

Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 529

Pretoria, 31 July
Julie 2009

No. 32440

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GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 1005 OF 2009

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 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the 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 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council 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 product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
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 1005 VAN 2009**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 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 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the 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 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van 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 produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleef tyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleef tydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
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 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number: 32/5.7.1/0374
Name of medicine: ZETOP TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CETIRIZINE DIHYDROCHLORIDE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: THEBE MEDICARE (PTY) LTD
Manufacturer: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA

Laboratory: FPRC: CADILA PHARMACEUTICALS, DHOLKA,
AHMEDABAD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: THEBE MEDICARE, NORTHRIDING, RANDBURG

Shelf-life: 24 months (Provisional)
Date of registration: 5 MARCH 2009

MRF 15

Registration number: A39/5.8/0026
Name of medicine: SINUSTOP JUNIOR
Dosage form: SYRUP
Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
PARACETAMOL 120,0 mg
CODEINE PHOSPHATE 5,0 mg
PSEUDOEPHEDRINE
HYDROCHLORIDE 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON
PHARMA-Q, INDUSTRIAL, JOHANNESBURG

Packer: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON
PHARMA-Q, INDUSTRIAL, JOHANNESBURG

Laboratory: FPRC: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON
PHARMA-Q, INDUSTRIAL, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, ERAND GARDENS,
MIDRAND

Shelf-life: 24 months (provisional)
Date of registration: 5 MARCH 2009

MRF 15

Registration number: A39/20.1.1/0128
 Name of medicine: AZIHEXAL 500 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 AZITHROMYCIN DIHYDRATE EQUIVALENT TO
 AZITHROMYCIN 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: HEXAL PHARMA (S.A.) (PTY) LTD
 Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY
 SANDOZ ILAC SANAYI ve TICARET, GEBZE/KOCAELI,
 TURKEY
 A/S GEA FARMACEUTISK FABRIK, HVIDOVRE,
 DENMARK
 Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 NOVARTIS, SPARTAN, KEMPRTON PARK, RSA
 Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
 SANDOZ ILAC SANAYI ve TICARET, GEBZE/KOCAELI,
 TURKEY
 A/S GEA FARMACEUTISK FABRIK, HVIDOVRE,
 DENMARK
 SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
 CONSULTING CHEMICAL LABORATORIES, STAR
 STREET, BOKSBURG, RSA
 FPRR: HEXAL PHARMA, PINETOWN, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: A39/20.1.1/0129
 Name of medicine: HEXAMAX 500 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 AZITHROMYCIN DIHYDRATE EQUIVALENT TO
 AZITHROMYCIN 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: HEXAL PHARMA (S.A.) (PTY) LTD
 Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY
 SANDOZ ILAC SANAYI ve TICARET,
 GEBZE/KOCAELI, TURKEY
 A/S GEA FARMACEUTISK FABRIK, HVIDOVRE,
 DENMARK
 Packer: SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 NOVARTIS, SPARTAN, KEMPRTON PARK, RSA
 Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
 SANDOZ ILAC SANAYI ve TICARET,
 GEBZE/KOCAELI, TURKEY
 A/S GEA FARMACEUTISK FABRIK, HVIDOVRE,
 DENMARK
 SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 CONSULTING CHEMICAL LABORATORIES, STAR
 STREET, BOKSBURG, RSA
 FPRR: HEXAL PHARMA, PINETOWN, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: A39/7.5/0358
 Name of medicine: ARROW PRAVASTATIN 10
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PRAVASTATIN SODIUM 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD
 Manufacturer: RX MANUFACTURING INC, MISSISSAUGA,
 ONTARIO, CANADA
 Packer: RX MANUFACTURING INC, MISSISSAUGA,
 ONTARIO, CANADA
 QUALITY (BURNLEY) LTD, BRIERCLIFFE,
 BURNLEY, LANCASTER, UK
 CONTRACT PHARMACEUTICALS LTD,
 MISSISSAUGA, ONTARIO, CANADA
 Laboratory: FPRC: RX MANUFACTURING INC, MISSISSAUGA,
 ONTARIO, CANADA
 QUALITY (BURNLEY) LTD, BRIERCLIFFE,
 BURNLEY, LANCASTER, UK
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORT-WEST UNIVERSITY,
 POTCHEFSTROOM
 SEDEK AGRICHEM, KAMEELDRIFT-EAST,
 PRETORIA
 FPRR: ARROW PHARMA SA, WOODMEAD,
 JOHANNESBURG
 Shelf-life: 18 months (Provisional)
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: A39/7.5/0359
 Name of medicine: ARROW PRAVASTATIN 20
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PRAVASTATIN SODIUM 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ARROW PHARMA SOUTH AFRICA (PTY)
 LTD
 Manufacturer: RX MANUFACTURING INC, MISSISSAUGA,
 ONTARIO, CANADA
 Packer: RX MANUFACTURING INC, MISSISSAUGA,
 ONTARIO, CANADA
 QUALITY (BURNLEY) LTD, BRIERCLIFFE,
 BURNLEY, LANCASTER, UK
 CONTRACT PHARMACEUTICALS LTD,
 MISSISSAUGA, ONTARIO, CANADA
 Laboratory: FPRC: RX MANUFACTURING INC, MISSISSAUGA,
 ONTARIO, CANADA
 QUALITY (BURNLEY) LTD, BRIERCLIFFE,
 BURNLEY, LANCASTER, UK
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORT-WEST UNIVERSITY,
 POTCHEFSTROOM
 SEDEK AGRICHEM, KAMEELDRIFT-EAST,
 PRETORIA
 FPRR: ARROW PHARMA SA, WOODMEAD,
 JOHANNESBURG
 Shelf-life: 18 months (Provisional)
 Date of registration: 5 MARCH 2009

MRF 15

Registration number:	A39/7.5/0360
Name of medicine:	ARROW PRAVASTATIN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LTD, BRIERCLIFFE, BURNLEY, LANCASTER, UK CONTRACT PHARMACEUTICALS LTD, MISSISSAUGA, ONTARIO, CANADA
Laboratory:	FPRC: RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LTD, BRIERCLIFFE, BURNLEY, LANCASTER, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORT-WEST UNIVERSITY, POTCHEFSTROOM SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA
	FPRR: ARROW PHARMA SA, WOODMEAD, JOHANNESBURG
Shelf-life:	18 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	A39/7.5/0361
Name of medicine:	AR PRAVASTATIN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LTD, BRIERCLIFFE, BURNLEY, LANCASTER, UK CONTRACT PHARMACEUTICALS LTD, MISSISSAUGA, ONTARIO, CANADA
Laboratory:	FPRC: RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LTD, BRIERCLIFFE, BURNLEY, LANCASTER, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORT-WEST UNIVERSITY, POTCHEFSTROOM SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA
	FPRR: ARROW PHARMA SA, WOODMEAD, JOHANNESBURG
Shelf-life:	18 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	A39/7.5/0362
Name of medicine:	AR PRAVASTATIN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 20 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LTD, BRIERCLIFFE, BURNLEY, LANCASTER, UK CONTRACT PHARMACEUTICALS LTD, MISSISSAUGA, ONTARIO, CANADA
Laboratory: FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LTD, BRIERCLIFFE, BURNLEY, LANCASTER, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORT-WEST UNIVERSITY, POTCHEFSTROOM SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA
FPRR	ARROW PHARMA SA, WOODMEAD, JOHANNESBURG
Shelf-life:	18 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	A39/7.5/0363
Name of medicine:	AR PRAVASTATIN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAVASTATIN SODIUM 40 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LTD, BRIERCLIFFE, BURNLEY, LANCASTER, UK CONTRACT PHARMACEUTICALS LTD, MISSISSAUGA, ONTARIO, CANADA
Laboratory: FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LTD, BRIERCLIFFE, BURNLEY, LANCASTER, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORT-WEST UNIVERSITY, POTCHEFSTROOM SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA
FPRR:	ARROW PHARMA SA, WOODMEAD, JOHANNESBURG
Shelf-life:	18 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	A40/16/0718
Name of medicine:	ANDOSEPT ORAL RINSE
Dosage form:	SOLUTION
Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: BENZYLAMINE HYDROCHLORIDE 22,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	CIPLA MEDPRO MANUFACTURING, MOBENI, DURBAN
Packer:	CIPLA MEDPRO MANUFACTURING, MOBENI, DURBAN
Laboratory: FPRC:	CIPLA MEDPRO MANUFACTURING, MOBENI, DURBAN SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR	PHARMACARE LIMITED, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	A40/26/0521
Name of medicine:	VIDAZA
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: AZACITIDINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	KEY ONCOLOGICS (PTY) LTD
Manufacturer:	BEN VENUE LABORATORIES, BEDFORD, OHIO, USA
Packer:	BEN VENUE LABORATORIES, BEDFORD, OHIO, USA CARDINAL HEALTH LTD, GREAT OAKLEY, CORBY, NORTHANTS, UK
Laboratory: FPRC	BEN VENUE LABORATORIES, BEDFORD, OHIO, USA CARDINAL HEALTH LTD, GREAT OAKLEY, CORBY, NORTHANTS, UK INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
FPRC/FPRR	KEY ONCOLOGICS, SANDTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number: A40/7.5/0749
 Name of medicine: NOVALES 20
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PRAVASTATIN SODIUM 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GULF DRUG COMPANY (PTY) LTD
 Manufacturer: PT NOVELL PHARMACEUTICAL LABORATORIES,
 GUNUNG PUTRI, BOGOR, INDONESIA
 Packer: PT NOVELL PHARMACEUTICAL LABORATORIES,
 GUNUNG PUTRI, BOGOR, INDONESIA
 Laboratory: FPRC: PT NOVELL PHARMACEUTICAL LABORATORIES,
 GUNUNG PUTRI, BOGOR, INDONESIA
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 CONSULTING CHEMICAL LABORATORIES
 ATLASVILLE, BOKSBURG
 PHARMA-Q, INDUSTRIA, JOHANNESBURG
 INSTITUTE FOR PHARMACEUTICAL SERVICES,
 SILVERTONDALE, PRETORIA
 CONSULTING MICROBIOLOGICAL LABORATORY,
 BEYERSPARK, BOKSBURG
 FPRR: GULF DRUG COMPANY, MOUNT EDGECOMBE,
 KZN
 Shelf-life: 24 months
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: A40/13.2/0756
 Name of medicine: SKABI-RID LOTION
 Dosage form: LOTION
 Active ingredients: EACH 1,0g LOTION CONTAINS:
 PERMETHRIN 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 8
 Applicant: TOMARMED (PTY) LTD
 Manufacturer: TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 Packer: TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 Laboratory: FPRC: TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 CONSULTING MICROBIOLOGICAL
 LABORATORY, MOREHILL, BENONI
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 LABHOUSE, EPSOM DOWNS, BRYANSTON,
 JOHANNESBURG
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: TOMARMED, SEDGEFIELD, KNYSNA
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 MARCH 2009

MRF 15

Registration number:	41/2.6.5/0493
Name of medicine:	ABILIFY 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ARIPRAZOLE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BRISTOL MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL MYERS SQUIBB, MAYAGUEZ, PUERTO RICO
Packer:	BRISTOL MYERS SQUIBB AUSTRALIA, NOBLE PARK, VICTORIA, AUSTRALIA
Laboratory::	FPRC BRISTOL MYERS SQUIBB, MAYAGUEZ, PUERTO RICO BRISTOL MYERS SQUIBB AUSTRALIA, NOBLE PARK, VICTORIA, AUSTRALIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
	FPRR BRISTOL MYERS SQUIBB, BEDFORDVIEW
Shelf-life:	36 months
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	41/3.2/0526
Name of medicine:	BONIVA 3 mg/3 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: IBANDRONIC ACID 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	VETTER PHARMA-FERTIGUNG GmbH & CO, LANGENARGEN, GERMANY
Packer:	VETTER PHARMA-FERTIGUNG GmbH & CO, LANGENARGEN, GERMANY ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY ROCHE PRODUCTS, ISANDO, RSA
Laboratory: FPRC:	ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY
	FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number: 41/3.2/0527
 Name of medicine: BONIVA 150 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 IBANDRONATE MONOSODIUM EQUIVALENT TO
 IBANDRONIC ACID 150,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ROCHE PRODUCTS (PTY) LTD
 Manufacturer: F. HOFFMAN-LA ROCHE LTD, BASEL,
 SWITZERLAND
 Packer: F. HOFFMAN-LA ROCHE LTD, BASEL,
 SWITZERLAND
 F. HOFFMAN-LA ROCHE LTD, KAISERAUGST,
 SWITZERLAND
 IVERS-LEE AG, BURGDORF, SWITZERLAND
 ROCHE PRODUCTS, ISANDO, RSA
 Laboratory: FPRC: F. HOFFMAN-LA ROCHE LTD, BASEL,
 SWITZERLAND
 FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA
 Shelf-life: 36 months
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: 41/2.7/0592
 Name of medicine: PANADO CAPLETS
 Dosage form: CAPLET
 Active ingredients: EACH CAPLET CONTAINS:
 PARACETAMOL 500,0
 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 8
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: ADCOCK INGRAM HEALTHCARE,
 WADEVILLE, GERMISTON
 Packer: ADCOCK INGRAM HEALTHCARE,
 WADEVILLE, GERMISTON
 Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE,
 WADEVILLE, GERMISTON
 FPRR: ADCOCK INGRAM LTD, ERAND GARDENS,
 MIDRAND
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 MARCH 2009

MRF 15

Registration number:	41/20.1.1/0689
Name of medicine:	AURO-CEFEPIME INJECTION 500 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME HYDROCHLORIDE EQUIVALENT TO CEFEPIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	41/20.1.1/0690
Name of medicine:	AURO-CEFEPIME INJECTION 1 000 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME HYDROCHLORIDE EQUIVALENT TO CEFEPIME 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC/FPRR:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number: 41/20.1.1/0691

Name of medicine: AURO-CEFEPIME INJECTION 2 000 mg

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFEPIME HYDROCHLORIDE EQUIVALENT TO
CEFEPIME 2 000,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, UNIT VI, MEDAK
DISTRICT, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, UNIT VI, MEDAK
DISTRICT, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT VI, MEDAK
DISTRICT, ANDHRA PRADESH, INDIA

FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 5 MARCH 2009

MRF 15

Registration number: 41/7.1/0749

Name of medicine: KEYSAL 5 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE BESILATE EQUIVALENT TO
AMLODIPINE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA

Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA

FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 5 MARCH 2009

MRF 15

Registration number: 41/7.1/0750
 Name of medicine: KEYSAL 10 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 AMLODIPINE BESILATE EQUIVALENT TO
 AMLODIPINE 10,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA

 FPRR: AUROBINDO PHARMA, MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: 41/20.2.8/0798
 Name of medicine: OSELFU
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 OSELTAMIVIR PHOSPHATE EQUIVALENT
 TO
 OSELTAMIVIR 75,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: CIPLA MEDPRO (PTY) LTD
 Manufacturer: CIPLA LTD, VERNA, GOA, INDIA
 Packer: CIPLA LTD, VERNA, GOA, INDIA
 Laboratory: FPRC: CIPLA LTD, VERNA, GOA, INDIA

 FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 MARCH 2009

MRF 15		
Registration number:	41/34/0815	
Name of medicine:	MYCOCEPT 250	
Dosage form:	CAPSULE	
Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250,0 mg	
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	
Applicant:	SANDOZ S.A. (PTY) LTD	
Manufacturer:	SANDOZ PRIVATE LTD, KALWE BLOCK, NAVI MUMBAI, INDIA	
Packer:	SANDOZ PRIVATE LTD, KALWE BLOCK, NAVI MUMBAI, INDIA	
Laboratory:	FPRC:	SANDOZ PRIVATE LTD, KALWE BLOCK, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months	
Date of registration:	5 MARCH 2009	

MRF 15		
Registration number:	41/21.12/0818	
Name of medicine:	BICALOX 50 mg	
Dosage form:	TABLET	
Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg	
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	
Applicant:	PHARMAPLAN (PTY) LTD	
Manufacturer:	DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND	
Packer:	DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND DOUGLAS PHARMACEUTICALS (FIJI) LTD, MARTINTAR, NADI, FIJI	
Laboratory:	FPRC:	DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months	
Date of registration:	5 MARCH 2009	

MRF 15

Registration number: 41/34/1010
 Name of medicine: SUBOXONE 2 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 BUPRENORPHINE HYDROCHLORIDE
 EQUIVALENT TO BUPRENORPHINE 2,0 mg
 NALOXONE HYDROCHLORIDE EQUIVALENT TO
 NALOXONE 0,50 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SCHERING-PLOUGH (PTY) LTD
 Manufacturer: RECKITT BENCKISER HEALTHCARE, HULL, EAST
 YORKSHIRE, UK
 Packer: RECKITT BENCKISER HEALTHCARE, HULL, EAST
 YORKSHIRE, UK
 CARDINAL HEALTH, WESTHOUGHTON, BOLTON,
 LANCASHIRE, UK
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE, HULL, EAST
 YORKSHIRE, UK
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: SCHERING-PLOUGH, WOODMEAD,
 JOHANNESBURG
 Shelf-life: 36 months
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: 41/34/1011
 Name of medicine: SUBOXONE 8 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 BUPRENORPHINE HYDROCHLORIDE
 EQUIVALENT TO BUPRENORPHINE 8,0 mg
 NALOXONE HYDROCHLORIDE
 EQUIVALENT TO NALOXONE 2,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SCHERING-PLOUGH (PTY) LTD
 Manufacturer: RECKITT BENCKISER HEALTHCARE, HULL,
 EAST YORKSHIRE, UK
 Packer: RECKITT BENCKISER HEALTHCARE, HULL,
 EAST YORKSHIRE, UK
 CARDINAL HEALTH, WESTHOUGHTON,
 BOLTON, LANCASHIRE, UK
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE, JOHANNESBURG
 Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE, HULL,
 EAST YORKSHIRE, UK
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: SCHERING-PLOUGH, WOODMEAD,
 JOHANNESBURG
 Shelf-life: 36 months
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: 41/20.1.1/1052
Name of medicine: LOXIP 250 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CIPROFLOXACIN HYDROCHLORIDE
EQUIVALENT TO CIPROFLOXACIN 250,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
 FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 MARCH 2009

MRF 15

Registration number: 41/20.1.1/1053
Name of medicine: LOXIP 500 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CIPROFLOXACIN HYDROCHLORIDE
EQUIVALENT TO CIPROFLOXACIN 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Laboratory: FPRC/FPRR: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 MARCH 2009

MRF 15

Registration number: 42/20.1.1/0003
 Name of medicine: TAZLIN 4,5
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 PIPERACILLIN SODIUM EQUIVALENT TO 4,0 g
 PIPERACILLIN
 TAZOBACTAM SODIUM EQUIVALENT TO 500,0 mg
 TAZOBACTAM
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SANDOZ S.A. (PTY) LTD
 Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
 Packer: SANDOZ GmbH, KUNDL, AUSTRIA
 Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
 Shelf-life: 24 months
 Date of registration: 5 MARCH 2009

MRF 15

Registration number: 42/2.6.5/0100
 Name of medicine: RISPERIDONE HEXAL 0,5 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 0.5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SANDOZ S.A.(PTY) LTD
 Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 Packer: SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 SANDOZ S.A., SPARTAN, KEMPTON PARK
 Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRC/FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
 Shelf-life: 24 months
 Date of registration: 5 MARCH 2009

MRF 15

Registration number:	42/8.3/0480
Name of medicine:	MIRCERA 50 ug/0,3 ml
Dosage form:	INJECTION
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA 50,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
Packer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co, SCHUTZENSTR, RAVENSBURG, GERMANY ROCHE PRODUCTS, ISANDO, GAUTENG
Laboratory:	FPRC: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
	FPRR: ROCHE PRODUCTS, ISANDO, GAUTENG
Shelf-life:	24 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	42/8.3/0481
Name of medicine:	MIRCERA 75 ug/0,3 ml
Dosage form:	INJECTION
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: METHOXY POLYETHYLENE GLYCOL- EPOETIN BETA 75,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
Packer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co, SCHUTZENSTR, RAVENSBURG, GERMANY ROCHE PRODUCTS, ISANDO, GAUTENG
Laboratory:	FPRC: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
	FPRR: ROCHE PRODUCTS, ISANDO, GAUTENG
Shelf-life:	24 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	42/8.3/0482
Name of medicine:	MIRCERA 100 ug/0,3 ml
Dosage form:	INJECTION
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA 100,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
Packer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co, SCHUTZENSTR, RAVENSBURG, GERMANY ROCHE PRODUCTS, ISANDO, GAUTENG
Laboratory:	FPRC: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
	FPRR: ROCHE PRODUCTS, ISANDO, GAUTENG
Shelf-life:	24 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number:	42/8.3/0483
Name of medicine:	MIRCERA 150 ug/0,3 ml
Dosage form:	INJECTION
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: METHOXY POLYETHYLENE GLYCOL- EPOETIN BETA 150,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
Packer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co, SCHUTZENSTR, RAVENSBURG, GERMANY ROCHE PRODUCTS, ISANDO, GAUTENG
Laboratory:	FPRC: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
	FPRR: ROCHE PRODUCTS, ISANDO, GAUTENG
Shelf-life:	24 months (Provisional)
Date of registration:	5 MARCH 2009

MRF 15

Registration number: 42/8.3/0484
Name of medicine: MIRCERA 200 ug/0,3 ml
Dosage form: INJECTION
Active ingredients: EACH PRE-FILLED SYRINGE CONTAINS:
METHOXY POLYETHYLENE GLYCOL-EPOETIN
BETA 200,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ROCHE PRODUCTS (PTY) LTD
Manufacturer: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
Packer: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
VETTER PHARMA-FERTIGUNG GmbH & Co,
SCHUTZENSTR, RAVENSBURG, GERMANY
ROCHE PRODUCTS, ISANDO, GAUTENG
Laboratory: FPRC: ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
FPRR: ROCHE PRODUCTS, ISANDO, GAUTENG
Shelf-life: 24 months (Provisional)
Date of registration: 5 MARCH 2009

MRF 15

Registration number: 42/8.3/0485
Name of medicine: MIRCERA 250 ug/0,3 ml
Dosage form: INJECTION
Active ingredients: EACH PRE-FILLED SYRINGE CONTAINS:
METHOXY POLYETHYLENE GLYCOL-
EPOETIN BETA 250,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ROCHE PRODUCTS (PTY) LTD
Manufacturer: ROCHE DIAGNOSTICS, MANNHEIM,
GERMANY
Packer: ROCHE DIAGNOSTICS, MANNHEIM,
GERMANY
VETTER PHARMA-FERTIGUNG GmbH & Co,
SCHUTZENSTR, RAVENSBURG, GERMANY
ROCHE PRODUCTS, ISANDO, GAUTENG
Laboratory: FPRC: ROCHE DIAGNOSTICS, MANNHEIM,
GERMANY
FPRR: ROCHE PRODUCTS, ISANDO, GAUTENG
Shelf-life: 24 months (Provisional)
Date of registration: 5 MARCH 2009

MRF 15

Registration number:	43/30.2/0290
Name of medicine:	ROTARIX LIQUID ORAL VACCINE
Dosage form:	SUSPENSION
Active ingredients:	EACH 1,5 ml DOSE CONTAINS: LIVE ATTENUATED HUMAN ROTAVIRUS RIX4414 STRAIN not less than $10^{6.0}$ CCID50
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS S.A, WAVRE, BELGIUM
Packer:	GLAXOSMITHKLINE BIOLOGICALS S.A, WAVRE, BELGIUM GLAXOSMITHKLINE S A, EPPING, CAPE TOWN
Laboratory:	FPRC: GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS S.A, WAVRE, BELGIUM
FPRC/FPRR:	GLAXOSMITHKLINE S A, EPPING, CAPE TOWN
Shelf-life:	36 months
Date of registration:	5 MARCH 2009

MRF 15

Registration number: 37/11.4.1/0074

Name of medicine: NEUTRACID

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DRIED ALUMINIUM HYDROXIDE 250,0 mg
MAGNESIUM TRISILICATE 500,0 mg

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

Applicant: LEBASI PHARMACEUTICALS cc

Manufacturer: VARICHEM LABORATORIES, HARARE,
ZIMBABWE

Packer: VARICHEM LABORATORIES, HARARE,
ZIMBABWE

Laboratory: FPRC: VARICHEM LABORATORIES, HARARE,
ZIMBABWE
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: LEBASI PHARMACEUTICALS, POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 37/2.8/0261

Name of medicine: VARI-COCODAMOL

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PARACETAMOL 500,0 mg
CODEINE PHOSPHATE 8,0 mg

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

Applicant: LEBASI PHARMACEUTICALS cc

Manufacturer: VARICHEM LABORATORIES, HARARE,
ZIMBABWE

Packer: VARICHEM LABORATORIES, HARARE,
ZIMBABWE

Laboratory: FPRC: VARICHEM LABORATORIES, HARARE,
ZIMBABWE
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: LEBASI PHARMACEUTICALS,
POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 37/20.1.1/0576
Name of medicine: CEFOTAXIME-FRESENIUS 0,5 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
CEFOTAXIME SODIUM EQUIVALENT TO
CEFOTAXIME 0,5 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BODENE (PTY) LTD t/a INTRAMED
Manufacturer: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA
BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH
Laboratory: FPRC: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA

FPRC/FPRR: BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH

Shelf-life: 24 months

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 37/20.1.1/0577
Name of medicine: CEFOTAXIME-FRESENIUS 1,0 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
CEFOTAXIME SODIUM EQUIVALENT TO
CEFOTAXIME 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BODENE (PTY) LTD t/a INTRAMED
Manufacturer: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA
BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH
Laboratory: FPRC: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA

FPRC/FPRR: BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH

Shelf-life: 24 months

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 37/20.1.1/0578
Name of medicine: CEFOTAXIME-FRESENIUS 2,0 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
CEFOTAXIME SODIUM EQUIVALENT TO
CEFOTAXIME 2,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BODENE (PTY) LTD t/a INTRAMED
Manufacturer: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA
BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH
Laboratory: FPRC: SANDOZ GmbH, KUNDL, TIROL, AUSTRIA
FPRC/FPRR: BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 38/2.7/0201
Name of medicine: VARIPAN SUGAR FREE SYRUP
Dosage form: SYRUP
Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
PARACETAMOL 120,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 8
Applicant: LEBASI PHARMACEUTICALS cc
Manufacturer: VARICHEM LABORATORIES, HARARE, ZIMBABWE
Packer: VARICHEM LABORATORIES, HARARE, ZIMBABWE
Laboratory: FPRC: VARICHEM LABORATORIES, HARARE, ZIMBABWE
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: LEBASI PHARMACEUTICALS, POTCHEFSTROOM
Shelf-life: 24 months (Provisional)
Date of registration: 17 APRIL 2009

MRF 15

Registration number:	38/10.1/0249
Name of medicine:	L.C.C. GUAIPHENESIN COUGH MIXTURE
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP ONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (provisional)
Date of registration:	17 APRIL 2009

MRF 15

Registration number:	A39/16.1/0211
Name of medicine:	NAZENE ADULT NASAL METERED SPRAY
Dosage form:	SPRAY
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: OXYMETAZOLINE HYDROCHLORIDE 0,50 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	17 APRIL 2009

MRF 15

Registration number: A39/7.5/0245
Name of medicine: NIASPAN 375 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
NICOTINIC ACID 375,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK (PTY) LTD
Manufacturer: KOS PHARMACEUTICALS INC, EDISON, NEW JERSEY, USA
Packer: MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
MERCK KgaA, DARMSTADT, GERMANY
Laboratory: FPRC: KOS PHARMACEUTICALS INC, EDISON, NEW JERSEY, USA
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR: MERCK, MODDERFONTEIN, RSA
Shelf-life: 36 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: A39/7.5/0246
Name of medicine: NIASPAN 500 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
NICOTINIC ACID 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK (PTY) LTD
Manufacturer: KOS PHARMACEUTICALS INC, EDISON, NEW JERSEY, USA
Packer: MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
MERCK KgaA, DARMSTADT, GERMANY
Laboratory: FPRC: KOS PHARMACEUTICALS INC, EDISON, NEW JERSEY, USA
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR: MERCK, MODDERFONTEIN, RSA
Shelf-life: 36 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: A39/7.5/0247
 Name of medicine: NIASPAN 750 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 NICOTINIC ACID 750,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MERCK (PTY) LTD
 Manufacturer: KOS PHARMACEUTICALS INC, EDISON, NEW JERSEY, USA
 Packer: MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
 MERCK KgaA, DARMSTADT, GERMANY
 Laboratory: FPRC: KOS PHARMACEUTICALS INC, EDISON, NEW JERSEY, USA
 MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
 SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
 FPRR: MERCK, MODDERFONTEIN, RSA
 Shelf-life: 36 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: A39/7.5/0248
 Name of medicine: NIASPAN 1 000 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 NICOTINIC ACID 1 000,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MERCK (PTY) LTD
 Manufacturer: KOS PHARMACEUTICALS INC, EDISON, NEW JERSEY, USA
 Packer: MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
 MERCK KgaA, DARMSTADT, GERMANY
 Laboratory: FPRC: KOS PHARMACEUTICALS INC, EDISON, NEW JERSEY, USA
 MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
 SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
 FPRR: MERCK, MODDERFONTEIN, RSA
 Shelf-life: 36 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number:	A39/21.3/0401
Name of medicine:	EUTHYROX 25 ug
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOTHYROXINE SODIUM 25,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK KgaA, DARMSTADT, GERMANY
Packer:	MERCK KgaA, DARMSTADT, GERMANY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC: MERCK KgaA, DARMSTADT, GERMANY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR: MERCK, MODDERFONTEIN, GAUTENG
Shelf-life:	36 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number:	A39/21.3/0402
Name of medicine:	EUTHYROX 50 ug
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOTHYROXINE SODIUM 50,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK KgaA, DARMSTADT, GERMANY
Packer:	MERCK KgaA, DARMSTADT, GERMANY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC: MERCK KgaA, DARMSTADT, GERMANY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR: MERCK, MODDERFONTEIN, GAUTENG
Shelf-life:	36 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number: A39/21.3/0403
 Name of medicine: EUTHYROX 100 ug
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LEVOTHYROXINE SODIUM 100,0 ug
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MERCK (PTY) LTD
 Manufacturer: MERCK KgaA, DARMSTADT, GERMANY
 Packer: MERCK KgaA, DARMSTADT, GERMANY
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON
 Laboratory: FPRC: MERCK KgaA, DARMSTADT, GERMANY
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRR: MERCK, MODDERFONTEIN, GAUTENG
 Shelf-life: 36 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: A39/26/0452
 Name of medicine: APEX-CYTARABINE INJECTION
 100 mg/ml (1 ml)
 Dosage form: INJECTION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 CYTARABINE 100,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: CAMOX PHARMACEUTICALS (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS, MATODA,
 SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS, MATODA,
 SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS, MATODA,
 SANAND, AHMEDABAD, INDIA
 SOUTH AFRICAN BUREAU OF
 STANDARDS, GROENKLOOF, PRETORIA
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE, PRETORIA
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG
 FPRR: CAMOX PHARMACEUTICALS, AMALGAM,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: A39/26/0453

Name of medicine: APEX-CYTARABINE INJECTION 100 mg/ml 5 ml)

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CYTARABINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA

Packer: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA

Laboratory: FPRC: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG

FPRR: CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 17 APRIL 2009

MRF 15

Registration number: A39/26/0454

Name of medicine: APEX-CYTARABINE INJECTION
100 mg/ml (10 ml)

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CYTARABINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA

Packer: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA

Laboratory: FPRC: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA
SOUTH AFRICAN BUREAU OF
STANDARDS, GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, PRETORIA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG

FPRR: CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 17 APRIL 2009

MRF 15

Registration number: A39/3.1/0588
Name of medicine: CATAFLAM SACHETS
Dosage form: POWDER
Active ingredients: EACH SACHET CONTAINS:
DICLOFENAC POTASSIUM 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: NOVARTIS S.A. (PTY) LTD
Manufacturer: MIPHARM S.p.A., MILAN, ITALY
Packer: MIPHARM S.p.A., MILAN, ITALY
NOVARTIS S.A., SPARTAN, KEMPTON
PARK
Laboratory: FPRC: MIPHARM S.p.A., MILAN, ITALY
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON
PARK
Shelf-life: 24 months (Provisional)
Date of registration: 17 APRIL 2009

MRF 15

Registration number: A40/13/0219
Name of medicine: PROTOPIC 0,03 % OINTMENT
Dosage form: OINTMENT
Active ingredients: EACH 1,0 g OINTMENT CONTAINS:
TACROLIMUS 0,3 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ASTELLAS PHARMA (PTY) LTD
Manufacturer: FUJISAWA HEALTHCARE INC, GRAND ISLAND,
NEW YORK, USA
Packer: FUJISAWA HEALTHCARE INC, GRAND ISLAND,
NEW YORK, USA
FUJISAWA IRELAND LTD, KERRY COUNTY,
KILLORGLIN, IRELAND
Laboratory: FPRC: FUJISAWA IRELAND LTD, KERRY COUNTY,
KILLORGLIN, IRELAND
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: ASTELLAS PHARMA, BEDFORDVIEW,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: A40/13/0231
Name of medicine: PROTOPIC 0,1 % OINTMENT
Dosage form: OINTMENT
Active ingredients: EACH 1,0 g OINTMENT CONTAINS:
TACROLIMUS 0,1 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ASTELLAS PHARMA (PTY) LTD
Manufacturer: FUJISAWA HEALTHCARE INC, GRAND
ISLAND, NEW YORK, USA
Packer: FUJISAWA HEALTHCARE INC, GRAND
ISLAND, NEW YORK, USA
FUJISAWA IRELAND LTD, KERRY COUNTY,
KILLORGLIN, IRELAND
Laboratory: FPRC: FUJISAWA IRELAND LTD, KERRY COUNTY,
KILLORGLIN, IRELAND
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: ASTELLAS PHARMA, BEDFORDVIEW,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: A40/15.4/0282
Name of medicine: ACULAR 0,4 %
Dosage form: SOLUTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
KETOROLAC TROMETHAMINE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer: ALLERGAN INC, WACO, TEXAS, USA
Packer: ALLERGAN INC, WACO, TEXAS, USA
Laboratory: FPRC: ALLERGAN INC, WACO, TEXAS, USA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, PRETORIA
FPRR: ALLERGAN PHARMACEUTICALS, HALFWAY
HOUSE, RSA
Shelf-life: 18 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: A40/26/0359
 Name of medicine: TARCEVA 25 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ERLOTINIB HYDROCHLORIDE EQUIVALENT TO
 ERLOTINIB 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ROCHE PRODUCTS (PTY) LTD
 Manufacturer: SCHWARZ PHARMA MANUFACTURING INC,
 SEYMOUR, INDIANAPOLIS, USA
 Packer: SCHWARZ PHARMA MANUFACTURING INC,
 SEYMOUR, INDIANAPOLIS, USA
 F. HOFFMANN-LA ROCHE LTD, KAISERAUGST,
 SWITZERLAND
 IVERS-LEE AG, BURGDORF, SWITZERLAND
 HOFFMANN-LA ROCHE AG, GRENZACH-
 WYHLEN, GERMANY
 ROCHE PRODUCTS, ISANDO, RSA
 Laboratory: FPRC: HOFFMANN-LA ROCHE AG, GRENZACH-
 WYHLEN, GERMANY
 F. HOFFMANN-LA ROCHE LTD, BASEL,
 SWITZERLAND
 FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA
 Shelf-life: 36 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: A40/26/0360
 Name of medicine: TARCEVA 100 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ERLOTINIB HYDROCHLORIDE
 EQUIVALENT TO ERLOTINIB 100,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ROCHE PRODUCTS (PTY) LTD
 Manufacturer: SCHWARZ PHARMA MANUFACTURING
 INC, SEYMOUR, INDIANAPOLIS, USA
 Packer: SCHWARZ PHARMA MANUFACTURING
 INC, SEYMOUR, INDIANAPOLIS, USA
 F. HOFFMANN-LA ROCHE LTD,
 KAISERAUGST, SWITZERLAND
 IVERS-LEE AG, BURGDORF,
 SWITZERLAND
 HOFFMANN-LA ROCHE AG, GRENZACH-
 WYHLEN, GERMANY
 ROCHE PRODUCTS, ISANDO, RSA
 Laboratory: FPRC: HOFFMANN-LA ROCHE AG, GRENZACH-
 WYHLEN, GERMANY
 F. HOFFMANN-LA ROCHE LTD, BASEL,
 SWITZERLAND
 FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA
 Shelf-life: 36 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: A40/26/0361

Name of medicine: TARCEVA 150 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ERLOTINIB HYDROCHLORIDE EQUIVALENT TO
ERLOTINIB 150,0 mg

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

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: SCHWARZ PHARMA MANUFACTURING INC,
SEYMOUR, INDIANAPOLIS, USA

Packer: SCHWARZ PHARMA MANUFACTURING INC,
SEYMOUR, INDIANAPOLIS, USA
F. HOFFMANN-LA ROCHE LTD, KAISERAUGST,
SWITZERLAND
IVERS-LEE AG, BURGDORF, SWITZERLAND
HOFFMANN-LA ROCHE AG, GRENZACH-WYHLEN,
GERMANY
ROCHE PRODUCTS, ISANDO, RSA

Laboratory: FPRC: HOFFMANN-LA ROCHE AG, GRENZACH-WYHLEN,
GERMANY
F. HOFFMANN-LA ROCHE LTD, BASEL,
SWITZERLAND

FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA

Shelf-life: 36 months

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/2.2/0019

Name of medicine: MILOZ 5

Dosage form: INJECTION

Active ingredients: EACH AMPOULE CONTAINS:
MIDAZOLAM HYDROCHLORIDE EQUIVALENT
TO MIDAZOLAM 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: GULF DRUG COMPANY (PTY) LTD

Manufacturer: PT NOVELL PHARMACEUTICAL
LABORATORIES, SENAYAN, JAKARTA

Packer: PT NOVELL PHARMACEUTICAL
LABORATORIES, SENAYAN, JAKARTA

Laboratory: FPRC: PT NOVELL PHARMACEUTICAL
LABORATORIES, SENAYAN, JAKARTA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, PRETORIA
CONSULTING MICROBIOLOGICAL
LABORATORY, BEYERSPARK, BOKSBURG

FPRC/FPRR: GULF DRUG COMPANY, MOUNT
EDGEcombe, KZN

Shelf-life: 24 months (Provisional)

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/26/0049
Name of medicine: CIPLA-IRINOTECAN 40 mg/2 ml
Dosage form: INFUSION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
IRINOTECAN HYDROCHLORIDE TRIHYDRATE
20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, (UNIT V), VERNA, GOA, INDIA
Packer: CIPLA LTD, (UNIT V), VERNA, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, (UNIT V), VERNA, GOA, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/26/0050
Name of medicine: CIPLA-IRINOTECAN 100 mg/5 ml
Dosage form: INFUSION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
IRINOTECAN HYDROCHLORIDE TRIHYDRATE
20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, (UNIT V), VERNA, GOA, INDIA
Packer: CIPLA LTD, (UNIT V), VERNA, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, (UNIT V), VERNA, GOA, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/24/0135

Name of medicine: B BRAUN 5 % GLUCOSE

Dosage form: INFUSION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
GLUCOSE MONOHYDRATE EQUIVALENT TO
GLUCOSE 50,0 g

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, MELSUNGEN,
GERMANY
B BRAUN MELSUNGEN AG, PFIEFFEWIESEN,
MELSUNGEN, GERMANY
B BRAUN MEDICAL S.A., RUBI, BARCELONA, SPAIN

Packer: B BRAUN MELSUNGEN AG, MELSUNGEN,
GERMANY
B BRAUN MELSUNGEN AG, PFIEFFEWIESEN,
MELSUNGEN, GERMANY
B BRAUN MEDICAL S.A., RUBI, BARCELONA, SPAIN

Laboratory: FPRC: B BRAUN MELSUNGEN AG, MELSUNGEN,
GERMANY
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
COSI PHARMACEUTICALS, INDUSTRIA WEST,
JOHANNESBURG
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG

Shelf-life: 36 months

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/2.2/0174

Name of medicine: MILOZ 15

Dosage form: INJECTION

Active ingredients: EACH AMPOULE CONTAINS:
MIDAZOLAM HYDROCHLORIDE EQUIVALENT TO
MIDAZOLAM 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: GULF DRUG COMPANY (PTY) LTD

Manufacturer: PT NOVELL PHARMACEUTICAL LABORATORIES,
SENAYAN, JAKARTA

Packer: PT NOVELL PHARMACEUTICAL LABORATORIES,
SENAYAN, JAKARTA

Laboratory: FPRC: PT NOVELL PHARMACEUTICAL LABORATORIES,
SENAYAN, JAKARTA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA
CONSULTING MICROBIOLOGICAL LABORATORY,
BEYERSPARK, BOKSBURG

FPRR: GULF DRUG COMPANY, MOUNT EDGECOMBE,
KZN

Shelf-life: 24 months (Provisional)

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/11.3/0312
Name of medicine: CIPLATRIM 10
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
SIBUTRAMINE HYDROCHLORIDE EQUIVALENT
TO SIBUTRAMINE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, KURKUMBH, PUNE,
MAHARASHTRA, INDIA
Packer: CIPLA LTD, KURKUMBH, PUNE,
MAHARASHTRA, INDIA
Laboratory: FPRC: CIPLA LTD, KURKUMBH, PUNE,
MAHARASHTRA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/11.3/0313
Name of medicine: CIPLATRIM 15
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
SIBUTRAMINE HYDROCHLORIDE EQUIVALENT
TO SIBUTRAMINE 15,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, KURKUMBH, PUNE,
MAHARASHTRA, INDIA
Packer: CIPLA LTD, KURKUMBH, PUNE,
MAHARASHTRA, INDIA
Laboratory: FPRC: CIPLA LTD, KURKUMBH, PUNE,
MAHARASHTRA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/11.3/0315
Name of medicine: CIPLA-SIBUTRAMINE 10
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
SIBUTRAMINE HYDROCHLORIDE EQUIVALENT
TO SIBUTRAMINE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, KURKUMBH, PUNE, MAHARASHTRA,
INDIA
Packer: CIPLA LTD, KURKUMBH, PUNE, MAHARASHTRA,
INDIA
Laboratory: FPRC: CIPLA LTD, KURKUMBH, PUNE, MAHARASHTRA,
INDIA

FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/11.3/0316
Name of medicine: CIPLA-SIBUTRAMINE 15
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
SIBUTRAMINE HYDROCHLORIDE EQUIVALENT
TO SIBUTRAMINE 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, KURKUMBH, PUNE, MAHARASHTRA,
INDIA
Packer: CIPLA LTD, KURKUMBH, PUNE, MAHARASHTRA,
INDIA
Laboratory: FPRC: CIPLA LTD, KURKUMBH, PUNE, MAHARASHTRA,
INDIA

FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/1.2/0373
 Name of medicine: VOXRA 150
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 BUPROPION HYDROCHLORIDE 150,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
 Manufacturer: BIOVAIL CORPORATION, STEINBACH, CANADA
 Packer: BIOVAIL CORPORATION, STEINBACH, CANADA
 GLAXO WELLCOME GmbH & Co, BAD
 OLDESLOE, GERMANY
 GLAXOSMITHKLINE, EPPING, CAPE TOWN
 Laboratory: FPRC: BIOVAIL CORPORATION, STEINBACH, CANADA
 INOPHARM INC, MARKHAM, CANADA
 GLAXO WELLCOME GmbH & Co, BAD
 OLDESLOE, GERMANY
 FPRC/FPRR: GLAXOSMITHKLINE, EPPING, CAPE TOWN
 Shelf-life: 18 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/1.2/0374
 Name of medicine: VOXRA 300
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 BUPROPION HYDROCHLORIDE 300,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
 Manufacturer: BIOVAIL CORPORATION, STEINBACH, CANADA
 Packer: BIOVAIL CORPORATION, STEINBACH, CANADA
 GLAXO WELLCOME GmbH & Co, BAD OLDESLOE,
 GERMANY
 GLAXOSMITHKLINE, EPPING, CAPE TOWN
 Laboratory: FPRC: BIOVAIL CORPORATION, STEINBACH, CANADA
 INOPHARM INC, MARKHAM, CANADA
 GLAXO WELLCOME GmbH & Co, BAD OLDESLOE,
 GERMANY
 FPRC/FPRR: GLAXOSMITHKLINE, EPPING, CAPE TOWN
 Shelf-life: 18 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/1.2/0458
 Name of medicine: ALAMIL 20
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 CITALOPRAM HYDROBROMIDE EQUIVALENT
 TO CITALOPRAM 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD, SURVEY
 NO 41, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 Packer: DR REDDY'S LABORATORIES LTD, SURVEY
 NO 41, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE, CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD, SURVEY
 NO 41, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE, PRETORIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
 PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/1.2/0459
 Name of medicine: ALAMIL 40
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 CITALOPRAM HYDROBROMIDE
 EQUIVALENT TO CITALOPRAM 40,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 SURVEY NO 41, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 SURVEY NO 41, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE,
 CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 SURVEY NO 41, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE, PRETORIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES,
 MURRAYFIELD, PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 17 APRIL 2009

MRF 15

Registration number:	41/2.7/0589
Name of medicine:	SOVENOR 5 PATCH
Dosage form:	PATCH
Active ingredients:	EACH PATCH CONTAINS: BUPRENORPHINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY
Packer:	LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY
Laboratory:	FPRC: LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
Shelf-life:	24 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number:	41/2.7/0590
Name of medicine:	SOVENOR 10 PATCH
Dosage form:	PATCH
Active ingredients:	EACH PATCH CONTAINS: BUPRENORPHINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY
Packer:	LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY
Laboratory:	FPRC: LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
Shelf-life:	24 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number: 41/2.7/0591
Name of medicine: SOVENOR 20 PATCH
Dosage form: PATCH
Active ingredients: EACH PATCH CONTAINS:
BUPRENORPHINE 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MEDWICH PHARMA (PTY) LTD
Manufacturer: LTS LOHMANN THERAPIE-SYSTEME AG,
ANDERNACH, GERMANY
Packer: LTS LOHMANN THERAPIE-SYSTEME AG,
ANDERNACH, GERMANY

Laboratory: FPRC: LTS LOHMANN THERAPIE-SYSTEME AG,
ANDERNACH, GERMANY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: MEDWICH PHARMA, LYNNWOOD GLEN,
PRETORIA

Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/7.1.3/0648
Name of medicine: PEARINDA 2
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL, TERT-BUTYLAMINE
2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS,
GREECE
Packer: SPECIFAR S.A., VARVARA, ATHENS,
GREECE
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE,
JOHANNESBURG

Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS,
GREECE

FPRR: SPECPHARM, HALFWAY HOUSE,
MIDRAND

Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/7.1.3/0649
Name of medicine: PEARINDA 4
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL, TERT-BUTYLAMINE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE

FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/7.1.3/0650
Name of medicine: PEARINDA 8
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE

FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/7.1.3/0651
Name of medicine: SPEC-PERINDOPRIL 2
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL, TERT-BUTYLAMINE 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE

FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND

Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/7.1.3/0652
Name of medicine: SPEC-PERINDOPRIL 4
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL, TERT-BUTYLAMINE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE

FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND

Shelf-life: 24 months
Date of registration: 17 APRIL 2009

MRF 15

Registration number:	41/7.1.3/0653
Name of medicine:	SPEC-PERINDOPRIL 8
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE
	FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number:	41/34/0816
Name of medicine:	MYCOPHENOLATE HEXAL 250
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PRIVATE LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PRIVATE LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Laboratory:	FPRC: SANDOZ PRIVATE LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA NOVARTIS SA, SPARTAN, KEMPTON PARK
	FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number:	41/26/0834
Name of medicine:	VINOREL 10
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA
Packer:	ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA
Laboratory:	FPRC: ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PHARMAPLAN, MIDRAND
Shelf-life:	24 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number:	41/20.1.2/0963
Name of medicine:	AURO-AMOXICLAV 125 – 31,25 mg/5 ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 125,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 31,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number:	41/20.1.2/0964
Name of medicine:	AURO-AMOXICLAV 250 – 62,5 mg/5 ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 62,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	17 APRIL 2009

MRF 15

Registration number:	41/26/1003
Name of medicine:	IRINOTAS
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml VIAL CONTAINS: IRINOTECAN HYDROCHLORIDE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	17 APRIL 2009

MRF 15

Registration number: 41/26/1004
 Name of medicine: ACCORD-IRINOTECAN
 Dosage form: INJECTION
 Active ingredients: EACH 2,0 ml VIAL CONTAINS:
 IRINOTECAN HYDROCHLORIDE 40,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/4/1024
 Name of medicine: EURO-MED LIGNOCAINE HCL 2 % 2 ml
 Dosage form: INJECTION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 LIGNOCAINE HYDROCHLORIDE 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: LEBASI PHARMACEUTICALS cc
 Manufacturer: EURO-MED LABORATORIES, CAVITE,
 PHILIPPINES
 Packer: EURO-MED LABORATORIES, CAVITE,
 PHILIPPINES
 Laboratory: FPRC: EURO-MED LABORATORIES, CAVITE,
 PHILIPPINES
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 INSTITUTE FOR PHARMACEUTICAL SERVICES,
 SILVERTONDALE, PRETORIA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: LEBASI PHARMACEUTICALS,
 POTCHEFSTROOM
 Shelf-life: 36 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/4/1025
 Name of medicine: EURO-MED LIGNOCAINE HCL 2 % 5 ml
 Dosage form: INJECTION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 LIGNOCAINE HYDROCHLORIDE 20,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: LEBASI PHARMACEUTICALS cc
 Manufacturer: EURO-MED LABORATORIES, CAVITE,
 PHILIPPINES

 Packer: EURO-MED LABORATORIES, CAVITE,
 PHILIPPINES

 Laboratory: FPRC: EURO-MED LABORATORIES, CAVITE,
 PHILIPPINES
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE, PRETORIA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG

 FPRR: LEBASI PHARMACEUTICALS,
 POTCHEFSTROOM

 Shelf-life: 36 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/1.2/1029
 Name of medicine: CYMGEN 30
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 DULOXETINE HYDROCHLORIDE EQUIVALENT
 TO DULOXETINE 30,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ELI LILLY (S.A.) (PTY) LTD
 Manufacturer: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
 INDIANAPOLIS, USA
 ELAN PHARMA INTERNATIONAL LTD,
 ATHLONE, COUNTY WESTMEATH, IRELAND

 Packer: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
 INDIANAPOLIS, USA
 LILLY S.A., SPAIN, ALCOBENDAS, MADRID,
 SPAIN

 Laboratory: FPRC: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
 INDIANAPOLIS, USA
 ELAN PHARMA INTERNATIONAL LTD,
 ATHLONE, COUNTY WESTMEATH, IRELAND
 LILLY S.A., SPAIN, ALCOBENDAS, MADRID,
 SPAIN
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA

 FPRR: ELI LILLY (S.A.), BRYANSTON,
 JOHANNESBURG

 Shelf-life: 24 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 41/1.2/1030
 Name of medicine: CYMGEN 60
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 DULOXETINE HYDROCHLORIDE EQUIVALENT
 TO DULOXETINE 60,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ELI LILLY (S.A.) (PTY) LTD
 Manufacturer: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
 INDIANAPOLIS, USA
 ELAN PHARMA INTERNATIONAL LTD,
 ATHLONE, COUNTY WESTMEATH, IRELAND
 Packer: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
 INDIANAPOLIS, USA
 LILLY S.A., SPAIN, ALCOBENDAS, MADRID,
 SPAIN
 Laboratory: FPRC: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
 INDIANAPOLIS, USA
 ELAN PHARMA INTERNATIONAL LTD,
 ATHLONE, COUNTY WESTMEATH, IRELAND
 LILLY S.A., SPAIN, ALCOBENDAS, MADRID,
 SPAIN
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRR: ELI LILLY (S.A.), BRYANSTON,
 JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 42/26/0005
 Name of medicine: VINOREL 50
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 VINORELBINE TARTRATE EQUIVALENT
 TO VINORELBINE 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMAPLAN (PTY) LTD
 Manufacturer: ERIOCHEM S.A., PARANA, ENTRE RIOS,
 ARGENTINA
 Packer: ERIOCHEM S.A., PARANA, ENTRE RIOS,
 ARGENTINA
 Laboratory: FPRC: ERIOCHEM S.A., PARANA, ENTRE RIOS,
 ARGENTINA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: PHARMAPLAN, MIDRAND
 Shelf-life: 24 months
 Date of registration: 17 APRIL 2009

MRF 15

Registration number: 42/20.2.8/0047
 Name of medicine: PHARMA-Q ZIDOVUDINE SYRUP 50 mg
 Dosage form: SYRUP
 Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
 ZIDOVUDINE 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: PHARMA-Q (PTY) LTD
 Manufacturer: PHARMA-Q, INDUSTRIA, JOHANNESBURG
 Packer: PHARMA-Q, INDUSTRIA, JOHANNESBURG

Laboratory: FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 CENTRE OF QUALITY ASSURANCE, NORTH-
 WEST UNIVERSITY, POTCHEFSTROOM
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE, PRETORIA

FPRC/FPRR: PHARMA-Q, INDUSTRIA, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 17 APRIL 2009

MRF 15

Registration number: 42/8.5/0598
 Name of medicine: NEULASTIM
 Dosage form: INJECTION
 Active ingredients: EACH PRE-FILLED SYRINGE CONTAINS:
 PEGFILGRASTIM 6,0 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
 ROCHE PRODUCTS, ISANDO, RSA

Laboratory: FPRC: F. HOFFMANN-LA ROCHE LTD, BASEL,
 SWITZERLAND

FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA

Shelf-life: 24 months

Date of registration: 17 APRIL 2009