Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 522 Pretoria, 19 December / Desember 2008 No. 31696

CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1534 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 1534 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:		T/30.1/0544
Name of medicine:		PNEUMOVAX 23
Dosage form:		INJECTION
Active ingredients:		EACH 0,5 ml DOSE CONTAINS STREPTOCOCCUS PNEUMONIA 250,0 ug OF EACH POLYSACHARIDE
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MSD (PTY) LTD
Manufacturer:		MERCK & CO INC, WESTPOINT, PENNSYLVANIA, USA
Packer:		MERCK & CO INC, WESTPOINT, PENNSYLVANIA, USA
Laboratory:	FPRC:	MERCK & CO INC, WESTPOINT, PENNSYLVANIA, USA
	FPRR:	MSD, HALFWAY HOUSE, RSA
Shelf-life:		30 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		30/2.10/0392
Name of medicine:		TEVA BACLOFEN 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: BACLOFEN 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:		BIOGAL PHARMACEUTICAL WORKS, DEBRECEN, PALLAGI, HUNGARY
Packer:		APS BERK PHARMACEUTICALS , EASTBOURNE, EAST SUSSEX, U.K.
Laboratory:	FPRC:	APS BERK PHARMACEUTICALS, EASTBOURNE, EAST SUSSEX, U.K. SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	TEVA PHARMACEUTICALS, RUIMSIG, ROODEPOORT
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:	38/10.1/0002
Name of medicine:	STEARNS COUGH SYRUP – PINE TAR AND HONEY FLAVOUR
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, BRYANSTON JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:		A38/8/0375
Name of medicine:		PCH ACETYLSALICYLIC ACID CARDIO 80
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ACETYLSALICYLIC ACID 80,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMACHEMIE (PTY) LTD
Manufacturer:		PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS BIOGAL PHARMACEUTICAL WORKS LTD, DEBRECEN, HUNGARY
Packer:		PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS BIOGAL PHARMACEUTICAL WORKS LTD, DEBRECEN, HUNGARY PHARMAPACK INTERNATIONAL BV, ZOETERMEER, THE NETHERLANDS
Laboratory:	FPRC:	PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS BIOGAL PHARMACEUTICAL WORKS LTD, DEBRECEN, HUNGARY CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
	FPRR:	PHARMACHEMIE, IRENE, CENTURION
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A38/1.2/0394
Name of medicine:		HEXALOFT 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		HEXAL A/S, HVIDOVRE, DENMARK ILSAN ILAC SANAYI VE TICARET, GEBZE-KOCAELI, TURKEY
Packer:		HEXAL A/S, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC SANAYI VE TICARET, GEBZE-KOCAELI, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	HEXAL A/S, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC SANAYI VE TICARET, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A38/1.2/0398
Name of medicine:		SERTRALINE HEXAL 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		HEXAL A/S, HVIDOVRE, DENMARK ILSAN ILAC SANAYI VE TICARET, GEBZE-KOCAELI, TURKEY
Packer:		HEXAL A/S, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC SANAYI VE TICARET, GEBZE-KOCAELI, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	HEXAL A/S, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC SANAYI VE TICARET, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A38/2.5/0458
Name of medicine:		LAMOTRIGINE HEXAL 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA S.A. (PTY) LTD
Manufacturer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
Packer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A38/2.5/0459
Name of medicine:		LAMOTRIGINE HEXAL 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA S.A. (PTY) LTD
Manufacturer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
Packer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A38/2.5/0460
Name of medicine:		LAMOTRIGINE HEXAL 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA S.A. (PTY) LTD
Manufacturer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
Packer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A38/2.5/0461
Name of medicine:		LAMOTRIGINE HEXAL 200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA S.A. (PTY) LTD
Manufacturer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
Packer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:	A39/33/0320
Name of medicine:	BIOPLUS SYRUP STRAWBERRY
Dosage form:	SYRUP
Active ingredients:	EACH 30,0 ml SYRUP CONTAINS: Calcium gluconate 900,0 mg Caffeine 270,0 mg Calcium citrate 180,0 mg Thiamine hydrochloride 16,0 mg Riboflavin 11,0 mg Pyridoxine 9,0 mg Nicotinamide 42,0 mg d-Pantothenol 11,0 mg Cyanocobalamin 26,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR	ADCOCK INGRAM, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	A39/20.1.1/0381
Name of medicine:	AZITHROHEXAL 500 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN DIHYDRATE EQUIVALENT TO AZITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG NOVARTIS PHARMA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL AG, HOLZKIRCHEN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	HEXAL PHARMA, PINETOWN, RSA
Shelf-life:	24 months (provisional)
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:		A39/20.1.1/0534
Name of medicine:		MYCOREST 150
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: FLUCONAZOLE 150,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
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 SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A39/7.1/0537
Name of medicine:		AMLODIPINE HEXAL 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
Applicant:		HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:		ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL A/S, HVIDOVRE, DENMARK
Packer:		SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A39/7.1/0539
Name of medicine:		VASCULEX 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
Applicant:		HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:		ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL A/S, HVIDOVRE, DENMARK
Packer:		SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A39/26/0648
Name of medicine:		ELIGARD 7,5 mg
Dosage form:		INJECTION
Active ingredients:		EACH SYRINGE DELIVERS: LEUPROLIDE 7,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		KEY ONCOLOGICS (PTY) LTD
Manufacturer:		ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA STERIS ISOMEDIX SERVICES, WHIPPANY, NEW JERSEY, USA
Packer:		ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA
Laboratory:	FPRC:	ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA SPECTRAL DATA SERVICES INC, CHAMPAIGN, ILLINOIS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	KEY ONCOLOGICS, HOUGHTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A39/26/0649
Name of medicine:		ELIGARD 22,5 mg
Dosage form:		INJECTION
Active ingredients:		EACH SYRINGE DELIVERS: LEUPROLIDE 22,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		KEY ONCOLOGICS (PTY) LTD
Manufacturer:		ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA STERIS ISOMEDIX SERVICES, WHIPPANY, NEW JERSEY, USA
Packer:		ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA
Laboratory:	FPRC:	ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA SPECTRAL DATA SERVICES INC, CHAMPAIGN, ILLINOIS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	KEY ONCOLOGICS, HOUGHTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A39/26/0650
Name of medicine:		ELIGARD 30,0 mg
Dosage form:		INJECTION
Active ingredients:		EACH SYRINGE DELIVERS: LEUPROLIDE 30,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		KEY ONCOLOGICS (PTY) LTD
Manufacturer:		ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA STERIS ISOMEDIX SERVICES, WHIPPANY, NEW JERSEY, USA
Packer:		ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA
Laboratory:	FPRC:	ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA SPECTRAL DATA SERVICES INC, CHAMPAIGN, ILLINOIS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	KEY ONCOLOGICS, HOUGHTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:	A39/26/0651
Name of medicine:	ELIGARD 45,0 mg
Dosage form:	INJECTION
Active ingredients:	EACH SYRINGE DELIVERS: LEUPROLIDE 45,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	KEY ONCOLOGICS (PTY) LTD
Manufacturer:	ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA STERIS ISOMEDIX SERVICES, WHIPPANY, NEW JERSEY, USA
Packer:	ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA
Laboratory: FPRC:	ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA SPECTRAL DATA SERVICES INC, CHAMPAIGN, ILLINOIS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
FPRR:	KEY ONCOLOGICS, HOUGHTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	A40/30.1/0180
Name of medicine:	POLIORIX
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: POLIO VIRUS TYPE 1 (MAHONEY STRAIN) 40,0 D ANTIGEN UNITS POLIO VIRUS TYPE 2 (MEF-1 STRAIN) 8,0 D ANTIGEN UNITS POLIO VIRUS TYPE 3 (SAUKETT STRAIN) 32,0 D ANTIGEN UNITS
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS, RIXENSART, BELGIUM
Packer:	GLAXOSMITHKLINE BIOLOGICALS, RIXENSART, BELGIUM SACHSISCHES SERUMWERK GmbH, DRESDEN, GERMANY GLAXOSMITHKLINE SOUTH AFRICA, EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXOSMITHKLINE BIOLOGICALS, RIXENSART, BELGIUM
FPRC/FPRR:	GLAXOSMITHKLINE SOUTH AFRICA, EPPING, CAPE TOWN
Shelf-life:	36 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	A40/34/0089
Name of medicine:	STRUCKTOKABIVEN
Dosage form:	INFUSION
Active ingredients:	EACH 1 000,0 ml SOLUTION CONTAINS: Glucose monohydrate equivalent to Glucose 420,0 g L-Alanine 14,0 g L-Arginine 12,0 g Glycine 11,0 g L-Histidine 3,0 g L-Isoleucine 5,0 g L-Leucine 7,4 g L-Lysine 6,6 g L-Methionine 4,3 g L-Phenylalanine 5,1 g L-Proline 11,2 g L-Serine 6,5 g Taurine 1,0 g L-Threonine 4,4 g L-Tryptophan 2,0 g L-Tyrosine 0,4 g L-Valine 6,2 g Calcium chloride 0,56 g Sodium glycerophosphate 4,18 g Magnesium sulphate 1,2 g Potassium chloride 4,48 g Sodium acetate 3,4 g Zinc sulphate 0,0129 Purified Structured Triglycerides 200,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS KABI AB, UPPSALA, SWEDEN
Packer:	FRESENIUS KABI AB, UPPSALA, SWEDEN

MRF 15

Registration number:	A40/34/0090
Name of medicine:	STRUCKTOKABIVEN EF
Dosage form:	INFUSION
Active ingredients:	EACH 1 000,0 ml SOLUTION CONTAINS: Glucose monohydrate equivalent to Glucose 420,0 g L-Alanine 14,0 g L-Arginine 12,0 g Glycine 11,0 g L-Histidine 3,0 g L-Isoleucine 5,0 g L-Leucine 7,4 g L-Lysine 6,6 g L-Methionine 4,3 g L-Phenylalanine 5,1 g L-Proline 11,2 g L-Serine 6,5 g Taurine 1,0 g L-Threonine 4,4 g L-Tryptophan 2,0 g L-Tyrosine 0,4 g L-Valine 6,2 g Purified Structured Triglycerides 200,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS KABI AB, UPPSALA, SWEDEN
Packer:	FRESENIUS KABI AB, UPPSALA, SWEDEN

Laboratory:	FPRC:	FRESENIUS KABI AB, UPPSALA, SWEDEN BODENE t/a INTRAMED, KORSTEN, PORT ELIZABETH KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR:	FRESENIUS KABI S.A., HALFWAY HOUSE
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

Laboratory:	FPRC:	FRESENIUS KABI AB, UPPSALA, SWEDEN BODENE t/a INTRAMED, KORSTEN, PORT ELIZABETH KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR:	FRESENIUS KABI S.A., HALFWAY HOUSE
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:	A40/2.2/0441
Name of medicine:	STILNOX MR 12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOLPIDEM TARTRATE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, TOURS, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, TOURS, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, TOURS, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	A40/2.2/0443
Name of medicine:	IVEDAL MR 12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOLPIDEM TARTRATE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, TOURS, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, TOURS, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, TOURS, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:		A40/1.2/0503
Name of medicine:		ARLOFT 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA
Packer:		ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Laboratory:	FPRC:	ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA ARROW GENERICS LTD, DUBLIN, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A40/1.2/0504
Name of medicine:		ARLOFT 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA
Packer:		ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Laboratory:	FPRC:	ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA ARROW GENERICS LTD, DUBLIN, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A40/1.2/0505
Name of medicine:		ARROW SERTRALINE 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA
Packer:		ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Laboratory:	FPRC:	ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA ARROW GENERICS LTD, DUBLIN, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A40/1.2/0506
Name of medicine:		ARROW SERTRALINE 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA
Packer:		ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Laboratory:	FPRC:	ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA ARROW GENERICS LTD, DUBLIN, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A40/30.1/0541
Name of medicine:		PEDIACEL
Dosage form:		INJECTION
Active ingredients:		EACH 0,5 ml DOSE CONTAINS: PERTUSSIS TOXOID 20,0 µg FILAMENTOUS HAEMAGGLUTININ 20,0 µg FIMBRIAL AGGLUTINOGENS 2+3 5,0 µg PERTACTIN 3,0 µg DIPHTHERIA TOXOID 15,0 Lf TETANUS TOXOID 5,0 Lf INACTIVATED POLIOMYELITIS VACCINE: TYPE 1 40,0 D-Antigen Units TYPE 2 8,0 D-Antigen Units TYPE 3 32,0 D-Antigen Units HAEMOPHILUS b CONJUGATE VACCINE 10,0 µg bound to TETANUS PROTEIN 20,0 µg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AVENTIS PHARMA (PTY) LTD
Manufacturer:		AVENTIS PASTEUR LTD, TORONTO, ONTARIO, Canada AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE
Packer:		AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA
Laboratory:	FPRC:	AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
	FPRR:	AVENTIS PHARMA, MIDRAND
Shelf-life:		36 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A40/2.2/0569
Name of medicine:		SABAX MIDAZOLAM INJECTION 5 mg/5 ml
Dosage form:		INJECTION
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: MIDAZOLAM 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG.
Packer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A40/2.2/0570
Name of medicine:		SABAX MIDAZOLAM INJECTION 15 mg/3 ml
Dosage form:		INJECTION
Active ingredients:		EACH 3,0 ml SOLUTION CONTAINS: MIDAZOLAM 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		A40/2.2/0571
Name of medicine:		SABAX MIDAZOLAM INJECTION 50 mg/10 ml
Dosage form:		INJECTION
Active ingredients:		EACH 10,0 ml SOLUTION CONTAINS: MIDAZOLAM 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/7.1.3/0176
Name of medicine:		QUINACE 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Packer:		ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/7.1.3/0177
Name of medicine:		QUINACE 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Packer:		ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/7.1.3/0178
Name of medicine:		QUINACE 20 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Packer:		ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/7.1.3/0179
Name of medicine:		QUINACE 40 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Packer:		ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:	41/7.1.3/0212
Name of medicine:	QUINACE CO 10/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Packer:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory: FPRC:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
FPRR	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	41/7.1.3/0213
Name of medicine:	QUINACE CO 20/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Packer:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURGPHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory: FPRC:	ACTAVIS Hf, HAFNARFJORDUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	41/7.3/0244
Name of medicine:	TRIPTAM 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAM 50 ,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GERARD LABORATORIES, DUBLIN, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL POTCHEFSTROOM
FPRR	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	41/7.1.3/0290
Name of medicine:	EXFORGE 5/80 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMA ANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	41/7.1.3/0291
Name of medicine:	EXFORGE 5/160 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMA ANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	41/7.1.3/0292
Name of medicine:	EXFORGE 10/160 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMA ANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:		41/34/0558
Name of medicine:		RENAGEL
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SEVELAMER HYDROCHLORIDE 800,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		LE BASI PHARMACEUTICALS CC
Manufacturer:		GENZYME IRELAND LTD, WATERFORD, IRELAND
Packer:		GENZYME IRELAND LTD, WATERFORD, IRELAND
Laboratory::	FPRC	GENZYME IRELAND LTD, WATERFORD, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICALS SERVICES, SILVERTONDALE, PRETORIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
	FPRR	LEBASI PHARMACEUTICALS, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/20.2.8/0596
Name of medicine:		PROPAN STAVUDINE 20 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: STAVUDINE 20,0 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
Laboratory: FPRC/FPRR:		ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
	FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:	41/20.2.8/0597
Name of medicine:	PROPAN STAVUDINE 30 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 30,0 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
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:	41/20.2.8/0598
Name of medicine:	PROPAN STAVUDINE 40 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 40,0 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
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2008

MRF 15

Registration number:		41/21.2/0700
Name of medicine:		GLIMARYL 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/21.2/0701
Name of medicine:		GLIMARYL 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/21.2/0702
Name of medicine:		GLIMARYL 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/8.1/1086
Name of medicine:		KOGENATE FS 250
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: OCTOCOG ALFA 250,0 I.U.
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BAYER (PTY) LTD
Manufacturer:		BAYER CORPORATION, BERKELEY, CALIFORNIA, USA
Packer:		BAYER CORPORATION, BERKELEY, CALIFORNIA, USA
Laboratory:	FPRC:	BAYER CORPORATION, BERKELEY, CALIFORNIA, USA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	BAYER, ISANDO, RSA
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/8.1/1087
Name of medicine:		KOGENATE FS 500
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: OCTOCOG ALFA 500,0 I.U.
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BAYER (PTY) LTD
Manufacturer:		BAYER CORPORATION, BERKELEY, CALIFORNIA, USA
Packer:		BAYER CORPORATION, BERKELEY, CALIFORNIA, USA
Laboratory:	FPRC:	BAYER CORPORATION, BERKELEY, CALIFORNIA, USA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	BAYER, ISANDO, RSA
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		41/8.1/1088
Name of medicine:		KOGENATE FS 1 000
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: OCTOCOG ALFA 1 000,0 I.U.
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BAYER (PTY) LTD
Manufacturer:		BAYER CORPORATION, BERKELEY, CALIFORNIA, USA
Packer:		BAYER CORPORATION, BERKELEY, CALIFORNIA, USA
Laboratory:	FPRC:	BAYER CORPORATION, BERKELEY, CALIFORNIA, USA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	BAYER, ISANDO, RSA
Shelf-life:		24 months
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		42/6.2/0035
Name of medicine:		AMIOTACH
Dosage form:		INJECTION
Active ingredients:		EACH 3,0 ml SOLUTION CONTAINS: AMIODARONE HYDROCHLORIDE 150,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Packer:		STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Laboratory:	FPRC:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		42/5.10/0109
Name of medicine:		VOMIZ 8 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 8,0 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 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		42/5.10/0110
Name of medicine:		VOMIZ 4 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 4,0 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 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:		42/20.2.8/0975
Name of medicine:		RENZIR 200 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: EFAVIRENZ 200,0 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
Laboratory: FPRC/FPRR:		ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
	FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		10 OCTOBER 2008

MRF 15

Registration number:	42/20.2.8/0981
Name of medicine:	ADCO EFAVIRENZ 200 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 200,0 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
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2008