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CONTENTS

No.		Page No.	Gazette No.
GENERAL NOTICE			
Health, Department of			
<i>General Notice</i>			
753	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	33435

INHOUD

No.		Bladsy No.	Koerant No.
ALGEMENE KENNISGEWING			
Gesondheid, Departement van			
<i>Algemene kennisgewing</i>			
753	Wet op Beheer van Medisyne en Verwante Stowwe (101-1965): Medisyne-beheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalinge van artikel 15 (7).....	4	33435

GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 753 OF 2010

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. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
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.

ALGEMENE KENNISGEWING 753 van 2010**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 goedgekeur 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. Die toegekende voorlopige rakleef tyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleef tydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
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 vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number: 37/2.7/0481
 Name of medicine: PANEZE
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ASPIRIN 400,0 mg
 CAFFEINE 24,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MEDICINE DEVELOPERS INTERNATIONAL cc
 Manufacturer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Packer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Laboratory: FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

FPRR: MEDICINE DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months
 Date of registration: 27 JANUARY 2010

MRF15

Registration number: 41/5.7.1/0032
 Name of medicine: XYZAL ORAL SOLUTION
 Dosage form: SOLUTION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 LEVOCETIRIZINE
 DIHYDROCHLORIDE 0,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: AHN PHARMA (PTY) LTD
 Manufacturer: UCB PHARMA S.p.A., PIANEZZA, TURIN, ITALY
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: UCB PHARMA S.p.A., PIANEZZA, TURIN, ITALY
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 DRA PHARMACEUTICALS, IRENE, CENTURION

Laboratory: FPRC: UCB PHARMA S.p.A., PIANEZZA, TURIN, ITALY
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: AHN PHARMA, WOODLANDS, WOODMEAD

Shelf-life: 24 months
 Date of registration: 27 JANUARY 2010

MRF 15

Registration number: 41/5.8/0038
 Name of medicine: DIMETAPP COLD AND ALLERGY
 Dosage form: ELIXIR
 Active ingredients: EACH 5,0 ml LIQUID CONTAINS:
 BROMPHENIRAMINE MALEATE 4,0 mg
 PHENYLEPHRINE
 HYDROCHLORIDE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: WYETH S.A. (PTY) LTD
 Manufacturer: WYETH PHARMACEUTICALS, SAINT-LAURENT, QUEBEC, CANADA

Packer: WYETH PHARMACEUTICALS, SAINT-LAURENT, QUEBEC, CANADA
 DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG

Laboratory: FPRC: WYETH PHARMACEUTICALS, SAINT-LAURENT, QUEBEC, CANADA
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: WYETH S.A., VORNA VALLEY, MIDRAND

Shelf-life: 24 months
 Date of registration: 27 JANUARY 2010

MRF 15

Registration number: 41/7.1.3/0903
 Name of medicine: LEPITRIN CO 50/12,5
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM
 50,0 mg
 HYDROCHLOROTHIAZIDE
 12,5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: ACTAVIS hf,
 HAFNARFJORDUR, ICELAND
 Packer: ACTAVIS hf,
 HAFNARFJORDUR, ICELAND
 ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 Laboratory: FPRC: ACTAVIS hf,
 HAFNARFJORDUR, ICELAND
 FPRC/FPRR: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 FPRR: ADCOCK INGRAM LIMITED,
 ERAND GARDENS, MIDRAND
 Shelf-life: 24 months (Provisional)
 Date of registration: 27 JANUARY 2010

MRF15

Registration number: 42/8.2/1046
 Name of medicine: XARELTO 10
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RIVAROXABAN 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: BAYER (PTY) LTD
 Manufacturer: BAYER HEALTHCARE AG,
 LEVERKUSEN, GERMANY
 Packer: BAYER HEALTHCARE AG,
 LEVERKUSEN, GERMANY
 BAYER ANIMAL HEALTH,
 PIETERMARITZBURG
 Laboratory: FPRC: BAYER HEALTHCARE AG,
 LEVERKUSEN, GERMANY
 RESEARCH INSTITUTE
 FOR INDUSTRIAL
 PHARMACY, NORTH
 WEST UNIVERSITY,
 POTCHEFSTROOM
 BIOCHEMICAL AND
 SCIENTIFIC
 CONSULTANTS, HILTON,
 KZN
 FPRR: BAYER, ISANDO, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 27 JANUARY 2010

MRF 15

Registration number: A40/2.5/0468
 Name of medicine: CIPLA TOPIRAMATE 25
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TOPIRAMATE 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: CIPLA LIFE SCIENCES (PTY)
 LTD
 Manufacturer: CIPLA LTD, KURKUMBH, PUNA,
 MAHARASHTRA, INDIA
 Packer: CIPLA LTD, KURKUMBH, PUNA,
 MAHARASHTRA, INDIA
 Laboratory: FPRC: CIPLA LTD, KURKUMBH, PUNA,
 MAHARASHTRA, INDIA
 FPRR: CIPLA LIFE SCIENCES, ROSEN
 PARK, BELLVILLE
 Shelf-life: 24 months
 Date of registration: 19 MARCH 2010

MRF 15

Registration number:	A40/2.5/0469
Name of medicine:	CIPLA TOPIRAMATE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNA, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNA, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSEN PARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF15

Registration number:	A40/2.5/0470
Name of medicine:	CIPLA TOPIRAMATE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNA, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNA, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSEN PARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	A40/1.2/0605
Name of medicine:	GULF AMITRIPTYLINE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMITRIPTYLINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG CONSULTING MICROBIOLOGICAL LABORATORY, MOREHILL, BENONI
FPRR:	GULF DRUG COMPANY, MOUNT EDGECOMBE, KZN
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	A40/35/0697
Name of medicine:	TECHNISCAN MAG3
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: BETIATIDE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	COVIDIEN (PTY) LTD
Manufacturer:	MALLINCKRODT MEDICAL B.V., PETTEN, THE NETHERLANDS
Packer:	MALLINCKRODT MEDICAL B.V., PETTEN, THE NETHERLANDS
Laboratory: FPRC:	MALLINCKRODT MEDICAL B.V., PETTEN, THE NETHERLANDS BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON, KZN PET LABS PHARMACEUTICAL, GROENKLOOF, PRETORIA
FPRR:	COVIDIEN, RANDJES PARK, MIDRAND
Shelf-life:	12 months
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/5.2/0004
Name of medicine:	GULF ATENOLOL 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATENOLOL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG CONSULTING MICROBIOLOGICAL LABORATORY, MOREHILL, BENONI
FPRR:	GULF DRUG COMPANY, MOUNT EDGEcombe, KZN
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/5.2/0005
Name of medicine:	GULF ATENOLOL 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATENOLOL 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ALEMBIC LTD, TAL-HALOL, PANCHMAHALS, GUJARAT, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG CONSULTING MICROBIOLOGICAL LABORATORY, MOREHILL, BENONI
FPRR:	GULF DRUG COMPANY, MOUNT EDGEcombe, KZN
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/21.5.1/0189
Name of medicine:	ASPELONE
Dosage form:	LIQUID
Active ingredients:	EACH 5.0 ml LIQUID CONTAINS: PREDNISOLONE SODIUM PHOSPHATE EQUIVALENT TO PREDNISOLONE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC: M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/21.2/0204
Name of medicine:	ASPEN GLIMEPIRIDE 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/21.2/0205
Name of medicine:	ASPEN GLIMEPIRIDE 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/21.2/0206
Name of medicine:	ASPEN GLIMEPIRIDE 3 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/21.2/0207
Name of medicine:	ASPEN GLIMEPIRIDE 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/20.2.8/0387
Name of medicine:	BAVIR ORAL SOLUTION 20 mg/ml
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:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/34/0406
Name of medicine:	AOSEPT PLUS
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: HYDROGEN PEROXIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	CIBA VISION, MISSISSAGUA, ONTARIO, CANADA
Packer:	CIBA VISION, MISSISSAGUA, ONTARIO, CANADA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	CIBA VISION, MISSISSAGUA, ONTARIO, CANADA
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/2.5/0460
Name of medicine:	REDILEV 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 250,0 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, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Secondary Packer:	DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR 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:	19 MARCH 2010

MRF 15

Registration number:	41/2.5/0461
Name of medicine:	REDILEV 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 500,0 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, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Secondary Packer:	DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR 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:	19 MARCH 2010

MRF 15

Registration number:	41/2.5/0462
Name of medicine:	REDILEV 750
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 750,0 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, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Secondary Packer:	DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR 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:	19 MARCH 2010

MRF15

Registration number:	41/11.4.3/0641
Name of medicine:	PENTOZ 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 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, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES LTD, 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:	19 MARCH 2010

MRF 15

Registration number:	41/11.4.3/0642
Name of medicine:	PENTOZ 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 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, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES LTD, 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:	19 MARCH 2010

MRF 15

Registration number:	41/7.1.3/0670
Name of medicine:	CIPLASYL 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ERBUMINE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/7.1.3/0671
Name of medicine:	CIPLASYL 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ERBUMINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/7.1.3/0672
Name of medicine:	CIPLASYL 8
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ERBUMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/21.2/0697
Name of medicine:	RAN-GLICLAZIDE MR 30
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/21.2/0698
Name of medicine:	DIARAN MR 30
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/2.5/0839
Name of medicine:	DRL LEVETIRACETAM 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 500,0 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, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Secondary Packer:	DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR 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:	19 MARCH 2010

MRF 15

Registration number: 41/2.5/0840

Name of medicine: DRL LEVETIRACETAM 750

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVETIRACETAM 750,0 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, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

Secondary Packer: DRA PHARMACEUTICALS, IRENE, CENTURION

Laboratory: FPRC: DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR 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: 19 MARCH 2010

MRF15

Registration number: 41/2.5/0841

Name of medicine: DRL LEVETIRACETAM 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVETIRACETAM 250,0 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, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

Secondary Packer: DRA PHARMACEUTICALS, IRENE, CENTURION

Laboratory: FPRC: DR REDDY'S LABORATORIES LTD, SURVEY NO 41, QUTHUBULLAPUR 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: 19 MARCH 2010

MRF 15

Registration number: 41/3.2/0907

Name of medicine: RISEDRONATE WINTHROP WEEKLY

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RISEDRONATE SODIUM 35,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANOFI-AVENTIS (PTY) LTD

Manufacturer: OSG NORWICH PHARMACEUTICALS INC, NORTH NORWICH, NEW YORK, USA
PROCTER & GAMBLE PHARMACEUTICALS, MANATI, PUERTO RICO

Packer: PROCTER & GAMBLE PHARMACEUTICALS, WEITERSTADT, GERMANY
WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA

Laboratory: FPRC: OSG NORWICH PHARMACEUTICALS INC, NORTH NORWICH, NEW YORK, USA
PROCTER & GAMBLE PHARMACEUTICALS, MANATI, PUERTO RICO
PROCTER & GAMBLE PHARMACEUTICALS, WEITERSTADT, GERMANY

FPRC/FPRR: WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA

FPRR: SANOFI-AVENTIS S.A., MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 19 MARCH 2010

MRF 15

Registration number:	41/7.1.3/0956
Name of medicine:	SARTOC 50/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/18.1/1028
Name of medicine:	FREMID
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FUROSEMIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LEBASI PHARMACEUTICALS cc
Manufacturer:	EURO-MED LABORATORIES, DASMARINAS, CAVITE, PHILIPPINES
Packer:	EURO-MED LABORATORIES, DASMARINAS, CAVITE, PHILIPPINES
Laboratory: FPRC:	EURO-MED LABORATORIES, DASMARINAS, CAVITE, PHILIPPINES RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	LEBASI PHARMACEUTICALS, POTCHEFSTROOM
Shelf-life:	36 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/7.1.3/1047
Name of medicine:	COVACE CO 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT- BUTYLAMINE 2,0 mg INDAPAMIDE 0,625 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/7.1.3/1048
Name of medicine:	COVACE CO 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT- BUTYLAMINE 4,0 mg INDAPAMIDE 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/11.4.3/1115
Name of medicine:	CONORAN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 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 KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORY SERVICES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/11.4.3/1116
Name of medicine:	CONORAN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 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 KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORY SERVICES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	41/11.4.3/1117
Name of medicine:	RAN-PANTOPRAZOLE 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 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 KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORY SERVICES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF15

Registration number:	41/11.4.3/1118
Name of medicine:	RAN-PANTOPRAZOLE 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 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 KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORY SERVICES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	42/11.4.3/0056
Name of medicine:	PEPLOC 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS NORMON S.A., TRES CANTOS, MADRID, SPAIN TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Packer:	LABORATORIOS NORMON S.A., TRES CANTOS, MADRID, SPAIN TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMACEUTICAL ENTERPRISES N'DABENI
Laboratory: FPRC:	LABORATORIOS NORMON S.A., TRES CANTOS, MADRID, SPAIN TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMA DYNAMICS, WESTLAKE, CAPE TOWN
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	42/11.4.3/0057
Name of medicine:	PEPLOC 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS NORMON S.A., TRES CANTOS, MADRID, SPAIN TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Packer:	LABORATORIOS NORMON S.A., TRES CANTOS, MADRID, SPAIN TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMACEUTICAL ENTERPRISES N'DABENI
Laboratory:	FPRC: LABORATORIOS NORMON S.A., TRES CANTOS, MADRID, SPAIN TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PHARMA DYNAMICS, WESTLAKE, CAPE TOWN
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF15

Registration number:	42/20.1.1/0108
Name of medicine:	CLINDASPEN 600 mg
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CLINDAMYCIN PHOSPHATE EQUIVALENT TO CLINDAMYCIN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC: STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	42/20.2.8/0111
Name of medicine:	AVIREZ
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:: RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	42/8.2/0130
Name of medicine:	PRADAXA 75 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: DABIGATRAN ETEXILATE MESILATE EQUIVALENT TO DABIGATRAN 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY BOEHRINGER INGELHEIM PHARMA GmbH, INGELHEIM AM RHEIN, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	INGELHEIM PHARMACEUTICALS, FERNDAL, RANDBURG
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF15

Registration number:	42/8.2/0131
Name of medicine:	PRADAXA 110 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: DABIGATRAN ETEXILATE MESILATE EQUIVALENT TO DABIGATRAN 110,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY BOEHRINGER INGELHEIM PHARMA GmbH, INGELHEIM AM RHEIN, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	INGELHEIM PHARMACEUTICALS, FERNDAL, RANDBURG
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	42/2.6.5/0179
Name of medicine:	ABILIFY IM
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ARIPRAZOLE 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BRISTOL MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL MYERS SQUIBB, MAYAGUEZ, PUERTO RICO
Packer:	BRISTOL MYERS SQUIBB, MAYAGUEZ, PUERTO RICO BRISTOL MYERS SQUIBB Srl, ANAGNI, ITALY
Laboratory: FPRC:	BRISTOL MYERS SQUIBB, MAYAGUEZ, PUERTO RICO BRISTOL MYERS SQUIBB Srl, ANAGNI, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
FPRR:	BRISTOL MYERS SQUIBB, BEDFORDVIEW
Shelf-life:	18 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number: 42/2.6.5/0179
 Name of medicine: ABILIFY IM
 Dosage form: INJECTION
 Active ingredients: EACH 1,0 ml SOLUTION
 CONTAINS:
 ARIPIRAZOLE 7,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: BRISTOL MYERS SQUIBB (PTY) LTD
 Manufacturer: BRISTOL MYERS SQUIBB, MAYAGUEZ, PUERTO RICO
 Packer: BRISTOL MYERS SQUIBB, MAYAGUEZ, PUERTO RICO
 BRISTOL MYERS SQUIBB Srl, ANAGNI, ITALY
 Laboratory: FPRC: BRISTOL MYERS SQUIBB, MAYAGUEZ, PUERTO RICO
 BRISTOL MYERS SQUIBB Srl, ANAGNI, ITALY
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
 FPRR: BRISTOL MYERS SQUIBB, BEDFORDVIEW
 Shelf-life: 18 months
 Date of registration: 19 MARCH 2010

MRF15

Registration number: 42/3.1/0411
 Name of medicine: BIO-DICLOFENAC 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: BIOTECH LABORATORIES (PTY) LTD
 Manufacturer: UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
 Packer: UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
 Laboratory: FPRC: UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
 M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
 FPRR: BIOTECH LABORATORIES, RANDJESPAK., MIDRAND
 Shelf-life: 24 months
 Date of registration: 19 MARCH 2010

MRF 15

Registration number: 42/20.1.1/0568
 Name of medicine: CLINDASPEN 300 mg
 Dosage form: INJECTION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 CLINDAMYCIN PHOSPHATE
 EQUIVALENT TO
 CLINDAMYCIN 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMACARE LIMITED
 Manufacturer: STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
 Packer: STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 Laboratory: FPRC: STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
 M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
 FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
 Shelf-life: 24 months
 Date of registration: 19 MARCH 2010

MRF 15

Registration number:	42/11.4.3/0599
Name of medicine:	SANDOZ OMEPRAZOLE 40 IVI
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: OMEPRazole SODIUM EQUIVALENT TO OMEPRazole 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF15

Registration number:	42/11.4.3/0600
Name of medicine:	OMILOC 40 IVI
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: OMEPRazole SODIUM EQUIVALENT TO OMEPRazole 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA SANDOZ SA, SPARTAN, KEMPRON PARK
Laboratory: FPRC:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPRON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	19 MARCH 2010

MRF 15

Registration number:	42/8.2/1085
Name of medicine:	CLOSOLVE
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:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	19 MARCH 2010

MRF 15

Registration number: 42/8.2/1086
 Name of medicine: BECLOP
 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: BE-TABS
 PHARMACEUTICALS (PTY)
 LTD
 Manufacturer: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 HIMACHAL PRADESH, INDIA
 Packer: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 HIMACHAL PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 HIMACHAL PRADESH, INDIA
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: BE-TABS
 PHARMACEUTICALS,
 ROODEPOORT, RSA
 Shelf-life: 24 months
 Date of registration: 19 MARCH 2010

MRF15

Registration number: 43/7.1.3/0434
 Name of medicine: LOVISPEs
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 NEBIVOLOL
 HYDROCHLORIDE
 EQUIVLENT TO
 NEBIVOLOL 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: LASARA TRADERS (PTY)
 LTD
 Manufacturer: SPECIFAR S.A., VARVARA,
 ATHENS, GREECE
 Packer: SPECIFAR S.A., VARVARA,
 ATHENS, GREECE
 SPECPHARM HOLDINGS,
 HALFWAY HOUSE,
 MIDRAND
 Laboratory: FPRC: SPECIFAR S.A., VARVARA,
 ATHENS, GREECE
 SPECPHARM HOLDINGS,
 HALFWAY HOUSE,
 MIDRAND
 FPRR: LASARA TRADERS,
 MORELETA PARK,
 PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 19 MARCH 2010

MRF 15

Registration number: 38/2.8/0097
 Name of medicine: PARACETAMOL ADCO 1 000
 Dosage form: POWDER
 Active ingredients: EACH SACHET CONTAINS:
 PARACETAMOL 1 000,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON, RSA
 Packer: WRAPSA PACKAGING, &
 MANUFACTURING,
 CENTURION, RSA
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE,
 JOHANNESBURG
 Laboratory: FPRC/FPRR: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON, RSA
 FPRR: ADCOCK INGRAM LTD, ERAND
 GARDENS, MIDRAND
 Shelf-life: 24 months
 Date of registration: 30 APRIL 2010

MRF 15

Registration number:	A38/2.5/0637
Name of medicine:	EPILIM CHRONOSPHERE
Dosage form:	GRANULES
Active ingredients:	EACH 100,0 g GRANULES CONTAIN: SODIUM VALPROATE 22,0 g VALPROIC ACID 9,58 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory: FPRC:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	SANOFI-AVENTIS SA, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF15

Registration number:	A38/2.5/0638
Name of medicine:	VALPROWIN CHRONOSPHERE
Dosage form:	GRANULES
Active ingredients:	EACH 100,0 g GRANULES CONTAIN: SODIUM VALPROATE 22,0 g VALPROIC ACID 9,58 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory: FPRC:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	A39/2.5/0204
Name of medicine:	EPILIZINE CR 300 BREAKABLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 199,8 mg VALPROIC ACID 87,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	WINTHROP PHARMACEUTICALS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	A39/2.5/0205
Name of medicine:	EPILIZINE CR 500 BREAKABLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 333,0 mg VALPROIC ACID 145,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	WINTHROP PHARMACEUTICALS MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	30 APRIL 2010

MRF15

Registration number:	A39/2.5/0206
Name of medicine:	EPILIM CR 300 BREAKABLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 199,8 mg VALPROIC ACID 87,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	SANOFI-AVENTIS SA, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	A39/2.5/0207
Name of medicine:	EPILIM CR 500 BREAKABLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 333,0 mg VALPROIC ACID 145,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	SANOFI-AVENTIS SA, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	A39/2.5/0208
Name of medicine:	VALPIREX CR 300 BREAKABLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 199,8 mg VALPROIC ACID 87,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	WINTHROP PHARMACEUTICALS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	30 APRIL 2010

MRF15

Registration number:	A39/2.5/0209
Name of medicine:	VALPIREX CR 500 BREAKABLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 333,0 mg VALPROIC ACID 145,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	WINTHROP PHARMACEUTICALS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	A39/16.1/0615
Name of medicine:	ILIADIN PRESERVATIVE-FREE 0,05 % METERED SPRAY
Dosage form:	METERED SPRAY
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: OXYMETAZOLINE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	MERCK (PTY) LTD
Manufacturer:	LABORATOIRES PHARMASTER, ERSTEIN, FRANCE
Packer:	LABORATOIRES PHARMASTER, ERSTEIN, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory: FPRC:	LABORATOIRES PHARMASTER, ERSTEIN, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	MERCK, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number: A39/16.1/0616

Name of medicine: ILIADIN PRESERVATIVE-FREE 0,025 % METERED SPRAY

Dosage form: METERED SPRAY

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
OXYMETAZOLINE 0,25 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 8

Applicant: MERCK (PTY) LTD

Manufacturer: LABORATOIRES PHARMASTER, ERSTEIN, FRANCE

Packer: LABORATOIRES PHARMASTER, ERSTEIN, FRANCE
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON

Laboratory: FPRC: LABORATOIRES PHARMASTER, ERSTEIN, FRANCE
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA

FPRR: MERCK, MODDERFONTEIN

Shelf-life: 24 months (Provisional)

Date of registration: 30 APRIL 2010

MRF15

Registration number: A40/7.1/0550

Name of medicine: MACOREL 30 SR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
NIFEDIPINE 30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SPECPHARM (PTY) LTD

Manufacturer: VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY
VALPHARMA s.a., SERRAVALLE, SAN MARINO, ITALY

Packer: ELPEN PHARMACEUTICALS CO, PIKERM, ATTICA, GREECE

Laboratory: FPRC: VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY
VALPHARMA s.a., SERRAVALLE, SAN MARINO, ITALY
ELPEN PHARMACEUTICALS CO, PIKERM, ATTICA, GREECE

FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND

Shelf-life: 36 months

Date of registration: 30 APRIL 2010

MRF 15

Registration number: A40/7.1/0551

Name of medicine: MACOREL 60 SR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
NIFEDIPINE 60,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SPECPHARM (PTY) LTD

Manufacturer: VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY
VALPHARMA s.a., SERRAVALLE, SAN MARINO, ITALY

Packer: ELPEN PHARMACEUTICALS CO, PIKERM, ATTICA, GREECE

Laboratory: FPRC: VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY
VALPHARMA s.a., SERRAVALLE, SAN MARINO, ITALY
ELPEN PHARMACEUTICALS CO, PIKERM, ATTICA, GREECE

FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND

Shelf-life: 36 months

Date of registration: 30 APRIL 2010

MRF 15

Registration number: A40/7.1/0552
 Name of medicine: SPEC-NIFEDIPINE 30 SR
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 NIFEDIPINE 30,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SPECPHARM (PTY) LTD
 Manufacturer: VALPHARMA
 INTERNATIONAL S.p.A.,
 PENNABILLI, PERSARO-
 URBINO, ITALY
 VALPHARMA s.a.,
 SERRAVALLE, SAN
 MARINO, ITALY

 Packer: ELPEN PHARMACEUTICALS
 CO, PIKERM, ATTICA,
 GREECE

 Laboratory: FPRC: VALPHARMA
 INTERNATIONAL S.p.A.,
 PENNABILLI, PERSARO-
 URBINO, ITALY
 VALPHARMA s.a.,
 SERRAVALLE, SAN
 MARINO, ITALY
 ELPEN PHARMACEUTICALS
 CO, PIKERM, ATTICA,
 GREECE

 FPRR: SPECPHARM, HALFWAY
 HOUSE, MIDRAND

 Shelf-life: 36 months
 Date of registration: 30 APRIL 2010

MRF15

Registration number: A40/7.1/0553
 Name of medicine: SPEC-NIFEDIPINE 60 SR
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 NIFEDIPINE 60,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SPECPHARM (PTY) LTD
 Manufacturer: VALPHARMA
 INTERNATIONAL S.p.A.,
 PENNABILLI, PERSARO-
 URBINO, ITALY
 VALPHARMA s.a.,
 SERRAVALLE, SAN
 MARINO, ITALY

 Packer: ELPEN
 PHARMACEUTICALS CO,
 PIKERM, ATTICA, GREECE

 Laboratory: FPRC: VALPHARMA
 INTERNATIONAL S.p.A.,
 PENNABILLI, PERSARO-
 URBINO, ITALY
 VALPHARMA s.a.,
 SERRAVALLE, SAN
 MARINO, ITALY
 ELPEN
 PHARMACEUTICALS CO,
 PIKERM, ATTICA, GREECE

 FPRR: SPECPHARM, HALFWAY
 HOUSE, MIDRAND

 Shelf-life: 36 months
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 41/18.8/0036
 Name of medicine: FAMYNOR
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 NORGESTREL 0,5 mg
 ETHINYL ESTRADIOL 0,05 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: TRINITY PHARMA (PTY) LTD
 Manufacturer: FAMY CARE LTD,
 UMBERGAON, VALSAD
 DISTRICT, GUJARAT, INDIA

 Packer: FAMY CARE LTD,
 UMBERGAON, VALSAD
 DISTRICT, GUJARAT, INDIA

 Laboratory: FPRC: FAMY CARE LTD,
 UMBERGAON, VALSAD
 DISTRICT, GUJARAT, INDIA
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM

 FPRR: TRINITY PHARMA,
 MURRAYFIELD, PRETORIA

 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number:	41/20.2.8/0593
Name of medicine:	STAID 20 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF15

Registration number:	41/20.2.8/0594
Name of medicine:	STAID 30 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	41/20.2.8/0595
Name of medicine:	STAID 40 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number: 41/20.2.8/0600
 Name of medicine: ADCO-STAVUDINE 20 mg
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 STAVUDINE 20,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 Packer: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 Laboratory: FPRC/FPRR: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM LTD,
 AEROTON,
 JOHANNESBURG

 FPRR: ADCOCK INGRAM LTD,
 ERAND GARDENS,
 MIDRAND

 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF15

Registration number: 41/20.2.8/0600
 Name of medicine: ADCO-STAVUDINE 30 mg
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE
 CONTAINS:
 STAVUDINE 30,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: ADCOCK INGRAM
 HEALTHCARE,
 WADEVILLE, GERMISTON
 Packer: ADCOCK INGRAM
 HEALTHCARE,
 WADEVILLE, GERMISTON
 Laboratory: FPRC/FPRR: ADCOCK INGRAM
 HEALTHCARE,
 WADEVILLE, GERMISTON
 ADCOCK INGRAM LTD,
 AEROTON,
 JOHANNESBURG

 FPRR: ADCOCK INGRAM LTD,
 ERAND GARDENS,
 MIDRAND

 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 41/20.2.8/0601
 Name of medicine: ADCO-STAVUDINE 40 mg
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 STAVUDINE 40,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 Packer: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 Laboratory: FPRC/FPRR: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM LTD,
 AEROTON, JOHANNESBURG

 FPRR: ADCOCK INGRAM LTD, ERAND
 GARDENS, MIDRAND

 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 41/7.1.3/0632
 Name of medicine: PEARINDA PLUS 2
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PERINDOPRIL, TERT-BUTYLAMINE 2,0 mg
 INDAPAMIDE 0,625 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SPECPHARM (PTY) LTD
 Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
 DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
 Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
 Shelf-life: 24 months
 Date of registration: 30 APRIL 2010

MRF15

Registration number: 41/7.1.3/0633
 Name of medicine: PEARINDA PLUS 4
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PERINDOPRIL, TERT-BUTYLAMINE 4,0 mg
 INDAPAMIDE 1,25 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SPECPHARM (PTY) LTD
 Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
 DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
 Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
 Shelf-life: 24 months
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 41/2.7/0647
 Name of medicine: PARAPYN
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PARACETAMOL 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
 Manufacturer: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
 Packer: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
 Laboratory: FPRC: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
 FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
 Shelf-life: 24 months
 Date of registration: 30 APRIL 2010

MRF 15

Registration number:	41/20.2.8/0685
Name of medicine:	ZYNOVIR CAPSULES 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:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF15

Registration number:	41/20.2.8/0686
Name of medicine:	ZYNOVIR CAPSULES 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:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	41/7.5/0848
Name of medicine:	TRICOR 160 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FENOFIBRATE 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SOLVAY PHARMA (PTY) LTD
Manufacturer:	LABORATORIES FOURNIER SA, FONTAINE-LES-DIJON, FRANCE
Packer:	LABORATORIES FOURNIER SA, FONTAINE-LES-DIJON, FRANCE
Laboratory: FPRC:	LABORATORIES FOURNIER SA, FONTAINE-LES-DIJON, FRANCE SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	SOLVAY PHARMA, RANDJESPAK, MIDRAND
Shelf-life:	24 months
Date of registration:	30 APRIL 2010

MRF 15

Registration number: 41/26/0915
 Name of medicine: GENEXOL 100 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 PACLITAXEL 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: PHARMACORP cc
 Manufacturer: INTAS PHARMACEUTICALS
 LTD, MATODA, TALUKA-
 SANAND, AHMEDABAD,
 INDIA

Packer: INTAS PHARMACEUTICALS
 LTD, MATODA, TALUKA-
 SANAND, AHMEDABAD,
 INDIA

Laboratory: FPRC: INTAS PHARMACEUTICALS
 LTD, MATODA, TALUKA-
 SANAND, AHMEDABAD,
 INDIA
 COLUMBIA
 PHARMACEUTICALS,
 BARDENE, BOKSBURG

FPRR: PHARMACORP cc,
 ARCADIA, PRETORIA

Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF15

Registration number: 41/20.2.8/0916
 Name of medicine: COLAZID
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LAMIVUDINE 150,0 mg
 ZIDOVUDINE 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA
 (PTY) LTD
 Manufacturer: AUROBINDO PHARMA
 LTD, UNIT III,
 QUTHUBULLAPUR
 MANDAL, RANGA REDDY
 DISTRICT, ANDHRA
 PRADESH, INDIA

Packer: AUROBINDO PHARMA
 LTD, UNIT III,
 QUTHUBULLAPUR
 MANDAL, RANGA REDDY
 DISTRICT, ANDHRA
 PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA
 LTD, UNIT III,
 QUTHUBULLAPUR
 MANDAL, RANGA REDDY
 DISTRICT, ANDHRA
 PRADESH, INDIA

FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG, RSA

Shelf-life: 24 months (provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 41/20.2.8/0917
 Name of medicine: BAVIR TABLETS 300 mg
 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: AUROBINDO PHARMA (PTY)
 LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 UNIT III, QUTHUPULLAPUR
 MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH,
 INDIA

Packer: AUROBINDO PHARMA LTD,
 UNIT III, QUTHUPULLAPUR
 MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH,
 INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
 UNIT III, QUTHUPULLAPUR
 MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH,
 INDIA

FPRR: AUROBINDO PHARMA,
 MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number:	41/26/0924
Name of medicine:	GENEXOL 30 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACORP cc
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA- SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA- SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA- SANAND, AHMEDABAD, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG
FPRR:	PHARMACORP cc, ARCADIA, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF15

Registration number:	42/20.2.8/0466
Name of medicine:	BINDOPIN TABLETS 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	42/20.2.8/0473
Name of medicine:	ZENVIR TABLETS 600 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number: 42/20.2.8/0476
 Name of medicine: ZELIVIRE 500
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 VALACICLOVIR
 HYDROCHLORIDE
 EQUIVALENT TO
 VALACICLOVIR 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: RANBAXY (SA) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA
 Packer: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: RANBAXY (SA),
 CENTURION, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF15

Registration number: 42/20.2.8/0477
 Name of medicine: RAN-VALACICLOVIR 500
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 VALACICLOVIR
 HYDROCHLORIDE
 EQUIVALENT TO
 VALACICLOVIR 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: RANBAXY (SA) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA
 Packer: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: RANBAXY (SA),
 CENTURION, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 42/5.3/0490
 Name of medicine: DONECEPT 5
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 DONEPEZIL HYDROCHLORIDE
 EQUIVALENT TO DONEPEZIL
 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: CIPLA MEDPRO (PTY) LTD
 Manufacturer: CIPLA LTD, (UNIT III), VERNA,
 GOA, INDIA
 Packer: CIPLA LTD, (UNIT III), VERNA,
 GOA, INDIA
 Laboratory: FPRC: CIPLA LTD, (UNIT III), VERNA,
 GOA, INDIA
 FPRR: CIPLA MEDPRO, ROSENPARK,
 BELLVILLE
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 42/5.3/0491
 Name of medicine: DONECEPT 10
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 DONEPEZIL HYDROCHLORIDE
 EQUIVALENT TO DONEPEZIL
 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: CIPLA MEDPRO (PTY) LTD
 Manufacturer: CIPLA LTD, (UNIT III), VERNA,
 GOA, INDIA
 Packer: CIPLA LTD, (UNIT III), VERNA,
 GOA, INDIA
 Laboratory: FPRC: CIPLA LTD, (UNIT III), VERNA,
 GOA, INDIA
 FPRR: CIPLA MEDPRO, ROSENPARK,
 BELLVILLE
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF15

Registration number: 42/34/0699
 Name of medicine: XIENCE V
 Dosage form: STENT
 Active ingredients: EACH STENT CONTAINS:
 EVEROLIMUS 100,0 ug/cm²
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: BAROQUE
 PHARMACEUTICALS (PTY)
 LTD
 Manufacturer: ABBOTT VASCULAR-CARDIAC
 THERAPIES, YNEZ,
 TEMECULA, CALIFORNIA, USA
 Packer: ABBOTT VASCULAR-CARDIAC
 THERAPIES, YNEZ,
 TEMECULA, CALIFORNIA, USA
 Laboratory: FPRC: ABBOTT VASCULAR-CARDIAC
 THERAPIES, YNEZ,
 TEMECULA, CALIFORNIA, USA
 FPRR: BAROQUE
 PHARMACEUTICALS, ILLOVO,
 JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 42/1.2/0911
 Name of medicine: ZYTOMIL 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: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: PHARMASCIENCE Inc,
 ROYALMOUNT, MONTREAL,
 QUEBEC, CANADA
 Packer: PHARMASCIENCE Inc, DE
 L'ESPLANADE, MONTREAL,
 QUEBEC, CANADA
 ROPACK INC, MIRABEAU,
 MONTREAL, QUEBEC, CANADA
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE,
 JOHANNESBURG
 TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 PHARMACEUTICAL ENTERPRISES,
 N'DABENI, PINELANDS
 Laboratory: FPRC: PHARMASCIENCE Inc,
 ROYALMOUNT, MONTREAL,
 QUEBEC, CANADA
 PHARMASCIENCE Inc, DE
 L'ESPLANADE, MONTREAL,
 QUEBEC, CANADA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: PHARMA DYNAMICS, SILVERWOOD,
 WESTLAKE
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 42/1.2/0912
 Name of medicine: ZYTOMIL 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: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: PHARMASCIENCE Inc,
 ROYALMOUNT, MONTREAL,
 QUEBEC, CANADA
 Packer: PHARMASCIENCE Inc, DE
 L'ESPLANADE, MONTREAL,
 QUEBEC, CANADA
 ROPACK INC, MIRABEAU,
 MONTREAL, QUEBEC, CANADA
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE,
 JOHANNESBURG
 TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 PHARMACEUTICAL
 ENTERPRISES, N'DABENI,
 PINELANDS
 Laboratory: FPRC: PHARMASCIENCE Inc,
 ROYALMOUNT, MONTREAL,
 QUEBEC, CANADA
 PHARMASCIENCE Inc, DE
 L'ESPLANADE, MONTREAL,
 QUEBEC, CANADA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: PHARMA DYNAMICS,
 SILVERWOOD, WESTLAKE
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF15

Registration number: 42/1.2/0913
 Name of medicine: ZYTOMIL 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: PHARMA DYNAMICS (PTY)
 LTD
 Manufacturer: PHARMASCIENCE Inc,
 ROYALMOUNT, MONTREAL,
 QUEBEC, CANADA
 Packer: PHARMASCIENCE Inc, DE
 L'ESPLANADE, MONTREAL,
 QUEBEC, CANADA
 ROPACK INC, MIRABEAU,
 MONTREAL, QUEBEC,
 CANADA
 DIVPHARM MANUFACTURING
 & PACKAGING, LONGDALE,
 JOHANNESBURG
 TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 PHARMACEUTICAL
 ENTERPRISES, N'DABENI,
 PINELANDS
 Laboratory: FPRC: PHARMASCIENCE Inc,
 ROYALMOUNT, MONTREAL,
 QUEBEC, CANADA
 PHARMASCIENCE Inc, DE
 L'ESPLANADE, MONTREAL,
 QUEBEC, CANADA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: PHARMA DYNAMICS,
 SILVERWOOD, WESTLAKE
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 42/1.2/0914
 Name of medicine: ZYTOMIL 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: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: PHARMASCIENCE Inc,
 ROYALMOUNT, MONTREAL,
 QUEBEC, CANADA
 Packer: PHARMASCIENCE Inc, DE
 L'ESPLANADE, MONTREAL,
 QUEBEC, CANADA
 ROPACK INC, MIRABEAU,
 MONTREAL, QUEBEC, CANADA
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE,
 JOHANNESBURG
 TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 PHARMACEUTICAL ENTERPRISES,
 N'DABENI, PINELANDS
 Laboratory: FPRC: PHARMASCIENCE Inc,
 ROYALMOUNT, MONTREAL,
 QUEBEC, CANADA
 PHARMASCIENCE Inc, DE
 L'ESPLANADE, MONTREAL,
 QUEBEC, CANADA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: PHARMA DYNAMICS, SILVERWOOD,
 WESTLAKE
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number:	42/20.2.8/1093
Name of medicine:	BINDOLAM ORAL SOLUTION 10 mg/ml
Dosage form:	SOLUTION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LAMIVUDINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	30 APRIL 2010

MRF15

Registration number:	43/20.2.8/0499
Name of medicine:	AURO-RIBAVIRIN TABLETS 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RIBAVIRIN.....200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number:	43/20.2.8/0500
Name of medicine:	DORIK TABLETS 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RIBAVIRIN200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	30 APRIL 2010

MRF 15

Registration number: 43/20.2.8/0695
 Name of medicine: SONKE-TENOFOVIR 300

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
 TENOFOVIR DISOPROXIL
 FUMARATE 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA

Packer: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA

Laboratory: FPRC: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND

FPRR: RANBAXY (SA),
 CENTURION, RSA

Shelf-life: 24 months

Date of registration: 30 APRIL 2010

MRF15

Registration number: 44/20.2.8/0288
 Name of medicine: STABINEZ 600 mg
 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
 EFAVIRENZ 600,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA
 (PTY) LTD

Manufacturer: AUROBINDO PHARMA
 LTD, QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA
 LTD, QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA
 LTD, QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND

FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0291
 Name of medicine: APAFAR 600 mg TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
 EFAVIRENZ 600,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY)
 LTD

Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY, ANDHRA
 PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY, ANDHRA
 PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY, ANDHRA
 PRADESH, INDIA
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG
 KHULULEKANI LABORATORY
 SERVICES, COVENTRY PARK,
 MIDRAND

FPRR: AUROBINDO PHARMA,
 MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0307
 Name of medicine: ZEFIN 300 mg TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TENOFOVIR DISOPROXIL
 FUMARATE 300,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND
 FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF15

Registration number: 44/20.2.8/0308
 Name of medicine: CYLOR 300 mg TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TENOFOVIR DISOPROXIL
 FUMARATE 300,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND
 FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0309
 Name of medicine: VIRENO 300 mg TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TENOFOVIR DISOPROXIL
 FUMARATE 300,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG
 KHULULEKANI LABORATORY
 SERVICES, COVENTRY PARK,
 MIDRAND
 FPRR: AUROBINDO PHARMA,
 MEYERSDAL, JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0588

Name of medicine: DELADEX 200 mg CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
DIDANOSINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA
M&L LABORATORY
SERVICES, ORMONDE,
JOHANNESBURG
KHULULEKANI
LABORATORY SERVICES,
COVENTRY PARK,
MIDRAND

FPRR: AUROBINDO PHARMA,
MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 30 APRIL 2010

MRF15

Registration number: 44/20.2.8/0589

Name of medicine: DELADEX 250 mg CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
DIDANOSINE 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY
SERVICES, COVENTRY PARK,
MIDRAND

FPRR: AUROBINDO PHARMA,
MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0590

Name of medicine: DELADEX 400 mg CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
DIDANOSINE 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY DISTRICT,
HYDERABAD, ANDHRA
PRADESH, INDIA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY
SERVICES, COVENTRY PARK,
MIDRAND

FPRR: AUROBINDO PHARMA,
MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0599
 Name of medicine: SEGIREF 200 mg CAPSULES
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 DIDANOSINE 200,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND
 FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF15

Registration number: 44/20.2.8/0600
 Name of medicine: SEGIREF 250 mg CAPSULES
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 DIDANOSINE 250,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA PRADESH, INDIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG
 KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND
 FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0601
 Name of medicine: SEGIREF 400 mg CAPSULES
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 DIDANOSINE 400,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 HYDERABAD, ANDHRA
 PRADESH, INDIA
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG
 KHULULEKANI LABORATORY
 SERVICES, COVENTRY PARK,
 MIDRAND
 FPRR: AUROBINDO PHARMA,
 MEYERSDAL, JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0602

Name of medicine: SONIREN 200 mg CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS: DIDANOSINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND

FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 30 APRIL 2010

MRF15

Registration number: 44/20.2.8/0603

Name of medicine: SONIREN 250 mg CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS: DIDANOSINE 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND

FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 30 APRIL 2010

MRF 15

Registration number: 44/20.2.8/0604

Name of medicine: SONIREN 400 mg CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS: DIDANOSINE 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND

FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (provisional)

Date of registration: 30 APRIL 2010

MRF 15

Registration number:	08/5.1/09
Name of medicine:	VETMEDIN 1,25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PIMOBENDAN 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDA MANUFACTURING GmbH, COLOGNE, GERMANY
Packer:	MEDA MANUFACTURING GmbH, COLOGNE, GERMANY
Laboratory: FPRC:	MEDA MANUFACTURING GmbH, COLOGNE, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	INGELHEIM PHARMACEUTICALS, FERNDAL, RANDBURG
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF15

Registration number:	08/5.1/10
Name of medicine:	VETMEDIN 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PIMOBENDAN 5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDA MANUFACTURING GmbH, COLOGNE, GERMANY
Packer:	MEDA MANUFACTURING GmbH, COLOGNE, GERMANY
Laboratory: FPRC:	MEDA MANUFACTURING GmbH, COLOGNE, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	INGELHEIM PHARMACEUTICALS, FERNDAL, RANDBURG
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	A39/23/0594
Name of medicine:	AMINOVEN 3,5 % GE
Dosage form:	SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: TOTAL AMINO ACIDS 35,0 g L-isoleucine 1,75 g L-leucine 2,59 g L-methionine 1,505 g L-lysine 2,31 g L-phenylalanine 1,785 g L-threonine 1,54 g L-tryptophan 0,70 g L-valine 2,17 g L-arginine 4,20 g L-histidine 1,05 g L-alanine 4,90 g Glycine 3,85 g L-proline 3,92 g L-serine 2,275 g Taurine 0,35 g Sodium Chloride 1,169 g Calcium Chloride 0,222 g Magnesium Chloride 0,286 g Zinc Chloride 0,00545 g Potassium Hydroxide 1,98 g Sodium Glycerophosphate 3,241 g Glucose Monohydrate 55,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA
Packer:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA
Laboratory: FPRC:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA KHULULEKANI LABORATORIES, COVENTRY PARK, MIDRAND, RSA BODENE Va INTRAMED, KORSTEN, PORT ELIZABETH
FPRR:	FRESENIUS KABI, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	A40/11.4.3/0192
Name of medicine:	ALTOSEC 40 mg/10 ml
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OMEPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALFA WASSERMANN, ALANNO, ITALY
Packer:	ALFA WASSERMANN, ALANNO, ITALY
Laboratory: FPRC:	ALFA WASSERMANN, ALANNO, ITALY SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF15

Registration number:	A40/34/0431
Name of medicine:	ALTOSEC SOLVENT FOR INJECTABLE SOLUTION
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTIONS 10,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALFA WASSERMANN, ALANNO, ITALY
Packer:	ALFA WASSERMANN, ALANNO, ITALY
Laboratory: FPRC:	ALFA WASSERMANN, ALANNO, ITALY SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	A40/7.1.3/0685
Name of medicine:	SPEC CARVEDILOL 6,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 6,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA
Packer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA
Laboratory: FPRC:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	36 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number: A40/7.1.3/0686
 Name of medicine: SPEC CARVEDILOL 12,5

Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 CARVEDILOL 12,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SPECPHARM (PTY) LTD

Manufacturer: PHARMASCIENCE INC,
 MONTREAL, QUEBEC,
 CANADA

Packer: PHARMASCIENCE INC,
 MONTREAL, QUEBEC,
 CANADA

Laboratory: FPRC: PHARMASCIENCE INC,
 MONTREAL, QUEBEC,
 CANADA

FPRR: SPECPHARM, HALFWAY
 HOUSE, MIDRAND

Shelf-life: 36 months
 Date of registration: 4 JUNE 2010

MRF15

Registration number: A40/7.1.3/0687
 Name of medicine: SPEC CARVEDILOL 25

Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 CARVEDILOL 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SPECPHARM (PTY) LTD

Manufacturer: PHARMASCIENCE INC,
 MONTREAL, QUEBEC,
 CANADA

Packer: PHARMASCIENCE INC,
 MONTREAL, QUEBEC,
 CANADA

Laboratory: FPRC: PHARMASCIENCE INC,
 MONTREAL, QUEBEC,
 CANADA

FPRR: SPECPHARM, HALFWAY
 HOUSE, MIDRAND

Shelf-life: 36 months
 Date of registration: 4 JUNE 2010

MRF 15

Registration number: A40/14.2/0698
 Name of medicine: AQUACEL-AG WITH
 HYDROFIBER

Dosage form: WOUND DRESSING
 Active ingredients: EACH 100,0 g of DRESSING
 CONTAINS:
 SODIUM SILVER
 CARBOXYMETHYL-CELLULOSE
 100,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: BRISTOL-MYERS SQUIBB (PTY)
 LTD

Manufacturer: CONVATEC-RHYMNEY,
 RHYMNEY, GWENT, UK

Packer: CONVATEC LTD, DEESIDE, UK
 ADCOCK INGRAM CRITICAL
 CARE, AEROTON,
 JOHANNESBURG
 ISOTRON PLC, BRADFORD,
 WEST YORKSHIRE, UK
 ISOTRON PLC, ELGIN,
 SWINDON, UK

Laboratory: FPRC: CONVATEC LTD, DEESIDE, UK
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG

FPRR: BRISTOL-MYERS SQUIBB,
 BEDFORDVIEW,
 JOHANNESBURG

Shelf-life: 36 months
 Date of registration: 4 JUNE 2010

MRF 15

Registration number:	41/8.1/0223
Name of medicine:	GOLDSHIELD TRANEXAMIC ACID 500 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRANEXAMIC ACID 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAFRICA (PTY) LTD
Manufacturer:	RIVOPHARM S.A., MANNO, SWITZERLAND
Packer:	RIVOPHARM S.A., MANNO, SWITZERLAND PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	RIVOPHARM S.A., MANNO, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	PHARMAFRICA, NEW CENTRE, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	4 JUNE 2010

MRF15

Registration number:	41/7.3/0369
Name of medicine:	MEGAN 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	41/7.3/0370
Name of medicine:	MEGAN 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	41/21.2/0487
Name of medicine:	GALVUS 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VILDAGLIPTIN 50,0 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 ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF15

Registration number:	41/20.2.8/0538
Name of medicine:	ZENVIR CAPSULES 50 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 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, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	41/20.2.8/0539
Name of medicine:	ZENVIR CAPSULES 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 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, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	41/20.2.8/0540
Name of medicine:	ZENVIR CAPSULES 200 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF15

Registration number:	41/20.3/0719
Name of medicine:	NOXAFIL 40 mg/ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: POSACONAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCHERING-PLOUGH (PTY) LTD
Manufacturer:	PATHEON INC, WHITBY, ONTARIO, CANADA
Packer:	PATHEON INC, WHITBY, ONTARIO, CANADA SCHERING-PLOUGH LABO NV, HEIST-OP-DEN-BERG, BELGIUM SCHERING-PLOUGH FRANCE, HEROUVILLE- SAINT-CLAIR, FRANCE
Laboratory: FPRC:	PATHEON INC, WHITBY, ONTARIO, CANADA SCHERING-PLOUGH FRANCE, HEROUVILLE- SAINT-CLAIR, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	SCHERING-PLOUGH, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	41/3.1/0996
Name of medicine:	KETOJECT 15 mg/1 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: KETOROLAC TROMETHAMINE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	STRIDES SA PHARMACEUTICALS (PTY) LTD
Manufacturer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Laboratory: FPRC:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG NOVARTIS, SPARTAN, KEMPTON PARK
FPRR:	STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF 15

Registration number: 41/3.1/0997

Name of medicine: KETOJECT 60 mg/2 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION
CONTAINS:
KETOROLAC
TROMETHAMINE 30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: STRIDES SA
PHARMACEUTICALS (PTY)
LTD

Manufacturer: STRIDES ARCOLAB LTD,
BILEKAHALLI, BANGALORE,
INDIA

Packer: STRIDES ARCOLAB LTD,
BILEKAHALLI, BANGALORE,
INDIA

Laboratory: FPRC: STRIDES ARCOLAB LTD,
BILEKAHALLI, BANGALORE,
INDIA
COLUMBIA
PHARMACEUTICALS,
BARDENE, BOKSBURG
NOVARTIS, SPARTAN,
KEMPTON PARK

FPRR: STRIDES SA
PHARMACEUTICALS,
ARCADIA, PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 4 JUNE 2010

MRF15

Registration number: 41/3.1/1085

Name of medicine: KETOJECT 30 mg/1 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION
CONTAINS:
KETOROLAC
TROMETHAMINE 30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: STRIDES SA
PHARMACEUTICALS (PTY)
LTD

Manufacturer: STRIDES ARCOLAB LTD,
BILEKAHALLI,
BANGALORE, INDIA

Packer: STRIDES ARCOLAB LTD,
BILEKAHALLI,
BANGALORE, INDIA

Laboratory: FPRC: STRIDES ARCOLAB LTD,
BILEKAHALLI,
BANGALORE, INDIA
COLUMBIA
PHARMACEUTICALS,
BARDENE, BOKSBURG
NOVARTIS, SPARTAN,
KEMPTON PARK

FPRR: STRIDES SA
PHARMACEUTICALS,
ARCADIA, PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 4 JUNE 2010

MRF 15

Registration number: 42/5.8/0099

Name of medicine: SUDAFED PE SINUS
DECONGESTANT

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PHENYLEPHRINE
HYDROCHLORIDE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 8

Applicant: JOHNSON & JOHNSON (PTY)
LTD

Manufacturer: PFIZER AUSTRALIA, WHARF
ROAD, NEW SOUTH WALES,
AUSTRALIA
JOHNSON & JOHNSON,
RETREAT, CAPE TOWN

Packer: PFIZER AUSTRALIA, WHARF
ROAD, NEW SOUTH WALES,
AUSTRALIA
JOHNSON & JOHNSON,
RETREAT, CAPE TOWN

Laboratory: FPRC: PFIZER AUSTRALIA, WHARF
ROAD, NEW SOUTH WALES,
AUSTRALIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

FPRC/FPRR: JOHNSON & JOHNSON,
RETREAT, CAPE TOWN

Shelf-life: 24 months (Provisional)

Date of registration: 4 JUNE 2010

MRF 15

Registration number:	42/34/0514
Name of medicine:	SOLVENT FOR OMEPRAZOLE-SAFELINE INJECTION 40 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTION qs 1,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A., PALLINI ATTICI, GREECE
Packer:	VIANEX S.A., PALLINI ATTICI, GREECE
Laboratory: FPRC:	VIANEX S.A., PALLINI ATTICI, GREECE
FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, RSA
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF15

Registration number:	42/21.5.4/0581
Name of medicine:	FOXAIR 50/100 ACCUHALER
Dosage form:	INHALER
Active ingredients:	EACH BLISTER CONTAINS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASONE PROPRIONATE 100,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK
Packer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
FPRR:	GROUP LABORATORIES S.A., EPPING, CAPE TOWN
Shelf-life:	18 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	42/21.5.4/0582
Name of medicine:	FOXAIR 50/250 ACCUHALER
Dosage form:	INHALER
Active ingredients:	EACH BLISTER CONTAINS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASONE PROPIONATE 250,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK
Packer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
FPRR:	GROUP LABORATORIES S.A., EPPING, CAPE TOWN
Shelf-life:	18 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	42/21.5.4/0583
Name of medicine:	FOXAIR 50/500 ACCUHALER
Dosage form:	INHALER
Active ingredients:	EACH BLISTER CONTAINS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASONE PROPIONATE 500,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK
Packer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
FPRR:	GROUP LABORATORIES S.A., EPPING, CAPE TOWN
Shelf-life:	18 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	42/21.5.4/0584
Name of medicine:	SALMEFLUT 50/100 ACCUHALER
Dosage form:	INHALER
Active ingredients:	EACH BLISTER CONTAINS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASONE PROPIONATE 100,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK
Packer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
FPRR:	GROUP LABORATORIES S.A., EPPING, CAPE TOWN
Shelf-life:	18 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	42/21.5.4/0585
Name of medicine:	SALMEFLUT 50/250 ACCUHALER
Dosage form:	INHALER
Active ingredients:	EACH BLISTER CONTAINS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASONE PROPIONATE 250,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK
Packer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
FPRR:	GROUP LABORATORIES S.A., EPPING, CAPE TOWN
Shelf-life:	18 months
Date of registration:	4 JUNE 2010

MRF 15	
Registration number:	42/21.5.4/0586
Name of medicine:	SALMEFLUT 50/500 ACCUHALER
Dosage form:	INHALER
Active ingredients:	EACH BLISTER CONTAINS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASON PROPIONATE 500,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK
Packer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
FPRR:	GROUP LABORATORIES S.A., EPPING, CAPE TOWN
Shelf-life:	18 months
Date of registration:	4 JUNE 2010

MRF15	
Registration number:	42/20.1.1/0636
Name of medicine:	BACQUIRE 500
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: IMIPENEM 500,0 mg CILASTATIN SODIUM EQUIVALENT TO CILASTATIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF 15	
Registration number:	42/20.1.1/0637
Name of medicine:	CILAPEN 500
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: IMIPENEM 500,0 mg CILASTATIN SODIUM EQUIVALENT TO CILASTATIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	42/26/0758
Name of medicine:	TEVA VINORELBINE 10
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LEMERY S.A. de C.V., HUICHAPAN XOCHIMILCO, MEXICO CITY, MEXICO
Packer:	LEMERY S.A. de C.V., HUICHAPAN XOCHIMILCO, MEXICO CITY, MEXICO
Laboratory: FPRC:	LEMERY S.A. de C.V., HUICHAPAN XOCHIMILCO, MEXICO CITY, MEXICO CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	TEVA PHARMACEUTICALS, RUIMSIG, ROODEPOORT
Shelf-life:	18 months
Date of registration:	4 JUNE 2010

MRF15

Registration number:	42/26/0759
Name of medicine:	TEVA VINORELBINE 50
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LEMERY S.A. de C.V., HUICHAPAN XOCHIMILCO, MEXICO CITY, MEXICO
Packer:	LEMERY S.A. de C.V., HUICHAPAN XOCHIMILCO, MEXICO CITY, MEXICO
Laboratory: FPRC:	LEMERY S.A. de C.V., HUICHAPAN XOCHIMILCO, MEXICO CITY, MEXICO CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	TEVA PHARMACEUTICALS, RUIMSIG, ROODEPOORT
Shelf-life:	18 months
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	42/20.2.8/0987
Name of medicine:	ZYNOVIR ORAL SOLUTION 50 mg/5 ml
Dosage form:	SOLUTION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: ZIDOVUDINE 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, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF 15

Registration number: 43/20.2.8/0181
 Name of medicine: ASPEN TENOFOVIR
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TENOFOVIR DISOPROXIL
 FUMARATE 300,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: PHARMACARE LIMITED
 Manufacturer: NYCOMED ORANIENBURG
 GmbH, ORANIENBURG,
 GERMANY
 PATHEON INC, MISSISSAUGA,
 ONTARIO, CANADA
 PHARMACARE LTD, KORSTEN,
 PORT ELIZABETH
 Packer: NYCOMED ORANIENBURG
 GmbH, ORANIENBURG,
 GERMANY
 PATHEON INC, MISSISSAUGA,
 ONTARIO, CANADA
 PHARMACARE LTD, KORSTEN,
 PORT ELIZABETH
 CARDINAL HEALTH GERMANY
 GmbH, SCHORNDORF,
 GERMANY
 GILEAD SCIENCES INC, SAN
 DIMAS, CALIFORNIA, USA
 GILEAD SCIENCES LTD,
 BLACKROCK DUBLIN, IRELAND
 Laboratory: FPRC: NYCOMED ORANIENBURG
 GmbH, ORANIENBURG,
 GERMANY
 PATHEON INC, MISSISSAUGA,
 ONTARIO, CANADA
 PATHEON INC, BURLINGTON,
 ONTARIO, CANADA
 GILEAD SCIENCES INC, SAN
 DIMAS, CALIFORNIA, USA
 GILEAD SCIENCES LTD,
 BLACKROCK DUBLIN, IRELAND
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRC/FPRR: PHARMACARE LTD, KORSTEN,
 PORT ELIZABETH
 FPRR: PHARMACARE LTD,
 WOODMEAD, SANDTON
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 JUNE 2010

MRF15

Registration number: 43/11.3/0192
 Name of medicine: ALLI
 Dosage form: CAPSULES
 Active ingredients: EACH CAPSULE CONTAINS:
 ORLISTAT 60,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GROUP LABORATORIES SOUTH AFRICA
 (PTY) LTD
 Manufacturer: GLAXOSMITHKLINE CONSUMER
 HEALTHCARE, AIKEN, SOUTH CAROLINA,
 USA
 Packer: GLAXOSMITHKLINE CONSUMER
 HEALTHCARE, AIKEN, SOUTH CAROLINA,
 USA
 FAMAR S.A., AVLONA, GREECE
 GLAXOSMITHKLINE S.A., EPPING, CAPE
 TOWN
 Laboratory: FPRC: GLAXOSMITHKLINE CONSUMER
 HEALTHCARE, AIKEN, SOUTH CAROLINA,
 USA
 FAMAR S.A., AVLONA, GREECE
 GLAXOSMITHKLINE S.A., EPPING, CAPE
 TOWN
 FPRR: GROUP LABORATORIES, EPPING, CAPE
 TOWN
 Shelf-life: 24 months
 Date of registration: 4 JUNE 2010

MRF 15

Registration number: 43/5.4.1/0216
 Name of medicine: RESURE 0,25 TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ROPINIROLE HYDROCHLORIDE
 EQUIVALENT TO ROPINIROLE 0,25 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ZYDUS HEALTHCARE SA (PTY) LTD
 Manufacturer: ZYDUS CADILA HEALTHCARE LTD,
 MORAIYA, SANAND, AHMEDABAD, INDIA
 Packer: ZYDUS CADILA HEALTHCARE LTD,
 MORAIYA, SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,
 MORAIYA, SANAND, AHMEDABAD, INDIA
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY, NORTH-WEST
 UNIVERSITY, POTCHEFSTROOM
 FPRR: ZYDUS HEALTHCARE, VAN DER HOFF
 PARK, POTCHEFSTROOM
 Shelf-life: 24 months
 Date of registration: 4 JUNE 2010

MRF 15

Registration number: 43/5.4.1/0217

Name of medicine: RESURE 0,5 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROPINIROLE HYDROCHLORIDE
EQUIVALENT TO ROPINIROLE
0,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ZYDUS HEALTHCARE SA (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND, AHMEDABAD,
INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND, AHMEDABAD,
INDIA

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND, AHMEDABAD,
INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY, NORTH-
WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE, VAN DER
HOFF PARK, POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 4 JUNE 2010

MRF15

Registration number: 43/5.4.1/0218

Name of medicine: RESURE 1,0 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROPINIROLE HYDROCHLORIDE
EQUIVALENT TO ROPINIROLE
1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ZYDUS HEALTHCARE SA (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND,
AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND,
AHMEDABAD, INDIA

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND,
AHMEDABAD, INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE, VAN DER
HOFF PARK, POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 4 JUNE 2010

MRF 15

Registration number: 43/5.4.1/0219

Name of medicine: RESURE 2,0 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROPINIROLE HYDROCHLORIDE
EQUIVALENT TO ROPINIROLE
2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ZYDUS HEALTHCARE SA (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND,
AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND,
AHMEDABAD, INDIA

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,
MORAIYA, SANAND,
AHMEDABAD, INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE, VAN DER
HOFF PARK, POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 4 JUNE 2010

MRF 15	
Registration number:	43/5.4.1/0220
Name of medicine:	RESURE 5,0 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HYDROCHLORIDE EQUIVALENT TO ROPINIROLE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months
Date of registration:	4 JUNE 2010

MRF15	
Registration number:	43/8.2/0242
Name of medicine:	EFIENT 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRASUGREL HYDROCHLORIDE EQUIVALENT TO PRASUGREL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY & CO, INDIANAPOLIS, INDIANA, USA
Packer:	LILLY S.A., ALCOBENDAS, MADRID, SPAIN
Laboratory: FPRC:	LILLY S.A., ALCOBENDAS, MADRID, SPAIN SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	ELI LILLY, BRYANSTON JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF 15	
Registration number:	43/8.2/0243
Name of medicine:	EFIENT 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRASUGREL HYDROCHLORIDE EQUIVALENT TO PRASUGREL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY & CO, INDIANAPOLIS, INDIANA, USA
Packer:	LILLY S.A., ALCOBENDAS, MADRID, SPAIN
Laboratory: FPRC:	LILLY S.A., ALCOBENDAS, MADRID, SPAIN SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	ELI LILLY, BRYANSTON JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	43/20.2.8/0287
Name of medicine:	BINDOPIN SUSPENSION 50 mg/5 ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: NEVIRAPINE 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, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010

MRF15

Registration number:	43/20.2.8/0356
Name of medicine:	ALUVIA 100/25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 100,0 mg RITONAVIR 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ABBOTT LABORATORIES S.A. (PTY) LTD
Manufacturer:	ABBOTT GmbH & CO, LUDWIGSHAFEN, GERMANY
Packer:	ABBOTT GmbH & CO, LUDWIGSHAFEN, GERMANY AESICA PHARMACEUTICALS LTD, QUEENSBOROUGH, KENT, UK SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND
Laboratory: FPRC:	ABBOTT GmbH & CO, LUDWIGSHAFEN, GERMANY AESICA PHARMACEUTICALS LTD, QUEENSBOROUGH, KENT, UK SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND PHYTOS, NEU-ULM, GERMANY SGS INSTITUT FRESENIUS GmbH, TAUNUSSTEIN, GERMANY
FPRR:	ABBOTT LABORATORIES S.A., CONSTANTIA KLOOF, JOHANNESBURG
Shelf-life:	24 month
Date of registration:	4 JUNE 2010

MRF 15

Registration number:	43/20.2.8/0385
Name of medicine:	ABAVOID TABLETS
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:	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:	4 JUNE 2010

MRF 15

Registration number: 43/20.2.8/0386

Name of medicine: ADCO ABACAVIR TABLETS

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: 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: 4 JUNE 2010

MRF15

Registration number: 43/30.2/0401

Name of medicine: SYNFLORIX

Dosage form: INJECTION

Active ingredients: EACH 0,5 ml DOSE CONTAINS: POLYSACCHARIDE FOR SEROTYPES:
1; 5; 6B; 7F; 9V; 14 23F 1,0 ug
4; 18CV; 19F 3,0 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM
GLAXOSMITHKLINE BIOLOGICALS S.A., WAVRE, BELGIUM

Packer: GLAXOSMITHKLINE BIOLOGICALS S.A., WAVRE, BELGIUM
GLAXOSMITHKLINE SOUTH AFRICA, EPPING, CAPE TOWN

Laboratory: FPRC: GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM
GLAXOSMITHKLINE BIOLOGICALS S.A., WAVRE, BELGIUM

FPRC/FPRR: GLAXOSMITHKLINE SOUTH AFRICA, EPPING, CAPE TOWN

Shelf-life: 36 months for storage at 2 - 8 °C

Date of registration: 4 JUNE 2010

MRF 15

Registration number: 43/20.2.8/0724

Name of medicine: ASPEN ABACAVIR 300

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: ABACAVIR 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: PHARMACARE LIMITED

Manufacturer: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
ASPEN OSD, KORSTEN, PORT ELIZABETH

Packer: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
ASPEN OSD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA

FPRC/FPRR: ASPEN OSD, KORSTEN, PORT ELIZABETH

FPRR: PHARMACARE LTD, WOODMEAD, SANDTON

Shelf-life: 24 months (Provisional)

Date of registration: 4 JUNE 2010

MRF 15

Registration number: 43/20.2.8/1102

Name of medicine: AP LAMIVUDINE 150 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMIVUDINE 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: STRIDES ARCOLAB LTD,
ANEKAL TALUK,
BANGALORE, INDIA
ASPEN OSD, GIBAUD ROAD,
PORT ELIZABETH
PHARMACARE LTD,
KORSTEN, PORT
ELIZABETH

Packer: STRIDES ARCOLAB LTD,
ANEKAL TALUK,
BANGALORE, INDIA
ASPEN OSD, GIBAUD ROAD,
PORT ELIZABETH
PHARMACARE LTD,
KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: STRIDES ARCOLAB LTD,
ANEKAL TALUK,
BANGALORE, INDIA
M&L LABORATORY
SERVICES, ORMONDE,
JOHANNESBURG
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRC/FPRR: ASPEN OSD, GIBAUD ROAD,
PORT ELIZABETH
PHARMACARE LTD,
KORSTEN, PORT
ELIZABETH

FPRR: PHARMACARE LTD,
WOODMEAD, SANDTON

Shelf-life: 24 months

Date of registration: 4 JUNE 2010

MRF15

Registration number: 44/20.2.8/0086

Name of medicine: TYRICTEN 200/300 mg TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TENOFVIR DISOPROXIL
FUMARATE 300,0 mg
EMTRICITABINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY
SERVICES, COVENTRY PARK,
MIDRAND

FPRR: AUROBINDO PHARMA,
MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 4 JUNE 2010

MRF 15

Registration number: 44/20.2.8/0087

Name of medicine: EMTRICITABINE/TENOFOVIR AURO
200/300 mg TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TENOFVIR DISOPROXIL
FUMARATE 300,0 mg
EMTRICITABINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY
SERVICES, COVENTRY PARK,
MIDRAND

FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 4 JUNE 2010

MRF 15

Registration number: 44/20.2.8/0344

Name of medicine: SONKE-DIDANOSINE 250

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
DIDANOSINE 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA

Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA

Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: RANBAXY (SA), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 4 JUNE 2010

MRF15

Registration number: 44/20.2.8/0345

Name of medicine: SONKE-DIDANOSINE 400

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
DIDANOSINE 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA

Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA

Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: RANBAXY (SA), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 4 JUNE 2010

MRF 15

Registration number: 44/20.2.8/0445

Name of medicine: CIPLA-TENOFOVIR/EMTRICITABINE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EMTRICITABINE 200,0 mg
TENOFIVIR DISOPROXIL FUMARATE 300,0 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: 4 JUNE 2010

MRF 15

Registration number:	44/20.2.8/0446
Name of medicine:	DIDIVIR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENOFIVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	4 JUNE 2010