GENERAL NOTICE

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:		41/20.2.8/0296
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