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CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1269 OF 2008

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. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 1269 VAN 2008

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. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslik vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemarking van die produk mag slegs '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:		36/2.2/0235
Name of medicine:		DOXYNITE DROPS
Dosage form:		DROPS
Active ingredients:		EACH 0,5 ml DROPS CONTAIN: DOXYLAMINE SUCCINATE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	EQUITY PHARMACEUTICALS, HAZELWOOD, PRETORIA
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		37/20.2.2/0100
Name of medicine:		TIBOZOLE
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MICONAZOLE NITRATE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:		CLONMEL HEALTHCARE LTD, CLONMEL, IRELAND
Packer:		SANICO NV, TURNHOUT, BELGIUM JANSSEN PHARMACEUTICA, WOODMEAD, JOHANNESBURG
Laboratory:	FPRC:	CLONMEL HEALTHCARE LTD, CLONMEL, IRELAND SANICO NV, TURNHOUT, BELGIUM
	FPRC/FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, JOHANNESBURG
Shelf-life:		30 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		37/7.1/0302
Name of medicine:		FEDALOC 30 mg SR
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: NIFEDIPINE 30,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		COMPUPHARM (PTY) LTD
Manufacturer:		VALPHARMA SA, SERRAVALLA, REPUBLIC OF SAN MARINO EUDERMA S.p.A.,RIMINI, ITALY
Packer:		VALPHARMA SA, SERRAVALLA, REPUBLIC OF SAN MARINO EUDERMA S.p.A.,RIMINI, ITALY
Laboratory:	FPRC:	VALPHARMA SA, SERRAVALLA, REPUBLIC OF SAN MARINO EUDERMA S.p.A.,RIMINI, ITALY SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	COMPUPHARM, LYNNWOOD, PRETORIA
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		37/7.1/0303
Name of medicine:		FEDALOC 60 mg SR
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: NIFEDIPINE 60,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		COMPUPHARM (PTY) LTD
Manufacturer:		VALPHARMA SA, SERRAVALLA, REPUBLIC OF SAN MARINO EUDERMA S.p.A.,RIMINI, ITALY
Packer:		VALPHARMA SA, SERRAVALLA, REPUBLIC OF SAN MARINO EUDERMA S.p.A.,RIMINI, ITALY
Laboratory:	FPRC:	VALPHARMA SA, SERRAVALLA, REPUBLIC OF SAN MARINO EUDERMA S.p.A.,RIMINI, ITALY SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	COMPUPHARM, LYNNWOOD, PRETORIA
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:	37/8.3/0434
Name of medicine:	COSMOFER
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: IRON DEXTRAN EQUIVALENT TO ELEMENTARY IRON 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SOLUPHARM GmbH, MELSUNGEN, GERMANY WEIMAR PHARMA GmbH, RASTATT, GERMANY
Packer:	SOLUPHARM GmbH, MELSUNGEN, GERMANY WEIMAR PHARMA GmbH, RASTATT, GERMANY
Laboratory: FPRC:	SOLUPHARM GmbH, MELSUNGEN, GERMANY WEIMAR PHARMA GmbH, RASTATT, GERMANY PHARMACOSMOS, SOENDERGADE, VIBY, DENMARK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	37/20.2.2/0630
Name of medicine:	MICMAT
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MICONAZOLE NITRATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	CLONMEL HEALTHCARE LTD, TIPPERARY, CLONMEL, IRELAND
Packer:	SANICO NV, TURNHOUT, BELGIUM JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Laboratory: FPRC:	CLONMEL HEALTHCARE LTD, TIPPERARY, CLONMEL, IRELAND SANICO NV, TURNHOUT, BELGIUM
FPRC/FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	38/20.2.2/0157
Name of medicine:	CANDIZOLE VAGINAL TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOTRIMAZOLE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	TECHNIKON LABORATORIES, ROBERTVILLE FLORIDA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG
Packer:	TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG
Laboratory: FPRC:	TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRC/FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	A05/3.1.1/03
Name of medicine:	PETCAM
Dosage form:	SUSPENSION
Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: MELOXICAM 1,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD (UNIT I), SALCETTE, GOA, INDIA
Packer:	CIPLA LTD (UNIT I), SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD (UNIT I), SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	A05/3.1.1/04
Name of medicine:	RIMADYL AQUEOUS INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CARPROFEN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	VERICORE LTD, DUNDEE, SCOTLAND
Packer:	VERICORE LTD, DUNDEE, SCOTLAND
Laboratory: FPRC:	VERICORE LTD, DUNDEE, SCOTLAND
FPRR	PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	A38/4/0412
Name of medicine:	SEPTANEST WITH ADRENALINE 1/100 000
Dosage form:	INJECTION
Active ingredients:	EACH 2,2 ml CARTRIDGE CONTAINS: ARTICAINE HYDROCHLORIDE 88,0 mg ADRENALINE TARTRATE EQUIVALENT TO ADRENALINE 22,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THE DENTAL WAREHOUSE (PTY) LTD
Manufacturer:	SEPTODONT, SAINT MAUR DES FOSSES, FRANCE
Packer:	SEPTODONT, SAINT MAUR DES FOSSES, FRANCE
Laboratory: FPRC:	SEPTODONT, SAINT MAUR DES FOSSES, FRANCE SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	THE DENTAL WAREHOUSE, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	A38/7.1.3/0604
Name of medicine:	ASPEN ENALAPRIL 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, MOLLET DEL VALLES, BARCELONA, SPAIN
Packer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory: FPRC:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, MOLLET DEL VALLES, BARCELONA, SPAIN SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	A38/7.1.3/0605
Name of medicine:	ASPEN ENALAPRIL 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, MOLLET DEL VALLES, BARCELONA, SPAIN
Packer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory: FPRC	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, MOLLET DEL VALLES, BARCELONA, SPAIN SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:		A39/20.2.2/0009
Name of medicine:		TERBANE 10 mg
Dosage form:		CREAM
Active ingredients:		EACH 1,0 g CREAM CONTAINS: TERBINAFINE HYDROCHLORIDE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (PTY) LTD
Manufacturer:		PHARMA-SKAN ApS, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:		PHARMA-SKAN ApS, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-SKAN ApS, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		A39/20.2.2/0010
Name of medicine:		TERBINISIL 10 mg
Dosage form:		CREAM
Active ingredients:		EACH 1,0 g CREAM CONTAINS: TERBINAFINE HYDROCHLORIDE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (PTY) LTD
Manufacturer:		PHARMA-SKAN ApS, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:		PHARMA-SKAN ApS, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-SKAN ApS, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		A40/2.5/0004
Name of medicine:		ASPEN PHENYTOIN SODIUM 250 mg/5 ml
Dosage form:		INJECTION
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: PHENYTOIN SODIUM 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		LABORATORIO REIG JOFRE S.A, BARCELONA, SPAIN STRIDES ARCOLAB LTD, BANGALORE, INDIA
Packer:		LABORATORIO REIG JOFRE S.A, BARCELONA, SPAIN STRIDES ARCOLAB LTD, BANGALORE, INDIA
Laboratory:	FPRC:	LABORATORIO REIG JOFRE S.A, BARCELONA, SPAIN STRIDES ARCOLAB LTD, BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		A40/20.1.1/0114
Name of medicine:		CIPROCINA
Dosage form:		INFUSION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		CLARIS LIFESCIENCES LTD, ELLISBRIDGE, AHMEDABAD, INDIA
Packer:		CLARIS LIFESCIENCES LTD, ELLISBRIDGE, AHMEDABAD, INDIA
Laboratory:	FPRC:	CLARIS LIFESCIENCES LTD, ELLISBRIDGE, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		A40/3.1/0174
Name of medicine:		PEDEA
Dosage form:		INJECTION
Active ingredients:		EACH AMPOULE CONTAINS: IBUPROFEN 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		TEMA MEDICAL (PTY) LTD
Manufacturer:		MERCKLE GmbH, BLAUBEUREN, GERMANY
Packer:		MERCKLE GmbH, BLAUBEUREN, GERMANY
Laboratory:	FPRC:	MERCKLE GmbH, BLAUBEUREN, GERMANY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	TEMA MEDICAL, SANDTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		A40/2.9/0203
Name of medicine:		DUROGESIC 12 µg/h
Dosage form:		TRANSDERMAL PATCH
Active ingredients:		EACH PATCH CONTAINS: FENTANYL 2,1 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:		ALZA IRELAND LTD, CASHEL, COUNTY TIPPERARY, IRELAND
Packer:		ALZA IRELAND LTD, CASHEL, COUNTY TIPPERARY, IRELAND JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
Laboratory:	FPRC:	ALZA IRELAND LTD, CASHEL, COUNTY TIPPERARY, IRELAND JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM MICROCHEM LABORATORIES, DUNGARVAN COUNTY, WATERFORD, IRELAND
	FPRC/FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:	A40/7.1.3/0292
Name of medicine:	CO-SARBEN 150/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB CO., EVANSVILLE INDIANA, USA SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	A40/7.1.3/0293
Name of medicine:	CO-SARBEN 300/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB CO., EVANSVILLE INDIANA, USA SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FRPC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:		A40/34/0502
Name of medicine:		AVONEX SOLUTION FOR INJECTION
Dosage form:		INJECTION
Active ingredients:		EACH PRE-FILLED SYRINGE CONTAINS: INTERFERON BETA 1a 30,0 µg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		VETTER PHARMA-FERTIGUNG GmbH & CO, SCHUTZENSTRASSE, RAVENBURG, GERMANY
Packer:		VETTER PHARMA-FERTIGUNG GmbH & CO, SCHUTZENSTRASSE, RAVENBURG, GERMANY BIOGEN IDEC B.V, HOOFDORP, THE NETHERLANDS VETTER PHARMA-FERTIGUNG GmbH & CO, LAGENARGEN, GERMANY VETTER PHARMA-FERTIGUNG GmbH & CO, HOLBEINSTRASSE, RAVENSBURG, GERMANY
Laboratory:	FPRC:	VETTER PHARMA-FERTIGUNG GmbH & CO, SCHUTZENSTRASSE, RAVENBURGS, GERMANY BIOGEN IDEC B.V, HOOFDORP, THE NETHERLANDS BIOGEN IDEC B.V, AMSTERDAM, THE NETHERLANDS BIORELIANCE LTD,STIRLING, SCOTLAND, UK COVANCE LABORATORIES LTD, HARROGATE, NORTH YORKSHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND
Shelf-life:		18 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		A40/21.12/0656
Name of medicine:		DRL-FINASTERIDE 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FINASTERIDE 1,0 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, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICALS 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:		15 AUGUST 2008

MRF 15

Registration number:		A40/7.5/0711
Name of medicine:		GULF 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
Applicant:		GULF DRUG COMPANY (PTY) LTD
Manufacturer:		PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA
Packer:		PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA
Laboratory:	FPRC:	PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY, MOREWILL, BEYERSPARK, BOKSBURG
	FPRR:	GULF DRUG COMPANY, MOUNT EDGECOMBE
Shelf-life:		36 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		A40/20.1.1/0734
Name of medicine:		OREOXAL 40 mg/5 ml
Dosage form:		SUSPENSION
Active ingredients:		EACH 5,0 ml SUSPENSION CONTAINS: CEFPODOXIME PROXETIL EQUIVALENT TO CEFPODOXIME 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ PVT LTD, TURBHE, NAVI MUMBAI, INDIA
Packer:		SANDOZ PVT LTD, TURBHE, NAVI MUMBAI, INDIA
Laboratory:	FPRC:	SANDOZ PVT LTD, TURBHE, NAVI MUMBAI, INDIA NOVARTIS, SPARTAN, KEMPTON PARK ANALYTICON, TERENURE, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:	A40/20.2.8/0736
Name of medicine:	STOCRIN 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME, SOUTH GRANVILLE, NEW SOUTH WALES, AUSTRALIA
Packer:	MERCK SHARP & DOHME, SOUTH GRANVILLE, NEW SOUTH WALES, AUSTRALIA MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS MSD, HAFWAY HOUSE, RSA
Laboratory: FPRC:	MERCK SHARP & DOHME, SOUTH GRANVILLE, NEW SOUTH WALES, AUSTRALIA
FPRC/FPRR:	MSD, HAFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	A40/20.2.8/0737
Name of medicine:	STOCRIN 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME, SOUTH GRANVILLE, NEW SOUTH WALES, AUSTRALIA
Packer:	MERCK SHARP & DOHME, SOUTH GRANVILLE, NEW SOUTH WALES, AUSTRALIA MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS MSD, HAFWAY HOUSE, RSA
Laboratory: FPRC:	MERCK SHARP & DOHME, SOUTH GRANVILLE, NEW SOUTH WALES, AUSTRALIA
FPRC/FPRR:	MSD, HAFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:		41/7.1.3/0042
Name of medicine:		DIACE CO 20 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/5.10/0075
Name of medicine:		DANTRON 4 VIAL
Dosage form:		INJECTION
Active ingredients:		EACH 2,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSTERON 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA
Packer:		SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/5.10/0076
Name of medicine:		DANTRON 8 VIAL
Dosage form:		INJECTION
Active ingredients:		EACH 4,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSTERON 8,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA
Packer:		SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/5.10/0077
Name of medicine:		NAUSETRON 4 VIAL
Dosage form:		INJECTION
Active ingredients:		EACH 2,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSTERON 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA
Packer:		SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/5.10/0078
Name of medicine:		NAUSETRON 8 VIAL
Dosage form:		INJECTION
Active ingredients:		EACH 4,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSTERON 8,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA
Packer:		SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.1.3/0187
Name of medicine:		LYSIN CO 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BE-TABS PHARMACEUTICALS (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:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.1.3/0188
Name of medicine:		LYSIN CO 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BE-TABS PHARMACEUTICALS (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:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/2.5/271
Name of medicine:		LAMOD 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA), HAL FAR, MALTA
Packer:		ARROW PHARMA (MALTA), HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMA (MALTA), HAL FAR, MALTA SELAMINE t/a ARROW GENERICS, DUBLIN, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA SA, WOODMEAD, SANDTON
Shelf-life		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/2.5/272
Name of medicine:		LAMOD 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA), HAL FAR, MALTA
Packer:		ARROW PHARMA (MALTA), HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMA (MALTA), HAL FAR, MALTA SELAMINE t/a ARROW GENERICS, DUBLIN, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA SA, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/2.5/273
Name of medicine:		LAMOD 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA), HAL FAR, MALTA
Packer:		ARROW PHARMA (MALTA), HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMA (MALTA), HAL FAR, MALTA SELAMINE t/a ARROW GENERICS, DUBLIN, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA SA, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/2.5/274
Name of medicine:		LAMOD 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA), HAL FAR, MALTA
Packer:		ARROW PHARMA (MALTA), HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMA (MALTA), HAL FAR, MALTA SELAMINE t/a ARROW GENERICS, DUBLIN, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA SA, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/2.5/275
Name of medicine:		LAMOD 200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA), HAL FAR, MALTA
Packer:		ARROW PHARMA (MALTA), HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMA (MALTA), HAL FAR, MALTA SELAMINE t/a ARROW GENERICS, DUBLIN, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA SA, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.2.8/0296
Name of medicine:		VARI-ZIDOVUDINE 300 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ZIDOVUDINE 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		LEBASI PHARMACEUTICALS CC
Manufacturer:		VARICHEM, PHARMACEUTICALS, HARARE, ZIMBABWE
Packer:		VARICHEM, PHARMACEUTICALS, HARARE, ZIMBABWE
Laboratory:	FPRC:	VARICHEM, PHARMACEUTICALS, HARARE, ZIMBABWE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	LEBASI PHARMACEUTICALS, NOORDBRUG, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/18/0299
Name of medicine:		FOSRENOL 250 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LANTHANUM CARBONATE HYDRATE EQUIVALENT TO LANTHANUM 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Packer:		BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Laboratory:	FPRC:	BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK READING SCIENTIFIC SERVICES LTD, READING, BERKSHIRE, UK SOUTHERN TESTING & RESEARCH, WILSON, NORTH CAROLINA, USA SSCI Inc, WEST LAFAYETTE, INDIANAPOLIS, USA TEPNEL SCIENTIFIC SERVICES, EDINBURGH, YORKSHIRE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/18/0300
Name of medicine:		FOSRENOL 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LANTHANUM CARBONATE HYDRATE EQUIVALENT TO LANTHANUM 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Packer:		BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Laboratory:	FPRC:	BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK READING SCIENTIFIC SERVICES LTD, READING, BERKSHIRE, UK SOUTHERN TESTING & RESEARCH, WILSON, NORTH CAROLINA, USA SSCI Inc, WEST LAFAYETTE, INDIANAPOLIS, USA TEPNEL SCIENTIFIC SERVICES, EDINBURGH, YORKSHIRE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/18/0301
Name of medicine:		FOSRENOL 750 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LANTHANUM CARBONATE HYDRATE EQUIVALENT TO LANTHANUM 750,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Packer:		BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Laboratory:	FPRC:	BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK READING SCIENTIFIC SERVICES LTD, READING, BERKSHIRE, UK SOUTHERN TESTING & RESEARCH, WILSON, NORTH CAROLINA, USA SSCI Inc, WEST LAFAYETTE, INDIANAPOLIS, USA TEPNEL SCIENTIFIC SERVICES, EDINBURGH, YORKSHIRE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/18/0302
Name of medicine:		FOSRENOL 1 000 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LANTHANUM CARBONATE HYDRATE EQUIVALENT TO LANTHANUM 1 000,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Packer:		BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK
Laboratory:	FPRC:	BCM LTD, NOTTINGHAM, NOTTINGHAMSHIRE, UK READING SCIENTIFIC SERVICES LTD, READING, BERKSHIRE, UK SOUTHERN TESTING & RESEARCH, WILSON, NORTH CAROLINA, USA SSCI Inc, WEST LAFAYETTE, INDIANAPOLIS, USA TEPNEL SCIENTIFIC SERVICES, EDINBURGH, YORKSHIRE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/0371
Name of medicine:		WELLBUTRIN XL 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:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/0372
Name of medicine:		WELLBUTRIN XL 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
	FPRR	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:		18 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.1.1/0388
Name of medicine:		AURO-CEFALEXIN TABLETS 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFALEXIN MONOHYDRATE EQUIVALENT TO CEFALEXIN 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, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.1.1/0389
Name of medicine:		AURO-CEFALEXIN TABLETS 1 000 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFALEXIN MONOHYDRATE EQUIVALENT TO CEFALEXIN 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:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRC/FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.5/0409
Name of medicine:		COLITE 10 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PRAVASTATIN SODIUM 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.5/0410
Name of medicine:		COLITE 20 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PRAVASTATIN SODIUM 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.5/0411
Name of medicine:		COLITE 40 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PRAVASTATIN SODIUM 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.5/0412
Name of medicine:		COLITE 80 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PRAVASTATIN SODIUM 80,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/0440
Name of medicine:		ODIVEN 37,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 37,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/0441
Name of medicine:		ODIVEN 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/0442
Name of medicine:		ODIVEN 75
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.1.2/0532
Name of medicine:		BINDOCLAV 375 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.1.2/0533
Name of medicine:		BINDOCLAV 625 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.1.2/0534
Name of medicine:		BINDOCLAV 1 000 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.1.2/0535
Name of medicine:		AURO-AMOXICLAV 375 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.1.2/0536
Name of medicine:		AURO-AMOXICLAV 625 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/20.1.2/0537
Name of medicine:		AURO-AMOXICLAV 1 000 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA, UNIT XII, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRC/FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:	41/20.1.2/0546
Name of medicine:	BETACLAV 375
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (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
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/20.1.2/0547
Name of medicine:	BETACLAV 625
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (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:	BE-TABS PHARMACEUTICALS, ROODEPOORT
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/20.1.2/0548
Name of medicine:	BETACLAV 1 000
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (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
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT
Shelf-life:	24 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/5.4.1/0604
Name of medicine:	REQUIP XL 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HYDROCHLORIDE EQUIVALENT TO ROPINIROLE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
Packer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK CARDINAL HEALTH LTD, GREAT OAKLEY, CORBY, NORTHAMPTONSHIRE, UK GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory: FPRC:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
FPRC/FPRR:	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/5.4.1/0605
Name of medicine:	REQUIP XL 3 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HYDROCHLORIDE EQUIVALENT TO ROPINIROLE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
Packer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK CARDINAL HEALTH LTD, GREAT OAKLEY, CORBY, NORTHAMPTONSHIRE, UK GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory: FPRC:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
FPRC/FPRR:	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/5.4.1/0606
Name of medicine:	REQUIP XL 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HYDROCHLORIDE EQUIVALENT TO ROPINIROLE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
Packer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK CARDINAL HEALTH LTD, GREAT OAKLEY, CORBY, NORTHAMPTONSHIRE, UK GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory: FPRC:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
FPRC/FPRR:	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/5.4.1/0607
Name of medicine:	REQUIP XL 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HYDROCHLORIDE EQUIVALENT TO ROPINIROLE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
Packer:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK CARDINAL HEALTH LTD, GREAT OAKLEY, CORBY, NORTHAMPTONSHIRE, UK GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory: FPRC:	SMITHKLINE BEECHAM PLC, CRAWLEY, WEST SUSSEX, UK
FPRC/FPRR:	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:	36 months
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/20.2.8/0737
Name of medicine:	ADCO-ZIDOVUDINE 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRC/FPRR:	ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/20.2.8/0738
Name of medicine:	ADCO-ZIDOVUDINE 250 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRC/FPRR:	ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:	41/8.1/0812
Name of medicine:	GULF AMLODIPINE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LTD, TAL-HALOL. PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG INSTITUTE FOR PHARMACEUTICALS SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORIES, MOREWILL, BOKSBURG
FPRR:	GULF DRUG CO, MOUNT EDGECOMBE, KZN
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2008

MRF 15

Registration number:		41/8.1/0813
Name of medicine:		GULF AMLODIPINE 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		GULF DRUG COMPANY (PTY) LTD
Manufacturer:		ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Packer:		ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Laboratory:	FPRC:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG INSTITUTE FOR PHARMACEUTICALS SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORIES, MOREWILL, BOKSBURG
	FPRR:	GULF DRUG CO, MOUNT EDGECOMBE, KZN
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.1.3/0820
Name of medicine:		CIPLAZAR 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM EQUIVALENT TO LOSARTAN 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.1.3/0821
Name of medicine:		CIPLAZAR 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM EQUIVALENT TO LOSARTAN 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.1.3/0822
Name of medicine:		CIPLAZAR 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM EQUIVALENT TO LOSARTAN 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/0843
Name of medicine:		CITRAZ 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, CENTURION, RSA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, 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:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/0844
Name of medicine:		CITRAZ 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, CENTURION, RSA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, 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:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/0845
Name of medicine:		CITRAZ 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, CENTURION, RSA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, 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:		15 AUGUST 2008

MRF 15

Registration number:		41/7.1/0935
Name of medicine:		ZANERIL 10/10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LERCANIDIPINE HYDROCHLORIDE 10,0 mg ENALAPRIL MALEATE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.p.A., MILAN, ITALY
Packer:		RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.p.A., MILAN, ITALY
Laboratory:	FPRC:	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.p.A., MILAN, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/7.1/0936
Name of medicine:		ZANERIL 10/20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LERCANIDIPINE HYDROCHLORIDE 10,0 mg ENALAPRIL MALEATE 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.p.A., MILAN, ITALY
Packer:		RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.p.A., MILAN, ITALY
Laboratory:	FPRC:	RECORDATI INDUSTRIA CHIMICA & FARMACEUTICA S.p.A., MILAN, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/1007
Name of medicine:		VENELA 37,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 37,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICALS 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:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/1008
Name of medicine:		VENELA 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 50 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, RANGA PEDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICALS 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:		15 AUGUST 2008

MRF 15

Registration number:		41/1.2/1009
Name of medicine:		VENELA 75
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75 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, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICALS 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:		15 AUGUST 2008

MRF 15

Registration number:		41/21.2/1089
Name of medicine:		METORED 500
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:		SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory:	FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/21.2/1090
Name of medicine:		METORED 850
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:		SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory:	FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		41/21.2/1091
Name of medicine:		METORED 1 000
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 1 000,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:		SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory:	FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		15 AUGUST 2008

MRF 15

Registration number:		34/30.2/0501
Name of medicine:		OCTAGAM
Dosage form:		INFUSION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: HUMAN NORMAL IMMUNOGLOBULIN G 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		JE ECKARD
Manufacturer:		OCTAPHARMA PHARMAZEUTIKA, VIENNA, AUSTRIA
Packer:		OCTAPHARMA PHARMAZEUTIKA, VIENNA, AUSTRIA
Laboratory:	FPRC:	OCTAPHARMA PHARMAZEUTIKA, VIENNA, AUSTRIA
	FPRR:	JE ECKARD, MONUMENT PARK, PRETORIA, RSA
Shelf-life:		24 months
Date of registration:		13 JUNE 2008