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AIDS HELPLINE 0800-0123-22 Prevention is the cure

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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 goedgecind 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. Bemaking 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-AMOCCLAV 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:
LAMOTRIGINE2,0 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-AMOXICLAV 1000

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMOXICILLIN TRIHYDRATE EQUIVALENT TO
AMOXICILLIN 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, RANDJES PARK, 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, RANDJES PARK, 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, RANDJESPAK, 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,
IRELANDPacker: WYETH MEDICA IRELAND, COUNTY KILDARE,
IRELAND
TECHNIKON LABORATORIES, FLORIDA,
JOHANNESBURG, RSALaboratory: 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

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