GENERAL NOTICE

NOTICE 163 OF 2009

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

Registration number:		34/7.1.3/0334
Name of medicine:		ENVAS 2,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ENALAPRIL MALEATE 2,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		THEBE MEDICARE (PTY) LTD
Manufacturer:		CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA
Packer:		CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA
Laboratory:	FPRC:	CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		34/7.1.3/0335
Name of medicine:		ENVAS 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ENALAPRIL MALEATE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		THEBE MEDICARE (PTY) LTD
Manufacturer:		CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA
Packer:		CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA
Laboratory:	FPRC:	CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	34/7.1.3/0336
Name of medicine:	ENVAS 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	CADILA PHARMACEUTICALS, DHOLKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	37/3.1/0229
Name of medicine:	CPL ALLIANCE DICLOFENAC 75 INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DICLOFENAC SODIUM 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		A38/2.5/0454
Name of medicine:		LAMOTEP 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA S.A. (PTY) LTD
Manufacturer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
Packer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A38/2.5/0455
Name of medicine:		LAMOTEP 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA S.A. (PTY) LTD
Manufacturer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
Packer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A38/2.5/0456
Name of medicine:		LAMOTEP 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA S.A. (PTY) LTD
Manufacturer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA
Packer:		WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	WELLSPRING PHARMACEUTICAL CANADA, OAKVILLE, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A38/2.5/0457
Name of medicine:		LAMOTEP 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
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	A39/34/0310
Name of medicine:	XOLAIR 75 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OMALIZUMAB 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA
Packer:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Laboratory: FPRC:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	48 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/34/0311
Name of medicine:	XOLAIR 150 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OMALIZUMAB 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA
Packer:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Laboratory: FPRC:	GENENTECH INC, SOUTH SAN FRANCISCO, CALIFORNIA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	48 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/20.1.1/0382
Name of medicine:	AZITHROMYCIN HEXAL 500 mg TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN DIHYDRATE EQUIVALENT TO AZITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG NOVARTIS PHARMA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL AG, HOLZKIRCHEN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR	HEXAL PHARMA, PINETOWN, RSA
Shelf-life:	24 months (provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/7.1.4/0408
Name of medicine:	CARANOR 5,0 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IVABRADINE HYDROCHLORIDE EQUIVALENT TO IVABRADINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory: FPRC	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR	BIOGARAN S.A., RIVONIA, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/7.1.4/0409
Name of medicine:	CARANOR 7,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IVABRADINE HYDROCHLORIDE EQUIVALENT TO IVABRADINE 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	BIOGARAN S.A., RIVONIA, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/7.1.4/0410
Name of medicine:	CORALAN 5,0 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IVABRADINE HYDROCHLORIDE EQUIVALENT TO IVABRADINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	SERVIER LABORATORIES S.A., RIVONIA, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		A39/7.1.4/0411
Name of medicine:		CORALAN 7,5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: IVABRADINE HYDROCHLORIDE EQUIVALENT TO IVABRADINE 7,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:		LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND
Packer:		LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory::	FPRC	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES WICKLOW, ARKLOW, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR	SERVIER LABORATORIES S.A., RIVONIA, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A39/8.2/0444
Name of medicine:		ADCO-ARAVIX
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ADCOCK INGRAM LIMITED
Manufacturer:		CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:		CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
	FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
	FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	A39/11.4.3/0466
Name of medicine:	ADCO-OMEPRAZOLE 10
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: OMEPRAZOLE ..... 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Packer:	LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE LTD, WADEVILLE, GERMISTON
Laboratory: FPRC:	LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE LTD, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/11.4.3/0467
Name of medicine:	ADCO-OMEPRAZOLE 40
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: OMEPRAZOLE ..... 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Packer:	LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE LTD, WADEVILLE, GERMISTON
Laboratory: FPRC:	LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE LTD, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/20.2.2/0572
Name of medicine:	ASPEN FLUCONAZOLE IV
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FLUCONAZOLE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	REIG JOFRE, S.A, SANT JOAN DESPI, BARCELONA, SPAIN
Packer:	REIG JOFRE, S.A, SANT JOAN DESPI, BARCELONA, SPAIN
Laboratory: FPRC:	REIG JOFRE, S.A, SANT JOAN DESPI,BARCELONA, SPAIN SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A39/20.1.1/0577
Name of medicine:	LEVOFLOXACIN-WINTHROP I.V. 250
Dosage form:	INJECTION
Active ingredients:	EACH 50,0 ml VIAL CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Packer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC:	AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	AVENTIS PHARMA, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		A39/20.1.1/0578
Name of medicine:		LEVOFLOXACIN-WINTHROP I.V. 500
Dosage form:		INJECTION
Active ingredients:		EACH 100,0 ml VIAL CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AVENTIS PHARMA (PTY) LTD
Manufacturer:		AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Packer:		AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
	FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
	FPRR:	AVENTIS PHARMA, MIDRAND, RSA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A39/7.1/0634
Name of medicine:		ADALAT XL 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: NIFEDIPINE 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BAYER (PTY) LTD
Manufacturer:		BAYER AG, LEVERKUSEN, GERMANY
Packer:		BAYER AG, LEVERKUSEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL CONTRACTORS, ISANDO, RSA BAYER ANIMAL HEALTH, WILLOWTON, PIETERMARITZBURG
Laboratory:	FPRC:	BAYER AG, LEVERKUSEN, GERMANY BAYER ANIMAL HEALTH, WILLOWTON, PIETERMARITZBURG SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	BAYER, ISANDO, RSA
Shelf-life:		36 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A40/20.2.2/0070
Name of medicine:		ITRACOL
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: ITRACONAZOLE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
Packer:		ILSAN ILTAS, GEBZE-KOCAELI, TURKEY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA
Laboratory:	FPRC:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
	FPRR:	HEXAL PHARMA, PINETOWN, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2009

MRF 15

Registration number:		A40/20.2.2/0071
Name of medicine:		ITRACONAZOLE HEXAL
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: ITRACONAZOLE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:		ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
Packer:		ILSAN ILTAS, GEBZE-KOCAELI, TURKEY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA
Laboratory:	FPRC:	ILSAN ILTAS, GEBZE-KOCAELI, TURKEY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
	FPRR:	HEXAL PHARMA, PINETOWN, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	A40/16.5/0136
Name of medicine:	MEDI-KEEL ANTISEPTIC AND ANTI-INFLAMMATORY THROAT SPRAY
Dosage form:	SPRAY
Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: BENZYDAMINE HYDROCHLORIDE 22,50 mg CETYLPYRIDINIUM CHLORIDE 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/20.2.6/0165
Name of medicine:	MALANIL PAEDIATRIC
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATOVAQUONE 62,5 mg PROGUANIL HYDROCHLORIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO, CANADA GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO, CANADA
FPRC/FPRR:	GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
Shelf-life:	60 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		A40/34/0211
Name of medicine:		CONTIFLO SR
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 0,4 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (SA) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A40/20.1.1/0321
Name of medicine:		SMARTSET GHV GENTAMICIN BONE CEMENT
Dosage form:		BONE CEMENT
Active ingredients:		EACH 40,0 g CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 1,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ORTHOMEDICS PHARMACEUTICALS (PTY) LTD
Manufacturer:		DEPUY CMW, BLACKPOOL, LANCASHIRE, UK
Packer:		DEPUY CMW, BLACKPOOL, LANCASHIRE, UK
Laboratory:	FPRC:	DEPUY CMW, BLACKPOOL, LANCASHIRE, UK
	FPRR:	ORTHOMEDICS PHARMACEUTICALS, SYBRAND PARK, CAPE TOWN
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	A40/20.2.2/0614
Name of medicine:	LAMISPOR 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/20.2.2/0615
Name of medicine:	CIPLA-TERBINAFINE 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		A40/8.2/0673
Name of medicine:		PLAGROL
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CLOPIDOGREL BISULFATE EQUIVALENT TO CLOPIDOGREL 75,0 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 DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:		36 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A40/2.6.5/0706
Name of medicine:		PERIZAL 0,5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
	FPRR:	SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A40/2.6.5/0707
Name of medicine:		PERIZAL 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
	FPRR:	SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A40/2.6.5/0708
Name of medicine:		PERIZAL 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
	FPRR:	SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A40/2.6.5/0709
Name of medicine:		PERIZAL 3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
	FPRR	SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A40/2.6.5/0710
Name of medicine:		PERIZAL 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AMMAN, JORDAN
	FPRR:	SPECPHARM, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0727
Name of medicine:	RISPERLET 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY
Packer:	JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Laboratory: FPRC:	JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY
FPRC/FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Shelf-life:	24 months in HDPE bottles 36 months in foil blisters
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0728
Name of medicine:	RISPERLET 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY
Packer:	JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Laboratory: FPRC:	JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY
FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Shelf-life:	24 months in HDPE bottles 36 months in foil blisters
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		A40/2.6.5/0729
Name of medicine:		RISPERLET 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:		JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY
Packer:		JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Laboratory:	FPRC:	JANSSEN-CILAG, BORGO SAN MICHELE, LATINA, ITALY
	FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Shelf-life:		24 months in HDPE bottles 36 months in foil blisters
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		A40/2.2/0760
Name of medicine:		SPEC MIDAZOLAM
Dosage form:		INJECTION
Active ingredients:		EACH 3,0 ml AMPOULE CONTAINS: MIDAZOLAM HYDROCHLORIDE EQUIVALENT TO MIDAZOLAM 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		HAMELN PHARMACEUTICALS, HAMELN, GERMANY
Packer:		HAMELN PHARMACEUTICALS, HAMELN, GERMANY
Laboratory:	FPRC:	HAMELN PHARMACEUTICALS, HAMELN, GERMANY
	FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/26/0028
Name of medicine:		SANDOZ IRINOTECAN 40
Dosage form:		INFUSION
Active ingredients:		EACH 2,0 ml SOLUTION CONTAINS: IRINOTECAN HYDROCHLORIDE 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer:		SANDOZ S.A., BUENOS AIRES, ARGENTINA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ S.A., BUENOS AIRES, ARGENTINA NOVARTIS S.A., SPARTAN, KEMPTON PARK LEK dd, VEROVSKOVA, LJUBLJANA, SLOVENIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/26/0029
Name of medicine:		SANDOZ IRINOTECAN 100
Dosage form:		INFUSION
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: IRINOTECAN HYDROCHLORIDE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer:		SANDOZ S.A., BUENOS AIRES, ARGENTINA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ S.A., BUENOS AIRES, ARGENTINA NOVARTIS S.A., SPARTAN, KEMPTON PARK LEK dd, VEROVSKOVA, LJUBLJANA, SLOVENIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/26/0030
Name of medicine:		TECORIN 40
Dosage form:		INFUSION
Active ingredients:		EACH 2,0 ml SOLUTION CONTAINS: IRINOTECAN HYDROCHLORIDE 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer:		SANDOZ S.A., BUENOS AIRES, ARGENTINA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ S.A., BUENOS AIRES, ARGENTINA NOVARTIS S.A., SPARTAN, KEMPTON PARK LEK dd, VEROVSKOVA, LJUBLJANA, SLOVENIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/26/0031
Name of medicine:		TECORIN 100
Dosage form:		INFUSION
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: IRINOTECAN HYDROCHLORIDE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer:		SANDOZ S.A., BUENOS AIRES, ARGENTINA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ S.A., BUENOS AIRES, ARGENTINA NOVARTIS S.A., SPARTAN, KEMPTON PARK LEK dd, VEROVSKOVA, LJUBLJANA, SLOVENIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/8.2/0051
Name of medicine:		CLOPIDOGREL-WINTHROP
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CLOPIDOGREL HYDROGEN SULPHATE EQUIVALENT TO CLOPIDPGREL 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:		SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:		SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG PHARMACEUTICAL CONTRACTORS, ISANDO
	FPRR:	SANOFI-SYNTHELABO, MIDRAND
Shelf-life:		36 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/8.2/0052
Name of medicine:		CLOPIDOGREL-SANOFI-AVENTIS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CLOPIDOGREL HYDROGEN SULPHATE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:		SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:		SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG PHARMACEUTICAL CONTRACTORS, ISANDO
	FPRR:	SANOFI-SYNTHELABO, MIDRAND
Shelf-life:		36 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/34/0068
Name of medicine:		BYETTA 5 ug
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: EXENATIDE 250,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ELI LILLY (S.A.) (PTY) LTD
Manufacturer:		WOCKHARDT UK LTD, WREXHAM, UK BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA
Packer:		LILLY PHARMA FERTIGUNG & DISTRIBUTION GmbH & Co, GIESSEN, GERMANY
Laboratory:	FPRC:	CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, TRANENT, EDINBURGH, SCOTLAND, UK SGS INSTITUT FRESENIUS BERLIN GmbH & Co, BERLIN, GERMANY SGS INSTITUT FRESENIUS GmbH, TAUNUS-STEIN, GERMANY LILLY PHARMA FERTIGUNG & DISTRIBUTION GmbH & Co, GIESSEN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	ELI LILLY, BRYANSTON, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/34/0069
Name of medicine:		BYETTA 10 ug
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: EXENATIDE 250,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ELI LILLY (S.A.) (PTY) LTD
Manufacturer:		WOCKHARDT UK LTD, WREXHAM, UK BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA
Packer:		LILLY PHARMA FERTIGUNG & DISTRIBUTION GmbH & Co, GIESSEN, GERMANY
Laboratory:	FPRC:	CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, TRANENT, EDINBURGH, SCOTLAND, UK SGS INSTITUT FRESENIUS BERLIN GmbH & Co, BERLIN, GERMANY SGS INSTITUT FRESENIUS GmbH, TAUNUS-STEIN, GERMANY LILLY PHARMA FERTIGUNG & DISTRIBUTION GmbH & Co, GIESSEN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	ELI LILLY, BRYANSTON, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/8.2/0146
Name of medicine:		MISTRO
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CLOPIDOGREL BISULFATE EQUIVALENT TO CLOPIDOGREL 75,0 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 DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.1/0191
Name of medicine:		TERRELL
Dosage form:		LIQUID
Active ingredients:		EACH GLASS BOTTLE CONTAINS: ISOFLURANE 100,0 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, PRETORIA
	FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, JOHANNESBURG
Shelf-life:		60 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	41/1.2/0209
Name of medicine:	SERMAX 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:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	36 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/1.2/0210
Name of medicine:	SERMAX 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:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	36 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		41/20.2.8/0218
Name of medicine:		CIPLA DUOVIR AND EFAVIRENZ CO-PACK
Dosage form:		TABLET
Active ingredients:		EACH PACK CONTAINS: DUOVIR TABLETS CONTAINING: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg EFAVIR 600 TABLETS CONTAINING: EFAVIRENZ 600,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, VIKHROLI, MUMBAI, INDIA CIPLA LTD, UNIT IV, SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, UNIT IV, SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, VIKHROLI, MUMBAI, INDIA CIPLA LTD, UNIT IV, SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/21.5.1/0238
Name of medicine:		INFLANAZE 100
Dosage form:		NASAL SPRAY
Active ingredients:		EACH METERED DOSE CONTAINS: BUDESONIDE 100,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:		MIPHARM S.p.A., MILAN, ITALY
Packer:		MIPHARM S.p.A., MILAN, ITALY
Laboratory:	FPRC:	MIPHARM S.p.A., MILAN, ITALY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
	FPRR:	INGELHEIM PHARMACEUTICALS, RANDBURG, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0264
Name of medicine:		AUROPIDONE 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0265
Name of medicine:		AUROPIDONE 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0266
Name of medicine:		AUROPIDONE 3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0267
Name of medicine:		AUROPIDONE 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0339
Name of medicine:		ASPEN RISPERIDONE 0,5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0340
Name of medicine:		ASPEN RISPERIDONE 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0341
Name of medicine:		ASPEN RISPERIDONE 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0346
Name of medicine:		ASPEN RISPERIDONE 3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0347
Name of medicine:		ASPEN RISPERIDONE 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND
Laboratory:	FPRC:	PHARMA INTERNATIONAL COMPANY, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, COUNTY GALWAY, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/21.12/0351
Name of medicine:		FINAP 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FINASTERIDE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		FAMAR S.A., ANTHOUSSA, ATTIKIS, GREECE
Packer:		FAMAR S.A., ANTHOUSSA, ATTIKIS, GREECE
Laboratory:	FPRC:	FAMAR S.A., ANTHOUSSA, ATTIKIS, GREECE PHARMATHEN S.A., PALLINI ATTIKIS, GREECE SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/5.7.1/0352
Name of medicine:		TELLERGE 120 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 120,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		CIPLA LTD, PLOT A, PATALGANGA, MAHARASHTRA, INDIA CHANELLE MEDICAL, GALWAY, IRELAND
Packer:		CIPLA LTD, PLOT A, PATALGANGA, MAHARASHTRA, INDIA CHANELLE MEDICAL, GALWAY, IRELAND
Laboratory:	FPRC:	CIPLA LTD, PLOT A, PATALGANGA, MAHARASHTRA, INDIA CHANELLE MEDICAL, GALWAY, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATOTY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/5.7.1/0353
Name of medicine:		TELLERGE 180 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 180,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		CIPLA LTD, PLOT A, PATALGANGA, MAHARASHTRA, INDIA CHANELLE MEDICAL, GALWAY, IRELAND
Packer:		CIPLA LTD, PLOT A, PATALGANGA, MAHARASHTRA, INDIA CHANELLE MEDICAL, GALWAY, IRELAND
Laboratory:	FPRC:	CIPLA LTD, PLOT A, PATALGANGA, MAHARASHTRA, INDIA CHANELLE MEDICAL, GALWAY, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATOTY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.5/0375
Name of medicine:		LAMITOR-200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA
Packer:		TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
	FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/3.2/0431
Name of medicine:		BONIRAN 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SODIUM ALENDRONATE EQUIVALENT TO ALENDRONIC ACID 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0445
Name of medicine:		ZOXADON 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0446
Name of medicine:		ZOXADON 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0447
Name of medicine:		ZOXADON 6 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 6,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0468
Name of medicine:		ZOXADON 0,5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0469
Name of medicine:		ZOXADON 3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0470
Name of medicine:		ZOXADON 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:		ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC:	ACTAVIS hf, KOPAVOGUR, ICELAND ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/24/0553
Name of medicine:		0,9 % SODIUM CHLORIDE AND 5 % GLUCOSE B BRAUN
Dosage form:		INFUSION
Active ingredients:		EACH 1000,0 ml SOLUTION CONTAINS: GLUCOSE MONOHYDRATE EQUIVALENT TO GLUCOSE 50,0 g SODIUM CHLORIDE 9,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		B BRAUN MEDICAL (PTY) LTD
Manufacturer:		B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY PRODUCTION PHARMA PFIEFFEWIESEN, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., BARCELONA, SPAIN
Packer:		B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY PRODUCTION PHARMA PFIEFFEWIESEN, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., BARCELONA, SPAIN
Laboratory:	FPRC:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG
Shelf-life:		36 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/7.1/0562
Name of medicine:		DYNA 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, 8
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
Laboratory:	FPRC:	KRKA , NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/7.1/0563
Name of medicine:		DYNA 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, 8
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
Laboratory:	FPRC:	KRKA , NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/20.2.8/0692
Name of medicine:		CIPLA-ABACAVIR 300
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Packer:		CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Laboratory:	FPRC:	CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/20.2.8/0693
Name of medicine:		ABAMUNE 300
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Packer:		CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Laboratory:	FPRC:	CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/20.2.8/0733
Name of medicine:		ZETRODIN 100 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: ZIDOVUDINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM LIMITED
Manufacturer:		ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:		ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC/FPRR:		ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
	FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	41/20.2.8/0734
Name of medicine:	ZETRODIN 250 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/8.2/0766
Name of medicine:	CLOPIVAS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		41/8.2/0767
Name of medicine:		CIPLA-CLOPIDOGREL
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:		CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/8.2/0768
Name of medicine:		MEDPRO-CLOPIDOGREL
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		MEDPRO PHARMACEUTICA (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:		CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
	FPRR:	MEDPRO PHARMACEUTICA, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	41/5.7.1/0780
Name of medicine:	RHINETON SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: CHLORPHENIRAMINE MALEATE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	BE-TABS PHARMACEUTICALS, ROODEPOORT
Packer:	BE-TABS PHARMACEUTICALS, ROODEPOORT
Laboratory: FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		41/5.4.1/0781
Name of medicine:		AZILECT 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RASAGILINE MESYLATE EQUIVALENT TO RASAGILINE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		H LUNDBECK (PTY) LTD
Manufacturer:		TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR-SABA, ISRAEL
Packer:		TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR-SABA, ISRAEL
Laboratory:	FPRC:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR-SABA, ISRAEL
	FPRR:	H LUNDBECK, NORTH RIDING, RSA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/20.2.8/0799
Name of medicine:		CIPLA-OSELTAMIVIR
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: OSELTAMIVIR PHOSPHATE EQUIVALENT TO OSELTAMIVIR 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, VERNA, GOA, INDIA
Packer:		CIPLA LTD, VERNA, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, VERNA, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/20.2.8/0856
Name of medicine:		ABAMUNE ORAL SOLUTION
Dosage form:		SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/20.2.8/0857
Name of medicine:		CIPLA-ABACAVIR ORAL SOLUTION
Dosage form:		SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/15.4/0860
Name of medicine:		LUCENTIS
Dosage form:		SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: RANIBIZUMAB 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:		NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:		NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMA AG, BASLE, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0874
Name of medicine:		MERCK-RISPERIDONE 0,25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 0,25 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory:	FPRC:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0875
Name of medicine:		MERCK-RISPERIDONE 0,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory:	FPRC:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0876
Name of medicine:		MERCK-RISPERIDONE 1
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory:	FPRC:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0877
Name of medicine:		MERCK-RISPERIDONE 2
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory:	FPRC:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	41/2.6.5/0878
Name of medicine:	MERCK-RISPERIDONE 3
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory: FPRC:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/2.6.5/0879
Name of medicine:	MERCK-RISPERIDONE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory: FPRC:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0880
Name of medicine:		MERCK-RISPERIDONE 6
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 6,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
Packer:		PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory:	FPRC:	PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN CHANELLE MEDICAL, LOUGHREA, Co GALWAY, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/1.2/0896
Name of medicine:		ASPEN ESCITALOPRAM 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5 ,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN
Packer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:	FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/1.2/0897
Name of medicine:		ASPEN ESCITALOPRAM 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10 ,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN
Packer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:	FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/1.2/0898
Name of medicine:		ASPEN ESCITALOPRAM 15 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 15 ,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN
Packer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:	FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/1.2/0899
Name of medicine:		ASPEN ESCITALOPRAM 20 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN
Packer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:	FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0937
Name of medicine:		RISPONZ 1 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0938
Name of medicine:		RISPONZ 2 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0939
Name of medicine:		RISPONZ 3 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/2.6.5/0940
Name of medicine:		RISPONZ 4 TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/26/1039
Name of medicine:		SPRYCEL 20 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DASATINIB 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:		BRISTOL-MYERS SQUIBB CO, VERNON, INDIANA, USA
Packer:		BRISTOL-MYERS SQUIBB CO, VERNON, INDIANA, USA BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
Laboratory:	FPRC:	BRISTOL-MYERS SQUIBB, EPERNON, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON CONSULTING CHEMICAL LABORATORIES, ATLASVILE, BOKSBURG
	FPRR:	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/26/1040
Name of medicine:		SPRYCEL 50 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DASATINIB 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:		BRISTOL-MYERS SQUIBB CO, VERNON, INDIANA, USA
Packer:		BRISTOL-MYERS SQUIBB CO, VERNON, INDIANA, USA BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
Laboratory:	FPRC:	BRISTOL-MYERS SQUIBB, EPERNON, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON CONSULTING CHEMICAL LABORATORIES, ATLASVILE, BOKSBURG
	FPRR:	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:		41/26/1041
Name of medicine:		SPRYCEL 70 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DASATINIB 70,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:		BRISTOL-MYERS SQUIBB CO, VERNON, INDIANA, USA
Packer:		BRISTOL-MYERS SQUIBB CO, VERNON, INDIANA, USA BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
Laboratory:	FPRC	BRISTOL-MYERS SQUIBB, EPERNON, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON CONSULTING CHEMICAL LABORATORIES, ATLASVILE, BOKSBURG
	FPRR:	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		9 DECEMBER 2008

MRF 15

Registration number:	41/2.6.5/1056
Name of medicine:	AUROPIDONE SOLUTION 1 mg/ml
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/2.6.5/1057
Name of medicine:	AURO-RISPERIDONE SOLUTION 1 mg/ml
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/26/1092
Name of medicine:	SANDOZ PACLITAXEL 30
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A.(PTY) LTD
Manufacturer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
Packer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
Laboratory: FPRC:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRC/FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/26/1093
Name of medicine:	SANDOZ PACLITAXEL 100
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A.(PTY) LTD
Manufacturer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
Packer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
Laboratory: FPRC:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRC/FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/26/1094
Name of medicine:	SANDOZ PACLITAXEL 300
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A.(PTY) LTD
Manufacturer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
Packer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
Laboratory: FPRC:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRC/FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisonal)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/34/1125
Name of medicine:	BICAVERA 1,5 % GLUCOSE (SOLUTION FOR PERITONEAL DIALYSIS)
Dosage form:	SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE 11,57 g CALCIUM CHLORIDE DIHYDRATE 0,5145 g MAGNESIUM CHLORIDE HEXA-HYDRATE 0,2033 g GLUCOSE MONOHYDRATE EQUIVALENT TO GLUCOSE 30,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Packer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Laboratory: FPRC:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY BODENE, t/a INTRAMED, KORSTEN, PORT ELIZABETH
FPRR:	FRESENIUS KABI SA, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/34/1126
Name of medicine:	BICAVERA 2,3 % GLUCOSE (SOLUTION FOR PERITONEAL DIALYSIS)
Dosage form:	SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE 11,57 g CALCIUM CHLORIDE DIHYDRATE 0,5145 g MAGNESIUM CHLORIDE HEXA-HYDRATE 0,2033 g GLUCOSE MONOHYDRATE EQUIVALENT TO GLUCOSE 45,46 g
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Packer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Laboratory: FPRC:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY BODENE, t/a INTRAMED, KORSTEN, PORT ELIZABETH
FPRR:	FRESENIUS KABI SA, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	41/34/1127
Name of medicine:	BICAVERA 4,25 % GLUCOSE (SOLUTION FOR PERITONEAL DIALYSIS)
Dosage form:	SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE 11,57 g CALCIUM CHLORIDE DIHYDRATE 0,5145 g MAGNESIUM CHLORIDE HEXA-HYDRATE 0,2033 g GLUCOSE MONOHYDRATE EQUIVALENT TO GLUCOSE 85,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Packer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY
Laboratory: FPRC:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, WENDEL, GERMANY BODENE, t/a INTRAMED, KORSTEN, PORT ELIZABETH
FPRR:	FRESENIUS KABI SA, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	42/20.1.1/0004
Name of medicine:	CURITAZ 4,5
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 4,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ GmbH, KUNDL, AUSTRIA
Packer:	SANDOZ GmbH, KUNDL, AUSTRIA
Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS S.A., SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	42/26/0018
Name of medicine:	ASPEN EPIRUBICIN 10 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: EPIRUBICIN HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	THYMOORGAN GmbH PHARMAZIE & CO, VIENENBURG, GERMANY S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA
Packer:	THYMOORGAN GmbH PHARMAZIE & CO, VIENENBURG, GERMANY S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA
Laboratory: FPRC:	THYMOORGAN GmbH PHARMAZIE & CO, VIENENBURG, GERMANY S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	42/26/0019
Name of medicine:	ASPEN EPIRUBICIN 50 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: EPIRUBICIN HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	THYMOORGAN GmbH PHARMAZIE & CO, VIENENBURG, GERMANY S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA
Packer:	THYMOORGAN GmbH PHARMAZIE & CO, VIENENBURG, GERMANY S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA
Laboratory: FPRC:	THYMOORGAN GmbH PHARMAZIE & CO, VIENENBURG, GERMANY S.C. SINDAN-PHARMA SRL, BUCHAREST, ROMANIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	42/2.6.5/0101
Name of medicine:	SANDOZ RISPERIDONE 0,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ANALYTICON, TERENURE, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	42/7.3/0269
Name of medicine:	AURO-SUMATRIPTAN TABLETS 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	42/7.3/0270
Name of medicine:	AURO-SUMATRIPTAN TABLETS 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0688
Name of medicine:	DRL RISPERIDONE 0,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0689
Name of medicine:	DRL RISPERIDONE 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0690
Name of medicine:	DRL RISPERIDONE 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0691
Name of medicine:	DRL RISPERIDONE 3
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008

MRF 15

Registration number:	A40/2.6.5/0692
Name of medicine:	DRL RISPERIDONE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 DECEMBER 2008