

Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 524

Pretoria, 20 February
Februarie 2009

No. 31881

CONTENTS

No.		Page No.	Gazette No.
GENERAL NOTICE			
Health, Department of			
<i>General Notice</i>			
163	Medicines and Related Substances Act (101/1965): Medicines Control Council: Conditions of registration of a medicine in terms of the provisions of section 15 (7)	3	31881

INHOUD

No.		Bladsy No.	Koerant No.
ALGEMENE KENNISGEWING			
Gesondheid, Departement van			
<i>Algemene Kennisgewing</i>			
163	Wet op Beheer van Medisyne en Verwante Stowwe (101/1965): Medi- synebeheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalings van artikel 15 (7).....	4	31881

GENERAL NOTICE ALGEMENE KENNISGEWING

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.

KENNISGEWING 163 VAN 2009**MEDISYNEBEHEERRAAD****VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE
BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN
VERWANTE STOWWE, 1965 (WET 101 VAN 1965)**

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslik vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemaking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingssertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number: 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: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 Packer: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 Laboratory: FPRC: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 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: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 Packer: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE, JOHANNESBURG
 Laboratory: FPRC: WELLSRING PHARMACEUTICAL CANADA,
 OAKVILLE, ONTARIO, CANADA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 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: BENZYLAMINE HYDROCHLORIDE 22,50 mg CETYLPIRIDINIUM 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, BORGIO SAN MICHELE, LATINA,
 ITALY
 Packer: JANSSEN-CILAG, BORGIO SAN MICHELE, LATINA,
 ITALY
 JANSSEN PHARMACEUTICA, WOODMEAD,
 SANDTON
 Laboratory: FPRC: JANSSEN-CILAG, BORGIO 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, BORGIO SAN MICHELE,
 LATINA, ITALY
 Packer: JANSSEN-CILAG, BORGIO SAN MICHELE,
 LATINA, ITALY
 JANSSEN PHARMACEUTICA, WOODMEAD,
 SANDTON
 Laboratory: FPRC: JANSSEN-CILAG, BORGIO 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 LABORATORY 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 LABORATORY 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: ZOAXDON 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: ZOAXDON 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, VERNAL, GOA, INDIA

Packer: CIPLA LTD, UNIT VII, VERNAL, GOA, INDIA

Laboratory: FPRC: CIPLA LTD, UNIT VII, VERNAL, 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: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
FPRC: 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: PHARMA INTERNATIONAL CO, AL-JUBEIHA, AMMAN, JORDAN
FPRC: 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 (Provisional)
 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 4,0 g
PIPERACILLIN
TAZOBACTAM SODIUM EQUIVALENT TO 500,0 mg
TAZOBACTAM

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
