GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE *77* OF *2007*

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by Council.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to regular review regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The registration dossier is subject to review at intervals as determined by Council.
8. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted an the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate af release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for tot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

MRF 15

Registration number:	29/34/0761
Name of medicine:	AIR LIQUIDE MEDICAL NITROUS OXIDE
Dosage form:	GAS
Active ingredients:	EACH CYLINDER CONTAINS: NITROUS OXIDE 100,0 %
Conditions of registration:	1 2, 3, 4, 5, ≤
Applicant:	AIR LIQUIDE (PTY) LTD
Manufacturer:	AIR LIQUIDE, ALRODE, GERMISTON
Packer:	AIR LIQUIDE, ALRODE, GERMISTON
Laboratory: FPRC/FPRR:	AIR LIQUIDE, ALRODE, GERMISTON
Shelf-life:	24 months
Date of registration:	1 DECEMBER Z 6 ≤

MRF 15

Registration number:	32/7.1.[illegible]Z8
Name of medicine:	DILTIAZEM HEXAL 90
Dosage form:	TABLETS
Active ingredients:	EACH TABLET CONTAINS: DILTIAZEM HYDROCHLORIDE 90,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Laboratory: FPRC:	HEXAL AG, HOLZKIRCHEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPF	HEXAL PHARMA, PINETOWN, RSA
She ife:	24 months (provisional)
Dat(f regist	1 DECEMBER 2006

MRF 15

Registration number:		34/16.1/0366
Name of medicine:		ILIADIN 0,01 %
Dosage form:		DROPS
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: OXYMETAZOLINE HYDROCHLORIDE 0,1 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK (PTY) LTD
Manufacturer:		MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
	FPRR:	MERCK, MODDERFONTEIN, RSA
Shelf-life:		36 months
Date of registration		1 DECEMBER 2006

MRF 15

Registration number:		36/2.7/0183
Name of medicine:		EXCEDRIN
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PARACETAMOL 250,0 mg ASPIRIN 250,0 mg CAFFEINE 65,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:		BRISTOL-MYERS SQUIBB, MOUNT VERNON, INDIANA, USA
Packer		BRISTOL-MYERS SQUIBB, MOUNT VERNON, INDIANA, USA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA
Laboratory: FPRC:		BRISTOL-MYERS SQUIBB, MOUNT VERNON, INDIANA, USA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON CONSULTING CHEMICAL LABORATORIES, ATLASVILLE BOKSBURG, RSA
	FPRR	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:	37/30.1/0221
Name of medicine:	TRITANRIX-HB + HIBERIX COMBO PACK
Dosage form:	INJECTION
Active ingredients:	EACH COMBO PACK CONTAINS: TRITANRIX-HB INJECTION CONTAINING PER 0,5 ml DOSE: DIPHTHERIA TOXOID 30,0 I.U. TETANUS TOXOID 60,0 I.U. INACTIVATED BORDETELLA PERTUSSIS 4,0 I.U. HEPATITIS B VIRUS SURFACE ANTIGEN 10,0 ug HIBERIX VACCINE CONTAINING PER 0,5 ml DOSE: HAEMOPHILUS INFLUENZA TYPE b 10,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS s.a, RIXENSART, BELGIUM SACHSISCHES SERUMWERK DRESDEN, DRESDEN, GERMANY
Packer:	GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING s.a, RIXENSART, BELGIUM SACHSISCHES SERUMWERK DRESDEN, DRESDEN, GERMANY GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING s.a, WAVRE, BELGIUM GLAXOSMITHKLINE S.A., EPPING INDUSTRIA
Laboratory: FPRC: FPRC/FPRR	GLAXOSMITHKLINE BIOLOGICALS s.a, RIXENSART, BELGIUM GLAXOSMITHKLINE S.A., EPPING INDUSTRIA
Shelf-life:	36 months
Date of registration	1 DECEMBER 2006

MRF 15

Registration number:	37/26/0158
Name of medicine:	EPIRUBICIN-LEMERY 10 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: EPIRUBICIN HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	KEY ONCOLOGICS (PTY) LTD
Manufacturer:	LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
Packer:	LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
Laboratory: FPRC: FPRR:	LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA KEY ONCOLOGICS, SANDTON, RSA
Shelf-life:	24 months
Date of registration	1 DECEMBER 2006

MRF 15

Registration number:		37/26/0539
Name of medicine:		EPIRUBICIN-LEMERY 50 mg
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: EPIRUBICIN HYDROCHLORIDE 50 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		KEY ONCOLOGICS (PTY) LTD
Manufacturer:		LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
Packer:		LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
Laboratory:	FPRC:	LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	KEY ONCOLOGICS, SANDTON, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		37/11.1/0629
Name of medicine:		ASACOL 800
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MESALAZINE 800,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AVENTIS PHARMA (PTY) LTD
		IE,
		IE, GERMANY AND
FPRC/FPRR:		AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		38/2.6.5/0030
Name of medicine		ZYPREXA VELOTAB 5 mg
Dosage form		TABLET
Active ingredients:		EACH TABLET CONTAINS: OLANZAPINE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ELI LILLY (S.A.) (PTY) LTD
Manufacturer:		CARDINAL HEALTH, SWINDON, WILTSHIRE, UK
Packer:		ELI LILLY & CO, BASINGSTOKE, HAMPSHIRE UK PCI SERVICES, SHOTGATE, ESSEX, UK PCI SERVICES, WESTHOUGHTON, BOLTON, UK PCI SERVICES, CORBY, NORTHAMPTONSHIRE, UK
Laboratory:	FPRC:	ELI LILLY & CO, BASINGSTOKE, HAMPSHIRE UK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	ELI LILLY, BRYANSTON, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		38/11.10/0070
Name of medicine:		MOASON 500 SUPPOSITORIES
Dosage form:		SUPPOSITORY
Active ingredients:		EACH SUPPOSITORY CONTAINS: MESALAZINE 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ASTELLAS PHARMA (PTY) LTD
Manufacturer:		AMCAPHARM GmbH, ROSBACH, GERMANY ASTELLAS PHARMA SpA, MILAN, ITALY
Packer:		AMCAPHARM GmbH, ROSBACH, GERMANY ASTELLAS PHARMA SpA, MILAN, ITALY
Laboratory:	FPRC:	AMCAPHARM GmbH, ROSBACH, GERMANY ASTELLAS PHARMA SpA, MILAN, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	ASTELLAS PHARMA, BEDFORDVIEW, RSA
Shelf-life:		24 months (provisional)
Date of registration		1 DECEMBER 2006

MRF 15

Registration number:	38/11.10/0071
Name of medicine:	MOASON 250 SUPPOSITORIES
Dosage form:	SUPPOSITORY
Active ingredients:	EACH SUPPOSITORY CONTAINS: MESALAZINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ASTELLAS PHARMA (PTY) LTD
Manufacturer:	AMCAPHARM GmbH, ROSBACH, GERMANY ASTELLAS PHARMA SpA, MILAN, ITALY
Packer:	AMCAPHARM GmbH, ROSBACH, GERMANY ASTELLAS PHARMA SpA, MILAN, ITALY
Laboratory: FPRC:	AMCAPHARM GmbH, ROSBACH, GERMANY ASTELLAS PHARMA SpA, MILAN, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ASTELLAS PHARMA, BEDFORDVIEW, RSA
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	38/2.6.5/0073
Name of medicine:	ZYPREXA VELOTAB 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	CARDINAL HEALTH, SWINDON, WILTSHIRE, UK
Packer:	ELI LILLY & CO, BASINGSTOKE, HAMPSHIRE UK PCI SERVICES, SHOTGATE, ESSEX, UK PCI SERVICES, WESTHOUGHTON, BOLTON, UK PCI SERVICES, CORBY, NORTHAMPTONSHIRE, UK
Laboratory: FPRC:	ELI LILLY & CO, BASINGSTOKE, HAMPSHIRE UK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	ELI LILLY, BRYANSTON, RSA
Shelf-life:	24 months
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	38/13.1/0194
Name of medicine:	POVIGEL
Dosage form:	GEL
Active ingredients:	EACH 1,0 g GEL CONTAINS: POVIDONE IODINE 100,0 mg
Conditions of registration	1, 2, 3, 4, 5, 6
Applicant:	MEDICINE DEVELOPERS INTERNATIONAL cc
Manufacturer	IMPILO DRUGS (1966), ISITHEBE, KZN, RSA
Packer:	IMPILO DRUGS (1966), ISITHEBE, KZN, RSA
Laboratory: FPRC	IMPILO DRUGS (1966), ISITHEBE, KZN, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG CONSULTING MICROBIOLOGICAL LABORATORIES, MOREHILL, BENONI SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICALS SERVICES, SILVERTONDALE, RSA
FPRR:	MDI cc, MENLO PARK, PRETORIA
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	38/30.3/0281
Name of medicine:	IMMUNINE 200 I.U
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: HUMAN COAGULATION FACTOR IX 200,0 I.U
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM CRITICAL CARE LTD
Manufacturer:	BAXTER AG, INDUSTRIESTRASSE,VIENNA, AUSTRIA BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA BAXTER HEALTHCARE CORP., ROCHESTER, MI, USA BAXTER S.p.A., RIETI, RUFINA, ITALY BAXTER AG, LANGE ALLEE 24-B, VIENNA, AUSTRIA
Packer:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Laboratory: FPRC:	BAXTER AG, LANGE ALLEE 24, A-1220, VIENNA, AUSTRIA BAXTER AG, LANG ALLEE 24, A-1220, VIENNA, AUSTRIA BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA BAXTER AG, ORTH/DONAU, AUSTRIA
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:		38/30.3/0282
Name of medicine:		IMMUNINE 600 I.U.
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: HUMAN COAGULATION FACTOR IX 600,0 I.U.
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ADCOCK INGRAM CRITICAL CARE LTD
Manufacturer:		BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA BAXTER HEALTHCARE CORP., ROCHESTER, MI, US BAXTER S.p.A., RIETI, RUFINA, ITALY BAXTER AG, LANGE ALLEE 24-B, VIENNA, AUSTRIA
Packer:		ADCOCK INGRAM CRITICAL CARE; AEROTON, JOHANNESBURG BAXTER AG, LANGE ALLEE 24, VIENNA, AUSTRIA
Laboratory :	FPRC:	BAXTER AG, LANG ALLEE 24, A-1220, VIENNA, AUSTRIA BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA BAXTER AG, ORTH/DONAU, AUSTRIA
	FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		38/30.3/0283
Name of medicine:		IMMUNINE 1 200 I.U.
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: HUMAN COAGULATION FACTOR IX 1 200,0 I.U.
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ADCOCK INGRAM CRITICAL CARE LTD
Manufacturer:		BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA BAXTER HEALTHCARE CORP., ROCHESTER, MI BAXTER S.p.A., RIETI, RUFINA, ITALY BAXTER AG, LANGE ALLEE 24-B, VIENNA, AUSTRIA
Packer:		ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG BAXTER AG, LANGE ALLEE 24, A-1220, VIENNA, AUSTRIA
Laboratory: FPRC:		BAXTER AG, LANG ALLEE 24, A-1220, VIENNA, AUSTRIA BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA BAXTER AG, ORTH/DONAU, AUSTRIA
	FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A38/21.2/0681
Name of medicine:		FORMINAL 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		GULF DRUG COMPANY (PTY) LTD
Manufacturer:		ALEMBIC LTD, GUJARAT, INDIA
Packer:		ALEMBIC LTD, GUJARAT, INDIA
Laboratory:	FPRC:	ALEMBIC LTD, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA PHARMA-Q, INDUSTRIA WEST, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA CONSULTING MICROBIOLOGICAL LABORATORY, MOREHILL, BOKSBURG, RSA
	FPRR:	GULF DRUG CO., MOUNT EDGECOMBE, RSA
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A38/21.2/0682
Name of medicine:		FORMINAL 850
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		GULF DRUG COMPANY (PTY) LTD
Manufacturer:		ALEMBIC LTD, GUJARAT, INDIA
Packer:		ALEMBIC LTD, GUJARAT, INDIA
Laboratory:	FPRC:	ALEMBIC LTD, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA PHARMA-Q, INDUSTRIA WEST, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA CONSULTING MICROBIOLOGICAL LABORATORY MOREHILL, BOKSBURG, RSA
	FPRR:	GULF DRUG CO., MOUNT EDGECOMBE, RSA
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

Registration number:		A38/7.5/0710
Name of medicine:		BIOVAC SIMVASTATIN 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, ONTARIO, CANADA
Packer:		RX MANUFACTURING INC, ONTARIO, CANADA CONTRACT PHARMACEUTICALS, ONTARIO, CANADA QUALITY LIMITED, BRIERCLIFFE, BURNLEY,UK
Laboratory:	FPRC:	RX MANUFACTURING INC, ONTARIO, CANADA QUALITY LIMITED, BRIERCLIFFE, BURNLEY,UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SEDEK AGRIKEM, KAMEELDRIFT
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

Registration number:		A38/7.5/0711
Name of medicine:		BIOVAC SIMVASTATIN 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS SIMVASTATIN 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, ONTARIO, CANADA
Packer:		RX MANUFACTURING INC, ONTARIO, CANADA CONTRACT PHARMACEUTICALS, ONTARIO, CANADA QUALITY LIMITED, BRIERCLIFFE, BURNLEY,UK
Laboratory:	FPRC:	RX MANUFACTURING INC, ONTARIO, CANADA QUALITY LIMITED, BRIERCLIFFE, BURNLEY,UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SEDEK AGRIKEM, KAMEELDRIFT
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:	A39/7.5/0017
Name of medicine:	ASPAVOR 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
	PFIZER LABORATORIES (PTY) LTD
	GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LTD PDPL, VEGA BEJA, PUERTO RICO PFIZER IRELAND PHARMACEUTICALS, CO CORK, IRELAND
	GODECKE GmbH, FREIBURG, GERMANY
FPRC:	GODECKE GmbH, FREIBURG, GERMANY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN
FPRR:	PFIZER LABORATORIES, SANDTON, RSA
Shelf-life:	36 months
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	A8/7.5/0717
Name of medicine:	BIOVAC SIMVASTATIN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 6
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	RX MANUFACTURING INC, ONTARIO, CANADA
Packer:	RX MANUFACTURING INC, ONTARIO, CANADA CONTRACT PHARMACEUTICALS, ONTARIO, CANADA QUALITY LIMITED, BRIERCLIFFE, BURNLEY,UK
Laboratory: FPRC	RX MANUFACTURING INC, ONTARIO, CANADA QUALITY LIMITED, BRIERCLIFFE BURNLEY,UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SEDEK AGRIKEM, KAMEELDRIFT
FPRR	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:		A39/7.5/0018
Name of medicine:		ASPAVOR 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PFIZER LABORATORIES (PTY) LTD
Manufacturer:		GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LTD PDPL, VEGA BEJA, PUERTO RICO PFIZER IRELAND PHARMACEUTICALS, CO CORK, IRELAND
Packer:		GODECKE GmbH, FREIBURG, GERMANY
Laboratory:	FPRC:	GODECKE GmbH, FREIBURG, GERMANY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN
	FPRR:	PFIZER LABORATORIES, SANDTON, RSA
Shelf-life:		36 months
Date of registration		1 DECEMBER 2006

MRF 15

Registration number:		A39/7.5/0019
Name of medicine:		ASPAVOR 40
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PFIZER LABORATORIES (PTY) LTD
Manufacturer:		GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LTD PDPL, VEGA BEJA, PUERTO RICO PFIZER IRELAND PHARMACEUTICALS, CO CORK, IRELAND
Packer:		GODECKE GmbH, FREIBURG, GERMANY
Laboratory:	FPRC:	GODECKE GmbH, FREIBURG, GERMANY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN
	FPRR:	PFIZER LABORATORIES, SANDTON, RSA
Shelf-life:		36 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A39/20.2.8/0112
Name of medicine:		VARI-NEVIRAPINE 200 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		LEBASI PHARMACEUTICALS cc
Manufacturer:		VARICHEM PHARMACEUTICALS (PVT) LTD, HARARE, ZIMBABWE
Packer:		VARICHEM PHARMACEUTICALS (PVT) LTD, HARARE, ZIMBABWE
Laboratory:	FPRC:	VARICHEM PHARMACEUTICALS (PVT) LTD, HARARE, ZIMBABWE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	LEBASI PHARMACEUTICALS, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2 0 6

MRF 15

Registration number:		A39/11.5/0115
Name of medicine:		ISPAGEL
Dosage form:		POWDER
Active ingredients:		EACH SACHET CONTAINS: ISPAGHULA HUSK 3,5 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		LABORATORIOS BELMAC S.A., ZARAGOZA, SPAIN
Packer:		LABORATORIOS BELMAC S.A., ZARAGOZA, SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory:	FPRC:	LABORATORIOS BELMAC S.A., ZARAGOZA, SPA IN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA IMPILO DRUGS, ISITHEBE, KZN
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE RSA
Shelf-life:		48 months
Date of registration:		1 DECEMBER 2006

H

Registration number:		A39/11.5/0135
Name of medicine:		PHARMA DYNAMICS ISPAGHULA HUSK
Dosage form:		POWDER
Active ingredients:		EACH SACHET CONTAINS: ISPAGHULA HUSK 3,5 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		LABORATORIOS BELMAC S.A., ZARAGOZA, SPAIN
Packer:		LABORATORIOS BELMAC S.A., ZARAGOZA, SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory:	FPRC:	LABORATORIOS BELMAC S.A., ZARAGOZA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA IMPILO DRUGS, ISITHEBE, KZN
	FPRR	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		48 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A39/20.2.8/0279
Name of medicine:		DAS – STAVUDINE 40 mg
Dosage form:		CAPSULES
Active ingredients:		EACH CAPSULE CONTAINS: STAVUDINE 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		STRIDES S.A. (PTY) LTD
Manufacturer:		STRIDES ARCOLAB LTD ANEKAL TALUK, BANGALORE, INDIA
Packer:		STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
Laboratory:	FPRC:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA NOVARTIS S.A., SPARTAN, KEMPTON PARK
	FPRR:	STRIDES S.A., ARCADIA, PRETORIA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A39/23/0182
Name of medicine:		AMINOVEN INFANT 10 %
Dosage form:		SOLUTION
Active ingredients:		EACH 1000,0 ml SOLUTION CONTAINS: TOTAL AMINO ACIDS 100,0 g SEE ADDENDUM
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:		FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA
Packer:		FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA
Laboratory:	FPRC:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA KHULULEKANI LABORATORIES, MIDRAND, RSA BODENE t/a INTRAMED, KORSTEN, PORT ELIZABETH
	FPRR:	FRESENIUS KABI MIDRAND, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

ADDENDUM:

L-isoleucine	8,00 g
L-leucine	13,00 g
L-methionine	3,12 g
L-lysine-acetate	12,00g
L-phenylalanine	3,75 g
L-threonine	4,40 g
L-tryptophan	2,01 g
L-valine	9,00 g
L-arginine	7,50 g
L-histidine	4,76 g
L-alanine	9,30 g
Glycine	4,15 g
L-proline	9,71 g
L-serine	7,67 g
N-acetyl- L-cysteine	0,77 g
Taurine	0,40 g
N-acetyl-L-tyrosine	5,176 g
L-malic acid	2,62 g

MRF 15

Registration number:	A39/25.2/0275
Name of medicine:	OLICLINOMEL N8-800
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS a) 12 % AMINO ACIDS SOLUTION compartment b) 31,25 % GLUCOSE SOLUTION compartment c) 15 % LIPID EMULSION compartment SEE ADDENDUM
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	CLINTEC PARENTERAL S.A., MONTARGIS, FRANCE BAXTER S.A., LESSINES, BELGIUM
Packer:	CLINTEC PARENTERAL S.A., MONTARGIS, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory: FPRC:	CLINTEC PARENTERAL S.A., MONTARGIS, FRANCE BAXTER S.A., LESSINES, BELGIUM
FPRC/FPRR	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	1 DECEMBER 2006

ADDE

a) 12 % AMINO ACIDS SOLUTION compartment containing per 1,0 litre:

L-alanine	25,88 g		
L-arginine		14,38 g	
Glycine	12,88 g		
L-histidine		6,00 g	
L-isoleucine	7,50 g		
L-leucine	9,13 g		
L-lysine	7,25 g		
L-methionine	5,00 g		
L-phenylalanine	7,00 g		
L-proline	8,50 g		
L-serine	6,25 g		
L-threonine	5,25 g		
L-tryptophan	2,25 g		
L-tyrosine	0,50 g		
L-valine	7,25 g		

b) 31,25 % GLUCOSE SOLUTION compartment containing per 1,0 litre:

Glucose monohydrate equivalent to Glucose	312,50 g

c) 15 % LIPID EMULSION compartment containing per 1,0 litre:

Refined soya-bean oil + Refined olive oil	150,00 g

MRF 15

Registration number:		A39/28/0614
Name of medicine:		OPTIRAY 80 -75 ml
Dosage form:		SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: IOVERSOL 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		TYCO HEALTHCARE (PTY) LTD
Manufacturer:		TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA TYCO HEALTHCARE INC, POINTE CLAIRE, QUEBEC, CANADA
acker		TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA USA TYCO HEALTHCARE INC, POINTE CLAIRE, QUEBEC, CANADA
Laboratory:	FPRC:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA TYCO HEALTHCARE INC, POINTE CLAIRE, QUEBEC, CANADA
	FPRR:	BIOCHEMICAL & SCIENTIFIC cc, HILTON, KZN TYCO HEALTHCARE, MIDRAND, RSA
Shelf-life:		36 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A39/20.1.1/618
Name of medicine:		RAN-CLARITHROMYCIN MR 50
Dosage form:		TABLET
Active ingredients		EACH TABLET CONTAINS: CLARITHROMYCIN
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD. DEWAS, INDIA
Packer:		RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:	FTTC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

MRF 5

Registration number:		A39/20.1.1/619
Name of medicine:		KLARITHRAN MR 500
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CLARITHROMYCIN 500,0 mg
Conditions of registration:		1 2, 3, 4, 5, 6
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:		RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:	FPMC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
	FPRR	RANBAXY, CENTURION, RSA
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A39/24/0620
Name of medicine:		POTASSIUM CHLORIDE B BRAUN 7,45 %
Dosage form:		SOLUTION
Active ingredients:		EACH 100,0 ml SOLUTION CONTAINS: POTASSIUM CHLORIDE 7,456 g
Conditions of registration:		1 2, 3, 4, 5, 6
Applicant:		B BRAUN MEDICAL (PTY) LTD
Manufacturer:		B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Packer:		B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Laboratory:	FPRC:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	B BRAUN MEDICAL, HONEYDEW, RSA
Shelf-life:		36 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:	A39/24/0621
Name of medicine:	POTASSIUM CHLORIDE B BRAUN 14,9 %
Dosage form:	SOLUTION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: POTASSIUM CHLORIDE 14,9 g
Conditions of registration:	1 2, 3, 4, 5, 6
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Packer:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Laboratory: FPRC	B BRAUN MELSUNGEN AG, BERLIN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR	B BRAUN MEDICAL, HONEYDEW, RSA
Shelf-life:	36 months
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	A40/20.1.1/0019
Name of medicine:	SPEC-CEFAXONE 250 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	LUPIN LTD, MANDIDEEP, MADHYA PRADESH, INDIA
Packer:	LUPIN LTD, MANDIDEEP, MADHYA PRADESH, INDIA
Laboratory: FPRC:	LUPIN LTD, MANDIDEEP, MADHYA PRADESH, INDIA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	SPECPHARM, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:		A40/20.1.1/0020
Name of medicine:		SPEC-CEFAXONE 500 mg
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		LUPIN LTD, MANDIDEEP, MADHYA PRADESH, IND
Packer:		LUPIN LTD, MANDIDEEP, MADHYA PRADESH, IND
Laboratory:	FPRC:	LUPIN LTD, MANDIDEEP, MADHYA PRADESH, IND ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SPECPHARM, SANDTON, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/20.1.1/0021
Name of medicine:		SPEC-CEFAXONE 1 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1000,0 mg
Conditions of registration:		1 2, 3, 4, 5, 6
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		LUPIN LTD, MANDIDEEP, MADHYA PRADESH, IND
Packer:		LUPIN LTD, MANDIDEEP, MADHYA PRADESH, IND
Laboratory:	FPRC:	LUPIN LTD, MANDIDEEP, MADHYA PRADESH, IND ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SPECPHARM, SANDTON, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:	A40/10.2.1/0064
Name of medicine:	SEREVENT INHALER CFC-FREE
Dosage Form:	INHALER
Active ingredients:	EACH ACTUATION DELIVERS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
Packer:	GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory:FPRC:	GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
FPRC/FPRR:	GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Shelf-life:	24 months (provisional)
Date of registration	1 DECEMBER 2006

MRF 15

Registration number:		A40/7.1/0106
Name of medicine:		ZANIDIP 20
Dosage Form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LERCANIDIPINE HYDROCHLORIDE 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA, MILAN, ITALY
Packer:		RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA, MILAN, ITALY
Laboratory:	FPRC:	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA, MILAN, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		36 months
Date of registration		1 DECEMBER 2006

MRF 15

Registration number:		A40/15.1/0164
Name of medicine:		VIGAMOX EYE DROPS
Dosage form:		DROPS
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ALCON LABORATORIES (S.A.) (PTY) LTD
Manufacturer:		S.A. ALCON-COUVREUR N.V, PUURS, BELGIUM
Laboratory:	FPRC:	S.A. ALCON-COUVREUR N.V, PUURS, BELGIUM RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
	FPRR:	ALCON LABORATORIES, BRYANSTON, JOHANNESBURG, RSA
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/21.2/0193
Name of medicine:		AUSTELL – GLIMEPIRIDE 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/21.2/0194
Name of medicine:		AUSTELL – GLIMEPIRIDE 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA
Packer		IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/21.2/0195
Name of medicine:		AUSTELL – GLIMEPIRIDE 3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/21.2/0196
Name of medicine:		AUSTELL – GLIMEPIRIDE 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
Conditions of registration		1, 2, 3, 4, 5, 6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, ATHAL, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/34/0258
Name of medicine:		COPAXONE 20 mg/ml
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: GLATIRAMER ACETATE 20,0 mg
Conditions of registration:		1 2, 3, 4, 5, 6
Applicant:		TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:		TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR-SAVA, ISRAEL
Packer:		TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR-SAVA, ISRAEL
Laboratory:	FPRC:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR-SAVA, ISRAEL RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
	FPRR:	TEVA PHARMACEUTICALS, RUIMSIG, ROODEPOORT, RSA
Shelf-life:		24 months
Date of registration		1 DECEMBER 2006

MRF 15

Registration number:		A40/20.1.2/0285
Name of medicine:		FLUPEN-250
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: FLUCLOXACILLIN SODIUM EQUIVALENT TO: FLUCLOXACILLIN 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		DEZZO TRADING (392) PTY LTD t/a INDO PHARMA
Manufacturer:		KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Packer:		KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Laboratory:	FPRC:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	DEZZO TRADING (392) t/a INDO PHARMA, LENASIA, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/5.10/0322
Name of medicine:		ONICIT
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: PALONOSETRON HYDROCHLORIDE EQUIVALENT TO PALONOSETRON 50,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PFIZER LABORATORIES (PTY) LTD
Manufacturer:		CARDINAL HEALTH, ALBUQUERQUE, NEW MEXICO, USA
[illegible]		CARDINAL HEALTH, ALBUQUERQUE, NEW MEXICO, USA HELSINN BIREX PHARMACEUTICALS, DUBLIN, IRELAND
Laboratory:	FPRC:	CARDINAL HEALTH, ALBUQUERQUE, NEW MEXICO, USA HELSINN BIREX PHARMACEUTICALS, DUBLIN, IRELAND PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN
	FPRR:	PFIZER LABORATORIES, SANDTON, RSA
Shelf-life:		36 months
Date of registration:		1 DECEMBER 2006

MDF 15

Registration number:	A40/11.4.3/0482
Name of medicine:	PANTOCID 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	M J PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Packer:	M J PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	M J PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

MDF 15

Registration number:	A40/3.2/0514
Name of medicine:	OSTOMIR 70
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS dd, VEROVSKOVA, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS dd, VEROVSKOVA, LJUBLJANA, SLOVENIA
Laboratory: FPRC:	LEK PHARMACEUTICALS dd, VEROVSKOVA, LJUBLJANA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

MRF 1<

Registration number:	A40/3.2/0515
Name of medicine:	SANDOZ ALENDRONATE 70
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d, VEROVSKOVA, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d, VEROVSKOVA, LJUBLJANA, SLOVENIA
Laboratory: FPRC:	LEK PHARMACEUTICALS d, VEROVSKOVA, LJUBLJANA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

MRF 1<

Registration number:	A40/20.2.3/0534
Name of medicine:	RIFINAH 150/75
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RIFAMPICIN 150,0 mg ISONIAZID 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PHARMA, WALTLOO, PRETORIA
Packer:	AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory: FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:		A40/1.2/0584
Name of medicine:		SANDOZ MIRTAZAPINE 15
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MIRTAZAPINE 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SANDOZ (PTY) LTD
Manufacturer:		NOVARTIS LTD, GAZIPUR, BANGLADESH
Packer:		NOVARTIS LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/1.2/0585
Name of medicine:		SANDOZ MIRTAZAPINE 30
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MIRTAZAPINE 30,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SANDOZ (PTY) LTD
Manufacturer:		NOVARTIS LTD, GAZIPUR, BANGLADESH
Packer:		NOVARTIS LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		1 DECEMBER

MRF 15

Registration number:		A40/1.2/0586
Name of medicine		SANDOZ MIRTAZAPINE 45
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MIRTAZAPINE 45,0 mg
Conditions of registration:		¶ ₽ 3, 4, 5, 6
Applicant:		SANDOZ (PTY) LTD
Manufacturer:		NOVARTIS LTD, GAZIPUR, BANGLADESH
Packer:		NOVARTIS LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:		A40/1.2/0654
Name of medicine:		AUROLIFT 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:		¶ ₽ 3, 4, 5, 6
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:	A40/1.2/0655
Name of medicine:	AUROLIFT 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:	1 2, 3, ◘ ♀ ≤
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	A40/20.2.3/0680
Name of medicine:	CAPASTAT 1 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CAPREOMYCIN SULPHATE EQUIVALENT TO CAPREOMYCIN 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	TEVA PHARMACEUTICAL WORKS CO LTD, TANCSICS M, HUNGARY
Packer:	TEVA PHARMACEUTICAL WORKS CO LTD, TANCSICS M, HUNGARY PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Laboratory: FPRC:	ELI LILLY ITALIA S.p.A, SESTO FIORENTINO, ITALY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Shelf-life:	24 months
Date of registration:	17 NOVEMBER

Registration number:	A40/7.1.3/0682
Name of medicine:	SANDOZ RAMIPRIL 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH
Packer:	NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

Registration number:	A40/7.1.3/0683
Name of medicine:	RAMIPRIL-HEXAL 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH
Packer:	NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

Registration number:		A40/7.1.3/0684
Name of medicine:		RETACE 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RAMIPRIL 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SANDOZ (PTY) LTD
Manufacturer:		NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH
Packer:		NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK NOVARTIS S.A., SPARTAN, KEMPTON PARK
	FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:		24 months (provisional)
Date of registration:		1 DECEMBER 2006