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CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 672 OF 2006

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 on 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 of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot 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.

KENNISGEWING 672 VAN 2006

MEDISYNEBEHEERRAAD

VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET No. 101 VAN 1965)

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 26 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in die voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies soos goedgedink deur die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die registrasie-aansoek is onderhewig aan hersiening met tussenposes soos deur die Raad bepaal.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslike vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemarking van die produk mag slegs in aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:	35/20.1.2/0232
Name of medicine:	AMOCLAN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN
Packer:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN
Laboratory:FPRC:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	35/20.1.2/0233
Name of medicine:	AMOCLAN FORTE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN
Packer:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN
Laboratory:FPRC:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	35/20.1.2/0249
Name of medicine:	AMOCLAN S
Dosage form:	POWDER FOR SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 125,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 31,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN
Packer:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN
Laboratory:FPRC:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	35/20.1.2/0250
Name of medicine:	AMOCLAN SF
Dosage form:	POWDER FOR SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 62,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN
Packer:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN
Laboratory:FPRC:	HIKMA PHARMACEUTICALS,AMMAN, JORDAN NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	36/30.1/0347
Name of medicine:	INFANRIX HEXA
Dosage form:	VACCINE
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: DIPHTHERIA TOXOID nlt 30,0 iu TETANUS TOXOID nlt 40,0 iu PERTUSSIS TOXOID 25,0 ug FILAMENTOUS HEMAGGLUTININ 25,0 ug PERTACTIN 8,0 ug RECOMBINANT HBsAg 10,0 ug POLIO VIRUS Type 1 Mahoney strain 40,0 du POLIO VIRUS Type 2 MEF-1 strain 8,0 du POLIO VIRUS Type 3 Saukett strain 32,0 du HAEMOPHILUS INFLUENZA TYPE B: PRP 10,0 ug T 20,0 – 40,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE S.A. (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM CHIRON BEHRING, MARBURG, GERMANY
Packer:	GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING S.A.,RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING S.A., WAVRE, BELGIUM SACHSISCHES SERUMWERK DRESDEN, DRESDEN, GERMANY GLAXOSMITHKLINE S.A., ALCALA DE HENARES, MADRID, SPAIN GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory:FPRC:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM
FPRC/FPRR:	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	36/7.5/0349
Name of medicine:	CRESTOR 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO IPR PHARMACEUTICALS, CAROLINA, PUERTO RICO
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Laboratory:FPRC:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO ANALYTICON, TERENURE, KEMPTON PARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
FPRC/FPRR:	JANSSEN PHARMACEUTICA, HALFWAY HOUSE ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	36/7.5/0350
Name of medicine:	CRESTOR 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO IPR PHARMACEUTICALS, CAROLINA, PUERTO RICO
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Laboratory:FPRC:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO ANALYTICON, TERENURE, KEMPTON PARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR:	ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	36/7.5/0351
Name of medicine:	CRESTOR 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO IPR PHARMACEUTICALS, CAROLINA, PUERTO RICO
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Laboratory:FPRC:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO ANALYTICON, TERENURE, KEMPTON PARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR:	ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	36/7.5/0353
Name of medicine:	AZESTOR 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO IPR PHARMACEUTICALS, CAROLINA, PUERTO RICO
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Laboratory:FPRC:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO ANALYTICON, TERENURE, KEMPTON PARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR:	ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	36/7.5/0354
Name of medicine:	AZESTOR 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO IPR PHARMACEUTICALS, CAROLINA, PUERTO RICO
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Laboratory:FPRC:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO ANALYTICON, TERENURE, KEMPTON PARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR:	ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	36/7.5/0355
Name of medicine:	AZESTOR 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO IPR PHARMACEUTICALS, CAROLINA, PUERTO RICO
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK JANSSEN PHARMACEUTICA, HALFWAY HOUSE ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Laboratory:FPRC:	ASTRAZENECA GmbH, PLANKSTADT, GERMANY IPR PHARMACEUTICALS, CANOVANAS, PUERTO RICO ANALYTICON, TERENURE, KEMPTON PARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
FPRC/FPRR:	JANSSEN PHARMACEUTICA, HALFWAY HOUSE ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0046
Name of medicine:	CPL ALLIANCE CEFTRIAXONE 250
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, 7
Applicant:	ALLIANCE PHARMA (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR:	ALLIANCE PHARMA, VILLAGE MAIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0048
Name of medicine:	CPL ALLIANCE CEFTRIAXONE 500
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, 7
Applicant:	ALLIANCE PHARMA (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR:	ALLIANCE PHARMA, VILLAGE MAIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0049
Name of medicine:	CPL ALLIANCE CEFTRIAXONE 1000
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, 7
Applicant:	ALLIANCE PHARMA (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR:	ALLIANCE PHARMA, VILLAGE MAIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	37/34/0090
Name of medicine:	ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 127 A
Dosage form:	SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE 6,43 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g GLACIAL ACETIC ACID 6,31 g GLUCOSE MONOHYDRATE EQUIVALENT TO ANHYDROUS GLUCOSE 35,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B. BRAUN MEDICAL (PTY) LTD
Manufacturer:	B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY
Packer:	B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY
Laboratory:FPRC:	B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	B. BRAUN MEDICAL, HONEYDEW, RANDBURG
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	37/34/0091
Name of medicine:	ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 139 A
Dosage form:	SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE 9,01 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g GLACIAL ACETIC ACID 6,31 g GLUCOSE MONOHYDRATE EQUIVALENT TO ANHYDROUS GLUCOSE 35,00 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B. BRAUN MEDICAL (PTY) LTD
Manufacturer:	B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY
Packer:	B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY
Laboratory:FPRC:	B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	B. BRAUN MEDICAL, HONEYDEW, RANDBURG
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0130
Name of medicine:	CPL ALLIANCE NORFLOXACIN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NORFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALLIANCE PHARMA (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS, AHMEDABAD, GUJARAT, INDIA
Laboratory:	CADILA PHARMACEUTICALS, AHMEDABAD, GUJARAT, INDIA ANALYTICON, KEMPTON PARK, RSA ALLIANCE PHARMA, VILLAGE MAIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

MRF 15

Registration number:	37/7.1/0376
Name of medicine:	ROLAB-AMLODIPINE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK
Packer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	37/7.1/0377
Name of medicine:	ROLAB-AMLODIPINE 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK
Packer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	37/20.1.1/0617
Name of medicine:	BELEX 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEPHALEXIN MONOHYDRATE EQUIVALENT TO CEPHALEXIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	HOVID SDN. BHD., PERAK, MALAYSIA
Packer:	HOVID SDN. BHD., PERAK, MALAYSIA
Laboratory:FPRC:	HOVID SDN. BHD., PERAK, MALAYSIA WRAPSA, CENTURION, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA CONSULTING MICROBIOLOGICAL LABORATORY, BEYERSPARK, RSA
FPRR:	*GULF DRUG CO, MOUNT EDGECOMBE, RSA*
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	37/20.1.1/0618
Name of medicine:	BELEX 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEPHALEXIN MONOHYDRATE EQUIVALENT TO CEPHALEXIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	HOVID SDN. BHD., PERAK, MALAYSIA
Packer:	HOVID SDN. BHD., PERAK, MALAYSIA
Laboratory:FPRC:	HOVID SDN. BHD., PERAK, MALAYSIA WRAPSA, CENTURION, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA CONSULTING MICROBIOLOGICAL LABORATORY, BEYERSPARK, RSA
FPRR:	*GULF DRUG CO, MOUNT EDGECOMBE, RSA*
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	37/3.2/0633
Name of medicine:	OSTEOHEXAL 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: POTASSIUM ALENDRONATE ANHYDRATE EQUIVALENT TO ALENDRONIC ACID 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, GAUTENG, RSA
Laboratory:FPRC:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	37/3.2/0634
Name of medicine:	KALENDROMAX 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: POTASSIUM ALENDRONATE ANHYDRATE EQUIVALENT TO ALENDRONIC ACID 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, GAUTENG, RSA
Laboratory:FPRC:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	37/3.1/0641
Name of medicine:	DIFEN SR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DICLOFENAC SODIUM 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	HOVID SDN. BHD., PERAK, MALAYSIA
Packer:	HOVID SDN. BHD., PERAK, MALAYSIA
Laboratory:FPRC:	HOVID SDN. BHD., PERAK, MALAYSIA WRAPSA, CENTURION, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA CONSULTING MICROBIOLOGICAL LABORATORY, BEYERSPARK, RSA
FPRR:	GULF DRUG CO, MOUNT EDGECOMBE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	37/3.1/0669
Name of medicine:	RESMED DICLOFENAC 75 INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: DICLOFENAC SODIUM 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RESMED PHARMACEUTICALS
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES, GUJARAT, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES, GUJARAT, INDIA
Laboratory:FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES, GUJARAT, INDIA
FPRR:	RESMED PHARMACEUTICALS, SPRINGFIELD PARK, DURBAN
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	38/20.1.1/0016
Name of medicine:	BINOCLAR 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Packer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Laboratory:FPRC:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/20.1.1/0017
Name of medicine:	BINOCLAR 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Packer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Laboratory:FPRC:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/20.1.1/0018
Name of medicine:	SANDOZ-CLARITHROMYCIN 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Packer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/20.1.1/0019
Name of medicine:	SANDOZ-CLARITHROMYCIN 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Packer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Laboratory:FPRC:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/20.1.1/0024
Name of medicine:	CIPROBAY XR 1000
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 1000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER AG, LEVERKUSEN, GERMANY
Packer:	BAYER AG, LEVERKUSEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA PHARMACEUTICAL CONTRACTORS, ISANDO, RSA
Laboratory: FPRC:	BAYER AG, LEVERKUSEN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	BAYER, ISANDO, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15

Registration number:	38/7.1.3/0116
Name of medicine:	VECTORYL 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, RSA
Laboratory:FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN S.A., RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/7.1.3/0119
Name of medicine:	COVERSYL 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, RSA
Laboratory:FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRR:	SERVIER LABORATORIES S.A., RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/7.1.3/0120
Name of medicine:	PREXUM 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, RSA
Laboratory:FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN S.A., RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/3.1/0141
Name of medicine:	PREXIGE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LUMIRACOXIB 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7 A PSUR to be submitted at six-monthly intervals
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/3.1/0142
Name of medicine:	PREXIGE 400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LUMIRACOXIB 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7 A PSUR to be submitted at six-monthly intervals
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/20.2.2/0148
Name of medicine:	TERBICIL 1 % CREAM
Dosage form:	CREAM
Active ingredients:	EACH 1,0 g CREAM CONTAINS: TERBINAFINE HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	LENNON LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA, EAST LONDON
Packer:	LENNON LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA, EAST LONDON
Laboratory:FPRC:	LENNON LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA, EAST LONDON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/21.8.2/0188
Name of medicine:	HEXAL-MPA 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MEDROXYPROGESTERONE ACETATE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL,PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/21.8.2/0189
Name of medicine:	HEXAL-MPA 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MEDROXYPROGESTERONE ACETATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/5.10/0197
Name of medicine:	HEXAL-ONDANSETRON 4 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	SOLUPHARM, MELSUNGEN, GERMANY
Packer:	SOLUPHARM, MELSUNGEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SOLUPHARM, MELSUNGEN, GERMANY SALUTAS PHARMA, BARLEBEN, GERMANY CONSULTING CHEMICAL LABS, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/5.10/0200
Name of medicine:	ONDANSETRON HEXAL 4 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	SOLUPHARM, MELSUNGEN, GERMANY
Packer:	SOLUPHARM, MELSUNGEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SOLUPHARM, MELSUNGEN, GERMANY SALUTAS PHARMA, BARLEBEN, GERMANY CONSULTING CHEMICAL LABS, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/5.10/0217
Name of medicine:	ONDANSETRON HEXAL 8 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	SOLUPHARM, MELSUNGEN, GERMANY
Packer:	SOLUPHARM, MELSUNGEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SOLUPHARM, MELSUNGEN, GERMANY SALUTAS PHARMA, BARLEBEN, GERMANY CONSULTING CHEMICAL LABS, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/21.2/0223
Name of medicine:	DIAGLUCIDE MR 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER INDUSTRIES LTD, WICKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER INDUSTRIES LTD, WICKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER INDUSTRIES LTD, WICKLOW, IRELAND INSPECTORATE M&L, ORMONDE, JOHANESBURG, RSA
FPRR:	BIOGARAN S.A., RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/10.1/0239
Name of medicine:	DILINCT DRY COUGH SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: DEXTROMETHORPHAN HYDROBROMIDE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	38/2.6.5/0259
Name of medicine:	SOLIAN 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMISULPRIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE SANOFI-SYNTHELABO,NEWCASTLE-ON-TYNE, TYNE AND WEAR, U.K.
Packer:	SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE SANOFI-SYNTHELABO,NEWCASTLE-ON-TYNE, TYNE AND WEAR, U.K. PHARMACEUTICAL CONTRACTORS, ISANDO, RSA
Laboratory:FPRC:	SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE SANOFI-SYNTHELABO,NEWCASTLE-ON-TYNE, TYNE AND WEAR, U.K. INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRR:	SANOFI-SYNTHELABO, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/5.10/0273
Name of medicine:	HEXAL-ONDANSETRON 8 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	SOLUPHARM, MELSUNGEN, GERMANY
Packer:	SOLUPHARM, MELSUNGEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SOLUPHARM, MELSUNGEN, GERMANY SALUTAS PHARMA, BARLEBEN, GERMANY CONSULTING CHEMICAL LABS, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	A38/7.5/0371
Name of medicine:	CIPLA-SIMVASTATIN 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA-MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	A38/7.5/0373
Name of medicine:	SIMCARD 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA-MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/5.7.1/0414
Name of medicine:	FEXO 120
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 120,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/5.7.1/0415
Name of medicine:	FEXO 180
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 180,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/5.7.1/0423
Name of medicine:	CIPLA-FEXOFENADINE HYDROCHLORIDE 120
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 120,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/5.7.1/0424
Name of medicine:	CIPLA-FEXOFENADINE HYDROCHLORIDE 180
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 180,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/20.1.1/0608
Name of medicine:	CEFTRIAXONE-COMBINOPHARM 1,0 g
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN
Packer:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN
Laboratory:FPRC:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN COMBINO PHARM S.L., BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/20.1.1/0609
Name of medicine:	CEFTRIAXONE-COMBINOPHARM 2,0 g
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 2,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN
Packer:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN
Laboratory:FPRC:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN COMBINO PHARM S.L., BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	*24 months*
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/20.1.1/0610
Name of medicine:	CEFTRIAXONE-COMBINOPHARM 250 mg
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN
Packer:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN
Laboratory:FPRC:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN COMBINO PHARM S.L., BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/20.1.1/0611
Name of medicine:	CEFTRIAXONE-COMBINOPHARM 500 mg
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN
Packer:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN
Laboratory:FPRC:	REIG JOFRE, S.A., SANT ADRIA DELS BESOS, SPAIN COMBINO PHARM S.L., BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	*24 months*
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/7.5/0707
Name of medicine:	ARROW SIMVASTATIN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/7.5/0708
Name of medicine:	ARROW SIMVASTATIN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A38/7.5/0709
Name of medicine:	ARROW SIMVASTATIN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/3.1/0008
Name of medicine:	FENISTIL EMULGEL
Dosage form:	GEL
Active ingredients:	EACH 100,0 g GEL CONTAINS: DICLOFENAC SODIUM 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS CONSUMER HEALTH, NYON, SWITZERLAND
Packer:	NOVARTIS CONSUMER HEALTH, NYON, SWITZERLAND
Laboratory:FPRC:	NOVARTIS CONSUMER HEALTH, NYON, SWITZERLAND
FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/20.2.8/0227
Name of medicine:	VARI-INDINAVIR 400 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: INDINAVIR 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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, STAR STREET, BOKSBURG, RSA
FPRR:	LEBASI PHARMACEUTICALS, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/11.4.3/0251
Name of medicine:	RAN-LANSOPRAZOLE 15
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: LANSOPRAZOLE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QAULITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/11.4.3/0252
Name of medicine:	RAN-LANSOPRAZOLE 30
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: LANSOPRAZOLE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QAULITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/11.4.3/0253
Name of medicine:	LANAZOLE 15
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: LANSOPRAZOLE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QAULITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/11.4.3/0254
Name of medicine:	LANAZOLE 30
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: LANSOPRAZOLE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QAULITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/1.2/0286
Name of medicine:	AUSTELL – SERTRALINE 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:FPRC:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/1.2/0287
Name of medicine:	AUSTELL – SERTRALINE 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:FPRC:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.5/0300
Name of medicine:	SANDOZ PRAVASTATIN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA ANALYTICON, TERENURE, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRC/ FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.5/0301
Name of medicine:	SANDOZ PRAVASTATIN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA ANALYTICON, TERENURE, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRC/ FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.5/0302
Name of medicine:	SANDOZ PRAVASTATIN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA ANALYTICON, TERENURE, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRC/ FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/26/0314
Name of medicine:	AVASTIN 100
Dosage form:	INFUSION
Active ingredients:	EACH 4,0 ml VIAL CONTAINS: BEVACIZUMAB 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	GENENTECH INC, SOUTH FRANCISCO, CA, USA GENENTECH INC, VACAVILLE, CA, USA
Packer:	GENENTECH INC, SOUTH FRANCISCO, CA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST, SWITZERLAND ROCHE PRODUCTS, ISANDO, RSA
Laboratory:FPRC:	HOFFMANN-LA ROCHE AG, GRENZACH-WYHLEN, GERMANY
FPRC/FPRR:	ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/26/0315
Name of medicine:	AVASTIN 400
Dosage form:	INFUSION
Active ingredients:	EACH 16,0 ml VIAL CONTAINS: BEVACIZUMAB 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	GENENTECH INC, SOUTH FRANCISCO, CA, USA GENENTECH INC, VACAVILLE, CA, USA
Packer:	GENENTECH INC, SOUTH FRANCISCO, CA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST, SWITZERLAND ROCHE PRODUCTS, ISANDO, RSA
Laboratory:FPRC:	HOFFMANN-LA ROCHE AG, GRENZACH-WYHLEN, GERMANY
FPRC/FPRR:	ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/6.2/0319
Name of medicine:	SABAX AMIODARONE 150 mg/3 ml
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: AMIODARONE HYDROCHLORIDE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	HAUPT PHARMA LIVRON, LIVRON, FRANCE
Packer:	HAUPT PHARMA LIVRON, LIVRON, FRANCE PHARMA-Q, INDUSTRIA, JOHANNESBURG ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory:FPRC:	HAUPT PHARMA LIVRON, LIVRON, FRANCE CEBIPHAR, FONDETTES, FRANCE
FPRC/FPRR:	PHARMA-Q, INDUSTRIA, JOHANNESBURG ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/6.2/0321
Name of medicine:	ADCORONE
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: AMIODARONE HYDROCHLORIDE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HAUPT PHARMA LIVRON, LIVRON, FRANCE
Packer:	HAUPT PHARMA LIVRON, LIVRON, FRANCE PHARMA-Q, INDUSTRIA, JOHANNESBURG ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory:FPRC:	HAUPT PHARMA LIVRON, LIVRON, FRANCE CEBIPHAR, FONDETTES, FRANCE PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/20.2.3/0324
Name of medicine:	RIFAMP-4
Dosage form:	TABLETS
Active ingredients:	EACH TABLET CONTAINS: RIFAMPICIN 150,0 mg PYRAZINAMIDE 400,0 mg ETHAMBUTOL HYDROCHLORIDE 275,0 mg ISONIAZID 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDICINE DEVELOPERS INTERNATIONAL cc
Manufacturer:	RUSAN PHARMA LTD, GANDHIHAM-KUTCH, INDIA
Packer:	RUSAN PHARMA LTD, GANDHIHAM-KUTCH, INDIA
Laboratory:FPRC:	RUSAN PHARMA LTD, GANDHIHAM-KUTCH, INDIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	MDI, MENLOPARK, PRETORIA, RSA
Shelf-life:	24 Months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/5.4/0490
Name of medicine:	VESICARE 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SOLIFENACIN SUCCINATE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	YAMANOUCHI PHARMA (PTY) LTD
Manufacturer:	YAMANOUCHI EUROPE B.V., JG MEPPEL, THE NETHERLANDS
Packer:	YAMANOUCHI EUROPE B.V., JG MEPPEL, THE NETHERLANDS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	YAMANOUCHI EUROPE B.V., JG MEPPEL, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	YAMANOUCHI PHARMA, BEDFORDVIEW, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/5.4/0491
Name of medicine:	VESICARE 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SOLIFENACIN SUCCINATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	YAMANOUCHI PHARMA (PTY) LTD
Manufacturer:	YAMANOUCHI EUROPE B.V., JG MEPPEL, THE NETHERLANDS
Packer:	YAMANOUCHI EUROPE B.V., JG MEPPEL, THE NETHERLANDS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	YAMANOUCHI EUROPE B.V., JG MEPPEL, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	YAMANOUCHI PHARMA, BEDFORDVIEW, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/5.10/0511
Name of medicine:	MERGENSIC 4 mg/2 ml
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml AMPOULE CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, U.K.
Laboratory:FPRC:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, U.K.
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/5.10/0512
Name of medicine:	MERGENSIC 8 mg/4 ml
Dosage form:	INJECTION
Active ingredients:	EACH 4,0 ml AMPOULE CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, U.K.
Laboratory:FPRC:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, U.K.
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/5.10/0573
Name of medicine:	ONDANTOR 4 mg/2 ml
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	PHARMATHEN S.A., ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., ATTIKIS, GREECE NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	PHARMATHEN S.A., ATTIKIS, GREECE 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
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/5.10/0574
Name of medicine:	ONDANTOR 8 mg/4 ml
Dosage form:	INJECTION
Active ingredients:	EACH 4,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	PHARMATHEN S.A., ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., ATTIKIS, GREECE NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	PHARMATHEN S.A., ATTIKIS, GREECE 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
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/3.2/0598
Name of medicine:	MERCK-ALENDRONATE 70 mg
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, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON
Packer:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory:FPRC:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.1.3/0600
Name of medicine:	PIRAMIL 1,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.1.3/0601
Name of medicine:	SANDOZ RAMIPRIL 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.1.3/0602
Name of medicine:	PIRAMIL 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.1.3/0603
Name of medicine:	PIRAMIL 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.1.3/0604
Name of medicine:	SANDOZ RAMIPRIL 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/6.1/0609
Name of medicine:	CARDIJECT 250
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: DOBUTAMINE HYDROCHLORIDE EQUIVALENT TO DOBUTAMINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Packer:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Laboratory:FPRC:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	PHARMAPLAN, MIDTAND, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/7.1.3/0612
Name of medicine:	SANDOZ RAMIPRIL 1,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/1.2/0640
Name of medicine:	*AUSTELL-PAROXETINE 20 mg*
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:FPRC:	*IPCA LABORATORIES LTD, DADRA & NAGAR* HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA INSTITUTE FOF PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/1.2/0641
Name of medicine:	AUSTELL-PAROXETINE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:FPRC:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/3.1/0642
Name of medicine:	PREXIGE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LUMIRACOXIB 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7 A PSUR to be submitted at six-monthly intervals
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A39/20.1.1/0646
Name of medicine:	SABAX CIPROFLOXACIN 2 mg/ml
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	ACS DOBFAR INFO, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO, CAMPASCIO, SWITZERLAND
Laboratory:FPRC:	ACS DOBFAR INFO, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0010
Name of medicine:	MERCK-LAMOTRIGINE DISPERSIBLE 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0011
Name of medicine:	MERCK-LAMOTRIGINE DISPERSIBLE 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0012
Name of medicine:	MERCK-LAMOTRIGINE DISPERSIBLE 25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0013
Name of medicine:	MERCK-LAMOTRIGINE DISPERSIBLE 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0014
Name of medicine:	MERCK-LAMOTRIGINE DISPERSIBLE 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0015
Name of medicine:	MERCK-LAMOTRIGINE DISPERSIBLE 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA QUIMICA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/3.1/0027
Name of medicine:	ARTHROCOX 7,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Packer:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/1.2/0029
Name of medicine:	CIPLA-VENLAFAXINE HYDROCHLORIDE XR 37,5
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 37,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/1.2/0030
Name of medicine:	CIPLA-VENLAFAXINE HYDROCHLORIDE XR 75
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/1.2/0031
Name of medicine:	CIPLA-VENLAFAXINE HYDROCHLORIDE XR 150
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/1.2/0032
Name of medicine:	VENLOR XR 37,5
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 37,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	*7 APRIL 2006*

MRF 15

Registration number:	A40/1.2/0033
Name of medicine:	VENLOR XR 75
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/1.2/0034
Name of medicine:	VENLOR XR 150
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0036
Name of medicine:	RAN-LAMOTRIGINE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	*7 APRIL 2006*

MRF 15

Registration number:	A40/2.5/0037
Name of medicine:	RAN-LAMOTRIGINE 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0038
Name of medicine:	RAN-LAMOTRIGINE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0039
Name of medicine:	RAN-LAMOTRIGINE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0040
Name of medicine:	TOCLON 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0041
Name of medicine:	TOCLON 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0042
Name of medicine:	TOCLON 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/2.5/0043
Name of medicine:	TOCLON 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/11.4.3/0072
Name of medicine:	PANTOCID 40 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: PANTOPRAZOLE SODIUM EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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, STAR STREET, BOKSBURG, RSA
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/1.2/0107
Name of medicine:	CITALOGEN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROCHLORIDE EQUIVALENT TO CITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	*7 APRIL 2006*

MRF 15

Registration number:	A40/1.2/0108
Name of medicine:	CITALOGEN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROCHLORIDE EQUIVALENT TO CITALOPRAM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/1.2/0109
Name of medicine:	CITALOGEN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROCHLORIDE EQUIVALENT TO CITALOPRAM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/20.2.8/0254
Name of medicine:	AVOCOMB
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/20.2.8/0272
Name of medicine:	LAMAID 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/34/0316
Name of medicine:	TAMSUL 0,4 SR
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 0,4 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENERIX INTERNATIONAL SA (PTY) LTD
Manufacturer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND ECZACIBASI, LULEBURGAZ, TURKEY
Packer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND ECZACIBASI, LULEBURGAZ, TURKEY
Laboratory:FPRC:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND ECZACIBASI, LULEBURGAZ, TURKEY SOLVIAS AG, ZOFINGEN, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA CONFARMA FRANCE SARL, HOMBOURG, FRANCE CONFARMA SCHWEIZ AG, MUNCHENSTEIN, SWITZERLAND
FPRR:	GENERIX INTERNATIONAL, ATHLONE, CAPE TOWN
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number:	A40/34/0317
Name of medicine:	GENERIX TAMSULOSIN 0,4 SR
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 0,4 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENERIX INTERNATIONAL SA (PTY) LTD
Manufacturer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND ECZACIBASI, LULEBURGAZ, TURKEY
Packer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND ECZACIBASI, LULEBURGAZ, TURKEY
Laboratory:FPRC:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND ECZACIBASI, LULEBURGAZ, TURKEY SOLVIAS AG, ZOFINGEN, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA CONFARMA FRANCE SARL, HOMBOURG, FRANCE CONFARMA SCHWEIZ AG, MUNCHENSTEIN, SWITZERLAND
FPRR:	GENERIX INTERNATIONAL, ATHLONE, CAPE TOWN
Shelf-life:	24 months
Date of registration:	7 APRIL 2006