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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

GENERAL NOTICE

NOTICE 1540 OF 2004

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 1540 VAN 2004

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:	36/20.1.2/0211
Name of medicine:	ADCO-AMOCLAV BD
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	BIOCHEMIE GmbH, KUNDL, AUSTRIA
Packer:	BIOCHEMIE GmbH, KUNDL, AUSTRIA
Laboratory:	BIOCHEMIE GmbH, KUNDL, AUSTRIA ADCOCK INGRAM HEALTHCARE (WADEVILLE), GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (CLAYVILLE), OLIFANTSFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/11.2/0327
Name of medicine:	SCOPEX SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: HYOSCINE BUTYLBROMIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE (WADEVILLE), WADEVILLE, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA
Packer:	ADCOCK INGRAM HEALTHCARE (WADEVILLE), WADEVILLE, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA
Laboratory:	ADCOCK INGRAM HEALTHCARE (WADEVILLE), WADEVILLE, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	35/15.4/0281
Name of medicine:	RESCULA
Dosage form:	DROPS
Active ingredients:	EACH 1,0 ml DROPS CONTAINS: UNOPROSTONE ISOPROPYLATE ..... 1,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	CIBA VISION CANADA, ONTARIO, CANADA
Packer:	CIBA VISION CANADA, ONTARIO, CANADA LABORATOIRE CIBA VISION FAURE, ANNONAY, FRANCE NOVO NORDISK, JOHANNESBURG, RSA
Laboratory:	LABORATOIRE CIBA VISION FAURE, ANNONAY, FRANCE NOVO NORDISK, JOHANNESBURG, RSA ADCOCK INGRAM, WADEVILLE, GERMISTON,RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/5.7.1/0368
Name of medicine:	ADCO-CETIRIZINE 10 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 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
Laboratory:	DELTA LTD, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE (WADEVILLE), GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (CLAYVILLE), OLIFANTSFONTEIN, RSA
Shelf-life:	36 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/3.1/0402
Name of medicine:	AUSTELL-IBUPROFEN TABLETS 200 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, NAGAR HAVELI INDIA
Packer:	IPCA LABORATORIES LTD, NAGAR HAVELI INDIA
Laboratory:	IPCA LABORATORIES LTD, NAGAR HAVELI INDIA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA AUSTELL LABORATORIES, SAXONWOLD, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/3.1/0403
Name of medicine:	AUSTELL-IBUPROFEN TABLETS 400 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, NAGAR HAVELI INDIA
Packer:	IPCA LABORATORIES LTD, NAGAR HAVELI INDIA
Laboratory:	IPCA LABORATORIES LTD, NAGAR HAVELI INDIA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA AUSTELL LABORATORIES, SAXONWOLD, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/20.2.3/0018
Name of medicine:	RIFATER JUNIOR DISPERSIBLE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RIFAMPICIN 60,0 mg ISONIAZID 30,0 mg PYRAZINAMIDE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PHARMA, WALTLOO, PRETORIA, RSA
Packer:	AVENTIS PHARMA, WALTLOO, PRETORIA, RSA DIVPHARM, LONGDALE, JOHANNESBURG,RSA
Laboratory:	AVENTIS PHARMA, WALTLOO, PRETORIA, RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/30.1/0128
Name of medicine:	DIFTAVAX
Dosage form:	SOLUTION
Active ingredients:	EACH DOSE CONTAINS: PURIFIED DIPHTHERIA TOXOID PURIFIED TETANUS TOXOID
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE AVENTIS PASTEUR, VAL DE REUIL, FRANCE
Packer:	AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE AVENTIS PASTEUR, VAL DE REUIL, FRANCE
Laboratory:	AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE AVENTIS PASTEUR, VAL DE REUIL, FRANCE AVENTIS PHARMA, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/34/0100
Name of medicine:	SOL-CART B
Dosage form:	POWDER
Active ingredients:	EACH CARTRIDGE CONTAINS: SODIUM BICARBONATE 650,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B. BRAUN MEDICAL (PTY) LTD
Manufacturer:	B. BRAUN SCHIWA, GLANDORF, GERMANY
Packer:	B. BRAUN SCHIWA, GLANDORF, GERMANY
Laboratory:	B. BRAUN SCHIWA, GLANDORF, GERMANY INSPECTORATE M&L, ORMONDE, JOHANNESBURG B. BRAUN MEDICAL, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	34/24/0371
Name of medicine:	EUROMED LACTATED RINGER'S SOLUTION
Dosage form:	SOLUTION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE 600,0 mg SODIUM LACTATE ANHYDROUS 310,0 mg POTASSIUM ACETATE 30,2 mg CALCIUM CHLORIDE DIHYDRATE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DANENE PHARMACEUTICALS (PTY) LTD
Manufacturer:	EUROMED LABORATORIES, CAVITE, PHILLIPINES
Packer:	EUROMED LABORATORIES, CAVITE, PHILLIPINES
Laboratory:	EUROMED LABORATORIES, CAVITE, PHILLIPINES DANENE PHARMACEUTICALS, GARSFONTEIN, PRETORIA, RSA
Shelf-life:	48 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number: 36/20.1.2/0288

Name of medicine: AUGMENTIN SR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 562,5 mg
AMOXYCILLIN SODIUM EQUIVALENT TO
AMOXYCILLIN 437,5 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 62,5 mg

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

Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: SMITHKLINE BEECHAM PHARMACEUTICALS, BRISTOL, TENNESSEE, USA

Packer: SMITHKLINE BEECHAM PHARMACEUTICALS, BRISTOL, TENNESSEE, USA
SMITHKLINE BEECHAM LABORATOIRES PHARMACEUTIQUES, MAYENNE, FRANCE
SMITHKLINE BEECHAM PHARMACEUTICALS, WORTHING WEST SUSSEX, UK
GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN, RSA

Laboratory: SMITHKLINE BEECHAM PHARMACEUTICALS, BRISTOL, TENNESSEE, USA
SMITHKLINE BEECHAM LABORATOIRES PHARMACEUTIQUES, MAYENNE, FRANCE
GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN, RSA

Shelf-life: 24 months

Date of registration: 28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/2.5/0407
Name of medicine:	LAMICTIN P2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE .....2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE S.A. (PTY) LTD
Manufacturer:	GLAXO WELLCOME, ZEBULON, NORTH CAROLINA USA
Packer:	GLAXO WELLCOME, ZEBULON, NORTH CAROLINA USA GLAXO WELLCOME OPERATIONS, HERTFORDSHIRE, U.K,. GLAXOSMITHKLINE, HALFWAY HOUSE, MIDRAND
Laboratory:	GLAXO WELLCOME, ZEBULON, NORTH CAROLINA USA GLAXO WELLCOME OPERATIONS, HERTFORDSHIRE, U.K,. GLAXOSMITHKLINE, HALFWAY HOUSE, MIDRAND
Shelf-life:	18 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/1.2/0318
Name of medicine:	CIPRALEX 5 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM ..... 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	H. LUNDBECK (PTY) LTD
Manufacturer:	H. LUNDBECK A/S, VALBY, DENMARK
Packer:	H. LUNDBECK A/S, VALBY, DENMARK
Laboratory:	H. LUNDBECK A/S, VALBY, DENMARK H. LUNDBECK, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/1.2/0319
Name of medicine:	CIPRALEX 10 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	H. LUNDBECK (PTY) LTD
Manufacturer:	H. LUNDBECK A/S, VALBY, DENMARK
Packer:	H. LUNDBECK A/S, VALBY, DENMARK
Laboratory:	H. LUNDBECK A/S, VALBY, DENMARK H. LUNDBECK, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/1.2/0320
Name of medicine:	CIPRALEX 15 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	H. LUNDBECK (PTY) LTD
Manufacturer:	H. LUNDBECK A/S, VALBY, DENMARK
Packer:	H. LUNDBECK A/S, VALBY, DENMARK
Laboratory:	H. LUNDBECK A/S, VALBY, DENMARK H. LUNDBECK, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/1.2/0321
Name of medicine:	CIPRALEX 20 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	H. LUNDBECK (PTY) LTD
Manufacturer:	H. LUNDBECK A/S, VALBY, DENMARK
Packer:	H. LUNDBECK A/S, VALBY, DENMARK
Laboratory:	H. LUNDBECK A/S, VALBY, DENMARK H. LUNDBECK, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/1.2/0322
Name of medicine:	CONCERTA 18 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METHYLPHENIDATE HYDROCHLORIDE 18,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA
Packer:	PACKAGING COORDINATORS INCORPORATED, PHILADELPHIA, USA SHARP, WEST CALDWELL, NJ, USA JANSSEN PHARMACEUTICA, HALFWAY HOUSE
Laboratory:	ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA JANSSEN PHARMACEUTICA, HALFWAY HOUSE
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/1.2/0323
Name of medicine:	CONCERTA 36 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METHYLPHENIDATE HYDROCHLORIDE 36,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA
Packer:	PACKAGING COORDINATORS INCORPORATED, PHILADELPHIA, USA SHARP, WEST CALDWELL, NJ, USA JANSSEN PHARMACEUTICA, HALFWAY HOUSE
Laboratory:	ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA JANSSEN PHARMACEUTICA, HALFWAY HOUSE
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/1.2/0324
Name of medicine:	CONCERTA 54 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METHYLPHENIDATE HYDROCHLORIDE 54,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA
Packer:	PACKAGING COORDINATORS INCORPORATED, PHILADELPHIA, USA SHARP, WEST CALDWELL, NJ, USA JANSSEN PHARMACEUTICA, HALFWAY HOUSE
Laboratory:	ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA JANSSEN PHARMACEUTICA, HALFWAY HOUSE
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0424
Name of medicine:	INVANZ
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ERTAPENEM SODIUM EQUIVALENT TO ERTAPENEM ..... 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	LABORATOIRE MERCK SHARP & DOHME, CEDEX, FRANCE
Packer:	LABORATOIRE MERCK SHARP & DOHME, CEDEX, FRANCE MERCK SHARP & DOHME, HAARLEM THE NETHERLANDS MSD, HALFWAY HOUSE, RSA
Laboratory:	LABORATOIRE MERCK SHARP & DOHME, CEDEX, FRANCE MERCK SHARP & DOHME, NORTHUMBERLAND, UK MSD, HALFWAY HOUSE, RSA
Shelf-life:	18 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/21.8.1/0493
Name of medicine:	ESTRADOT 25
Dosage form:	TRANSDERMAL PATCH
Active ingredients:	EACH PATCH CONTAINS: OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 0,39 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVEN PHARMACEUTICALS, MIAMI, USA
Packer:	NOVEN PHARMACEUTICALS, MIAMI, USA NOVARTIS, SPARTAN, KEMPTON PARK,RSA
Laboratory:	NOVEN PHARMACEUTICALS, MIAMI, USA INSPECTORATE M&L, ORMONDE, RSA NOVARTIS PHARMA, STEIN, SWITZERLAND NORTHVIEW LABORATORIES, NORTHBROOK, ILLINOIS, USA NOVARTIS, SPARTAN, KEMPTON PARK,RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/3.2/0473
Name of medicine:	OSTEO-CAL 200 IU
Dosage form:	NASAL SPRAY
Active ingredients:	EACH METERED DOSE CONTAINS: SALMON CALCITONIN 200,0 iu
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA AG, BASLE, SWITZERLAND MIPHARM S.p.A, MILAN, ITALY NOVARTIS PHARMA S.A., HUNINGUE, FRANCE
Packer:	NOVARTIS PHARMA AG, BASLE, SWITZERLAND MIPHARM S.p.A, MILAN, ITALY NOVARTIS PHARMA S.A., HUNINGUE, FRANCE NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Laboratory:	NOVARTIS PHARMA AG, BASLE, SWITZERLAND MIPHARM S.p.A, MILAN, ITALY NOVARTIS PHARMA S.A., HUNINGUE, FRANCE GLAXO, MIDRAND, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	36 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	35/11/0186
Name of medicine:	XAVENA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TEGASEROD 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LIMITED
Manufacturer:	NOVARTIS PHARMA STEIN AG, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, SWITZERLAND ALLPACK AG, MUTTENZ, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND PROMOLOG AG, PRATTELN, SWITZERLAND NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Laboratory:	NOVARTIS PHARMA STEIN AG, SWITZERLAND INSPECTORATE M&L, ORMONDE, RSA NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/20.2.2/0369
Name of medicine:	ASPEN FLUCONAZOLE 50 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months/maande
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/20.2.2/0370
Name of medicine:	ASPEN FLUCONAZOLE 100 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months/maande
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/20.2.2/0371
Name of medicine:	ASPEN FLUCONAZOLE 150 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months/maande
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/20.2.2/0372
Name of medicine:	ASPEN FLUCONAZOLE 200 MG
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months/maande
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/7.5/0370
Name of medicine:	SIMVOR 10 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Laboratory:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA CENTRE FOR QUALITY ASSURANCE, POTCHEFSTROOM, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/7.5/0371
Name of medicine:	SIMVOR 20 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Laboratory:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA CENTRE FOR QUALITY ASSURANCE, POTCHEFSTROOM, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/7.5/0372
Name of medicine:	SIMVOR 40 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Laboratory:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA CENTRE FOR QUALITY ASSURANCE, POTCHEFSTROOM, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/7.5/0373
Name of medicine:	SIMVOTIN 10 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Laboratory:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA CENTRE FOR QUALITY ASSURANCE, POTCHEFSTROOM, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/7.5/0374
Name of medicine:	SIMVOTIN 20 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Laboratory:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA CENTRE FOR QUALITY ASSURANCE, POTCHEFSTROOM, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/7.5/0375
Name of medicine:	SIMVOTIN 40 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA
Laboratory:	RANBAXY LABORATORIES LTD, HIMACHAL PRADESH, INDIA CENTRE FOR QUALITY ASSURANCE, POTCHEFSTROOM, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	35/2.6.5/0087
Name of medicine:	ENDEPEX
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: SULPIRIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROLAB (PTY) LIMITED
Manufacturer:	NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA
Packer:	NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA
Laboratory:	NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months packed in PVC blisters 36 months packed in amber glass and securitainers
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/20.1.2/0180
Name of medicine:	SANDOZ CO-AMOXYCLAV 1000
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LIMITED
Manufacturer:	BIOCHEMIE GmbH, KUNDL, AUSTRIA
Packer:	BIOCHEMIE GmbH, KUNDL, AUSTRIA
Laboratory:	BIOCHEMIE GmbH, KUNDL, AUSTRIA NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/21.8.2/0451
Name of medicine:	ANGELIQ
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESTRADIOL HEMIHYDRATE EQUIVALENT TO ESTRADIOL 1,0 mg DROSPIRENONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCHERING (PTY) LTD
Manufacturer:	SCHERING GmbH & CO, WEIMAR, GERMANY
Packer:	SCHERING GmbH & CO, WEIMAR, GERMANY SCHERING AG, BERLIN, GERMANY
Laboratory:	SCHERING GmbH & CO, WEIMAR, GERMANY SCHERING AG, BERLIN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA SCHERING, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	35/28/0360
Name of medicine:	RESOVIST 0,9 ML
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FERUCARBOTRAN ..... 540,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCHERING (PTY) LTD
Manufacturer:	SCHERING AG, BERLIN, GERMANY VETTER PHARMA-FERTIGUNG, RAVENBURG, GERMANY
Packer:	SCHERING AG, BERLIN, GERMANY VETTER PHARMA-FERTIGUNG, RAVENBURG, GERMANY
Laboratory:	SCHERING AG, BERLIN, GERMANY SCHERING, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	35/28/0361
Name of medicine:	RESOVIST 1,4 ML
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FERUCARBOTRAN ..... 540,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCHERING (PTY) LTD
Manufacturer:	SCHERING AG, BERLIN, GERMANY VETTER PHARMA-FERTIGUNG, RAVENBURG, GERMANY
Packer:	SCHERING AG, BERLIN, GERMANY VETTER PHARMA-FERTIGUNG, RAVENBURG, GERMANY
Laboratory:	SCHERING AG, BERLIN, GERMANY SCHERING, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	35/28/0362
Name of medicine:	RESOVIST 1,6 ML
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FERUCARBOTRAN ..... 540,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCHERING (PTY) LTD
Manufacturer:	SCHERING AG, BERLIN, GERMANY VETTER PHARMA-FERTIGUNG, RAVENBURG, GERMANY
Packer:	SCHERING AG, BERLIN, GERMANY VETTER PHARMA-FERTIGUNG, RAVENBURG, GERMANY
Laboratory:	SCHERING AG, BERLIN, GERMANY SCHERING, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	36/5.7.1/0425
Name of medicine:	XYZAL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOCETIRIZINE DIHYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UCB (S.A.) (PTY) LTD
Manufacturer:	UCB FARCHIM S.A., BULLE, SWITZERLAND
Packer:	UCB PHARMA SpA, TURIN, ITALY ASPEN PHARMACARE, KORSTEN, PORT ELIZABETH, RSA
Laboratory:	UCB FARCHIM S.A., BULLE, SWITZERLAND UCB PHARMA SpA, TURIN, ITALY ASPEN PHARMACARE, KORSTEN, PORT ELIZABETH, RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA UCB, PARKTOWN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/21.8/0397
Name of medicine:	TOTELLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRIMEGESTONE ..... . 0,125 mg 17B-OESTRADIOL HEMIHYDRATE EQUIVALENT TO 17B-OESTRADIOL ..... 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WYETH SOUTH AFRICA (PTY) LTD
Manufacturer:	WYETH MEDICA IRELAND, COUNTY KILDARE, IRELAND
Packer:	WYETH MEDICA IRELAND, COUNTY KILDARE, IRELAND TECHNIKON LABORATORIES, FLORIDA, JOHANNESBURG, RSA
Laboratory:	WYETH MEDICA IRELAND, COUNTY KILDARE, IRELAND TECHNIKON LABORATORIES, FLORIDA, JOHANNESBURG, RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA WYETH, VORNA VALLEY, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004

MRF 15 (MBR 15)

Registration number:	37/21.8/0398
Name of medicine:	TOTELLE CYCLE LD
Dosage form:	TABLET
Active ingredients:	EACH PINK TABLET CONTAINS: TRIMEGESTONE ..... . 0,250 mg 17B-OESTRADIOL HEMIHYDRATE EQUIVALENT TO 17B-OESTRADIOL ..... 1,0 mg EACH LIGHT PINK TABLET CONTAINS: 17B-OESTRADIOL HEMIHYDRATE EQUIVALENT TO 17B-OESTRADIOL ..... 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WYETH SOUTH AFRICA (PTY) LTD
Manufacturer:	WYETH MEDICA IRELAND, COUNTY KILDARE, IRELAND
Packer:	WYETH MEDICA IRELAND, COUNTY KILDARE, IRELAND TECHNIKON LABORATORIES, FLORIDA, JOHANNESBURG, RSA
Laboratory:	WYETH MEDICA IRELAND, COUNTY KILDARE, IRELAND TECHNIKON LABORATORIES, FLORIDA, JOHANNESBURG, RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA WYETH, VORNA VALLEY, RSA
Shelf-life:	24 months
Date of registration:	28 MAY 2004