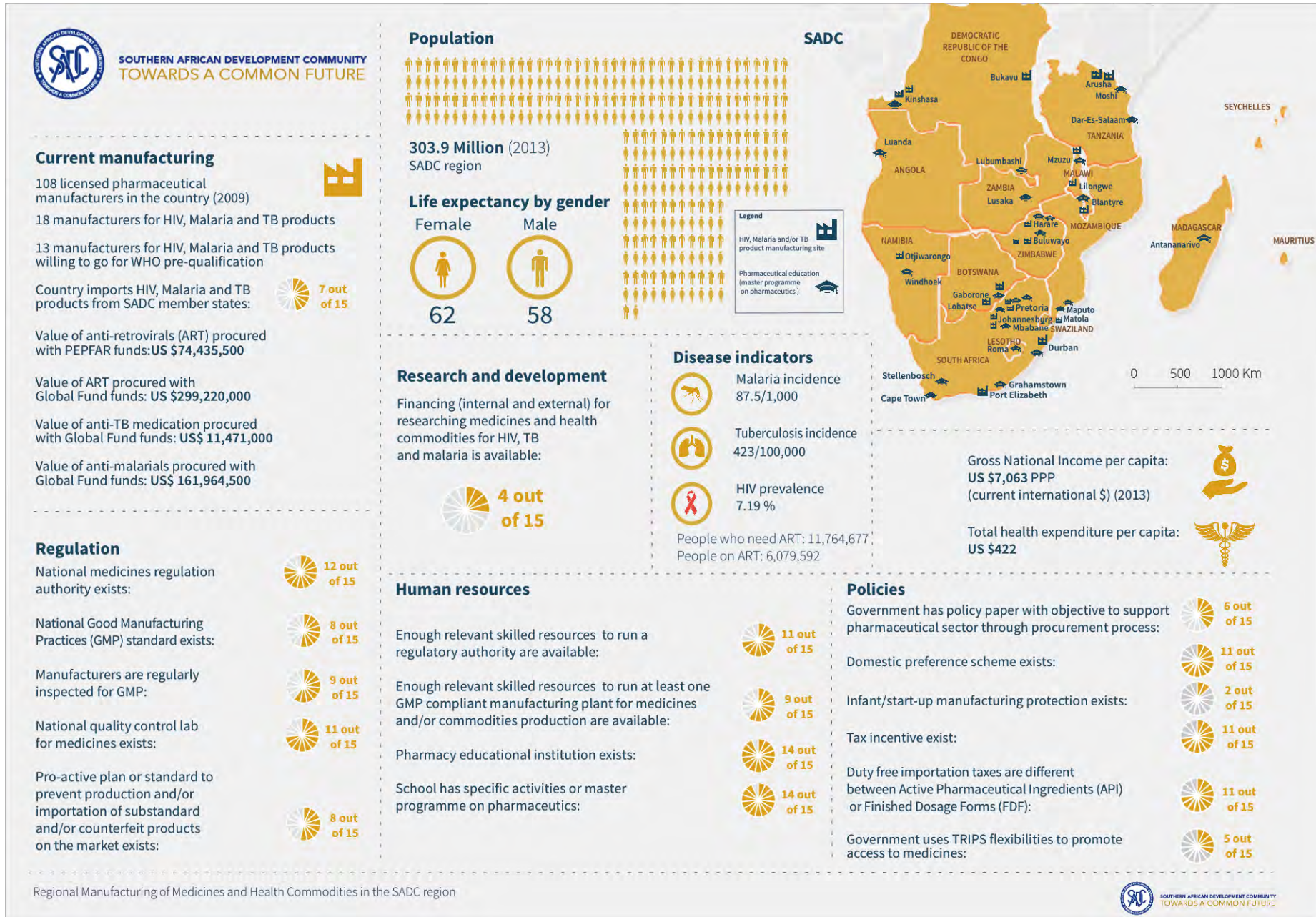
(SADC-SHD&SP/CD/C39/2014)

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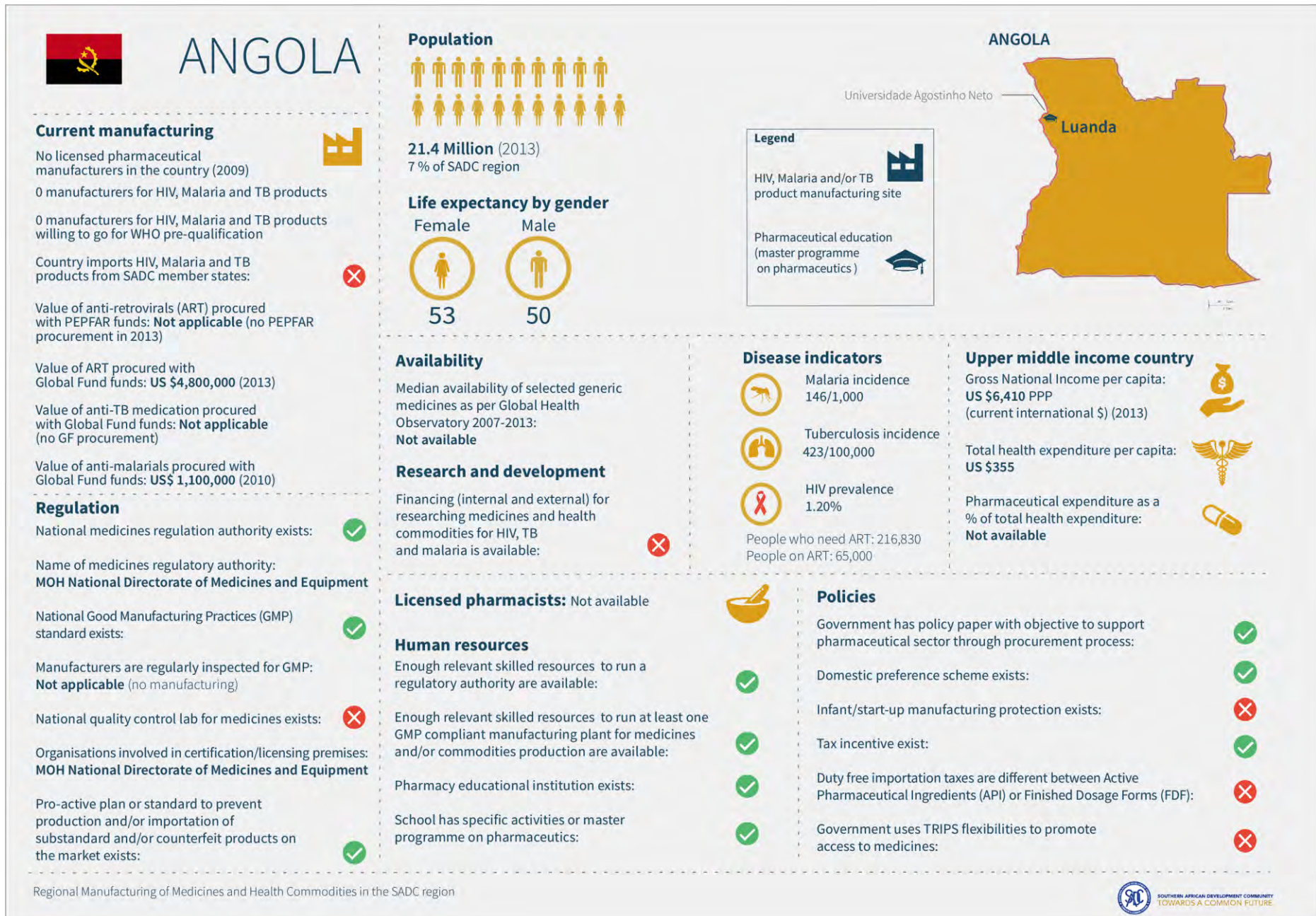
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# 1. SADC REGION



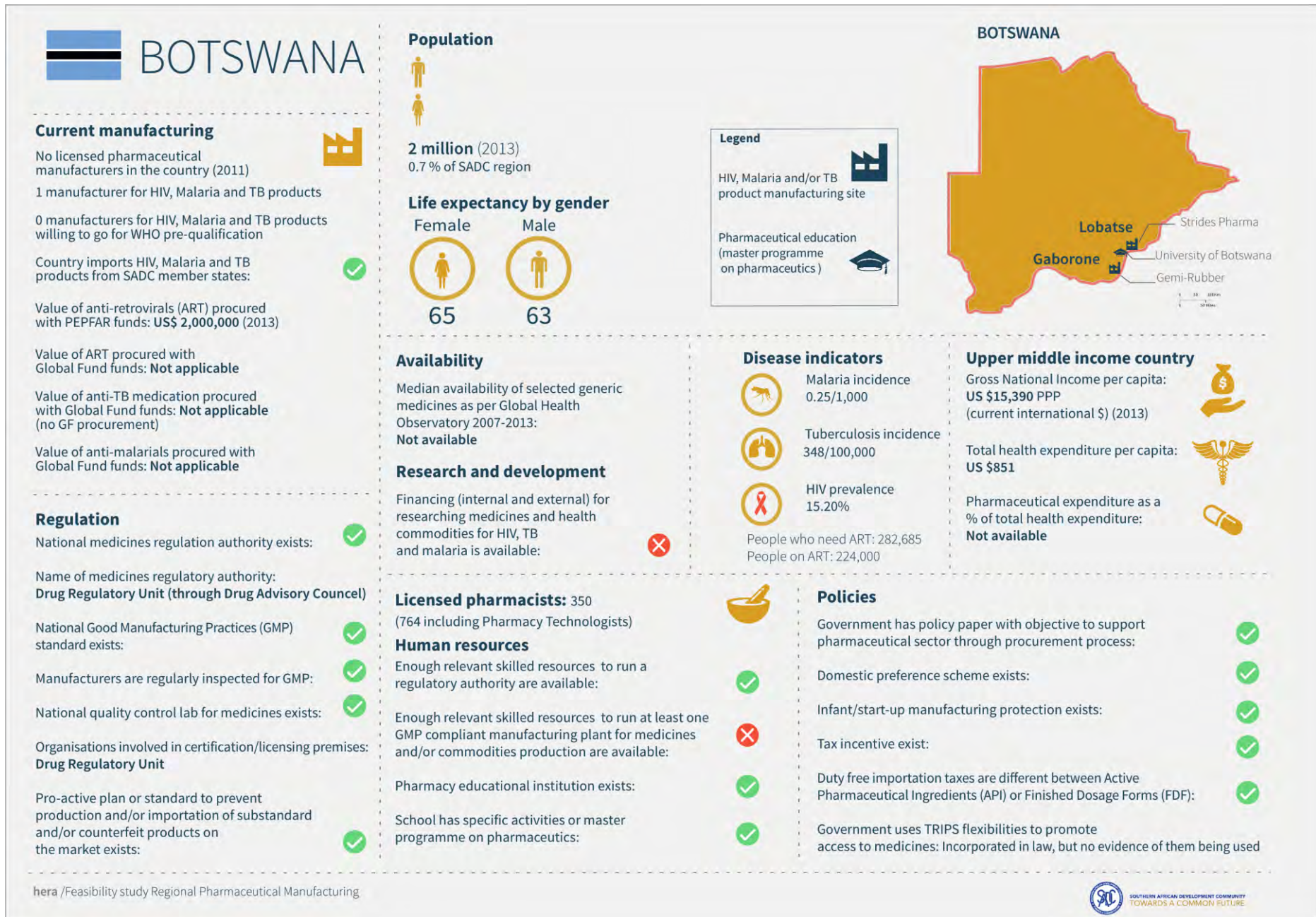


## 2. ANGOLA



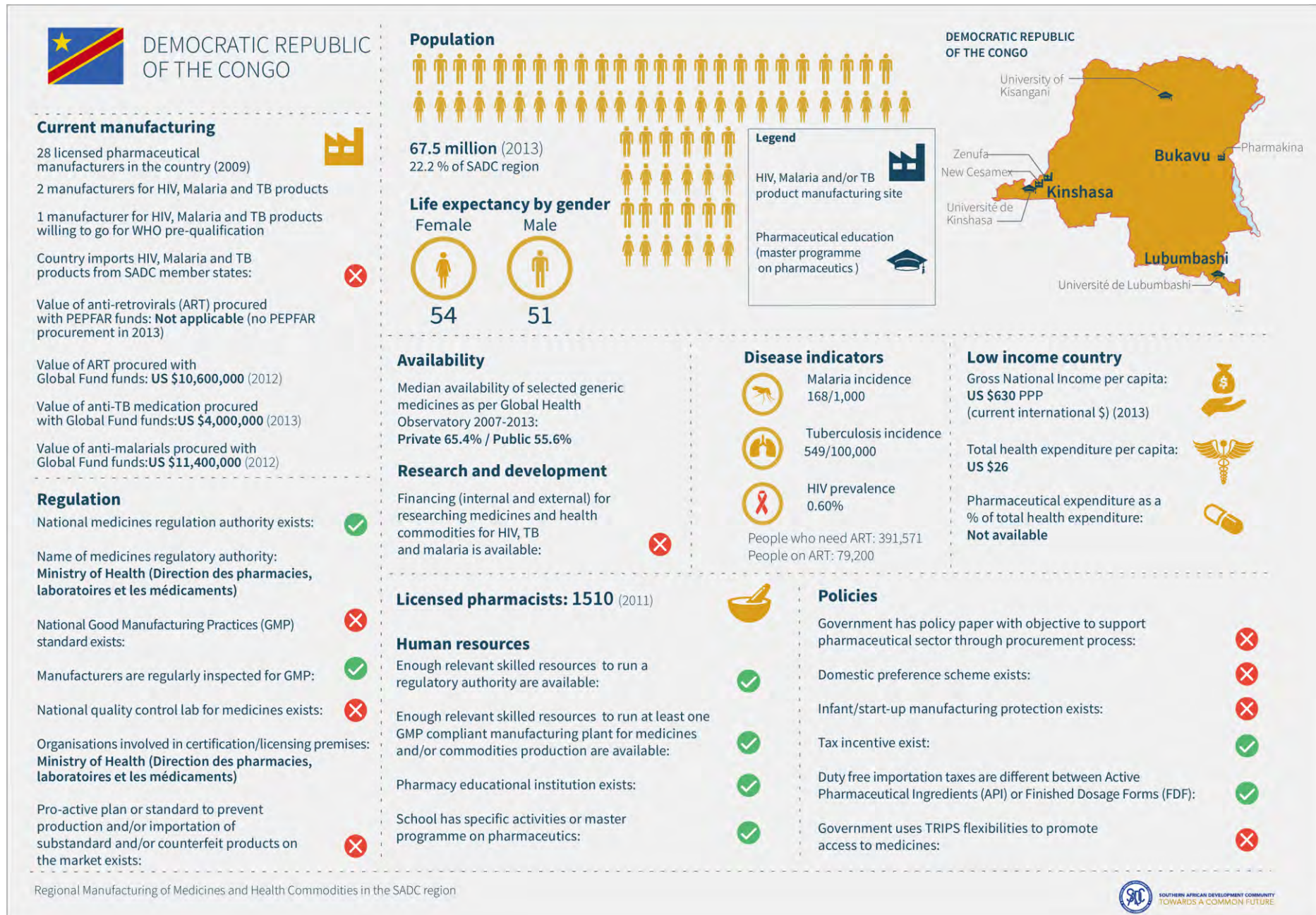


### 3. BOTSWANA





## 4. DEMOCRATIC REPUBLIC OF THE CONGO





# 5. LESOTHO




## LESOTHO

### Population

 **2 million** (2013)  
0.70 % of SADC region

### Life expectancy by gender

Female	Male
 <b>52</b>	 <b>48</b>

### LESOTHO



National University of Lesotho  
Roma

0 50 100Km  
0 50 Miles

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### Current manufacturing

0 licensed pharmaceutical manufacturers in the country (2009) 

0 manufacturers for HIV, Malaria and TB products

0 manufacturer for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states: 

Value of anti-retrovirals (ART) procured with PEPFAR funds: **US \$20,500** (2013)

Value of ART procured with Global Fund funds: **US \$7,400,000** (2013)


Value of anti-TB medication procured with Global Fund funds: **US \$1,200,000** (2011)

Value of anti-malarials procured with Global Fund funds: **Not applicable** (no GF procurement)


### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013: **Not available**

### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: 

### Disease indicators

-  Malaria incidence: No malaria
-  Tuberculosis incidence: 613/100,000
-  HIV prevalence: 18.70%

People who need ART: 291,354  
People on ART: 100,800

### Lower middle income country

Gross National Income per capita: **US \$3,390** PPP (current international \$) (2013) 

Total health expenditure per capita: **US \$297** 

Pharmaceutical expenditure as a % of total health expenditure: **15.3%** (2011) 

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### Regulation

National medicines regulation authority exists: 

Name of medicines regulatory authority: **Not applicable** (No registration)

National Good Manufacturing Practices (GMP) standard exists: 

Manufacturers are regularly inspected for GMP: **Not applicable** (No manufacturing)

National quality control lab for medicines exists: 

Organisations involved in certification/licensing premises: **Ministry of Health**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: 

### Licensed pharmacists: 93

 (2011)

### Human resources

Enough relevant skilled resources to run a regulatory authority are available: 


Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: 

Pharmacy educational institution exists: 

School has specific activities or master programme on pharmaceuticals: 

### Policies

Government has policy paper with objective to support pharmaceutical sector through procurement process: 

Domestic preference scheme exists: 

Infant/start-up manufacturing protection exists: 


Tax incentive exist: 

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): 

Government uses TRIPS flexibilities to promote access to medicines: 


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Regional Manufacturing of Medicines and Health Commodities in the SADC region

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TOWARDS A COMMON FUTURE




# 6. MADAGASCAR




## MADAGASCAR

### Population



**22.9 million** (2013)  
7.5 % of SADC region


### MADAGASCAR



Université d'Antananarivo  
**Antananarivo**


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### Current manufacturing

2 licensed pharmaceutical manufacturers in the country (2009) 

0 manufacturers for HIV, Malaria and TB products

0 manufacturers for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states: 


Value of anti-retrovirals (ART) procured with PEPFAR funds: **Not applicable** (no PEPFAR procurement in 2013)

Value of ART procured with Global Fund funds: **US \$120,000** (2013)


Value of anti-TB medication procured with Global Fund funds: **US \$130,000** (2011)


Value of anti-malarials procured with Global Fund funds: **US \$430,000** (2014)


### Regulation

National medicines regulation authority exists: 


Name of medicines regulatory authority: **Agence de Médicaments de Madagascar**

National Good Manufacturing Practices (GMP) standard exists: 


Manufacturers are regularly inspected for GMP: **Not applicable** (No manufacturing) 


National quality control lab for medicines exists: 

Organisations involved in certification/licensing premises: **MOH Direction des Pharmacies, des Laboratoires et de la Médecine Traditionnelle (DPLMT) and Ordre des pharmaciens**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: 

### Life expectancy by gender


Female:  **66**

Male:  **63**

### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013: **Not available**


### Research and development


Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: 


### Licensed pharmacists: 246


 (2011)
 

### Human resources


Enough relevant skilled resources to run a regulatory authority are available: 


Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: 

Pharmacy educational institution exists: 


School has specific activities or master programme on pharmaceuticals: 


### Legend


HIV, Malaria and/or TB product manufacturing site 

Pharmaceutical education (master programme on pharmaceuticals) 

### Disease indicators


 Malaria incidence: 17/1,000


 Tuberculosis incidence: 413/100,000


 HIV prevalence: 0.20%

People who need ART: 45,632  
People on ART: 540


### Low income country


Gross National Income per capita: **US \$1,370 PPP** (current international \$) (2013) 


Total health expenditure per capita: **US \$58** 


Pharmaceutical expenditure as a % of total health expenditure: **15.9%** (2010) 


### Policies


Government has policy paper with objective to support pharmaceutical sector through procurement process: 

Domestic preference scheme exists: 

Infant/start-up manufacturing protection exists: 


Tax incentive exist: 

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): 

Government uses TRIPS flexibilities to promote access to medicines: 

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hera /Feasibility study Regional Pharmaceutical Manufacturing



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# 7. MALAWI





## MALAWI

### Population




**16.3 Million**  
5.3 % of SADC region

### Life expectancy by gender

Female	Male
	
61	58

### MALAWI



University of Mzuzu  
Kentam  
Mzuzu  
SADM  
Lilongwe  
University of Malawi  
Pharmanova  
Blantyre

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### Current manufacturing

4 licensed pharmaceutical manufacturers in the country (2009)

3 manufacturers for HIV, Malaria and TB products

3 manufacturers for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states:

Value of anti-retrovirals (ART) procured with PEPFAR funds: **US \$15,341** (2013)

Value of ART procured with Global Fund funds: **US \$43,500,000** (2014)

Value of anti-TB medication procured with Global Fund funds: **US \$1,200,000** (2012)

Value of anti-malarials procured with Global Fund funds: **US \$850,0000** (2011)

### Regulation

National medicines regulation authority exists: ✔

Name of medicines regulatory authority: **Pharmacy, Medicines and Poisons Board (PMPB)**

National Good Manufacturing Practices (GMP) standard exists: ✔

Manufacturers are regularly inspected for GMP: ✔

National quality control lab for medicines exists: ✔

Organisations involved in certification/licensing premises: **Ministry of Labour, Ministry of Industry and Trade, City or Town Council, PMPB**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: ✔

### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013: **Not available**

### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: ✘

### Licensed pharmacists

164

### Human resources


Enough relevant skilled resources to run a regulatory authority are available: ✔


Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: ✔

Pharmacy educational institution exists: ✔


School has specific activities or master programme on pharmaceuticals: ✘


### Legend


HIV, Malaria and/or TB product manufacturing site 

Pharmaceutical education (master programme on pharmaceuticals) 

### Disease indicators

 Malaria incidence: 330/1,000

 Tuberculosis incidence: 225/100,000

 HIV prevalence: 10.40%

People who need ART: 803,801  
People on ART: 460,000

### Low income country

Gross National Income per capita: **US \$760 PPP** (current international \$) (2013)

Total health expenditure per capita: **US \$40**

Pharmaceutical expenditure as a % of total health expenditure: **40%**

### Policies

Government has policy paper with objective to support pharmaceutical sector through procurement process: ✔

Domestic preference scheme exists: ✔

Infant/start-up manufacturing protection exists: ✘


Tax incentive exist: ✔

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): ✘

Government uses TRIPS flexibilities to promote access to medicines: ✘

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# 8. MAURITIUS



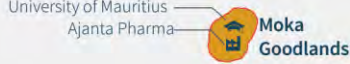
## MAURITIUS

### Population



**1.2 Million**  
0.40 % of SADC region


### MAURITIUS



0 50 100Km  
0 50 Miles

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### Current manufacturing



2 licensed pharmaceutical manufacturers in the country (2009)

1 manufacturers for HIV, Malaria and TB products

1 manufacturers for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states: ✔

Value of anti-retrovirals (ART) procured with PEPFAR funds: **No PEPFAR procurement in 2013**

Value of ART procured with Global Fund funds: **US \$200,000 (2014)**

Value of anti-TB medication procured with Global Fund funds: **Not applicable (no GF procurement)**

Value of anti-malarials procured with Global Fund funds: **Not applicable (no GF procurement)**

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### Regulation

National medicines regulation authority exists: ✘

Name of medicines regulatory authority: **Pharmacy board**

National Good Manufacturing Practices (GMP) standard exists: ✘

Manufacturers are regularly inspected for GMP: ✔


National quality control lab for medicines exists: ✔

Organisations involved in certification/licensing premises: **Pharmacy Board**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: ✘


### Life expectancy by gender

Female



**78**

Male



**70**

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### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013:  
**Private 70% / Public 88.8%**

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### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: ✘

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### Licensed pharmacists 302 (2004)

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### Human resources



Enough relevant skilled resources to run a regulatory authority are available: ✔

Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: ✔

Pharmacy educational institution exists: ✔


School has specific activities or master programme on pharmaceuticals: ✔

#### Legend


 HIV, Malaria and/or TB product manufacturing site  
 Pharmaceutical education (master programme on pharmaceuticals)

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### Disease indicators



Malaria incidence  
**No malaria**



Tuberculosis incidence  
32/100,000





HIV prevalence  
0.70%


People who need ART: Not available  
People on ART: 1,824

---

### Upper middle income country

Gross National Income per capita:  
**US \$17,730 PPP** (current international \$) (2013) 

Total health expenditure per capita:  
**US \$864** 

Pharmaceutical expenditure as a % of total health expenditure:  
**Not available** 

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### Policies

Government has policy paper with objective to support pharmaceutical sector through procurement process: ✘

Domestic preference scheme exists: ✔

Infant/start-up manufacturing protection exists: ✘


Tax incentive exist: ✔

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): ✘

Government uses TRIPS flexibilities to promote access to medicines: ✔


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# 9. MOZAMBIQUE




## MOZAMBIQUE

### Population



**25.8 Million** (2013)  
8.5 % of SADC region

### MOZAMBIQUE




**Maputo**  
**Matola**

- Universidade Pedagógica
- Universidade Eduardo Mondlane
- Sociedade Moçambicana de Medicamentos

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### Current manufacturing



1 licensed pharmaceutical manufacturers in the country (2009)

1 manufacturer for HIV, Malaria and TB products

1 manufacturer for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states: ✗

Value of anti-retrovirals (ART) procured with PEPFAR funds: **US \$20,400,000** (2013)

Value of ART procured with Global Fund funds: **US \$12,900,000** (2012)

Value of anti-TB medication procured with Global Fund funds: **US \$865,000** (2013)



Value of anti-malarials procured with Global Fund funds: **US \$3,800,000** (2013)

### Life expectancy by gender

Female: **55**

Male: **53**

### Legend

-  HIV, Malaria and/or TB product manufacturing site
-  Pharmaceutical education (master programme on pharmaceuticals)

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### Regulation

National medicines regulation authority exists: ✔

Name of medicines regulatory authority: **Ministry of Health Pharmaceutical Department**

National Good Manufacturing Practices (GMP) standard exists: ✗

Manufacturers are regularly inspected for GMP: ✗

National quality control lab for medicines exists: ✔




Organisations involved in certification/licensing premises: **MoH Pharmaceutical Department, Ministry of Industry and Commerce for licensing of industrial activities, Instituto Nacional de Normalização e Qualidade (INNOQ - National Institute of Normalisation and Quality) for accreditation of international norms**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: ✗

### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013: **Not available**

### Disease indicators

-  Malaria incidence: 152/1,000
-  Tuberculosis incidence: 559/100,000
-  HIV prevalence: 6.20%


People who need ART: 1,355,164  
People on ART: 512,000


---


### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: ✔

### Low income country

Gross National Income per capita: **US \$1,140 PPP** (current international \$) (2013) 

Total health expenditure per capita: **US \$71** 

Pharmaceutical expenditure as a % of total health expenditure: **Not available** 

### Licensed pharmacists: 111

 (2009)

---

### Human resources

Enough relevant skilled resources to run a regulatory authority are available: ✔

Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: ✔

Pharmacy educational institution exists: ✔

School has specific activities or master programme on pharmaceuticals: ✔

### Policies

Government has policy paper with objective to support pharmaceutical sector through procurement process: ✔


Domestic preference scheme exists: ✔

Infant/start-up manufacturing protection exists: ✗

Tax incentive exist: ✔


Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): ✔

Government uses TRIPS flexibilities to promote access to medicines: ✗




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Regional Manufacturing of Medicines and Health Commodities in the SADC region


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TOWARDS A COMMON FUTURE







## NAMIBIA

### Population




**2.3 Million** (2013)  
0.8 % of SADC region

### Life expectancy by gender

Female	Male
	
<b>61</b>	<b>54</b>

### NAMIBIA




University of Namibia  
(currently training BPharm and Diploma in Pharmacy and planning a Masters in Pharmacy Regulation / Industry)

Windhoek


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#### Current manufacturing

1 licensed pharmaceutical manufacturers in the country (2009) 

0 manufacturers for HIV, Malaria and TB products

0 manufacturers for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states: 

Value of anti-retrovirals (ART) procured with PEPFAR funds: **no PEPFAR procurement in** (2013)


Value of ART procured with Global Fund funds: **US \$4,400,000** (2012)

Value of anti-TB medication procured with Global Fund funds: **no GF procurement**


Value of anti-malarials procured with Global Fund funds: **US \$72,000** (2012)


---


#### Regulation

National medicines regulation authority exists: 


Name of medicines regulatory authority: **Namibia Medicines Regulatory Council**

National Good Manufacturing Practices (GMP) standard exists: 

Manufacturers are regularly inspected for GMP: 

National quality control lab for medicines exists: 


Organisations involved in certification/licensing premises: **Namibia Medicines Regulatory Council**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: 


#### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013:  
**Not available**


#### Research and development


Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: 


#### Licensed pharmacists:


**285** (2009) 

#### Human resources


Enough relevant skilled resources to run a regulatory authority are available: 


Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: 


Pharmacy educational institution exists: 

School has specific activities or master programme on pharmaceuticals: 

#### Disease indicators

 Malaria incidence: 2/1,000


 Tuberculosis incidence: 651/100,000


 HIV prevalence: 10.60%


People who need ART: 211,556  
People on ART: 130,000


---


#### Policies


Government has policy paper with objective to support pharmaceutical sector through procurement process: 

Domestic preference scheme exists: 

Infant/start-up manufacturing protection exists: 


Tax incentive exist: 

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): 

Government uses TRIPS flexibilities to promote access to medicines: 

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# 11. SOUTH AFRICA




## SOUTH AFRICA

### Population



**52.7 Million (2013)**  
17.3 % of SADC region

### SOUTH AFRICA



**Legend**

- HIV, Malaria and/or TB product manufacturing site
- Pharmaceutical education (master programme on pharmaceuticals)

---

### Current manufacturing

42 licensed pharmaceutical manufacturers in the country (2009)

3 manufacturer for HIV, Malaria and TB products

2 manufacturer for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states:

Value of anti-retrovirals (ART) procured with PEPFAR funds: **US \$2,600,000** (2013)

Value of ART procured with Global Fund funds: **US \$25,500,000** (2013)

Value of anti-TB medication procured with Global Fund funds: **no GF procurement**

Value of anti-malarials procured with Global Fund funds: **no GF procurement**

### Life expectancy by gender

Female: **64**

Male: **57**

### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013:  
**Not available**

### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available:

---

### Regulation

National medicines regulation authority exists:

Name of medicines regulatory authority:  
**Medicines Control Council**

National Good Manufacturing Practices (GMP) standard exists:

Manufacturers are regularly inspected for GMP:

National quality control lab for medicines exists:

Organisations involved in certification/licensing premises:  
**Medicines Control Council**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists:

### Licensed pharmacists: 11,833 (2009)

### Human resources

Enough relevant skilled resources to run a regulatory authority are available:

Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available:

Pharmacy educational institution exists:

School has specific activities or master programme on pharmaceuticals:

### Disease indicators

Malaria incidence: 0.2/1,000

Tuberculosis incidence: 715/100,000

HIV prevalence: 12.10%

People who need ART: 4,679,005  
People on ART: 2,646,000

### Upper middle income country

Gross National Income per capita: **US \$ 12,530 PPP** (current international \$) (2013)

Total health expenditure per capita: **US \$1,121**

Pharmaceutical expenditure as a % of total health expenditure: **Not available**

---

### Policies

Government has policy paper with objective to support pharmaceutical sector through procurement process:

Domestic preference scheme exists:

Infant/start-up manufacturing protection exists:

Tax incentive exist:

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF):

Government uses TRIPS flexibilities to promote access to medicines:

✗

✓

✗


✓

✓

✗


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Regional Manufacturing of Medicines and Health Commodities in the SADC region




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TOWARDS A COMMON FUTURE







## SEYCHELLES


### Population

 **93,000** (2013)  
0.03 % of SADC region

### Life expectancy by gender

Female	Male
	
<b>78</b>	<b>70</b>

### SEYCHELLES



0 50 100Km  
0 50 Miles

---

### Current manufacturing

0 licensed pharmaceutical manufacturers in the country (2009)

0 manufacturers for HIV, Malaria and TB products

0 manufacturers for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states: ✔

Value of anti-retrovirals (ART) procured with PEPFAR funds: **no PEPFAR procurement** (2013)

Value of ART procured with Global Fund funds: **no GF procurement**

Value of anti-TB medication procured with Global Fund funds: **no GF procurement**

Value of anti-malarials procured with Global Fund funds: **no GF procurement**


### Availability


Median availability of selected generic medicines as per Global Health Observatory 2007-2013: **Not available**


### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: ✘

### Disease indicators

 Malaria incidence  
No malaria

 Tuberculosis incidence  
37/100,000

 HIV prevalence  
0.50%

People who need ART: Not available  
People on ART: 228

---

### Regulation

National medicines regulation authority exists: ✘

Name of medicines regulatory authority:  
**Not applicable / No registration**

National Good Manufacturing Practices (GMP) standard exists: ✘

Manufacturers are regularly inspected for GMP: ✘

National quality control lab for medicines exists: ✔

Organisations involved in certification/licensing premises:  
**None**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: ✘

### Licensed pharmacists: 9

(2009)

### Human resources

Enough relevant skilled resources to run a regulatory authority are available: ✘

Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: ✘

Pharmacy educational institution exists: ✘

School has specific activities or master programme on pharmaceuticals: ✘

### High income country (non OECD)

Gross National Income per capita:  
**US \$24,120 PPP**  
(current international \$) (2013)

Total health expenditure per capita:  
**US \$937**

Pharmaceutical expenditure as a % of total health expenditure:  
**3.1% (2011)**

---

### Policies

Government has policy paper with objective to support pharmaceutical sector through procurement process: ✘

Domestic preference scheme exists: ✘


Infant/start-up manufacturing protection exists: ✘

Tax incentive exist: ✘

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): ✔


Government uses TRIPS flexibilities to promote access to medicines: ✔

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## SWAZILAND

### Population

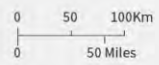


**1.2 million** (2013)  
0.04 % of SADC region

### SWAZILAND




University of Swaziland  
Mbabane




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#### Current manufacturing

1 licensed pharmaceutical manufacturer in the country (2009) 

0 manufacturers for HIV, Malaria and TB products

0 manufacturers for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states: 


Value of anti-retrovirals (ART) procured with PEPFAR funds: **no PEPFAR procurement** (2013)

Value of ART procured with Global Fund funds: **US \$9,600,000** (2010)


Value of anti-TB medication procured with Global Fund funds: **US \$976,000** (2012)


Value of anti-malarials procured with Global Fund funds: **US \$ 3,100,000** (2010)


#### Regulation

National medicines regulation authority exists: 


Name of medicines regulatory authority: **Not applicable / No registration**

National Good Manufacturing Practices (GMP) standard exists: 



Manufacturers are regularly inspected for GMP: 

National quality control lab for medicines exists: 

Organisations involved in certification/licensing premises: **Ministry of Health Environmental Office**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: 

#### Life expectancy by gender

Female	Male
	
<b>53</b>	<b>53</b>

#### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013: **Not available**


#### Research and development


Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: 


#### Licensed pharmacists: 44


 (2009)
 

#### Human resources


Enough relevant skilled resources to run a regulatory authority are available: 


Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: 

Pharmacy educational institution exists: 


School has specific activities or master programme on pharmaceuticals: 


#### Legend


HIV, Malaria and/or TB product manufacturing site 

Pharmaceutical education (master programme on pharmaceuticals) 

#### Disease indicators


 Malaria incidence: 0.5/1,000


 Tuberculosis incidence: 945/100,000


 HIV prevalence: 15.50%

People who need ART: 168,880  
People on ART: 98,000


#### Lower middle income


Gross National Income per capita: **US \$5,560 PPP** (current international \$) (2013) 


Total health expenditure per capita: **US \$564** 


Pharmaceutical expenditure as a % of total health expenditure: **Not available** 


#### Policies


Government has policy paper with objective to support pharmaceutical sector through procurement process: 

Domestic preference scheme exists: 

Infant/start-up manufacturing protection exists: 


Tax incentive exist: 

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): 


Government uses TRIPS flexibilities to promote access to medicines: 

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Regional Manufacturing of Medicines and Health Commodities in the SADC region


 SOUTHERN AFRICAN DEVELOPMENT COMMUNITY  
TOWARDS A COMMON FUTURE





## TANZANIA


### Population

 **49.2 Million** (2013)  
16.2 % of SADC region

### Life expectancy by gender

Female **65** Male **61**

### TANZANIA



### Current manufacturing

9 licensed pharmaceutical manufacturers in the country (2011)

3 manufacturer for HIV, Malaria and TB products

3 manufacturer for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states:

Value of anti-retrovirals (ART) procured with PEPFAR funds: **US \$11,500,000** (2013)

Value of ART procured with Global Fund funds: **US \$70,800,000** (2013)

Value of anti-TB medication procured with Global Fund funds: **US \$1,500,000** (2013)

Value of anti-malarials procured with Global Fund funds: **US \$25,600,000** (2012)

### Regulation

National medicines regulation authority exists: ✓

Name of medicines regulatory authority: **Tanzania Food and Drugs Authority (TFDA)**

National Good Manufacturing Practices (GMP) standard exists: ✓

Manufacturers are regularly inspected for GMP: ✓

National quality control lab for medicines exists: ✓

Organisations involved in certification/licensing premises: ✓

TFDA  
Tanzania Pharmacy Council (TPC)  
Tanzania Bureau of Standards (TBS)  
Tanzania Pesticide Control Board  
Public Health Private Laboratory Board  
National Environment Management Council

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: ✓

### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013:  
**Private 50% / Public 37.8%**

### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: **Unknown**

### Licensed pharmacists: 640 (2009)

### Human resources

Enough relevant skilled resources to run a regulatory authority are available: ✓

Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: ✓

Pharmacy educational institution exists: ✓

School has specific activities or master programme on pharmaceuticals: ✓

### Disease indicators

Malaria incidence: 174/1,000

Tuberculosis incidence: 172/100,000

HIV prevalence: 2.80%

People who need ART: 1,201,327  
People on ART: 518,000

### Low income country

Gross National Income per capita: **US \$2,380 PPP** (current international \$) (2013)

Total health expenditure per capita: **US \$126**

Pharmaceutical expenditure as a % of total health expenditure: **Not available**

### Policies

Government has policy paper with objective to support pharmaceutical sector through procurement process: ✗

Domestic preference scheme exists: ✓


Infant/start-up manufacturing protection exists: ✓

Tax incentive exist: ✓

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): ✓


Government uses TRIPS flexibilities to promote access to medicines: ✓

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# ZAMBIA

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### Current manufacturing

5 licensed pharmaceutical manufacturers in the country (2009)

2 manufacturers for HIV, Malaria and TB products

0 manufacturers for HIV, Malaria and TB products willing to go for WHO pre-qualification

Country imports HIV, Malaria and TB products from SADC member states:

Value of anti-retrovirals (ART) procured with PEPFAR funds: **US\$ 25,900,000 for HIV (2013)**

Value of ART procured with Global Fund funds: **US\$ 62,400,000 for HIV (2013)**

Value of anti-TB medication procured with Global Fund funds: **US\$ 1,600,000 for TB (2014)** (no GF procurement)

Value of anti-malarials procured with Global Fund funds: **US\$ 4,700,000 (2012)**

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### Regulation

National medicines regulation authority exists: ✔

Name of medicines regulatory authority: **Zambia Medicines Regulatory Authority**

National Good Manufacturing Practices (GMP) standard exists: ✔


Manufacturers are regularly inspected for GMP: ✔

National quality control lab for medicines exists: ✔

Organisations involved in certification/licensing premises: **Zambia Medicines Regulatory Authority**

Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: ✔

### Population

 **14.5 Million (2013)**  
4.8 % of SADC region

### Life expectancy by gender

Female **60** Male **57**

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### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013:  
**Private 81.3% / Public 74%**

### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: ✘

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### Licensed pharmacists: 309 (2010)

### Human resources


Enough relevant skilled resources to run a regulatory authority are available: ✔

Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: ✔

Pharmacy educational institution exists: ✔

School has specific activities or master programme on pharmaceuticals: ✔

### ZAMBIA




**Legend**


- HIV, Malaria and/or TB product manufacturing site
- Pharmaceutical education (master programme on pharmaceuticals)


Map labels: Baxy Pharmaceuticals Manufacturing Company Limited, Ndola, Lusaka, Pharmanova Zambia Limited, University of Zambia

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### Disease indicators

 Malaria incidence: **382/1,000**

 Tuberculosis incidence: **338/100,000**

 HIV prevalence: **7.50%**

People who need ART: 961,071  
People on ART: 572,000

### Lower middle income country

Gross National Income per capita: **US\$ 3,580 PPP** (current international \$) (2013)

Total health expenditure per capita: **US\$ 192**

Pharmaceutical expenditure as a % of total health expenditure: **0.14%**

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### Policies

Government has policy paper with objective to support pharmaceutical sector through procurement process: ✘

Domestic preference scheme exists: ✔


Infant/start-up manufacturing protection exists: ✘

Tax incentive exist: ✔

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): ✘


Government uses TRIPS flexibilities to promote access to medicines: ✘





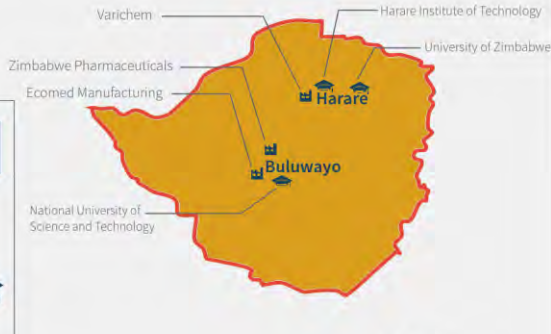
## ZIMBABWE

### Population




**14.1 Million** (2013)  
4.6 % of SADC region

### ZIMBABWE




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### Current manufacturing



13 licensed pharmaceutical manufacturers in the country (2011)  
3 manufacturers for HIV, Malaria and TB products

1 manufacturers for HIV, Malaria and TB products willing to go for WHO pre-qualification



Country imports HIV, Malaria and TB products from SADC member states: 

Value of anti-retrovirals (ART) procured with PEPFAR funds: **US \$12,000,000** (2013)  
Value of ART procured with Global Fund funds: **US \$47,000,000** (2014)



Value of anti-TB medication procured with Global Fund funds: **Not applicable** (no GF procurement)

Value of anti-malarials procured with Global Fund funds: **US \$662,500** (2012)

### Life expectancy by gender


Female  **61**  
Male  **56**

### Legend


 HIV, Malaria and/or TB product manufacturing site  
  
 Pharmaceutical education (master programme on pharmaceuticals)


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### Regulation

National medicines regulation authority exists: 


Name of medicines regulatory authority: **Medicines Control Authority of Zimbabwe**

National Good Manufacturing Practices (GMP) standard exists: 

Manufacturers are regularly inspected for GMP: 

National quality control lab for medicines exists: 


Organisations involved in certification/licensing premises: **Medicines Control Authority of Zimbabwe**


Pro-active plan or standard to prevent production and/or importation of substandard and/or counterfeit products on the market exists: 


### Availability

Median availability of selected generic medicines as per Global Health Observatory 2007-2013: **Not available**

### Disease indicators

 Malaria incidence: 32/1,000

 Tuberculosis incidence: 409/100,000

 HIV prevalence: 14.80%


People who need ART: 1,155,793  
People on ART: 672,000


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### Research and development

Financing (internal and external) for researching medicines and health commodities for HIV, TB and malaria is available: **Unknown**


### Low income country


Gross National Income per capita: **US \$1,610 PPP** (current international \$) (2013) 


Total health expenditure per capita: **US \$25** 


Pharmaceutical expenditure as a % of total health expenditure: **Not available** 


### Policy


Government has policy paper with objective to support pharmaceutical sector through procurement process: 

Domestic preference scheme exists: 

Infant/start-up manufacturing protection exists: 

Tax incentive exist: 


Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): 


Government uses TRIPS flexibilities to promote access to medicines: **TRIPS flexibilities were used in the past.** 


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### Licensed pharmacists: 567 (2011)

### Human resources


Enough relevant skilled resources to run a regulatory authority are available: 


Enough relevant skilled resources to run at least one GMP compliant manufacturing plant for medicines and/or commodities production are available: 


Pharmacy educational institution exists: 


School has specific activities or master programme on pharmaceuticals: 


### Policies


Government has policy paper with objective to support pharmaceutical sector through procurement process: 

Domestic preference scheme exists: 

Infant/start-up manufacturing protection exists: 


Tax incentive exist: 

Duty free importation taxes are different between Active Pharmaceutical Ingredients (API) or Finished Dosage Forms (FDF): 

Government uses TRIPS flexibilities to promote access to medicines: **TRIPS flexibilities were used in the past.** 

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