GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 453 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.
8. 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.
0. 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 453 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 (MBR 15)

Registration number:	93/16.1/3
Name of medicine:	SYNULOC PRED LC
Dosage form:	INFUSION
Active ingredients:	EACH SYRINGE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 200,0 MG POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 50,0 MG PREDNISOLONE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER ITALIANA S.p.A, LATINA, ITALY
Packer:	PFIZER ITALIANA S.p.A, LATINA, ITALY
Laboratory: FPRC:	PFIZER ITALIANA S.p.A, LATINA, ITALY
FPRR:	PFIZER LABORATORIES, PIETERMARITZBURG, RSA
Shelf-life:	18 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	93/1.3.2/8
Name of medicine:	ACTIVON
Dosage form:	INJECTION
Active ingredients:	EACH 1,0ml SOLUTION CONTAINS: DIPRENORPHINE HYDROCHLORIDE 12,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	PHARMA-Q, INDUSTRIA, JOHANNESBURG MC PHARMA, LYTTELTON MANOR, CENTURION
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	93/1.3.1/9
Name of medicine:	CAPTIVON 49
Dosage form:	INJECTION
Active ingredients:	EACH 1,0ml SOLUTION CONTAINS: ETORPHINE HYDROCHLORIDE 4,9 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	PHARMA-Q, INDUSTRIA, JOHANNESBURG MC PHARMA, LYTTELTON MANOR, CENTURION
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	93/1.3.1/10
Name of medicine:	CAPTIVON 98
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ETORPHINE HYDROCHLORIDE 9,8 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	PHARMA-Q, INDUSTRIA, JOHANNESBURG MC PHARMA, LYTTELTON MANOR, CENTURION
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	3115.310394
Name of medicine:	MICRO NEOSTIGMINE METHYL SULPHATE INJECTION 2,5 MG/ML (5 ML A/V)
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: NEOSTIGMINE METHYL SULPHATE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	31/2.9/0459
Name of medicine:	**ALCHEMIST** PETHIDINE HCL INJECTION **25** MG/1 ML
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml AMPOULE ***CONTAINS:*** **PETHIDINE** HYDROCHLORIDE 25,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO **HEALTHCARE,** BETHLEHEM **RSA**
Packer:	MICRO HEALTHCARE, BETHLEHEM **RSA**
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM **RSA**
Shelf-life:	**24** months
Date of registration:	**17** FEBRUARY **2006**

MRF 15

Registration number:	31/2.9/0460
Name of medicine:	ALCHEMIST PETHIDINE HCL INJECTION 50 MG/1 ML
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml AMPOULE CONTAINS: PETHIDINE HYDROCHLORIDE 50,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM **RSA**
Packer:	MICRO HEALTHCARE, BETHLEHEM **RSA**
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM RSA
Shelf-life:	24 months
Date **of registration:**	17 FEBRUARY 2006

MRF 15

Registration number:	31/2.9/0461
Name of medicine:	ALCHEMIST PETHIDINE HCL INJECTION 100 MG/2 ML
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml AMPOULE CONTAINS: PETHIDINE HYDROCHLORIDE 100,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM **RSA**
Packer:	MICRO HEALTHCARE, BETHLEHEM **RSA**
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM **RSA**
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	31/13.5/0475
Name of medicine:	MICRO LUBRICATING JELLY
Dosage form:	JELLY
Active ingredients:	EACH 100,0 g JELLY CONTAINS: GLYCERINE 11,25 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/ FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	32/17.1/0241
Name of medicine:	ALCHEMIST SUXAMETHONIUM INJECTION 100 MG/2 ML
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: SUXAMETHONIUM CHLORIDE DIHYDRATE .....100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	32/10.2/0333
Name of medicine:	MICRO THEOPHYLLIN ETHYLENE DIAMINE I.V. INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: AMINOPHYLLINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, **RSA**
Packer:	MICRO HEALTHCARE, BETHLEHEM, **RSA**
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	32/2.6.1/0334
Name of medicine:	ALCHEMIST PROMAZINE HCL INJECTION 50 MG/1 ML
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: PROMAZINE HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	**24** months
Date of **registration:**	17 FEBRUARY 2006

MRF 15

Registration number:	33/2.7/0397
Name of medicine:	MICRO SUFENTANIL INJECTION 10ug/2 ml
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: SUFENTANIL CITRATE EQUIVALENT TO SUFENTAML 10,0 ug
Conditions ofregistration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO **HEALTHCARE,** BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, **RSA**
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY **2006**

MRF 15

Registration number:	33/2.7/0398
Name of medicine:	MICRO SUFENTANIL INJECTION 50 ug/10 ml
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: SUFENTANIL CITRATE EQUIVALENT TO SUFENTANIL 50,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6,7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, **RSA**
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	**24** months
Date of registration:	**17** FEBRUARY 2006

MRF 15

Registration number:	33/2.1/0423
Name of medicine:	MICRO KETAMINE INJECTION 10MG/ML
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: KETAMINE **HYDROCHLORIDE** EQUIVALENT TO KETAMINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, **RSA**
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	33/1.2/0473
Name of medicine:	MICRO CLOMIPRAMINE HCL INJECTION 25 MG/2ML
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: CLOMIPRAMINE HYDROCHLORIDE 25,0 mg
Conditions of registration:	1, 2, 3, **4,** 5, **6,** 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	34/5.7.2/0051
Name of medicine:	MICRO METOCLOPRAMIDE INJECTION 10MG/2 ML
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: METOCLOPRAMIDE MONOHYDRATE EQUIVALENT TO METOCLOPWIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCAFE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	34/2.6.5/0126
Name of medicine:	MICRO DROPEFUDOL INJECTION 5 MG/2 ML
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: DROPERIDOL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE,, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR **15)**

Registration number:	34/7.1.3/0229
Name of medicine:	**ACCUMAX 5 MG**
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	GOEDECKE GmbH., FREIBURG, GERMANY PFIZER PHARMACEUTICALS LTD, **VEGA** BAJA, PUERTO RICO
Packer:	GOEDECKE GmbH., FREIBURG, GERMANY
Laboratory:FPRC: FPRC/FPRR:	GOEDECKE **GmbH.,** FREIBURG, GERMANY PFLZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, **RSA**
Shelf-life:	***36*** months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	34/7.1.3/0230
Name of medicine:	ACCUMAX 10 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET **CONTAINS:** QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	GOEDECKE GrnbH., FREIBURG, GERMANY PFIZER PHARMACEUTICALS, VEGA BAJA, PUERTO RICO
Packer:	GOEDECKE GmbH, FREIBURG, GERMANY
Laboratory:FPRC: FPRC/FPRR:	GOEDECKE GmbH., FREIBURG, GERMANY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	**36** months
Date of registration:	**17** FEBRUARY **2006**

MRF 15 (MBR 15)

Registration number:	34/7.1.3/0231
Name of medicine:	ACCUMAX 20 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg .
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	GOEDECKE GmbH., FREIBURG, GERMANY PFIZER PHARMACEUTICALS LTD, VEGA BAJA, PUERTO RICO
Packer:	GOEDECKE GmbH., FREIBURG, GERMANY
Laboratory:FPRC: FPRC/FPRR:	GOEDECKE GmbH., FREIBURG, GERMANY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	34/7.1.3/0232
Name of medicine:	ACCUMAX 40 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL **HYDROCHLORIDE** EQUIVALENT TO QUINAPRIL 40,0 mg
Conditions **of** registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) **LTD**
Manufacturer:	GOEDECKE GmbH., FREIBURG, **GERMANY** PFIZER PHARMACEUTICALS, VEGA BAJA, PUERTO RICO
Packer:	GOEDECKE GmbH., FREIBURG, **GERMANY**
Laboratory:FPRC: FPRC/FPRR:	GOEDECKE GmbH., FREIBURG, GERMANY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, **RSA**
Shelf-life:	36 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	36/34/0432
Name of medicine:	SUN PHARMA STERILE WATER FOR INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 2,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	M J PHARMACEUTICALS LTD, HALOL, GUJARAT, INDIA
Packer:	M J PHARMACEUTICALS LTD, HALOL, GUJARAT, INDIA
Laboratory:	M J PHARMACEUTICALS LTD, HALOL, GUJARAT, INDIA MC PHARMA, LYTTELTON MANOR, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	37/26/0103
Name of medicine:	HX-MITOXANTRONE 20 MG/10 ML
Dosage form:	INFUSION
Active ingredients:	EACH 10 ml SOLUTION CONTAINS: MITOXANTONE HYDROCHLORIDE EQUIVALENT TO MITOXANTRONE 2,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	EBEWE ARZNEIMITTEL GESELLSCHAFT, UNTERLACH, AUSTRIA
Packer:	EBEWE ARZNEIMITTEL GESELLSCHAFT, UNTERLACH, AUSTRIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA PHARMA-Q, INDUSTRIA WEST, RSA
Laboratory:FPRC:	EBEWE ARZNEIMITTEL GESELLSCHAFT, UNTERLACH, AUSTRIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA PHARMA-Q, INDUSTRIA WEST, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	36/7.1.3/0382
Name of medicine:	DIOVAN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND ALLPACK AG, MUTTENZ, SWITZERLAND KONPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR, GERMANY NOVARTIS, SPARTAN, KEMPTON PARK, **RSA**
Laboratory: FPRC:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK, **RSA**
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37/5.8/0138
Name of medicine:	SINUTAB SINUS PAIN **AND** CONGESTION
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 500,0 mg PSEUDOEPHEDRINE HYDROCHLORIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WARNER-LAMBERT S.A. (PTY) LTD
Manufacturer:	GOEDECKE AG, FREIBURG, GERMANY
Packer:	GOEDECKE AG, FREIBURG, GERMANY WARNER-LAMBERT, RETREAT, RSA
Laboratory: FPRC: **FPRR:**	GOEDECKE **AG,** FREIBURG, GERMANY WARNER-LAMBERT, RETREAT, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15

Registration number:	37/26/0168
Name of medicine:	MITOXANTRONE-HEXAL 20 MG/10 ML
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: MITOXANTONE HYDROCHLORIDE EQUIVALENT TO MITOXANTRONE 2,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	EBEWE ARZNEIMITTEL GESELLSCHAFT, UNTERLACH, AUSTRLA
Packer:	EBEWE ARZNEIMITTEL GESELLSCHAFT, UNTERLACH, **AUSTRIA** DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA PHARMA-Q, INDUSTRIA WEST, RSA
Laboratory:FPRC:	EBEWE ARZNEIMITTEL GESELLSCHAFT, UNTERLACH, AUSTRIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, **RSA** ANALYTICON, KEMPTON PARK, RSA **PHARMA-Q,** INDUSTRIA WEST, **RSA**
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY **2006**

MRF 15

Registration number:	37/3/0186
Name of medicine:	FASTURTEC 1,5 MG/ML
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: RASBURICASE 1,5 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, NOTRE DAME de BONDEVILLE, FRANCE
Packer:	SANOFI WINTHROP INDUSTRE, NOTRE **DAME** de BONDEVILLE, FRANCE
Laboratory:FPRC:	SANOFI WINTHROP INDUSTRIE, NOTRE DAME de BONDEVILLE, FRANCE INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	SANOFI-SYNTHELABO, WOODMEAD, RSA
Shelf-life:	*36* months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	**37/34/0187**
Name of medicine:	**SOLVENT** FOR FASTURTEC
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: POLOXAMER 188 1,0 MG WATER FOR INJECTIONS qs 1,0 ML
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, NOTRE DAME de BONDEVILLE, FRANCE SANOFI WINTHROP INDUSTFUE, AMBARES, FRANCE
Laboratory:FPRC:	SANOFI *WINTHROP* INDUSTRIE, NOTRE DAME de BONDEVILLE, FRANCE SANOFI WINTHROP INDUSTRE, AMBARES, FRANCE INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	SANOFI-SYNTHELABO, WOODMEAD, RSA
Shelf-life:	**48** months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	37/7.1.3/0225
Name of medicine:	CO-DIOVAN 160 PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 MG HYDROCHLOROTHIAZIDE 25,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND ALLPACK AG, MUTTENZ, SWITZERLAND KONPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR, GERMANY NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLANR INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA
FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15

Registration number:	37/34/0243
Name of medicine:	NUTRINEAL PD4 WITH 1,1 % *AMINO* ACIDS
Dosage form:	DIALYSIS SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: CALCIUM CHLORIDE DIHYDRATE 0,184 g MAGNESIUM CHLORIDE HEXAHYDRATE 0,0508 g SODIUM LACTATE 4,480 g SODIUM CHLORIDE 5,380 g *AMINO* ACID BLEND: L-ALANINE 951,0 mg L-ARGININE 1071,0 mg GLYCINE 510,0 mg L-HISTIDINE 714,0 mg L-ISOLEUCINE 850,0 mg L-LEUCINE 1020,0 mg L-LYSINE 950,0 mg L-METHIONINE 850,0 mg L-PHENYLALANINE 570,0 mg L-PROLINE 595,0 mg L-SERINE 510,0 mg L-THREONINE 646,0 mg L-TRYPTOPHAN 270,0 mg L-TYROSINE 300,0 mg L-VALINE 1393,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	BAXTER HEALTHCARE S.A, CASTLE BAR, ***COUNTY*** MAYO, IRELAND

Packer:	BAXTER HEALTHCARE S.A, CASTLE BAR, ***COUNTY*** MAYO, IRELAND ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, **RSA**
Laboratory:FPRC:	BAXTER HEALTHCARE S.A, CASTLE BAR, COUNTY MAYO, IRELAND BAXTER R&D EUROPE, NIVELLES, BELGIUM
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, **RSA**
Shelf-life:	24 months
Date **of** registration:	17 FEBRUARY 2006

MRF 15 **(MBR 15)**

Registration number:	37/5.8/0260
Name of medicine:	**SINUTAB** SINUS ALLERGY
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 500,0 **MG** CHLORPHENIRAMINE MALEATE 2,0 MG PSEUDOEPHEDRINE HYDROCHLORIDE 30,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WARNER-LAMBERT S.A. (PTY) LTD
Manufacturer:	WARNER-LAMBERT, RETREAT, **RSA**
Packer:	WARNER-LAMBERT, RETREAT, RSA
Laboratory: FPRC:	WARNER-LAMBERT, RETREAT, RSA
FPRR:	WARNER-LAMBERT, **RETREAT, RSA**
Shelf-life:	**24** months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0362
Name of medicine:	PHARMACARE AZITHROMYCIN 500 **MG**
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN MONOHYDRATE EQUIVALENT TO AZITHROMYCIN 500,0 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:	LENNON LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA, EAST LONDON PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	37/10.2.1/463
Name of **medicine:**	CIPLA-IPRATROPIUM BROMIDE RESPULES
Dosage form:	INHALATION
Active ingredients:	**EACH 2,0 ml SOLUTION CONTAINS:** **IPRATROPIUM BROMIDE** 0,50 **MG**
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	**CIPLA** MEDPRO (PTY) **LTD**
Manufacturer:	**CIPLA** LTD, VIKHROLI, MUMBAI, INDIA
Packer:	**CIPLA LTD, VIKHROLI, MUMBAI, INDIA**
Laboratory:	**CPLA LTD, VIKHROLI, MUMBAI, INDIA** **CIPLA MEDPRO,** ROSENPARK, BELLVILLE, **RSA**
Shelf-life:	**24** months
Date of registration:	**17** FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	37/1.2/0533
Name of medicine:	VENLOR 37,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 37,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CPLA LTD, PATALGANGA, RAIGAD, INDIA
Packer:	CIPLA LTD, PATALGANGA, ***RAIGAD,*** INDIA
Laboratory: FPRC: FPRR:	CIPLA LTD, PATALGANGA, RAIGAD, INDIA CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	37/1.2/0534
Name of medicine:	VENLOR *75*
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, ***RAIGAD,*** INDIA
Packer:	CIPLA LTD, PATALGANGA, ***RAIGAD,*** **INDIA**
Laboratory:FPRC:	CIPLA LTD, PATALGANGA, ***RAIGAD,*** INDIA
FPRR:	**CIPLA** LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	37/2.1/0553
Name of medicine:	PROPOFOL 2 % FRESENIUS (20ML AMPOULE)
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml EMULSION CONTAINS: PROPOFOL 20,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI S.A. (PTY) LTD
Manufacturer:	FRESENIUS KABI AUSTRJA GmbH, GRAS, AUSTRIA
Packer:	FRESENIUS KABI AUSTRIA GmbH, GRAS, AUSTRIA
Laboratory: FPRC:	FRESENIUS KABI AUSTRIA GmbH, GRAS, AUSTRIA FRESENTUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA BODENE, KORSTEN, PORT ELIZABETH
FPRR:	FRESENIUS KABI, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER *2005*

MRF 15 (MBR **15)**

Registration number:		37/2.1/0554
Name of medicine:		PROPOFOL 2 % FRESENIUS (50 ML VIAL)
Dosage form:		INJECTION
Active ingredients:		**EACH** 1,0 ml EMULSION CONTAINS: PROPOFOL 20,0 MG
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		FRESENIUS KABI S.A. (PTY) LTD
Manufacturer:		FRESENIUS KABI AUSTRIA GmbH, GRAS, AUSTRIA
Packer:		FRESENIUS KABI AUSTRIA GmbH, GRAS, AUSTRIA
Laboratory:	FPRC:	FRESENIUS KABI AUSTRIA GrnbH, GRAS, AUSTRIA FRESENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA BODENE, KORSTEN, PORT ELIZABETH
	FPRR:	F R E S E W S KABI, MIDRAND, RSA
Shelf-life:		**24** months
Date of registration:		25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37121/0555
Name of medicine:	PROPOFOL 2 % FRESENIUS (100 ML VIAL)
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml EMULSION CONTAINS: PROPOFOL 20,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI S.A. (PTY) LTD
Manufacturer:	FRESENIUS KABI AUSTRIA GmbH, GRAS, AUSTRIA
Packer:	FRESENIUS KABI AUSTRIA GmbH, GRAS, AUSTRIA
Laboratory: FPRC:	FRESENIUS KABI AUSTRIA GmbH, GRAS, AUSTRIA FRESENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA BODENE, KORSTEN, PORT ELIZABETH
FPRR:	FRESENIUS KABI, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15

Registration number:	38/2.9/0092
Name of medicine:	TRAMAHEXAL SR 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 100,0 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, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, **RSA**
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	38/2.9/0093
Name of medicine:	TRAMAHEXAL SR 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 150,0 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, KEMPTON PARK, **RSA**
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	38/2.9/0094
Name of medicine:	TRAMAHEXAL SR 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 200,0 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 DNPHARM MANUFACTURING & **PACKAGING,** LONGDALE, **RSA**
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, **STAR** STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, **RSA**
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	38/5.8/0115
Name of medicine:	SINUTAB SINUS ALLERGY CONGESTION
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PSEUDOEPHEDRINE HYDROCHLORIDE 120,0 MG CETIRIZINE DIHYDROCHLORIDE 5,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WARNER-LAMBERT S.A. (PTY) LTD
Manufacturer:	UCB FARCHIM S.A., BULLE, SWITZERLAND
Packer:	UCB PHARMA S.A., PIANEZZA, ITALY
Laboratory: FPRC:	UCB FARCHIM S.A., BULLE, SWITZERLAND WARNER-LAMBERT RETREAT, RSA
FPRR:	WARNER-LAMBERT RETREAT, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	38/20.2.8/0151
Name of medicine:	ELIVIR
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:	LE BASI PHARMACEUTICALS CC
Manufacturer:	VARICHEM LABORATORIES, HARARE, ZIMBABWE
Packer:	VARICHEM LABORATORIES, HARARE, ZIMBABWE
Laboratory: FPRC:	VARICHEM LABORATORIES, HARARE, ZIMBABWE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, BARDENE, BOKSBURG, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, **RSA**
FPRR:	LE BASI PHARMACEUTICALS, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	38/5.10/0160
Name of medicine:	ONDANSETRON-HEXAL 4 MG FILM COATED TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 4,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	HEXAL AG, HOLZKJRCHEN, GERMANY SALUTAS PHARMA, BARLEBEN, GERMANY CONSULTING CHEMICAL LABS, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA HEXAL PHARMA, WSTMEAD, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF *15* (MBR 15)

Registration number:	38/5.10/0161
Name of medicine:	ONDANSETRON-HEXAL 8 MG FILM COATED TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 8,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL **PHARMA (SA)** (PTY) LTD
Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	DIVPHARM MANUFACTURING &PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	HEXAL **AG,** HOLZKIRCHEN, GERMANY **SALUTAS** PHARMA, **BARLEBEN,** GERMANY CONSULTING CHEMICAL *LABS*, STAR STREET, BOKSBURG, **RSA** ANALYTICON, KEMPTON PARK, **RSA** HEXAL **PHARMA,** WESTMEAD, **RSA**
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number: 38/25.2/0165

Name of medicine: KABIVEN PERIPHERAL

Dosage form: INFUSION

Active ingredients: EACH SYSTEM CONTAINS THREE CHAMBERS:

GLUCOSE 11 % CHAMBER CONTAINS PER 1180 ml:

Glucose anhydrous	130,0 g

VAMIN 18 NOVUM CHAMBER CONTAINS PER 400 ml:

L-Alanine	6,4 g
L-Arginine	4,5 g
L-Aspartic Acid	1,4 g
L-Glutamic Acid	2,2 g
Glycine	3,2 g
L-Histidine	2,7 g
L-Isoleucine	2,2 g
L-Leucine	3,2 g
L-Lysine hydrochloride	4,5 g
L-Methionine	2,2 g
L-Phenylalanine	3,2 g
L-Proline	2,7 g
L-Serine	1,8 g
L-Threonine	2,2 g
L-Tryptophan	0,76 g
L-Tyrosine	0,092 g
L-Valine	2,90 g
Calcium Chloride	0,30 g
Sodium Glycerophosphate	2,0 g
Magnesium Sulphate	0,64 g
Potassium Chloride	2,4 g
Sodium Acetate	2,0 g

INTRALIPID 20 % CHAMBER CONTAINS PER 340 ml:

Purified Soybean Oil	68,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: FRESENIUS KABI S.A. (PTY) LTD

Manufacturer:	FRESEMUS KABI AB, UPPSALA, SWEDEN
Packer:	FRESENTUS KABI AB, UPPSALA, SWEDEN
Laboratory:FPRC:	FRESENTUS KABI AB, UPPSALA, SWEDEN KHULULEKANI LABORATORY SERVICE, MIDRAND
	BODENE, PORT ELIZABETH, RSA
FPRR:	FRESEWS KABI, MIDRAND, RSA
	BODENE, PORT ELIZABETH, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	38/34/0227
Name of medicine:	EBIXA 10 MG/G DROPS
Dosage form:	DROPS
Active ingredients:	EACH 1,0 g SOLUTION CONTAINS: MEMANTINE HYDROCHLORIDE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	H. LUNDBECK (PTY) LTD
Manufacturer:	MERZ + CO. GmbH & CO., REINHEIM, GERMANY
Packer:	MERZ + CO. GmbH & CO., REINHEIM, GERMANY
Laboratory: FPRC:	MERZ + CO. GmbH & CO., REINHEIM, GERMANY H. LUNDBECK A/S, COPENHAGEN, DENMARK
FPRR:	H. LUNDBECK, NORTH RIDING, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	38/20.1.1/0237
Name of **medicine:**	ADCO-MINOCYCLINE 50
Dosage form:	**CAPSULE**
Active ingredients:	**EACH CAPSULE** CONTAINS: MINOCYCLINE HYDROCHLORIDE EQUIVALENT TO MINOCYCLINE 50,0 MG
Conditions **of** registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	**ADCOCK** INGRAM LIMITED
Manufacturer:	ETHYPHARM INDUSTRIES, CHATEAUNEUF-EN-THYMERAIS, FRANCE
Packer:	ETHYPHARM INDUSTRIES, CHATEAUNEUF-EN-THYMERAIS, FRANCE ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM HEALTHCARE, OLIFANTSFONTEIN, CLAYVILLE
Laboratory: FPRC:	ETHYPHARM INDUSTRIES, CHATEAUNEUF-EN-THYMERAIS, FRANCE
FPRC/FPRR:	**ADCOCK** INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM HEALTHCARE, OLEANTSFONTEIN, CLAYVILLE
Shelf-life:	**24** months
Date **of** registration:	**17** FEBRUARY **2006**

MRF 15

Registration number:	38/20.1.1/0238
Name of medicine:	ADCO-MINOCYCLINE 100
Dosage form:	CAPSULE
Active ingredients:	**EACH** CAPSULE CONTAINS: MINOCYCLINE HYDROCHLORIDE EQUIVALENT TO MINOCYCLINE 100,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM **LIMITED**
Manufacturer:	ETHYPHARM INDUSTRIES, CHATEAUNEUF-EN-THYMERAIS, FRANCE
Packer:	ETHYPHARM INDUSTRIES, CHATEAUNEW-EN-THYMERAIS, FRANCE ADCOCK **INGRAM** HEALTHCARE, WADEVILLE, GERMISTON ADCOCK **INGRAM** HEALTHCARE, OLIFANTSFONTEIN, CLAYVILLE
Laboratory:FPRC:	ETHYPHARM INDUSTRIES, CHATEAUNEW-EN-THYMERAIS, FRANCE
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM HEALTHCARE, OLIFANTSFONTEIN, CLAYVILLE
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY **2006**

MRF 15 (MBR 15)

Registration number:	38113.4.210265
Name of medicine:	APEX-ISOTRETINOIN 20 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ISOTRETINOIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	FARMACEUTISCH ANALYTISCH LABORATORIUM B.V., DUIVEN, THE NETHERLANDS
Packer:	FARMACEUTISCH ANALYTISCH LABORATORIUM B.V., DUIVEN, THE NETHERLANDS
Laboratory:FPRC:	FARMACEUTISCH ANALYTISCH LABORATORIUM B.V., DUIVEN, THE NETHERLANDS SOUTH ***AFRICAN*** BUREAU OF STANDARDS, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICALS SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, SAXONWOLD, **RSA**
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	38/13.4.2/0267
Name of medicine:	APEX-ISOTRETINOIN 10 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ISOTRETINOIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	FARMACEUTISCH ANALYTISCH LABORATORIUM B.V., DUIVEN, THE NETHERLANDS
Packer:	FARMACEUTISCH ANALYTISCH LABORATORIUM B.V., DUIVEN, THE NETHERLANDS
Laboratory:FPRC:	FARMACEUTISCH ANALYTISCH LABORATORIUM B.V., DUIVEN, THE NETHERLANDS SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICALS SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, SAXONWOLD, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	38/34/0275
Name of medicine:	MERCK-CEFTIUAXONE WFI
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTIONS
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	LABORATOIRES INIBSA S.A., BARCELONA, SPAIN
Packer:	LABORATOIRES INIBSA S.A., BARCELONA, SPAIN LDP-LABORATOIRES TORLAN SA, BARCELONA, SPAIN
Laboratory:FPRC:	LDP-LABOMTOIRES TORLAN SA, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA
FPRR:	MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	

MRF 15 (MBR 15)

Registration number:	38/1.2/0290
Name of medicine:	ADCO-ZERTRA 50
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:	ADCOCK INGRAM LIMITED
Manufacturer:	DELTA LTD, HAFNARFJORDUR, ICELAND
Packer:	DELTA LTD, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN
Laboratory:FPRC: FPRC/FPRR:	DELTA LTD, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	38/1.2/0291
Name of medicine:	ADCO-ZERTRA 100
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:	ADCOCK INGRAM LIMITED
Manufacturer:	DELTA LTD, HAFNARFJORDUR, ICELAND
Packer:	DELTA LTD, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN
Laboratory: FPRC: FPRC/FPRR:	DELTA LTD, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15(MBR 15)

Registration number:	A38/5.7.1/0380
Name of medicine:	APEX-LORATADINE 10 MG TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LORATADINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory: FPRC:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	A38/20.2.8/0409
Name of medicine:	TRIOMUNE 40
Dosage form:	TABLET
Active ingredients:	**EACH** TABLET CONTAINS: LAMIVUDINE 150,0 **mg** **STAVUDINE** 40,0 mg NEVIRAPINE 200,0 **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:	**CIPLA** LTD, PATALGANGA, MAHARASHTRA, INDIA **CPLA-MEDPRO,** ROSENPARK, BELLVILLE, **RSA**
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration **number:**	A38/2.2/0564
Name of medicine:	MICRO MIDAZOLAM INJECTION 5 MG/5 ML
Dosage form:	INJECTION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: MIDAZOLAM HYDROCHLORIDE EQUIVALENT TO MIDAZOLAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCAFE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, **RSA**
Packer:	MICRO HEALTHCARE, BETHLEHEM, **RSA**
Laboratory:FPRC/FPRR:	MICRO ***HEALTHCARE,*** BETHLEHEM, RSA
Shelf-life:	**24** months
Date of registration:	**17** FEBRUARY 2006

MRF 15

Registration number:	A3812.210565
Name of medicine:	MICRO MIDAZOLAM INJECTION 15 MG/3 ML
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: MIDAZOLAM HYDROCHLOFUDE EQUIVALENT TO MIDAZOLAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A38/2.2/0566
Name of medicine:	MICRO MIDAZOLAM INJECTION 50 MG/10 ML
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: MIDAZOLAM HYDROCHLORIDE EQUIVALENT TO MIDAZOLAM 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MICRO HEALTHCARE (PTY) LTD
Manufacturer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Packer:	MICRO HEALTHCARE, BETHLEHEM, RSA
Laboratory:FPRC/FPRR:	MICRO HEALTHCARE, BETHLEHEM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A38/21.1/0506
Name of medicine:	APIDRA
Dosage form:	INJECTION
Active ingredients:	EACH 10 ml SOLUTION CONTAINS: INSULIN GLULISINE EQUIMOLAR TO INSULIN 100,0 iu
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Packer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A38/21.12/0656
Name of medicine:	FASLODEX
Dosage form:	INJECTION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: FULVESTRANT 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	VETTER PHARMA-FERTIGUNG GmbH, SCHUTZENSTRASSE, RAVENSBURG, GERMANY
Packer:	VETTER PHARMA-FERTIGUNG GmbH, SCHUTZENSTRASSE, RAVENSBURG, GERMANY VETTER PHARMA-FERTIGUNG GmbH, HOLBEINSTRASSE, RAVENSBURG, GERMANY ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Laboratory:FPRC:	VETTER PHARMA-FERTIGUNG GmbH, SCHUTZENSTRASSE, RAVENSBURG, GERMANY VETTER PHARMA-FERTIGUNG GmbH, KOLBEINSTRASSE, RAVENSBURG, GERMANY VETTER PHARMA-FERTIGUNG GmbH, LANGENARGEN, GERMANY ASTRAZENECA UK, MACCLESFIELD,CHESHIRE,UK ANALYTICON, KEMPTON PARK, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRC/FPRR:	ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON, RSA
Shelf-life:	36 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	A38/5.4/0699
Name of medicine:	ENABLEX 7,5 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DARIFENACIN HYDROBROMIDE EQWALENT TO DARIFENACIN 7,5 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	PFIZER INC, BROOKLYN, NEW YORK, USA
Packer:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Laboratory:FPRC:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	A38/5.4/0700
Name of medicine:	ENABLEX 15 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DARIFENACIN HYDROBROMIDE EQUIVALENT TO DARIFENACIN 15,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	PFIZER INC, BROOKLYN, NEW YORK, **USA**
Packer:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND NOVARTIS, SPARTAN, KEMPTON PARK, **RSA**
Laboratory:	NOVARTIS PHARMA STEIN, SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG NOVARTIS, SPARTAN, KEMPTON PARK, **RSA**
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/2.2/0021
Name of medicine:	APEX-ZOPICLONE 7,5 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOPICLONE 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA
FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/2.2/0022
Name of medicine:	ZOPIVANE 7,5 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOPICLONE 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA
FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/26/0028
Name of medicine:	ALIMTA 500 MG
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: PEMETREXED DISODIUM EQUIVALENT TO PEMETREXED 500,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	LILLY FRANCE S.A.S., FEGERSHEIM, FRANCE
Packer:	LILLY FRANCE S.A.S.,FEGERSHEM, FRANCE
Laboratory:FPRC:	LILLY FRANCE S.A.S.,FEGERSHEIM, FRANCE SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	ELI LILLY, BRYANSTON, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	A39/8.2/0079
Name of medicine:	CLEXANE 20
Dosage form:	INJECTION
Active ingredients:	EACH 0,2 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PHARMA SPECIALITES, CEDEX, FRANCE AVENTIS PHARMA le TRAIT, le TRAIT, FRANCE
Packer:	AVENTIS PHARMA SPECIALITES, CEDEX, FRANCE AVENTIS PHARMA le TRAIT, le TRAIT, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC:	AVENTIS PHARMA SPECIALITES, CEDEX, FRANCE AVENTIS PHARMA le TRAIT, le TRAIT, FRANCE
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	A39/6.4/0106
Name of medicine:	INSPRA 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EPLERENONE 25,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	SEARLE LTD, CAGUAS, PUERTO RICO
Packer:	SEARLE LTD, CAGUAS, PUERTO RICO PHARMACIA LTD, MORPETH, NORTHUMBERLAND UK
Laboratory:FPRC:	PHARMACIA LTD, MORPETH, NORTHUMBERLAND UK
FPRC/FPRR:	PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15(MBR 15)

Registration number:	A39/6.4/0107
Name **of** medicine:	INSPRA 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET **CONTAINS:** EPLEFSNONE 50,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	**SEARLE** LTD, CAGUAS, PUERTO RICO
Packer:	**SEARLE** LTD, **CAGUAS,** PUERTO RICO **PHARMACIA** LTD, MORPETH, NORTHUMBERLAND **UK**
Laboratory:FPRC:	**PHARMACIA** LTD, MORPETH, NORTHUMBERLAND **UK**
FPRC/FPRR:	**PFIZER** GLOBAL **MANUFACTURING,** RETREAT, CAPE TOWN, **RSA**
Shelf-life:	**24** months
Date of registration:	**17** FEBRUARY ***2006***

MRF 15

Registration number:	A39/20.2.8/0110
Name of medicine:	VARI-STAVUDINE 30 MG
Dosage form:	CAPSULE
Active ingredients:	EACH **CAPSULE** CONTAINS: STAVUDINE 30,0 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*
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/20.2.8/0111
Name of **medicine:**	VARI-STAVUDINE 40 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 40,0 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
Shelf-life:	**24** months
Date **of** registration:	**17** FEBRUARY 2006

MRF 15

Registration number:	A39/20.2.2/0118
Name of medicine:	NAFIN 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 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, UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.1.3/0138
Name of medicine:	QUINAHEXAL 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	MERCK FARMA y QUIMICA, BARCELONA, SPAIN
Packer:	MERCK FARMA y QUIMICA, BARCELONA, SPAIN DIVPHARM MANUFACTURING &PACKAGING, LONGDALE, GAUTENG, RSA
Laboratory:FPRC:	MERCK FARMA y QUIMICA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.1.3/0139
Name of medicine:	QUINAHEXAL 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 40,0 mg
Conditions of registration:	1,2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	MERCK FARMA y QUIMICA, BARCELONA, SPAIN
Packer:	MERCK FARMA y QUIMICA, BARCELONA, SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, GAUTENG, RSA
Laboratory:FPRC:	MERCK FARMA y QUIMICA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	A39/11.5/0263
Name of medicine:	LENNON LACTULOSE LEMON
Dosage form:	SOLUTION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: LACTULOSE ANHYDROUS **3,297** g
Conditions **of** registration:	**1, 2, 3, 4,** 5, **6, 7**
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:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON **SOUTH** AFRICAN **BUREAU** OF **STANDARDS,** GROENKLOOF, PRETORIA, **RSA** RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
Shelf-life:	**24** months
Date of registration:	**23** SEPTEMBER 2005

MRF 15

Registration number:	A39/1.2/0308
Name of medicine:	SERTRA TABLETS 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:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER ITALIA S.r.l., BORGO SAN MICHELE, ITALY
Packer:	PFIZER ITALIA S.r.l., BORGO SAN MICHELE, ITALY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Laboratory:FPRC: FPRC/FPRR:	PFIZER ITALIA S.r.l., BORGO SAN MICHELE, ITALY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	17 FEBRUARY *2006*

MRF 15

Registration number:	A39/7.0/0326
Name of medicine:	CADUET 5 MG/10 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 MG ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY
Packer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA PFIZER GLOBAL, MANUFACTURING, RETREAT, CAPE TOWN, RSA
Laboratory:FPRC:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA
FPRC/FPRR:	PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A3917.010327
Name of medicine:	CADUET 5 MG/20 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODPINE 5,0 MG ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY
Packer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Laboratory: FPRC: FPRC/FPRR:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.0/0328
Name **of** medicine:	CADUET 5 MG/40 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 MG ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY
Packer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, **RSA**
Laboratory:FPRC:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY
FPRC/FPRR:	PFIZER INC, BROOIUYN, NEW YORK, USA PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY **2006**

MRF 15

Registration number:	A39/7.0/0329
Name of medicine:	CADUET 5 MG/80 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE **BESYLATE** EQUIVALENT TO AMLODIPINE 5,0 MG ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 **MG**
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, *FREIBURG*, GERMANY
Packer:	PFIZER GmbH **ARZNEIMITTELWERK** GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW ***YORK***, USA PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, **RSA**
Laboratory: FPRC:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW ***YORK*, USA**
FPRC/FPRR:	PFIZER GLOBAL **MANUFACTURING,** RETREAT, *CAPE* TOWN, **RSA**
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.0/0330
Name of medicine:	CADUET 10MG/10 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPPINE BESYLATE EQUIVALENT TO AMLODIPPINE 10,0 MG ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES **(PTY)** LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY
Packer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA PFIZER GLOBAL MANUFACTURING, RETREAT, **CAPE** TOWN, RSA
Laboratory:FPRC:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, **NEW** YORK, USA
FPRC/FPRR:	PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.0/0331
Name of medicine:	CADUET 10 MG/20 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 MG ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY
Packer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Laboratory: FPRC:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA
FPRC/FPRR:	PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.0/0332
Name of medicine:	CADUET 10 MG/40 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 MG ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY
Packer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA PFIZER GLOBAL, MANUFACTURING, RETREAT, CAPE TOWN, RSA
Laboratory: FPRC:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA
FPRC/FPRR:	PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	24 months
Date **of** registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.0/0333
Name of medicine:	CADUET 10MG/80 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 MG ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY
Packer:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Laboratory:FPRC:	PFIZER GmbH ARZNEIMITTELWERK GOEDECKE, FREIBURG, GERMANY PFIZER INC, BROOKLYN, NEW YORK, USA
FPRC/FPRR:	PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.1/0368
Name of medicine:	APEX-AMLODIPINE 5 MG
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, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	**INTAS** PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SEVERTONDALE, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	**24** months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.1/0369
Name of medicine:	APEX-AMLODIPINE 10 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/2.9/0415
Name of medicine:	TRAMAZAC CAPSULES
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TRAMADOL HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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 S.A, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/2.5/0492
Name of medicine:	MERCK-LAMOTRIGINE 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, CANADA
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA y QUIMICA **S.A.,** BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA y QUIMICA **S.A.,** BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/2.5/0493
Name of medicine:	MERCK-LAMOTRIGINE 50 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTATNS: 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, CANADA
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, **RSA**
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN
Shelf-life:	*24* months
Date of registration:	**17** FEBRUARY 2006

MRF 15

Registration number:	A39/2.5/0494
Name of medicine:	MERCK-LAMOTRIGINE 100 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 100,0 MG
Conditions of regstration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA y QUIMICA **S.A.,** BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, **RSA** RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/2.5/0495
Name of medicine:	MERCK-LAMOTRIGINE 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, CANADA
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GENERICS LTD, POTTERS BAR, HXRTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA y QUTMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.1.3/0541
Name of medicine:	CORYOL 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	KRKA, D.D., NOVO MESTO, SLOVENIA
Packer:	KRKA, D.D., NOVO MESTO, SLOVENIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	KRKA, D.D., NOVO MESTO, SLOVENIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, KEMPTON PARK, RSA NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR:	*SANDOZ*, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	17 FEBRUARY *2006*

MRF 15

Registration number:	A39/7.1.3/0542
Name of medicine:	CORYOL 6,25
Dosage form:	TABLET
Active ingredients:	**EACH** TABLET CONTAINS: **CARVEDILOL** 6,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	KRKA, D.D., NOVO MESTO, SLOVENLA
Packer:	KRKA, D.D., NOVO MESTO, SLOVENIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	KRKA, D.D., NOVO MESTO, SLOVENIA **SOUTH *AFRICAN*** BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, KEMPTON PARK, RSA NOVARTIS **S.A.,** SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	**24** months
Date of registration:	**17** FEBRUARY **2006**

MRF 15

Registration number:	A39/7.1.3/0543
Name of medicine:	CORYOL 12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	KRKA, D.D., NOVO MESTO, SLOVENIA
Packer:	KRKA, D.D., NOVO MESTO, SLOVENIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	KRKA, D.D., NOVO MESTO, SLOVENIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, KEMPTON PARK, RSA NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/34/0549
Name of medicine:	DOCETERE SOLVENT
Dosage form:	SOLUTION
Active ingredients:	**EACH** VIAL CONTAINS: WATER FOR INECTIONS 1,5 ML
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PHARMA, **DAGENHAM,** EAST-ESSEX, UK
Packer:	AVENTIS PHARMA, DAGENHAM, EAST-ESSEX, UK AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC: FPRC/FPRR:	AVENTIS PHARMA, DAGENHAM, EAST-ESSEX, UK AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	*36* months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/26/0550
Name of medicine:	DOCETERE 20 MG
Dosage form:	INFUSION
Active ingredients:	EACH SINGLE-DOSE VIAL CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 20,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PRICIPES ACTIFS PHARMACEUTIQUES, VITRY-SUR-SEINE, FRANCE AVENTIS PHARMA, DAGENHAM, EAST-ESSEX, UK PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Packer:	AVENTIS PHARMA, DAGENHAM, EAST-ESSEX, UK PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC:	AVENTIS PHARMA, DAGENHAM, EAST-ESSEX, UK PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/26/0551
Name of medicine:	DOCETERE 80 MG
Dosage form:	INFUSION
Active ingredients:	EACH SINGLE-DOSE VIAL CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 80,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PRICIPES ACTIFS PHARMACEUTIQUES, VITRY-SUR.-SEINE, FRANCE AVENTIS PHARMA, DAGENHAM, EAST-ESSEX, UK PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Packer:	AVENTIS PHARMA, DAGENHAM, EAST-ESSEX, UK PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC:	AVENTIS PHARMA, DAGENHAM, EAST-ESSEX, UK **PIERRE FABRE** MEDICAMENT PRODUCTION, IDRON, FRANCE
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	**36** months
Date **of** registration:	**17** FEBRUARY 2006

MRF 15

Registration number:	A39/7.1.3/0554
Name of medicine:	SANDOZ CARVEDILOL 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDLLOL 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	KRKA, D.D., NOVO MESTO, SLOVENIA
Packer:	KRKA, D.D., NOVO MESTO, SLOVENLA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:FPRC:	KRKA, D.D., NOVO MESTO, SLOVEMA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, KEMPTON PARK, RSA NOVARTIS **S.A.,** SPARTAN, KEMPTON PARK
FPRR:	*SANDOZ,* SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.1.3/0555
Name of medicine:	SANDOZ CARVEDILOL 6,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 6,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	KRKA, D.D., NOVO MESTO, SLOVENIA
Packer:	KRKA, D.D., NOVO MESTO, SLOVENLA NOVARTIS **S.A.,** SPARTAN, KEMPTON PARK
Laboratory: FPRC:	KRKA, D.D., NOVO MESTO, SLOVENIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, KEMPTON PARK, RSA **NOVARTIS S.A.,** SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/7.1.3/0556
Name of medicine:	SANDOZ CARVEDILOL 12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	KRKA, D.D., NOVO MESTO, SLOVENIA
Packer:	KRKA, D.D., NOVO MESTO, SLOVENIA NOVARTIS **S.A.,** SPARTAN, KEMPTON PARK
Laboratory: FPRC:	KRKA, D.D., NOVO **MESTO,** SLOVENIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, KEMPTON PARK, RSA NOVARTIS **S.A.,** SPARTAN, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15

Registration number:	A39/3.2/0597
Name of medicine:	FOSAGEN 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, WADEVTLLE, 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:	17 FEBRUARY 2006

MRF 15

Registration number:	A40/1.2/0085
Name of medicine:	MERCK-SERTRALINE 50
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:	MERCK GENERICS **RSA** (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON
Packer:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND 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:	17 FEBRUARY 2006

MRF 15

Registration number:	A40/1.2/0086
Name of medicine:	MERCK-SERTRALINE 100
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:	MERCK GENERICS **RSA** (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS **MANUFACTURING,** WADEVILLE, GERMISTON
Packer:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS **MANUFACTURING,** WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND 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:	17 FEBRUARY 2006

MRF 15

Registration number:	A40/20.2.8/0578
Name of medicine:	TAMIFLU 75 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: OSELTAMIVIR PHOSPHATE EQUNALENT TO OSELTAMIVIR 75,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND
Packer:	F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND F. HOFFMANN LA ROCHE LTD, KAISERAUGST, SWITZERLAND GP GRENZACH PRODUKTIONS GmbH, GRENZACH-WYHLEN, GERMANY ROCHE PRODUCTS, ISANDO, RSA
Laboratory:FPRC:	F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND
FPRC/FPRR:	ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	60 months
Date **of** registration:	17 FEBRUARY 2006