CONTENTS

INHOUD

GENERAL NOTICE

NOTICE 155 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. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
8. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
9. A post-registration inspection must be conducted on the first production batch of the imported product.
10. Marketing of the product may only commence following a satisfactory post-registration inspection report.
11. 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.
12. 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.
13. The strains of the master seed viruses must be approved by the Department of Health for each year.

MRF 15

Registration number:		35/16.1/0369
Name of medicine:		EQUI-SINUS DROPS
Dosage form:		DROPS
Active ingredients:		EACH 0,5 ml DROPS CONTAINS: PHENYLPROPANOLAMINE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
	FPRR:	EQUITY PHARMACEUTICALS, HAZELWOOD, PRETORIA
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		35/16.1/0378
Name of medicine:		EQUI-DECON ORAL DROPS
Dosage form:		DROPS
Active ingredients:		EACH 0,5 ml DROPS CONTAINS: PHENYLPROPANOLAMINE HYDROCHLORIDE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
	FPRR:	EQUITY PHARMACEUTICALS, HAZELWOOD, PRETORIA
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:	36/8.3/0466
Name of medicine:	EQUI-FERRO SOLUTION
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FERROUS LACTATE EQUIVALENT TO ELEMENTAL IRON 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory: FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR:	EQUITY PHARMACEUTICALS, HAZELWOOD, PRETORIA
Shelf-life:	24 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	36/8.3/0467
Name of medicine:	EQUI-FERRO INFANT DROPS
Dosage form:	DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FERROUS LACTATE EQUIVALENT TO ELEMENTAL IRON 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory: FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR:	EQUITY PHARMACEUTICALS, HAZELWOOD, PRETORIA
Shelf-life:	24 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:		36/7.1.3/0490
Name of medicine:		COZAAR 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MSD (PTY) LTD
Manufacturer:		MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK
Packer:		MSD, HALFWAY HOUSE, RSA
Laboratory:	FPRC:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK
	FPRR:	MSD, HALFWAY HOUSE, RSA
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		37/20.1.1/0608
Name of medicine:		TEVA-CEFUROXIME SODIUM FOR INJECTION 750 mg
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:		TEVA PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL
Packer:		TEVA PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL
Laboratory:	FPRC:	TEVA PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	TEVA PHARMACEUTICALS, RUIMSIG, ROODEPOORT
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		37/20.1.1/0609
Name of medicine:		TEVA-CEFUROXIME SODIUM FOR INJECTION 1,5 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1,50 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:		TEVA PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL
Packer:		TEVA PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL
Laboratory:	FPRC:	TEVA PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	TEVA PHARMACEUTICALS, RUIMSIG, ROODEPOORT
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A38/13.1/0472
Name of medicine:		BACTIZIP
Dosage form:		SPRAY
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: CHLORHEXIDINE GLUCONATE 0,00375 ml CETRIMIDE 0,0075 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	EQUITY PHARMACEUTICALS, HAZELWOOD, PRETORIA
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:	A39/2.6.1/0080
Name of medicine:	AUSTELL-PROCHLORPERAZINE 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PROCHLORPERAZINE MALEATE EQUIVALENT TO PROCHLORPERAZINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
FPRR	AUSTELL LABORATORIES, SPRINGFIELD JOHANNESBURG
Shelf-life:	24 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	A39/20.1.2/0130
Name of medicine:	AUGMENTIN ES 600
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 600,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 42,9 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	SMITHKLINE BEECHAM CORPORATION, BRISTOL, TENNESSEE, USA
Packer:	SMITHKLINE BEECHAM CORPORATION, BRISTOL, TENNESSEE, USA
Laboratory: FPRC:	SMITHKLINE BEECHAM CORPORATION, BRISTOL, TENNESSEE, USA
FPRC/FPRR:	GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
Shelf-life:	18 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	A39/26/0195
Name of medicine:	FLUOROURACIL – HEXAL 250 mg/5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: 5-FLUOROURACIL 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY
Packer:	WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
FPRR	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:	24 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	A39/2.5/0264
Name of medicine:	LYRICA 25 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: PREGABALIN 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Packer:	PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Laboratory: FPRC	PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY WARNER LAMBERT, RETREAT, CAPE TOWN
FPRR	PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:		A39/2.5/0265
Name of medicine:		LYRICA 50 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: PREGABALIN 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PFIZER LABORATORIES (PTY) LTD
Manufacturer:		PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Packer:		PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Laboratory:	FPRC:	PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY WARNER LAMBERT, RETREAT, CAPE TOWN
	FPRR:	PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/2.5/0266
Name of medicine:		LYRICA 75 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: PREGABALIN 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PFIZER LABORATORIES (PTY) LTD
Manufacturer:		PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Packer:		PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Laboratory:	FPRC:	PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY WARNER LAMBERT, RETREAT, CAPE TOWN
	FPRR:	PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/2.5/0267
Name of medicine:		LYRICA 100 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: PREGABALIN 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PFIZER LABORATORIES (PTY) LTD
Manufacturer:		PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Packer:		PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Laboratory:	FPRC:	PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY WARNER LAMBERT, RETREAT, CAPE TOWN
	FPRR:	PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/2.5/0268
Name of medicine:		LYRICA 150 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: PREGABALIN 150,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PFIZER LABORATORIES (PTY) LTD
Manufacturer:		PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Packer:		PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY
Laboratory:	FPRC:	PFIZER GmbH ARZNEIMITTELWERK, FREIBURG, GERMANY WARNER LAMBERT, RETREAT, CAPE TOWN
	FPRR:	PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/26/0282
Name of medicine:		FLUOROURACIL – HEXAL 500 mg/10 ml
Dosage form:		INJECTION
Active ingredients:		EACH 10,0 ml SOLUTION CONTAINS: 5-FLUOROURACIL 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY
Packer:		WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/26/0283
Name of medicine:		FLUOROURACIL – HEXAL 1000 mg/20 ml
Dosage form:		INJECTION
Active ingredients:		EACH 20,0 ml SOLUTION CONTAINS: 5-FLUOROURACIL 1000,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY
Packer:		WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/26/0284
Name of medicine:		FLUOROURACIL – HEXAL 5000 mg/100 ml
Dosage form:		INJECTION
Active ingredients:		EACH 100,0 ml SOLUTION CONTAINS: 5-FLUOROURACIL 5000,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY
Packer:		WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WASSERBURGER ARZNEIMITTELWERK, WASSERBURG, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/15.1/0367
Name of medicine:		ZYMAR
Dosage form:		OPHTHALMIC SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: GATIFLOXACIN 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer:		ALLERGAN INC, WACO, TEXAS, USA
Packer:		ALLERGAN INC, WACO, TEXAS, USA
Laboratory:	FPRC:	ALLERGAN INC, WACO, TEXAS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	ALLERGAN PHARMACEUTICALS, HALFWAY HOUSE
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/20.2.2/0439
Name of medicine:		LAMISIL FILM FORMING SOLUTION
Dosage form:		SOLUTION
Active ingredients:		EACH 1,0 g SOLUTION CONTAINS: TERBINAFINE HYDROCHLORIDE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:		NOVARTIS CONSUMER HEALTH S.A., NYON, SWITZERLAND
Packer:		NOVARTIS CONSUMER HEALTH S.A., NYON, SWITZERLAND
Laboratory:	FPRC:	NOVARTIS CONSUMER HEALTH S.A., NYON, SWITZERLAND
	FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A39/7.1.3/0442
Name of medicine:		LEPITRIN 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ADCOCK INGRAM LIMITED
Manufacturer:		ACTAVIS hf, KOPAVOGUR, ICELAND
Packer:		ACTAVIS hf, KOPAVOGUR, ICELAND
Laboratory:	FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND
	FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILE, GERMISTON
	FPRR	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:	A39/7.1.3/0443
Name of medicine:	LEPITRIN 12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, KOPAVOGUR, ICELAND
Packer:	ACTAVIS hf, KOPAVOGUR, ICELAND
Laboratory: FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILE, GERMISTON
FPRR	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	A39/15.4/0464
Name of medicine:	COMBIGAN
Dosage form:	OPHTHALMIC SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: BRIMONIDINE TARTRATE 2,0 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALLERGAN INC, WACO, TEXAS, USA
Packer:	ALLERGAN INC, WACO, TEXAS, USA
Laboratory: FPRC:	ALLERGAN INC, WACO, TEXAS, USA INSTITUTE FOR PHARMACEUTICALS SERVICES, SILVERTONDALE
FPRR:	ALLERGAN PHARMACEUTICALS, HALFWAY HOUSE
Shelf-life:	24 months (Provisional)
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	A39/34/0575
Name of medicine:	ACLASTA
Dosage form:	INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: ZOLEDRONIC ACID MONOHYDRATE EQUIVALENT TO ZOLEDRONIC ACID 5,0 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 NOVARTIS PHARMA S.A.S, HUNINGUE, FRANCE NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	A40/2.5/0024
Name of medicine:	GABAPENTIN-CP 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	KERN PHARMA, TERASSA, BARCELONA, SPAIN
Packer:	KERN PHARMA, TERASSA, BARCELONA, SPAIN
Laboratory: FPRC:	COMBINO PHARM S.L., SANT JOAN DESPI, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:		A40/2.5/0025
Name of medicine:		GABAPENTIN-CP 300 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		KERN PHARMA, TERASSA, BARCELONA, SPAIN
Packer:		KERN PHARMA, TERASSA, BARCELONA, SPAIN
Laboratory:	FPRC:	COMBINO PHARM S.L., SANT JOAN DESPI, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/2.5/0026
Name of medicine:		GABAPENTIN-CP 400 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		KERN PHARMA, TERASSA, BARCELONA, SPAIN
Packer:		KERN PHARMA, TERASSA, BARCELONA, SPAIN
Laboratory:	FPRC:	COMBINO PHARM S.L., SANT JOAN DESPI, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/3.2/0053
Name of medicine:		PERFALGAN PAEDIATRIC 10 mg/ml
Dosage form:		SOLUTION
Active ingredients:		EACH 50,0 ml SOLUTION CONTAINS: PARACETAMOL 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:		LABORATORIES RENAUDIN, ITXASSOU, FRANCE
Packer:		LABORATORIES RENAUDIN, ITXASSOU, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	LABORATORIES RENAUDIN, ITXASSOU, FRANCE BRISTOL-MYERS SQUIBB, AGEN, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0063
Name of medicine:		LOS-ARB 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:		SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL A/S, HVIDOVRE, DENMARK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA (SA), PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0069
Name of medicine:		LOSARTAN HEXAL 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:		SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL A/S, HVIDOVRE, DENMARK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA (SA), PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/34/0162
Name of medicine:		CETROTIDE 0,25 mg SOLVENT
Dosage form:		INJECTION
Active ingredients:		EACH PRE-FILLED SYRINGE CONTAINS: WATER FOR INJECTIONS 1,0 ml
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SERONO SOUTH AFRICA (PTY) LTD
Manufacturer:		SOLVAY PHARMACEUTICAL BV, OLST, THE NETHERLANDS
Packer:		SOLVAY PHARMACEUTICAL BV, OLST, THE NETHERLANDS
Laboratory:	FPRC:	SOLVAY PHARMACEUTICAL BV, OLST, THE NETHERLANDS SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SERONO S.A., FOURWAYS, SANDTON
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/34/0163
Name of medicine:		CETROTIDE 3 mg SOLVENT
Dosage form:		INJECTION
Active ingredients:		EACH PRE-FILLED SYRINGE CONTAINS: WATER FOR INJECTIONS 3,0 ml
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SERONO SOUTH AFRICA (PTY) LTD
Manufacturer:		SOLVAY PHARMACEUTICAL BV, OLST, THE NETHERLANDS
Packer:		SOLVAY PHARMACEUTICAL BV, OLST, THE NETHERLANDS
Laboratory:	FPRC:	SOLVAY PHARMACEUTICAL BV, OLST, THE NETHERLANDS SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SERONO S.A., FOURWAYS, SANDTON
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/3.2/0259
Name of medicine:		FOSAVANCE
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONIC ACID 70,0 mg CHOLECALCIFEROL 70,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MSD (PTY) LTD
Manufacturer:		MSD FROSST IBERICA S.A., ALCALA DE HENARES, MADRID, SPAIN
Packer:		MSD FROSST IBERICA S.A., ALCALA DE HENARES, MADRID, SPAIN MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS MERCK SHARP & DOHME S.p.A., PAVIA, ITALY MSD, HALFWAY HOUSE, RSA
Laboratory:	FPRC:	MSD FROSST IBERICA S.A., ALCALA DE HENARES, MADRID, SPAIN
	FPRR:	MSD, HALFWAY HOUSE, RSA
Shelf-life:		18 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0423
Name of medicine:		ARACE 1,25
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: RAMIPRIL 1,25 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA SEDEK AGRICHEM, KAMEELDRIFT, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0424
Name of medicine:		ARACE 2,5
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: RAMIPRIL 2,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA SEDEK AGRICHEM, KAMEELDRIFT, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRC/FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0425
Name of medicine:		ARACE 5
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: RAMIPRIL 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA SEDEK AGRICHEM, KAMEELDRIFT, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0426
Name of medicine:		ARACE 10
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: RAMIPRIL 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA SEDEK AGRICHEM, KAMEELDRIFT, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0427
Name of medicine:		ARROW RAMIPRIL 1,25
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: RAMIPRIL 1,25 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA SEDEK AGRICHEM, KAMEELDRIFT, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0428
Name of medicine:		ARROW RAMIPRIL 2,5
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: RAMIPRIL 2,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA SEDEK AGRICHEM, KAMEELDRIFT, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0429
Name of medicine:		ARROW RAMIPRIL 5
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: RAMIPRIL 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA SEDEK AGRICHEM, KAMEELDRIFT, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0430
Name of medicine:		ARROW RAMIPRIL 10
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: RAMIPRIL 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA ARROW PHARMA (MALTA), BIRZEBBUGIA, MALTA SEDEK AGRICHEM, KAMEELDRIFT, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/20.2.8/0513
Name of medicine:		AURO-EFAVIRENZ TABLETS 600 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/5.10/0516
Name of medicine:		NAVETRON-4
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/5.10/0518
Name of medicine:		NAVETRON-8
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE 8,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0542
Name of medicine:		DIOVAN 320 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: VALSARTAN 320,0 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, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/20.1.1/0618
Name of medicine:		CIPROGEN IV 200 mg/100 ml
Dosage form:		INFUSION
Active ingredients:		EACH 100,0 ml SOLUTION CONTAINS: CIPROFLOXACIN 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SCP PHARMACEUTICALS (PTY) LTD
Manufacturer:		BIOMENDI S.A., BERNEDO, ALAVA, SPAIN
Packer:		BIOMENDI S.A., BERNEDO, ALAVA, SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	BIOMENDI S.A., BERNEDO, ALAVA, SPAIN RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	SCP PHARMACEUTICALS, MODDERFONTEIN, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/7.1.3/0658
Name of medicine:		LOSARTAN-WINTHROP 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:		ACTAVIS hf, HAFNARFJORDUR, ICELAND
Packer:		ACTAVIS hf, HAFNARFJORDUR, ICELAND WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
	FPRR	SANOFI-SYNTHELABO, MIDRAND,RSA
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:	A40/7.1.3/0658
Name of medicine:	LOSARTAN-WINTHROP 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	A40/20.2.8/0659
Name of medicine:	SONKE-LAMINEVSTAV 30
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg STAVUDINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTASAHIB, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:		A40/20.2.8/0660
Name of medicine:		SONKE-LAMINEVSTAV 40
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg STAVUDINE 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/1.2/0742
Name of medicine:		SERTRALINE-WINTHROP 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:		ACTIVIS hf, KOPAVOGUR, ICELAND SANOFI-SYNTHELABO Sp, RZESZOW, POLAND
Packer:		ACTAVIS hf, KOPAVOGUR, ICELAND SANOFI-SYNTHELABO Sp, RZESZOW, POLAND WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, REYKJAVIK, ICELAND SANOFI-SYNTHELABO Sp, RZESZOW, POLAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
	FPRR	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/21.2/0757
Name of medicine:		EUGLIM 1 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 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, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/21.2/0758
Name of medicine:		EUGLIM 2 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 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, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/21.2/0759
Name of medicine:		EUGLIM 4 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 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, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		A40/21.2/0022
Name of medicine:		ZIDUS-GLIMEPIRIDE 1 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 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, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/21.2/0023
Name of medicine:		ZYDUS-GLIMEPIRIDE 2 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 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, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/21.2/0024
Name of medicine:		ZYDUS-GLIMEPIRIDE 4 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 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, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/2.1/0098
Name of medicine:		SOJOURN
Dosage form:		LIQUID
Active ingredients:		EACH GLASS BOTTLE CONTAINS: SEVOFLURANE 250,0 ml
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:		MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA
Packer:		MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA
Laboratory:	FPRC:	MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, RSA
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/7.1.3/0147
Name of medicine:		CO-DIOVAN 320/12,5 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: VALSARTAN 320,0 mg HYDROCHLOROTHIAZIDE 12,5 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, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:	41/7.1.3/0148
Name of medicine:	CO-DIOVAN 320/25 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 320,0 mg HYDROCHLOROTHIAZIDE 25,0 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, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:	41/5.7.1/0448
Name of medicine:	DAZIT TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESLORATADINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	PHARMAPLAN, MIDRAND
Shelf-life:	24 months
Date of registration:	30 NOVEMBER 2007

MRF 15

Registration number:		41/20.2.8/0522
Name of medicine:		SONKE-INDINAVIR 400
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: INDINAVIR SULFATE EQUIVALENT TO INDINAVIR 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SONKE PHARMACEUTICALS
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORIES LTD, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	SONKE PHARMACEUTICALS, CENTURION
Shelf-life:		24 months (Provisional)
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/7.1/0560
Name of medicine:		PHARMA DYNAMICS AMLODIPINE BESYLATE 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		KRKA , NOVO MESTO, SLOVENIA
Packer:		KRKA , NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, PINELANDS, KZN
Laboratory:	FPRC:	KRKA , NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		48 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/7.1/0561
Name of medicine:		PHARMA DYNAMICS AMLODIPINE BESYLATE 10 mg
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:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		KRKA , NOVO MESTO, SLOVENIA
Packer:		KRKA , NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, PINELANDS, KZN
Laboratory:	FPRC:	KRKA , NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		48 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/7.1/0634
Name of medicine:		STAMLO 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/7.1/0635
Name of medicine:		STAMLO 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:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/2.5/0727
Name of medicine:		RAN-GABAPENTIN 100
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: GABAPENTIN 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY S.A., CENTURION, RSA
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/2.5/0728
Name of medicine:		RAN-GABAPENTIN 300
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY S.A., CENTURION, RSA
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/2.5/0729
Name of medicine:		RAN-GABAPENTIN 400
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY S.A., CENTURION, RSA
Shelf-life:		36 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/7.1.3/0823
Name of medicine:		CIPLA-LOSARTAN 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM EQUIVALENT TO LOSARTAN 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/7.1.3/0824
Name of medicine:		CIPLA-LOSARTAN 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM EQUIVALENT TO LOSARTAN 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007

MRF 15

Registration number:		41/7.1.3/0825
Name of medicine:		CIPLA-LOSARTAN 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM EQUIVALENT TO LOSARTAN 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT III), SALCETTE, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		30 NOVEMBER 2007