

# **SA PORT HEALTH: REGULATORY PROCESSES IMPORT AND EXPORTATION OF HEALTH PRODUCTS**



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REPUBLIC OF SOUTH AFRICA

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# PURPOSE

- Governance Matters
- Documents for Importation
- Processes to be followed
- Roles of different Stakeholders
  - SARS
  - Port Health
  - MCC/NDoH



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# Governance Matters

- Section 27 of the Constitution (Act 108 of 1998)
  - Every citizen of the Republic of South Africa has the right to access to healthcare facilities
- Medicines and Related Substances Act, 1965 (Act 101 of 1965)
  - Makes provision for the control and access to medicines
  - Provides for medicines registration.
  - Provides for the registration of facilities whereby medicines can be manufactured and stored
  - Provides for procedures to be adopted when selling medicines
  - Provides for dedicated port of entries for medicines
  - Provides for the appointment of Inspectors



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# Governance Matters

- ❑ Promotion of Administration Justice Act, 2000 (Act 3 of 2000)
- ❑ Promotion of Access to Information Act, 2000 (Act 2 of 2000)



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# Control of Access to Medicines

Medicine means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

- (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or
- (b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine;



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# Control of Access to Medicines

## □ Section 22A:

- Only pharmacist, doctors, veterinarians, those registered under SA Allied Health Professional
- Nurses under certain conditions
- Prescription presentation



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# PORTS OF ENTRY

## AIR BORDERS

1. OR TAMBO INTERNATIONAL AIRPORT - GAUTENG
2. DURBAN INTERNATIONAL AIRPORT - KZN
3. CAPE TOWN INTERNATIONAL AIRPORT - WC
4. UPINGTON INTERNATIONAL AIRPORT - NC
5. PILANESBERG INTERNATIONAL AIRPORT - MW
6. POLOKWANE INTERNATIONAL AIRPORT - LIM
7. KRUGER MPUMALANGA INTERNATIONAL AIRPORT - MPU
8. PORT ELIZABETH INTERNATIONAL AIRPORT - EC
9. BLOEMFONTEIN INTERNATIONAL AIRPORT - FS
10. LANSERIA INTERNATIONAL AIRPORT - GAUTENG

## TRANSFRONTIER CONSERVATION AREAS

1. Ai-Ais - Richtersveld
2. Kgalagadi
3. Limpopo/Shashe
4. Great Limpopo
5. Lubombo
6. Maloti - Drakensberg

## RAIL BORDERS

1. NARROGAS / MAKOP (4)
2. RAMATLABAMA (15)
3. BEIT BRIDGE (25)
4. LEBOMBO (27)
5. GOLELA (38)
6. MASERU BRIDGE (44)

LAND BORDER DISTANCE: 4 750km

SEA BORDER DISTANCE: 2 800km

## SEA BORDERS

1. SALDANHA BAY - WESTERN CAPE
2. CAPE TOWN - WESTERN CAPE
3. SIMONSTAD (NAVAL BASE) - WESTERN CAPE
4. MOSSEL BAY HARBOUR - WESTERN CAPE
5. PORT ELIZABETH HARBOUR - EASTERN CAPE
6. EAST LONDON HARBOUR - EASTERN CAPE
7. DURBAN HARBOUR - KWAZULU NATAL
8. RICHARDS BAY HARBOUR - KWAZULU NATAL
9. CITY DEEP (Container depot) - GAUTENG

## LAND BORDERS

### NAMIBIA

1. ALEXANDER BAY - NC
2. VIOOLDRIFT - NC
3. ONSEEPKANS - NC
4. NAKOP - NC
5. ROEMIEPUT - NC
6. RIETfontein - NC
55. SEHDELINGSDRIFT - NC

### BOTSWANA

7. TWEE RIVIEREN - NC
8. GEMSBOK - NC
9. MIDDELPUTS - NC
10. McCARTHY'S RUST - NC
11. MAKOPONG - MW
12. BRAY - MW
13. BOSHOEK - MW

### LESOTHO

14. MAKGOBISTAD - MW
15. RAMATLABAMA - MW
16. SKILPADSHEK - MW
17. SWARTKOPfontein - MW
18. KOPfontein - MW
19. DERDEPOORT - MW
20. STOCKPOORT - LIM
21. GROBLERSBRUG - LIM
22. ZANZIBAR - LIM
23. PLATJAN - LIM
24. PONTDRIFT - LIM

### ZIMBABWE

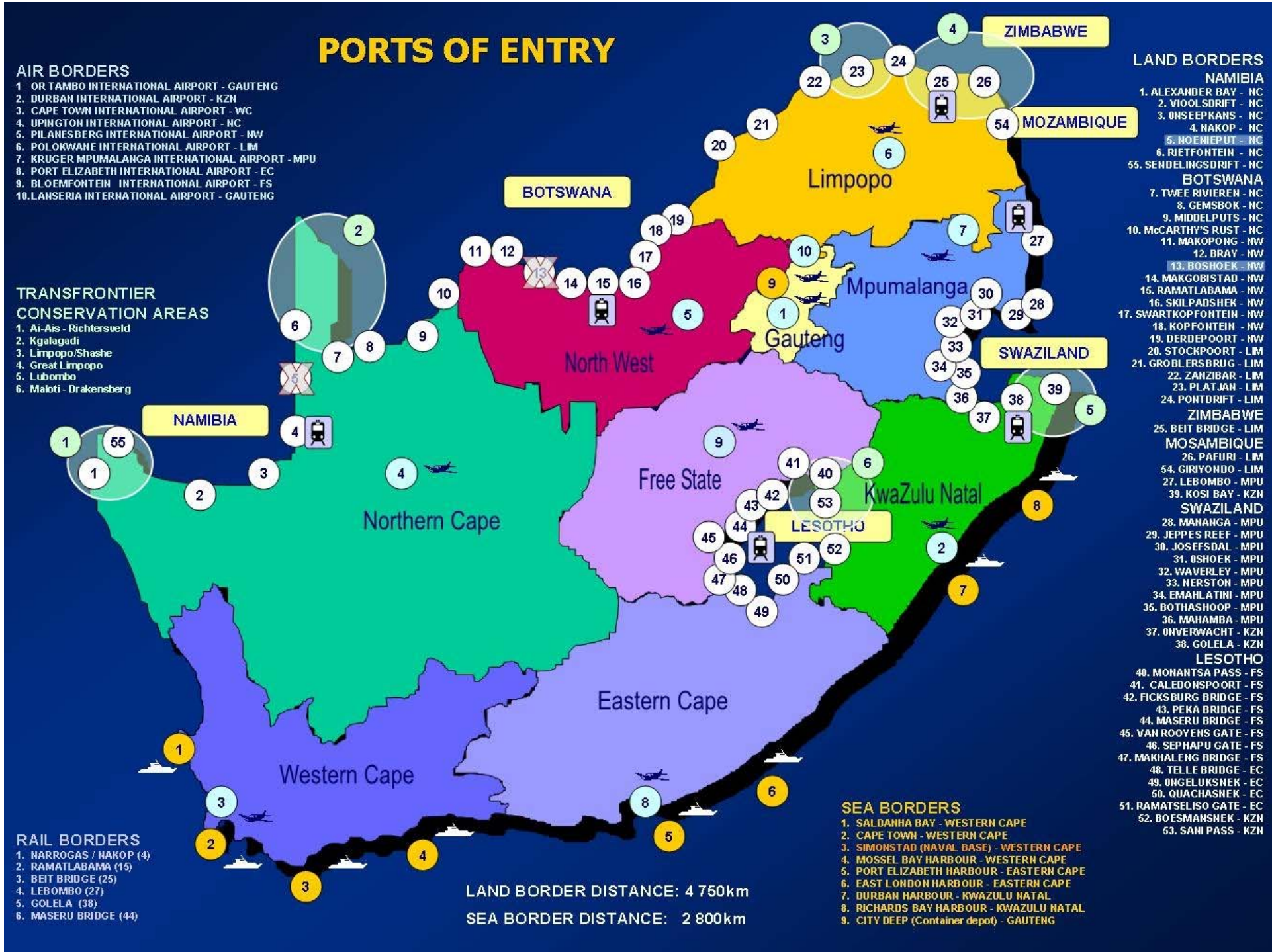
25. BEIT BRIDGE - LIM
26. PAFURI - LIM
54. GIRYONDO - LIM
27. LEBOMBO - MPU
39. KOSI BAY - KZN

### SWAZILAND

28. MANANGA - MPU
29. JEPPE'S REEF - MPU
30. JOSEFSDAL - MPU
31. OSHOEK - MPU
32. WAVERLEY - MPU
33. NERSTON - MPU
34. EMAHLATINI - MPU
35. BOTHASHOOP - MPU
36. MAHAMBAMBA - MPU
37. ONVERWACHT - KZN
38. GOLELA - KZN

### LESOTHO

40. MONANTSA PASS - FS
41. CALEDONSPPOORT - FS
42. FICKSBURG BRIDGE - FS
43. PEKA BRIDGE - FS
44. MASERU BRIDGE - FS
45. VAN ROOYENS GATE - FS
46. SEPHAPU GATE - FS
47. MAKHALENG BRIDGE - FS
48. TELLE BRIDGE - EC
49. ONGELUKSNEK - EC
50. QUACHASNEK - EC
51. RAMATSELISO GATE - EC
52. BOESMANSNEK - KZN
53. SAHI PASS - KZN





# Controls on Importation of Medicines

## REGULATION 12: IMPORTATION OF MEDICINES INTO THE REPUBLIC

(1) No person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C of the Act, read together with regulation 7, into the Republic except through one of the following ports of entry:

- Cape Town Airport or harbour;
- Port Elizabeth Airport or harbour;
- Durban Airport or harbour; and
- OR Tambo International Airport (JHB)

# Controls on Importation of Medicines

## REGULATION 12: continues

- (2) A person can only import a medicine or scheduled substance if such person:
- (a) is licensed in terms of the Act to import medicines; and
  - (b) in the case of unregistered medicines, is authorised by the Council to import such unregistered medicines.

# Controls on Importation of Medicines

- Port of Exit – any border post
- Goods in Transit – facilitated through designated port of entries



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# Goods in Transit

## □ REGULATION 13:

(1) Medicines, scheduled substances and mixtures containing scheduled substances that are transmitted through the Republic shall:

- a) while in the Republic be stored in a bonded warehouse which is registered with the Council; and
- b) not be manipulated while in the bonded warehouse unless authorised by the Council.

(2) A bonded warehouse referred to in subregulation (1) must comply with good storage conditions as determined by the Council.

# Documents Required for Importation of Medicines

- Registered Medicines
  - Copy of Registration Certificate
  - Import permit – narcotic drugs and psychotropic substances
  - Copy of company's registration certificate
  
- Unregistered Medicines and experimental drugs
  - Section 21 Approval
  - Section 15 Approval
  - Regulation 16 – Personal use



# Process to be Followed

## □ Customs:

- Receives documents from clearing agent of importer
- If product imported is medicine or raw materials – detained for Port Health
- If documents are acceptable – passed over to Port Health

## □ Port Health

- Documents from Customs, satisfactory – approve cargo
- Narcotics or psychotropic substances – accompanied by Import Permits issued by DG of DoH
- If Port Health Officials are not satisfied with the information - referred to Law Enforcement for ruling or inspection

# Process to be Followed

## □ Law Enforcement Referrals:

- No import permits for narcotics or psychotropics
- Product registration certificates not attached
- Importation of medicines by Wholesalers and Importers not registered in terms of section 22C of Act 101
- Port Health may refer imported products when in doubt

# Process to be Followed

- Importation of Unregistered Medicines:
  - Section 21 – Council authorisation – Port Health only releases the unregistered medicine – Council approval
  - Samples Required for Product Registration in Terms of Section 15 – Importer will be issued with a letter of authorisation
  - Medicines for Personal use by Persons Visiting the Republic of South Africa – persons visiting RSA – apply for permission to bring their personal medicine – letter of authorisation – Port Health / Port of Entry

# Roles of different stakeholders

## SARS

- Guardians
- Assessment of Documents
- Referrals to relevant bodies (for medicines based on Restricted and Prohibited list)

## Port Health

- In case of doubt, refer to MCC

## PROHIBITED AND RESTRICTED CHAPTER 29 ORGANIC CHEMICALS

HEADING	DESIGNATION OF GOODS	RESTRICTION	AUTHORITY	ACTION
	<p>NOTES:</p> <p>29.1 Habit forming drugs as listed in chapter 30</p> <p>29.4 Products of subheading 2937.00 may only be imported through the following ports;</p> <p>a. Cape Town (Airport and Harbor)</p> <p>b. Port Elizabeth</p> <p>c. Durban (Airport and Harbor)</p> <p>d. ORTIA</p>	Narcotic or Psychotropic Permit from DG: Department of Health	Medicines and Related Substances Act; Act 101 of 1965	Detain for Port Health Endorse Permit
2921.46	Amfetamine(INN)Benzfetamine(INN) Dexamfetamine(INN),Etilamfetamine(INN) Fencamfamin(INN)Lefetamine(INN) Levamfetamine(INN),Mefenorex(INN)and Phentermine(INN);salts thereof Bezylpiperazine(INN): salts thereof	Psychotropic Permit from DG: Department of Health	Medicines and Related Substances Act;Act 101 of 1965	Detain for Port Health Endorse Permit
2922.14	Dextropropoxyphene(INN)and its salts	Narcotic Permit from DG: Department of Health	Medicines and Related Substances Act;Act 101 of 1965	Detain for Port Health Endorse Permit
2922.31 2922.44	Amfepramone(INN),Methadone(INN)and Normethadone(INN) salts thereof Tilidine (INN) and its salts	Psychotropic/ Narcotic Permit from DG: Department of Health	Medicines and Related Substances Act;Act 101 of 1965	Detain for Port Health Endorse Permit



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# THANK YOU

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