CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1680 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 1680 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:	A04/2.1/9
Name of medicine:	RAPINOVET INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml EMULSION CONTAINS: Propofol ..... 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SCHERING-PLOUGH (PTY) LTD
Manufacturer:	SICOR PHARMACEUTICALS INC, IRVINE, CALIFORNIA, USA
Packer:	SICOR PHARMACEUTICALS INC, IRVINE, CALIFORNIA, USA SCHERING-PLOUGH, BRAY, WICKLOW, IRELAND SCHERING-PLOUGH, ISANDO, RSA
Laboratory:FPRC:	SICOR PHARMACEUTICALS INC, IRVINE, CALIFORNIA, USA SCHERING-PLOUGH, BRAY, WICKLOW, IRELAND CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	SCHERING-PLOUGH, ISANDO, RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	34/7.1.3/0137
Name of medicine:	CONCOR 5 PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 5,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK KGaA, DARMSTADT, GERMANY
Packer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:FPRC:	MERCK KGaA, DARMSTADT, GERMANY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
FPRR:	MERCK, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	34/7.1.3/0138	
Name of medicine:	CONCOR 10 PLUS	
Dosage form:	TABLET	
Active ingredients:	EACH TABLET CONTAINS:	
	BISOPROLOL FUMARATE	10,0 mg
	HYDROCHLOROTHIAZIDE	25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6	
Applicant:	MERCK (PTY) LTD	
Manufacturer:	MERCK KGaA, DARMSTADT, GERMANY	
Packer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON	
Laboratory:FPRC:	MERCK KGaA, DARMSTADT, GERMANY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON	
FPRR:	MERCK, MODDERFONTEIN, RSA	
Shelf-life:	24 months	
Date of registration:	6 OCTOBER 2006	

MRF 15

Registration number:	36/7.1.3/0383
Name of medicine:	TAREG 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND KONPHARMA AG, PRATTELN, SWITZERLAND ALLPACK AG, MUTTENZ, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	37/7.1.3/0327
Name of medicine:	BIO-ENALAPRIL MALEATE 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA
Packer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	BIOTECH LABORATORIES, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	37/7.1.3/0328
Name of medicine:	BIO-ENALAPRIL MALEATE 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA
Packer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	BIOTECH LABORATORIES, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	37/7.1.3/0329
Name of medicine:	BIO-ENALAPRIL MALEATE 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA
Packer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	LEK PHARMACEUTICAL & CHEMICAL COMPANY, VEROVSKOVA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	BIOTECH LABORATORIES, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	37/7.1.4/0339
Name of medicine:	IMOTRATE 60 mg SR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ISOSORBIDE-5-MONONITRATE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	COMPUPHARM (PTY) LTD
Manufacturer:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY
Packer:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY
Laboratory:FPRC:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
FPRR:	COMPUPHARM, LYNNWOOD, PRETORIA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	37/7.1.4/0340
Name of medicine:	VALPHARMA ISOSORBIDE-5-MONONITRATE 60 mg SR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ISOSORBIDE-5-MONONITRATE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	COMPUPHARM (PTY) LTD
Manufacturer:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY
Packer:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY
Laboratory:FPRC:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
FPRR:	COMPUPHARM, LYNNWOOD, PRETORIA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	37/7.1/0378
Name of medicine:	OROVASC 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
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:	6 OCTOBER 2006

MRF 15

Registration number:	37/7.1/0379
Name of medicine:	OROVASC 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
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:	6 OCTOBER 2006

MRF 15

Registration number:	38/7.5/0225
Name of medicine:	BEZACHOLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BEZAFIBRATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, U.K.
Laboratory:FPRC:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/7.1.3/0392
Name of medicine:	QUINAZIDE 10/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/7.1.3/0393
Name of medicine:	QUINAZIDE 20/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/1.2/0482
Name of medicine:	ASPEN 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
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/1.2/0483
Name of medicine:	ASPEN 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
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/21.2/0560
Name of medicine:	ALEMBIC GLICLAZIDE 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA
Laboratory:FPRC:	ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA CONSULTING MICROBIOLOGICAL LABORATORY, MOREWILL, BEYERSPARK, RSA
FPRR:	GULF DRUG CO, MOUNT EDGECOMBE, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/7.1.3/0639
Name of medicine:	PHARMAPRESS 2,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES LTD, DUBLIN, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:FPRC:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN SOUTH AFRICAN BUREAU OF STANDRADS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/7.1.3/0640
Name of medicine:	PHARMAPRESS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES LTD, DUBLIN, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:FPRC:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN SOUTH AFRICAN BUREAU OF STANDRADS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/30.1/0717
Name of medicine:	IMOVAX POLIO
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: POLIO VIRUS TYPE 1 (MAHONEY) 40,0 ANTIGEN D UNITS POLIO VIRUS TYPE 2 (MEF-1) 8,0 ANTIGEN D UNITS POLIO VIRUS TYPE 3 (SAUKETT) 32,0 ANTIGEN D UNITS
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE
Packer:	AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE
Laboratory:FPRC:	AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE
FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/21.12/0258
Name of medicine:	FINAHEXAL 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FINASTERIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:FPRC:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/21.12/0259
Name of medicine:	FINASTERIDE HEXAL 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FINASTERIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:FPRC:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/24/0312
Name of medicine:	0,9 % w/v SODIUM CHLORIDE INJECTION B BRAUN
Dosage form:	INJECTION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE 0,9 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, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG,RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/34/0313
Name of medicine:	WATER FOR INJECTIONS B BRAUN
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: WATER FOR INJECTIONS 1,0 ml
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: FPRR:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY B BRAUN MEDICAL, HONEYDEW, GAUTENG
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/20.1.1/0334
Name of medicine:	CIPROFLOXACIN – SAFELINE 100
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Laboratory:FPRC:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/20.1.1/0335
Name of medicine:	CIPROFLOXACIN – SAFELINE 200
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Laboratory:FPRC:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/20.1.1/0336
Name of medicine:	CIPROFLOXACIN – SAFELINE 400
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Laboratory:FPRC:	DEMO S.A. PHARMACEUTICAL INDUSTRY, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/21.10/0357
Name of medicine:	MENOPUR POWDER FOR SOLUTION FOR INJECTION
Dosage form:	POWDER
Active ingredients:	EACH VIAL CONTAINS: MENOTROPHIN EQUIVALENT TO FOLLICLE STIMULATING HORMONE 75,0 iu LUTEINISING HORMONE 75,0 iu
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	FERRING (PTY) LTD
Manufacturer:	DR RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM, GERMANY PATHEON ITALIA S.p.A, MONZA, ITALY FERRING GmbH, KIEL, GERMANY
Packer:	DR RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM, GERMANY PATHEON ITALIA S.p.A, MONZA, ITALY FERRING GmbH, KIEL, GERMANY
Laboratory:FPRC:	FERRING GmbH, KIEL, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING, IRENE, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/8.2/0375
Name of medicine:	ENOXAPARIN-HEXAL 40 PRE-FILLED SYRINGE
Dosage form:	INJECTION
Active ingredients:	EACH 0,4 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY
Packer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA , PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/8.2/0376
Name of medicine:	ENOXAPARIN-HEXAL 60 PRE-FILLED SYRINGE
Dosage form:	INJECTION
Active ingredients:	EACH 0,6 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY
Packer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA , PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/8.2/0377
Name of medicine:	ENOXAPARIN-HEXAL 80 PRE-FILLED SYRINGE
Dosage form:	INJECTION
Active ingredients:	EACH 0,8 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY
Packer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA , PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/8.2/0378
Name of medicine:	ENOXAPARIN-HEXAL 100 PRE-FILLED SYRINGE
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY
Packer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA , PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/8.2/0379
Name of medicine:	ENOXAPARIN-HEXAL 40 AMPOULES
Dosage form:	INJECTION
Active ingredients:	EACH 0,4 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY
Packer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA , PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/8.2/0380
Name of medicine:	ENOXAPARIN-HEXAL 300 MULTI-DOSE VIAL
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY
Packer:	IMPFSTOFFWERK DESSAU-TORNAU GmbH, RODLEBEN/ORTSTEIL TORNAU, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA , PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/5.7.1/0395
Name of medicine:	ALLERCHLOR 2 mg/5 ml LIQUID
Dosage form:	LIQUID
Active ingredients:	EACH 5,0 ml LIQUID CONTAINS: CHLORPHENAMINE MALEATE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM ASPEN PHARMACARE, WILSONIA, EAST LONDON
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/34/0412
Name of medicine:	MENOPUR SOLVENT FOR SOLUTION FOR INJECTION
Dosage form:	SOLUTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTIONS 1,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	FERRING (PTY) LTD
Manufacturer:	WEIMAR PHARMA GmbH, RASTATT, GERMANY WULFING PHARMA GmbH, GRONAU, GERMANY
Packer:	WEIMAR PHARMA GmbH, RASTATT, GERMANY WULFING PHARMA GmbH, GRONAU, GERMANY
Laboratory:FPRC:	FERRING GmbH, KIEL, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING, IRENE, RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/4/0436
Name of medicine:	LIGNOCAINE-HCl B BRAUN 1 % 5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LIGNOCAINE HYDROCHLORIDE 10,0 mg
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, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/4/0437
Name of medicine:	LIGNOCAINE-HCl B BRAUN 2 % 5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LIGNOCAINE HYDROCHLORIDE 20,0 mg
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, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/2.7/0440
Name of medicine:	ZYDUS-PARACETAMOL 500 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/7.1.3/0531
Name of medicine:	MAVIK 4 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TRANDOLAPRIL 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ABBOTT LABORATORIES S.A. (PTY) LTD
Manufacturer:	ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY
Packer:	ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY
Laboratory:FPRC: FPRC/FPRR:	ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY ABBOTT LABORATORIES, CONSTANTIA KLOOF, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/20.2.2/0617
Name of medicine:	TRISPORAL
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ITRACONAZOLE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM JANSSEN PHARMACEUTICA NV, OLEN, BELGIUM ETHYPHARM INDUSTRIES, CHATEAUNEUF-en-THYMERAIS, FRANCE
Packer:	JANSSEN-CILAG SpA, LATINA, ITALY JANSSEN PHARMACEUTICA, WOODMEAD, RSA
Laboratory:FPRC:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/28/0001
Name of medicine:	PRIMOVIST 5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: GADOXETIC ACID 181,43 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SCHERING (PTY) LTD
Manufacturer:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY
Packer:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY
Laboratory:FPRC:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY SOUTH AFRICAN BUREUA OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SCHERING, RANDJESPARK, MIDRAND
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/28/0002
Name of medicine:	PRIMOVIST 7,5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: GADOXETIC ACID 181,43 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SCHERING (PTY) LTD
Manufacturer:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY
Packer:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY
Laboratory:FPRC:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY SOUTH AFRICAN BUREUA OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SCHERING, RANDJESPARK, MIDRAND
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/28/0003
Name of medicine:	PRIMOVIST 10 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: GADOXETIC ACID 181,43 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SCHERING (PTY) LTD
Manufacturer:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY
Packer:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY
Laboratory:FPRC:	SCHERING AG CHARLOTTENBURG, BERLIN, GERMANY SCHERING AG WEDDING, BERLIN, GERMANY SOUTH AFRICAN BUREUA OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SCHERING, RANDJESPARK, MIDRAND
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/2.5/0158
Name of medicine:	EPLEPTIN 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
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, MIDRAND, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/2.5/0159
Name of medicine:	EPLEPTIN 300 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
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, MIDRAND, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/2.5/0160
Name of medicine:	EPLEPTIN 400 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
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, MIDRAND, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/20.1.1/0212
Name of medicine:	SANDOZ CEFUROXIME 125 mg/5 ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	GfM GESELLSCHAFT FÜR MIKRONISIERUNG GmbH, BREMEN, GERMANY PENCEF PHARMA GmbH, GOTTINGEN, GERMANY
Packer:	PENCEF PHARMA GmbH, GOTTINGEN, GERMANY NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	PENCEF PHARMA GmbH, GOTTINGEN, GERMANY NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/7.1/0283
Name of medicine:	KLODIP-5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	DEZZO TRADING (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, RSA
FPRR:	DEZZO TRADING, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/21.12/0304
Name of medicine:	BICADEX
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, VIRGONAR, BANGALORE, INDIA CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, VIRGONAR, BANGALORE, INDIA CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA
Laboratory:FPRC:	CIPLA LTD, VIRGONAR, BANGALORE, INDIA CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/21.12/0305
Name of medicine:	CIPLA-BICALUTAMIDE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, VIRGONAR, BANGALORE, INDIA CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, VIRGONAR, BANGALORE, INDIA CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA
Laboratory:FPRC:	CIPLA LTD, VIRGONAR, BANGALORE, INDIA CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/20.1.2/0331
Name of medicine:	AMYN 250
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	DEZZO TRADING (PTY) LTD t/a INDO PHARMA
Manufacturer:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Packer:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Laboratory:FPRC: FPRR:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA DEZZO TRADING, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/20.1.2/0332
Name of medicine:	AMYN 500
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	DEZZO TRADING (PTY) LTD t/a INDO PHARMA
Manufacturer:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Packer:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Laboratory:FPRC: FPRR:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA DEZZO TRADING, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/7.5/0397
Name of medicine:	CIPLA-SIMVASTATIN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory:FPRC: FPRR:	CIPLA LTD, KURKUMBH, PUNE, INDIA CIPLA LIFE SCIENCES, ROSENPARK, BELLVILE
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/7.5/0398
Name of medicine:	CIPLA-SIMVASTATIN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory:FPRC: FPRR:	CIPLA LTD, KURKUMBH, PUNE, INDIA CIPLA LIFE SCIENCES, ROSENPARK, BELLVILE
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/26/0416
Name of medicine:	MABCAMPATH 30 mg/ml
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ALEMTUZUMAB 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SCHERING (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY SCHERING AG, BERLIN, GERMANY
Laboratory:FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY SCHERING AG, BERLIN, GERMANY
FPRR:	SCHERING, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/20.1.1/0525
Name of medicine:	SANDOZ LEVOFLOXACIN 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/20.1.1/0526
Name of medicine:	SANDOZ LEVOFLOXACIN 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/20.2.8/0531
Name of medicine:	AURO-STAVUDINE CAPSULES 30 mg
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/20.2.8/0532
Name of medicine:	AURO-STAVUDINE CAPSULES 40 mg
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA .
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/20.1.2/0563
Name of medicine:	AMYN S 250
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	DEZZO TRADING (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, RSA
FPRR:	DEZZO TRADING, LENASIA, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	41/4/0063
Name of medicine:	LIGNOCAINE-HCl B BRAUN 1 % 10 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LIGNOCAINE HYDROCHLORIDE 10,0 mg
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, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	41/4/0064
Name of medicine:	LIGNOCAINE-HCl B BRAUN 1 % 20 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LIGNOCAINE HYDROCHLORIDE 10,0 mg
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, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	41/4/0065
Name of medicine:	LIGNOCAINE-HCl B BRAUN 2 % 10 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LIGNOCAINE HYDROCHLORIDE 20,0 mg
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, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	41/4/0066
Name of medicine:	LIGNOCAINE-HCl B BRAUN 2 % 20 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LIGNOCAINE HYDROCHLORIDE 20,0 mg
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, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

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We look forward to your ongoing support

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