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IMPORTANT NOTICE

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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 goedgekeurde 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 rakleefyd 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 rakleefydperiode dek. Stabiliteitstoets wat op proefflotte 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:	TECHNESCAN 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, RANDJESPAK, 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/FPFR: PHARMACARE LTD, KORSTEN,
 PORT ELIZABETH
FPFR: 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
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 KORSTEN, PORT ELIZABETH
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Laboratory: FPRC: MERCK FARMA y QUIMICA
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 BAR, HERTFORDSHIRE, UK
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 INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG
FPRC/FPFR: PHARMACARE LTD,
 KORSTEN, PORT ELIZABETH
FPFR: 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
FPFR: 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: RANBAXY LABORATORIES
 LTD, PAONTA SAHIB,
 SIRMOUR, HIMACHAL
 PRADESH, INDIA
FPRC: 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:	FREMIID
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, FERNDALÉ, 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, FERNDALÉ, 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: ARIPIPRAZOLE 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:
ARIPIPRAZOLE 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, PIKERMI, ATTICA, GREECE
Laboratory: FPRC:	VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY VALPHARMA s.a., SERRAVALLE, SAN MARINO, ITALY ELPEN PHARMACEUTICALS CO, PIKERMI, 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, PIKERMI, ATTICA, GREECE
Laboratory: FPRC:	VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY VALPHARMA s.a., SERRAVALLE, SAN MARINO, ITALY ELPEN PHARMACEUTICALS CO, PIKERMI, 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, PIKERMI, ATTICA,
 GREECE

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

 Laboratory: FPRC: VALPHARMA
 INTERNATIONAL S.p.A.,
 PENNABILLI, PERSARO-
 URBINO, ITALY
 VALPHARMA s.a.,
 SERRAVALLE, SAN
 MARINO, ITALY
 ELPEN
 PHARMACEUTICALS CO,
 PIKERMI, 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, ROSEN PARK, 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/cm ²
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:
TENOFIVIR 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, FERNDALE, 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, FERNDALE, 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 1/4 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 FLUTICASON 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:	42/21.5.4/0582
Name of medicine:	FOXAIR 50/250 ACCUHALER
Dosage form:	INHALER
Active ingredients:	EACH BLISTER CONTAINS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASON 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
 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

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: ABAVAID 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:
 TENOFOVIR 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:
 TENOFOVIR 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 TENOFVIR 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