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CONTENTS

INHOUD

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 goekgekeur 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 rakleeftyd 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 rakleeftydperiode 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. Bemarking 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, INDUSTRIA, JOHANNESBURG
Packer:		ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON PHARMA-Q, INDUSTRIA, 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 SOLUTIUON CONTAINS: BENZYDAMINE 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: ARIPIPRAZOLE 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:		OSELFLU
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 PIPERACILLIN 4,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 500,0 mg
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: OXYMETAZOLENE 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