
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.

MRF 15	MRF 15
Registration number: T/30.1/0544	Registration number: 30/2.10/0392
Name of medicine: PNEUMOVAX 23	Name of medicine: TEVA BACLOFEN 10
Dosage form: INJECTION	Dosage form: TABLET
Active ingredients: EACH 0,5 ml DOSE CONTAINS STREPTOCOCCUS PNEUMONIA 250,0 ug OF EACH POLYSACCHARIDE	Active ingredients: EACH TABLET CONTAINS: BACLOFEN 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: MSD (PTY) LTD	Applicant: TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer: MERCK & CO INC, WESTPOINT, PENNSYLVANIA, USA	Manufacturer: BIOGAL PHARMACEUTICAL WORKS, DEBRECEN, PALLAGI, HUNGARY
Packer: MERCK & CO INC, WESTPOINT, PENNSYLVANIA, USA	Packer: APS BERK PHARMACEUTICALS, EASTBOURNE, EAST SUSSEX, U.K.
Laboratory: FPRC; MERCK & CO INC, WESTPOINT, PENNSYLVANIA, USA	Laboratory: FPRC; APS BERK PHARMACEUTICALS, EASTBOURNE, EAST SUSSEX, U.K. SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR: MSD, HALFWAY HOUSE, RSA	FPRR: TEVA PHARMACEUTICALS, RUIMSIG, ROODEPOORT
Shelf-life: 30 months	Shelf-life: 24 months (Provisional)
Date of registration: 10 OCTOBER 2008	Date of registration: 10 OCTOBER 2008

MRF 15	MRF 15
Registration number: 38/10.1/0002	Registration number: A38/8/0375
Name of medicine: STEARNS COUGH SYRUP – PINE TAR AND HONEY FLAVOUR	Name of medicine: PCH ACETYLSALICYLIC ACID CARDIO 80
Dosage form: SYRUP	Dosage form: TABLET
Active ingredients: EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg	Active ingredients: EACH TABLET CONTAINS: ACETYLSALICYLIC ACID 80,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 8	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: ADCOCK INGRAM LIMITED	Applicant: PHARMACHEMIE (PTY) LTD
Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	Manufacturer: PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS BIOGAL PHARMACEUTICAL WORKS LTD, DEBRECEN, HUNGARY
Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	Packer: PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS BIOGAL PHARMACEUTICAL WORKS LTD, DEBRECEN, HUNGARY PHARMAPACK INTERNATIONAL BV, ZOETERMEER, THE NETHERLANDS
Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	Laboratory: FPRC: PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS BIOGAL PHARMACEUTICAL WORKS LTD, DEBRECEN, HUNGARY CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG
FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG	FPRR: PHARMACHEMIE, IRENE, CENTURION
Shelf-life: 24 months (provisional)	Shelf-life: 24 months
Date of registration: 10 OCTOBER 2008	Date of registration: 10 OCTOBER 2008

MRF 15	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
Shelf-life:	FPRR: HEXAL PHARMA, PINETOWN, KZN 24 months
Date of registration:	10 OCTOBER 2008

MRF 15	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
Shelf-life:	FPRR: HEXAL PHARMA, PINETOWN, KZN 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: WELLSRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA

Packer: WELLSRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG

Laboratory: FPRC: WELLSRING 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: WELLSRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA

Packer: WELLSRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG

Laboratory: FPRC: WELLSRING 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	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 & 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	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	MRF 15
Registration number: A39/33/0320	Registration number: A39/20.1.1/0381
Name of medicine: BIOPLUS SYRUP STRAWBERRY	Name of medicine: AZITHROHEXAL 500 mg TABLETS
Dosage form: SYRUP	Dosage form: TABLET
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	Active ingredients: EACH TABLET CONTAINS: AZITHROMYCIN DIHYDRATE EQUIVALENT TO AZITHROMYCIN 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED	Applicant: HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	Manufacturer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL AG, HOLZKIRCHEN, GERMANY
Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	Packer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG NOVARTIS PHARMA, SPARTAN, KEMPTON PARK
Laboratory: FPRC: SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA	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, TERENCEUR, KEMPTON PARK
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	FPRR: HEXAL PHARMA, PINETOWN, RSA
FPRR: ADCOCK INGRAM, BRYANSTON, JOHANNESBURG	24 months (provisional)
Shelf-life: 24 months	10 OCTOBER 2008
Date of registration: 10 OCTOBER 2008	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
FPRC:	
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
FPRC:	
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15		MRF 15	
Registration number:	A39/7.1/0539	Registration number:	A39/26/0648
Name of medicine:	VASCULEX 10	Name of medicine:	ELIGARD 7,5 mg
Dosage form:	TABLET	Dosage form:	INJECTION
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg	Active ingredients:	EACH SYRINGE DELIVERS: LEUPROLIDE 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD	Applicant:	KEY ONCOLOGICS (PTY) LTD
Manufacturer:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL A/S, HVIDOVRE, DENMARK	Manufacturer:	ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA STERIS ISOMEDIX SERVICES, WHIPPANY, NEW JERSEY, USA
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA CHESAPEAKE BIOLOGICAL LABORATORIES INC, BALTIMORE, MARYLAND, USA
Laboratory:	FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, ATLASVILLE, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK	Laboratory:	FPRC: ATRIX LABORATORIES INC, FORT COLLINS, COLORADO, USA SPECTRAL DATA SERVICES INC, CHAMPAIGN, ILLINOIS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008	Date of registration:	10 OCTOBER 2008
			FPRR: KEY ONCOLOGICS, HOUGHTON, JOHANNESBURG

MRF 15	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
Shelf-life:	FPRR: KEY ONCOLOGICS, HOUGHTON, JOHANNESBURG 24 months
Date of registration:	10 OCTOBER 2008

MRF 15	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
Shelf-life:	FPRR: KEY ONCOLOGICS, HOUGHTON, JOHANNESBURG 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: 45,0 mg
LEUPROLIDE

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

FPRC: 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: 40,0 D ANTIGEN UNITS
POLIO VIRUS TYPE 1 (MAHONEY STRAIN)
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 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

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

Packer: AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE

Laboratory: AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA

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: PHARMA-Q, INDUSTRIA, JOHANNESBURG

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	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:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRC:	FPRC:
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2008

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:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRC:	FPRC:
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2008

MRF 15	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
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

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
Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008

MRF 15	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
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	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

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, 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:	41/7.3/0244
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	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, PRATTEN, 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

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, PRATTEN, 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	MRF 15
Registration number:	41/20.2.8/0597
Name of medicine:	PROPAN STAVUDINE 30 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: 30,0 mg STAVUDINE
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

Registration number:	41/20.2.8/0598
Name of medicine:	PROPAN STAVUDINE 40 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: 40,0 mg STAVUDINE
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	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

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	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
Shelf-life:	FPRC: 24 months
Date of registration:	10 OCTOBER 2008

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
Shelf-life:	FPRC: 24 months
Date of registration:	10 OCTOBER 2008

MRF 15		MRF 15	
Registration number:	41/8.1/1087	Registration number:	41/8.1/1088
Name of medicine:	KOGENATE FS 500	Name of medicine:	KOGENATE FS 1 000
Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OCTOCOG ALFA 500,0 I.U.	Active ingredients:	EACH VIAL CONTAINS: OCTOCOG ALFA 1 000,0 I.U.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD	Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER CORPORATION, BERKELEY, CALIFORNIA, USA	Manufacturer:	BAYER CORPORATION, BERKELEY, CALIFORNIA, USA
Packer:	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	Laboratory:	FPRC: BAYER CORPORATION, BERKELEY, CALIFORNIA, USA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	BAYER, ISANDO, RSA	FPRR:	BAYER, ISANDO, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	10 OCTOBER 2008	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: 150.0 mg
 AMIODARONE HYDROCHLORIDE

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: 200,0 mg EFAVIRENZ
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