

IMPORTANT NOTICE

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Health, Department of			Gesondheid, Departement van		
<i>General Notice</i>			<i>Algemene Kennisgewing</i>		
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Medicines and Related Substances Act (101/1965): Medicines Control Council: Conditions of registration of a medicine in terms of the provisions of section 15 (7).....			Wet op Beheer van Medisyne en Verwante Stowwe (101/1965): Medisynebeheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalings van artikel 15 (7).....		
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GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 58 OF 2011

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.

KENNISGEWING 58 VAN 2011**MEDISYNEBEHEERRAAD****VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE
BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN
VERWANTE STOWWE, 1965 (WET 101 VAN 1965)**

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverlag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleef tyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleef tydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemaking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverlag 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: 06/17.1.6/03
Name of medicine: ENROVET 10 %
Dosage form: SOLUTION
Active ingredients: EACH 1,0 ml SOLUTION
CONTAINS:
ENROFLOXACIN 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: MEDIORALS
LABORATORIES PVT LTD,
SATARA, MAHARASHTRA,
INDIA
Packer: MEDIORALS
LABORATORIES PVT LTD,
SATARA, MAHARASHTRA,
INDIA
Laboratory: FPRC: MEDIORALS
LABORATORIES PVT LTD,
SATARA, MAHARASHTRA,
INDIA

FPRR: CIPLA MEDPRO,
ROSENPARK, BELLVILLE

Shelf-life: 30 months
Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 06/21.1/17
Name of medicine: RESFLOR
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION
CONTAINS:
FLORFENICOL 300,0 mg
FLUNIXIN MEGLUMINE
EQUIVALENT TO
FLUNIXIN 16,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SCHERING-PLOUGH
(PTY) LTD
Manufacturer: ESSEX ANIMAL
HEALTH, FRIESOYTHE,
GERMANY
Packer: ESSEX ANIMAL
HEALTH, FRIESOYTHE,
GERMANY
Laboratory: FPRC: ESSEX ANIMAL
HEALTH, FRIESOYTHE,
GERMANY
CONSULTING
CHEMICAL
LABORATORIES,
ATLASVILLE,
BOKSBURG

FPRR: SCHERING-PLOUGH,
WOODMEAD, SANDTON

Shelf-life: 24 months
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number:
Name of medicine: DAS-STAVUDINE 40 & LAMIVUDINE
150
Dosage form: TABLET
Active ingredients: EACH TABLET
CONTAINS:
STAVUDINE 40,0 mg
LAMIVUDINE 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: STRIDES S.A. PHARMACEUTICALS
(PTY) LTD
Manufacturer: STRIDES ARCOLAB LTD, ANEKAL
TALUK, BANGALORE, INDIA
Packer: STRIDES ARCOLAB LTD, ANEKAL
TALUK, BANGALORE, INDIA
Laboratory: FPRC: STRIDES ARCOLAB LTD, ANEKAL
TALUK, BANGALORE, INDIA
COLUMBIA PHARMACEUTICALS,
BARDENE, BOKSBURG
NOVARTIS S.A., SPARTAN,
KEMPTON PARK

FPRR: STRIDES S.A. PHARMACEUTICALS,
ARCADIA, PRETORIA

Shelf-life: 24 months (Provisional)
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: A40/21.7/0260
 Name of medicine: ANDROGEL
 Dosage form: GEL
 Active ingredients: EACH 5,0 g SACHET CONTAINS:
 TESTOSTERONE 50,0 mg

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

Applicant: SOLVAY PHARMA (PTY) LTD

Manufacturer: LABORATOIRES BESINS
 INTERNATIONAL, MONTRouGE,
 FRANCE
 BESINS INTERNATIONAL
 BELGIQUE, DROGENBOS,
 BELGIUM

Packer: LABORATOIRES BESINS
 INTERNATIONAL, MONTRouGE,
 FRANCE
 BUDELPAK HAMONT NV,
 HAMONT, BELGIUM
 PHARMATIS, ESTREES-SAINT-
 DENIS, FRANCE

Laboratory: FPRC: LABORATOIRES BESINS
 INTERNATIONAL, MONTRouGE,
 FRANCE
 BESINS INTERNATIONAL
 BELGIQUE, DROGENBOS,
 BELGIUM
 PHARMATIS, ESTREES-SAINT-
 DENIS, FRANCE
 LABORATOIRES SIMON FRANCE,
 CLICHY, FRANCE
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA

FPRR: SOLVAY PHARMA,
 RANDJESPAK, MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 41/20.2.8/0141
 Name of medicine: COPEGUS 400
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RIBAVIRIN 400,0 mg

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

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: HOFFMANN-LA ROCHE INC,
 NUTLEY, NEW JERSEY, USA
 PATHEON INC, MISSISSAUGA,
 ONTARIO, CANADA

Packer: HOFFMANN-LA ROCHE INC,
 NUTLEY, NEW JERSEY, USA
 PATHEON INC, MISSISSAUGA,
 ONTARIO, CANADA
 F HOFFMANN-LA ROCHE,
 KAISERAUGST,
 SWITZERLAND
 MERS-LEE AG, BURGDORF,
 SWITZERLAND
 ROCHE PRODUCTS, ISANDO,
 RSA

Laboratory: FPRC: HOFFMANN-LA ROCHE INC,
 NUTLEY,
 NEW JERSEY, USA
 PATHEON INC, MISSISSAUGA,
 ONTARIO, CANADA
 HOFFMANN-LA ROCHE AG,
 GRENZACH-WYHLEN,
 GERMANY
 F HOFFMANN-LA ROCHE,
 BASEL, SWITZERLAND

FPRC/FPRR: ROCHE PRODUCTS, ISANDO,
 RSA

Shelf-life: 36 months

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 41/26/0413
 Name of medicine: VINORELBIN "EBEWE" 10 mg
 Dosage form: INFUSION
 Active ingredients: EACH 1,0 ml SOLUTION
 CONTAINS:
 VINORELBINE TARTRATE
 EQUIVALENT TO
 VINORELBINE 10,0 mg

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

Applicant: KEY ONCOLOGICS (PTY)
 LTD

Manufacturer: EBEWE PHARMA GmbH,
 UNTERACH, AUSTRIA

Packer: EBEWE PHARMA GmbH,
 UNTERACH, AUSTRIA

Laboratory: FPRC: EBEWE PHARMA GmbH,
 UNTERACH, AUSTRIA
 MIKROBIOLOGISCHES
 PRUFLABOR, INNSBRUCK,
 AUSTRIA
 LABOR L+SAG, BAD
 BOCKLET, GERMANY
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA

FPRR: KEY ONCOLOGICS,
 SANDTON, RSA

Shelf-life: 36 months

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 41/26/0414
Name of medicine: VINORELBIN "EBEWE" 50 mg
Dosage form: INFUSION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: KEY ONCOLOGICS (PTY) LTD
Manufacturer: EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Packer: EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Laboratory: FPRC: EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA
LABOR L+SAG, BAD BOCKLET, GERMANY
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
KEY ONCOLOGICS, SANDTON, RSA
Shelf-life: 36 months
Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 41/2.5/0443
Name of medicine: TOPIROL 25
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: TOPIRAMATE 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 36 months
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 41/2.5/0444
Name of medicine: TOPIROL 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 36 months
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 41/20.2.8/0735
Name of medicine: ZYDORIN 100 mg CAPSULES
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
ZIDOVUDINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

Packer: ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON
ADCOCK INGRAM LTD,
AEROTON, JOHANNESBURG

Laboratory: FPRC/FPRR: ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON
ADCOCK INGRAM LTD,
AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, ERAND
GARDENS, MIDRAND

Shelf-life: 24 months (Provisional)
Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 41/20.2.8/0736
Name of medicine: ZYDORIN 250 mg CAPSULES
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
ZIDOVUDINE 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

Packer: ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON
ADCOCK INGRAM LTD,
AEROTON, JOHANNESBURG

Laboratory: FPRC/FPRR: ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON
ADCOCK INGRAM LTD,
AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, ERAND
GARDENS, MIDRAND

Shelf-life: 24 months (Provisional)
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 41/11.4.3/0787
Name of medicine: PANTOCID 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
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: M J PHARMACEUTICALS
LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA

Packer: M J PHARMACEUTICALS
LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA

Laboratory: FPRC: M J PHARMACEUTICALS
LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: PHARMAPLAN, MIDRAND,
RSA

Shelf-life: 24 months
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 41/26/0979
Name of medicine: CIPLA-EPIRUBICIN 10
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 EPIRUBICIN
 HYDROCHLORIDE
 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, UNIT V, VERNA,
 GOA, INDIA

Packer: CIPLA LTD, UNIT V, VERNA,
 GOA, INDIA

Laboratory: CIPLA LTD, UNIT V, VERNA,
 GOA, INDIA
FPRC:

FPRR: CIPLA MEDPRO,
 ROSEN PARK, BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 41/26/0980
Name of medicine: CIPLA-EPIRUBICIN 50
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 EPIRUBICIN
 HYDROCHLORIDE
 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, UNIT V,
 VERNA, GOA, INDIA

Packer: CIPLA LTD, UNIT V,
 VERNA, GOA, INDIA

Laboratory: CIPLA LTD, UNIT V,
 VERNA, GOA, INDIA
FPRC:

FPRR: CIPLA MEDPRO,
 ROSEN PARK, BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/2.6.5/0065
Name of medicine: GULF HALOPERIDOL 5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 HALOPERIDOL 5,0 mg

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

Manufacturer: WRAPSA, HENOSPARK,
 CENTURION

Packer: WRAPSA, HENOSPARK,
 CENTURION

Laboratory: WRAPSA, HENOSPARK,
 CENTURION
FPRC: SABS PHARMACEUTICAL
 CHEMISTRY
 LABORATORY,
 GROENKLOOF, PRETORIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 PHARMA-Q, INDUSTRIA
 WEST, JOHANNESBURG
 CONSULTING
 MICROBIOLOGICAL
 LABORATORY, MOREHILL,
 BENONI

FPRR: GULF DRUG CO, MOUNT
 EDGEcombe, KZN

Shelf-life: 24 months

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/3.2/0236
Name of medicine: ALDREN 70 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ALENDRONATE
MONOSODIUM
TRIHYDRATE EQUIVALENT
TO ALENDRONIC ACID
70,0 mg

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

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 SA,
VAN DER HOFF PARK,
POTCHEFSTROOM

Shelf-life: 24 months (Provisional)

Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 42/26/0275
Name of medicine: TYKERB

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAPATINIB DITOSYLATE
EQUIVALENT TO
LAPATINIB 250,0 mg

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

Applicant: GLAXOSMITHKLINE
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

FPRC/FPRR: GLAXOSMITHKLINE S.A.,
EPPING, CAPE TOWN1
OCTOBER 2010

Shelf-life: 24 months

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/3.2/0276
Name of medicine: ZYDUS
ALENDRONATE 70
TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET
CONTAINS:
ALENDRONATE
MONOSODIUM
TRIHYDRATE
EQUIVALENT TO
ALENDRONIC ACID
70,0 mg

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

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
SA, VAN DER HOFF
PARK,
POTCHEFSTROOM

Shelf-life: 24 months (Provisional)

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/2.5/0277
Name of medicine: ZYDUS TOPIRAMATE 25

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ZYDUS HEALTHCARE S.A.
 (PTY) LTD
Manufacturer: ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND, AHMEDABAD,
 INDIA
Packer: ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND, AHMEDABAD,
 INDIA
Laboratory: FPRC: ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND, AHMEDABAD,
 INDIA
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE S.A.,
 VAN DER HOFF PARK,
 POTCHEFSTROOM

Shelf-life: 24 months (Provisional)
Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 42/2.5/0278
Name of medicine: ZYDUS TOPIRAMATE 50

Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 TOPIRAMATE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ZYDUS HEALTHCARE S.A.
 (PTY) LTD
Manufacturer: ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND, AHMEDABAD,
 INDIA
Packer: ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND, AHMEDABAD,
 INDIA
Laboratory: FPRC/FPRR ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND, AHMEDABAD,
 INDIA
 RESEARCH INSTITUTE
 FOR INDUSTRIAL
 PHARMACY, NORTH-WEST
 UNIVERSITY,
 POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE S.A.,
 VAN DER HOFF PARK,
 POTCHEFSTROOM

Shelf-life: 24 months (Provisional)
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/2.5/0279
Name of medicine: ZYDUS TOPIRAMATE
 100

Dosage form: TABLET
Active ingredients: EACH TABLET
 CONTAINS:
 TOPIRAMATE
 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ZYDUS HEALTHCARE
 S.A. (PTY) LTD
Manufacturer: ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND,
 AHMEDABAD, INDIA
Packer: ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND,
 AHMEDABAD, INDIA
Laboratory: FPRC/FPRR ZYDUS CADILA
 HEALTHCARE LTD,
 SANAND,
 AHMEDABAD, INDIA
 RESEARCH
 INSTITUTE FOR
 INDUSTRIAL
 PHARMACY, NORTH-
 WEST UNIVERSITY,
 POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE
 S.A., VAN DER HOFF
 PARK,
 POTCHEFSTROOM

Shelf-life: 24 months (Provisional)
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/2.6.5/0284
Name of medicine: INVEGA 3 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PALIPERIDONE 3,0 mg

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

Manufacturer: ALZA CORPORATION,
VACAVILLE, CALIFORNIA,
USA

Packer: JANSSEN-CILAG SpA,
BORGO SAN MICHELE,
LATINA, ITALY

Laboratory: FPRC ALZA CORPORATION,
VACAVILLE, CALIFORNIA,
USA
JANSSEN-CILAG SpA,
BORGO SAN MICHELE,
LATINA, ITALY

FPRR: JANSSEN
PHARMACEUTICA,
WOODMEAD, SANDTON

Shelf-life: 24 months
Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 42/2.6.5/0285
Name of medicine: INVEGA 6 mg
Dosage form: TABLET
Active ingredients: EACH TABLET
CONTAINS:
PALIPERIDONE 6,0
mg

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

Manufacturer: ALZA
CORPORATION,
VACAVILLE,
CALIFORNIA, USA

Packer: JANSSEN-CILAG
SpA, BORGO SAN
MICHELE, LATINA,
ITALY

Laboratory: FPRC/FPRR: ALZA
CORPORATION,
VACAVILLE,
CALIFORNIA, USA
JANSSEN-CILAG
SpA, BORGO SAN
MICHELE, LATINA,
ITALY

FPRR: JANSSEN
PHARMACEUTICA,
WOODMEAD,
SANDTON

Shelf-life: 24 months
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/2.6.5/0286
Name of medicine: INVEGA 9 mg
Dosage form: TABLET
Active ingredients: EACH TABLET
CONTAINS:
PALIPERIDONE 9,0 mg

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

Manufacturer: ALZA CORPORATION,
VACAVILLE,
CALIFORNIA, USA

Packer: JANSSEN-CILAG SpA,
BORGO SAN MICHELE,
LATINA, ITALY

Laboratory: FPRC/FPRR: ALZA CORPORATION,
VACAVILLE,
CALIFORNIA, USA
JANSSEN-CILAG SpA,
BORGO SAN MICHELE,
LATINA, ITALY

FPRR: JANSSEN
PHARMACEUTICA,
WOODMEAD, SANDTON

Shelf-life: 24 months
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/2.6.5/0287
 Name of medicine: INVEGA 12 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PALIPERIDONE 12,0 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA

Packer: JANSSEN-CILAG SpA, BORGO SAN MICHELE, LATINA, ITALY

Laboratory: FPRC/FPRR: ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA
 JANSSEN-CILAG SpA, BORGO SAN MICHELE, LATINA, ITALY

FPRR: JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON

Shelf-life: 24 months

Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 42/7.3/0353
 Name of medicine: ADCO-SUMATRIPTAN 100
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SUMATRIPTAN
 SUCCINATE EQUIVALENT TO
 SUMATRIPTAN 100,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: LABORATORIOS LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN

Packer: LABORATORIOS LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN

Laboratory: FPRC: LABORATORIOS LICONSA SA, AZUQUECA DE HENARES, GUADALAJARA, SPAIN

FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
 ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND

Shelf-life: 24 months

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/7.3/0367
 Name of medicine: SUROGRAN 50 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SUMATRIPTAN SUCCINATE EQUIVALENT TO
 SUMATRIPTAN 50,0 mg

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

Applicant: AUROBINDO PHARMA (PTY) LTD

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

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

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

FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/7.3/0368
 Name of medicine: SUROGRAN 100 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SUMATRIPTAN SUCCINATE
 EQUIVALENT TO
 SUMATRIPTAN 100,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR, RANGA
 REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR, RANGA
 REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR, RANGA
 REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 42/20.2.8/0729
 Name of medicine: ATRIPLA
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 EFAVIRENZ 600,0 mg
 EMTRICITABINE 200,0 mg
 TENOFOVIR DISOPROXIL
 FUMARATE 300,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: MSD (PTY) LTD
 Manufacturer: PATHEON INC,
 MISSISSAUGA, ONTARIO,
 CANADA
 Packer: PATHEON INC,
 MISSISSAUGA, ONTARIO,
 CANADA
 MERCK SHARP & DOHME
 B.V., HAARLEM, THE
 NETHERLANDS
 MSD, HALFWAY
 HOUSE, RSA
 Laboratory: FPRC: PATHEON INC,
 MISSISSAUGA, ONTARIO,
 CANADA
 PATHEON INC,
 BURLINGTON, ONTARIO,
 CANADA
 FPRC/FPRR: MSD, HALFWAY
 HOUSE, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/20.2.8/1011
 Name of medicine: DYNAVIR CAPSULES
 30 mg
 Dosage form: CAPSULES
 Active ingredients: EACH CAPSULE
 CONTAINS:
 STAVUDINE 30,0 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
 FPRR: AUROBINDO PHARMA,
 MEYERSDAL
 JOHANNESBURG
 Shelf-life: 24 months (provisional)
 Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 42/20.2.8/1012
Name of medicine: DYNAVIR CAPSULES 40 mg
Dosage form: CAPSULES
Active ingredients: EACH CAPSULE CONTAINS:
 STAVUDINE 40,0 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: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY, ANDHRA
 PRADESH, INDIA
FPRC:

FPRC/FPRR: AUROBINDO PHARMA,
 MEYERSDAL
 JOHANNESBURG

Shelf-life: 24 months (provisional)
Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 43/2.2/0064
Name of medicine: SEDASTELL 3,75 mg
Dosage form: TABLET
Active ingredients: EACH TABLET
 CONTAINS:
 ZOPICLONE 3,75 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUSTELL
 LABORATORIES (PTY)
 LTD

Manufacturer: IPCA LABORATORIES
 LTD, SILVASSA, DADRA &
 NAGAR HAVELI, INDIA

Packer: IPCA LABORATORIES
 LTD, SILVASSA, DADRA &
 NAGAR HAVELI, INDIA

Laboratory: FPRC: IPCA LABORATORIES
 LTD, SILVASSA, DADRA &
 NAGAR HAVELI, INDIA
 SABS PHARMACEUTICAL
 CHEMISTRY
 LABORATORY,
 GROENKLOOF,
 PRETORIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG

FPRR: AUSTELL
 LABORATORIES,
 SPRINGFIELD,
 JOHANNESBURG

Shelf-life: 24 months (Provisional)
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 43/2.2/0065
Name of medicine: SEDASTELL 7,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET
 CONTAINS:
 ZOPICLONE 7,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUSTELL
 LABORATORIES (PTY)
 LTD

Manufacturer: IPCA LABORATORIES
 LTD, SILVASSA,
 DADRA & NAGAR
 HAVELI, INDIA

Packer: IPCA LABORATORIES
 LTD, SILVASSA,
 DADRA & NAGAR
 HAVELI, INDIA

Laboratory: FPRC: IPCA LABORATORIES
 LTD, SILVASSA,
 DADRA & NAGAR
 HAVELI, INDIA
 SABS
 PHARMACEUTICAL
 CHEMISTRY
 LABORATORY,
 GROENKLOOF,
 PRETORIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG

FPRC/FPRR: AUSTELL
 LABORATORIES,
 SPRINGFIELD,
 JOHANNESBURG

Shelf-life: 24 months (Provisional)
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number:	43/2.2/0068
Name of medicine:	AUSTOVANE 3,75 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOPICLONE 3,75 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	1 OCTOBER 2010

MRF15

Registration number:	43/2.2/0067
Name of medicine:	AUSTOVANE 7,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOPICLONE 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	1 OCTOBER 2010

MRF 15

Registration number:	43/20.2.8/0130
Name of medicine:	ASPEN TENOFOVIR & EMTRICITABINE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORTELIZABETH
Packer:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA CARDINAL HEALTH GmbH, SCHORNDORF, GERMANY GILEAD SCIENCES INC, SAN DIMAS, CALIFORNIA, USA GILEAD SCIENCES LTD, BLACKROCK, DUBLIN, IRELAND PHARMACARE LTD, KORSTEN, PORTELIZABETH
Laboratory: FPRC:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA GILEAD SCIENCES INC, SAN DIMAS, CALIFORNIA, USA GILEAD SCIENCES LTD, BLACKROCK, DUBLIN, IRELAND PATHEON INC, BURLINGTON, ONTARIO, CANADA 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
Date of registration:	1 OCTOBER 2010

MRF 15

Registration number: 43/17.1/0324
Name of medicine: ASPEN VECURONIUM 10 mg

Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 VECURONIUM BROMIDE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
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
 SABS PHARMACEUTICAL CHEMISTRY
 LABORATORY, GROENKLOOF, PRETORIA
 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: 1 OCTOBER 2010

MRF15

Registration number: 43/17.1/0325
Name of medicine: ASPEN VECURONIUM 20
 mg

Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 VECURONIUM BROMIDE
 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
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
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 M&L LABORATORY
 SERVICES, ORMONDE,
 JOHANNESBURG
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM

FPRC/FPRR: PHARMACARE LTD,
 KORSTEN, PORT
 ELIZABETH

Shelf-life: PHARMACARE LTD,
 WOODMEAD, SANDTON

Date of registration: 24 months (Provisional)

 1 OCTOBER 2010

MRF 15

Registration number: 43/20.2.8/0362
Name of medicine: COMBOZIL 150/300

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: BLISS PHARMACEUTICALS cc
Manufacturer: HETERO DRUG LTD,
 JEEDIMETLA HYDERABAD,
 INDIA

Packer: HETERO DRUG LTD,
 JEEDIMETLA HYDERABAD,
 INDIA

Laboratory: FPRC: HETERO DRUG LTD,
 JEEDIMETLA HYDERABAD,
 INDIA

FPRR: BLISS PHARMACEUTICALS,
 WOODMEAD, SANDTON

Shelf-life: 24 months (Provisional)

Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 43/20.2.8/0363
 Name of medicine: HEVAZ 600

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: BLISS PHARMACEUTICALS
 cc
 Manufacturer: HETERO DRUG LTD,
 JEEDIMETLA HYDERABAD,
 INDIA
 Packer: HETERO DRUG LTD,
 JEEDIMETLA HYDERABAD,
 INDIA

Laboratory: FPRC: HETERO DRUG LTD,
 JEEDIMETLA HYDERABAD,
 INDIA

FPRR: BLISS PHARMACEUTICALS,
 WOODMEAD, SANDTON

Shelf-life: 24 months (Provisional)
 Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 43/20.2.8/0387
 Name of medicine: PROPAN ABACAVIR 300
 mg 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: 1 OCTOBER 2010

MRF 15

Registration number: 43/10.2.1/0544
 Name of medicine: IPVENT 40 HFA

Dosage form: INHALER
 Active ingredients: EACH ACTUATION CONTAINS:
 IPRATROPIUM BROMIDE 40,0
 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: CIPLA MEDPRO (PTY) LTD
 Manufacturer: CIPLA LTD, UNIT II, VERNA,
 GOA, INDIA
 Packer: CIPLA LTD, UNIT II, VERNA,
 GOA, INDIA
 Laboratory: FPRC: CIPLA LTD, UNIT II, VERNA,
 GOA, INDIA
 FPRR: CIPLA MEDPRO, ROSENPARK,
 BELLVILLE

Shelf-life: 24 months (Provisional)
 Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 43/20.1.1/0767
Name of medicine: RAN MEROPENEM 500
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 MEROPENEM 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: RANBAXY LABORATORIES
 LTD, DEWAS, MADHYA
 PRADESH, INDIA
Packer: RANBAXY LABORATORIES
 LTD, DEWAS, MADHYA
 PRADESH, INDIA
Laboratory: RANBAXY LABORATORIES
 LTD, DEWAS, MADHYA
 PRADESH, INDIA
FPRC: KHULULEKANI
 LABORATORY SERVICES,
 COVENTRY PARK,
 MIDRAND
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
FPRR: RANBAXY (S.A.),
 CENTURION, RSA
Shelf-life: 24 months
Date of registration: 1 OCTOBER 2010

MRF15

Registration number: 43/20.1.1/0768
Name of medicine: RAN MEROPENEM 1 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 MEROPENEM 1 000,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (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 (S.A.), CENTURION,
 RSA
Shelf-life: 24 months
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number: 43/20.1.1/0769
Name of medicine: MERCIDE 500
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 MEROPENEM 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (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 (S.A.), CENTURION,
 RSA
Shelf-life: 24 months
Date of registration: 1 OCTOBER 2010

MRF 15

Registration number:	43/20.1.1/0770
Name of medicine:	MERCIDE 1 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (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 (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	1 OCTOBER 2010

MRF 15

Registration number: A38/34/0404
 Name of medicine: NIQUITIN CQ LOZENGE 2 mg
 Dosage form: LOZENGE
 Active ingredients: EACH LOZENGE CONTAINS:
 NICOTINE POLACRILEX
 EQUIVALENT TO NICOTINE
 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GROUP LABORATORIES
 S.A. (PTY) LTD
 Manufacturer: GLAXOSMITHKLINE
 CONSUMER HEALTHCARE
 LP, AIKEN, SOUTH
 CAROLINA, USA
 Packer: SMITHKLINE BEECHAM plc,
 CRAWLEY, WEST SUSSEX,
 UK
 GLAXOSMITHKLINE SOUTH
 AFRICA, EPPING
 INDUSTRIA, CAPE TOWN
 Laboratory: FPRC: GLAXOSMITHKLINE
 CONSUMER HEALTHCARE
 LP, AIKEN, SOUTH
 CAROLINA, USA
 SMITHKLINE BEECHAM plc,
 CRAWLEY, WEST SUSSEX,
 UK
 GLAXOSMITHKLINE SOUTH
 AFRICA (PTY) LIMITED,
 EPPING INDUSTRIA, CAPE
 TOWN
 FPRR: GROUP LABORATORIES
 S.A, EPPING, CAPE TOWN,
 RSA
 Shelf-life: 24 months
 Date of registration: 28 November 2010

MRF15

Registration number: A38/34/0405
 Name of medicine: NIQUITIN CQ LOZENGE
 4 mg
 Dosage form: LOZENGE
 Active ingredients: EACH LOZENGE
 CONTAINS:
 NICOTINE POLACRILEX
 EQUIVALENT TO
 NICOTINE 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GROUP LABORATORIES
 S.A. (PTY) LTD
 Manufacturer: GLAXOSMITHKLINE
 CONSUMER
 HEALTHCARE LP, AIKEN,
 SOUTH CAROLINA, USA
 Packer: SMITHKLINE BEECHAM
 plc, CRAWLEY, WEST
 SUSSEX, UK
 GLAXOSMITHKLINE
 SOUTH AFRICA, EPPING
 INDUSTRIA, CAPE TOWN
 Laboratory: FPRC: GLAXOSMITHKLINE
 CONSUMER
 HEALTHCARE LP, AIKEN,
 SOUTH CAROLINA, USA
 SMITHKLINE BEECHAM
 plc, CRAWLEY, WEST
 SUSSEX, UK
 GLAXOSMITHKLINE
 SOUTH AFRICA (PTY)
 LIMITED, EPPING
 INDUSTRIA, CAPE TOWN
 FPRR: GROUP LABORATORIES
 S.A, EPPING, CAPE
 TOWN, RSA
 Shelf-life: 24 months
 Date of registration: 28 November 2010

MRF 15

Registration number: A40/20.2.8/0311
 Name of medicine: ASPEN LAMIVUDINE & ZIDOVUDINE
 COMBIPACK
 Dosage form: TABLET
 Active ingredients: EACH COMBIPACK CONTAINS:
 ASPEN LAMIVUDINE TABLETS
 CONTAINING:
 LAMIVUDINE 150,0
 mg
 ASPEN ZIDOVUDINE TABLETS
 CONTAINING:
 ZIDOVUDINE 300,0 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
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY, GROENKLOOF,
 PRETORIA
 ASPEN PHARMACARE, WILSONIA, EAST
 LONDON
 FPRC/FPRR: PHARMACARE LTD, KORSTEN,
 PORT ELIZABETH
 FPRR: PHARMACARE LTD, WOODMEAD,
 SANDTON
 Shelf-life: 24 months (Provisional)
 Date of registration: 28 NOVEMBER 2010

MRF 15

Registration number:	A40/5.2/0392
Name of medicine:	RANTRAL MR 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALFUZOSIN HYDROCHLORIDE 10,0 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, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY SA, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 NOVEMBER 2010

MRF15

Registration number:	41/1.2/0048
Name of medicine:	DETRAX 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 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:	26 NOVEMBER 2010

MRF 15

Registration number:	41/1.2/0047
Name of medicine:	DETRAX 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 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:	26 NOVEMBER 2010

MRF 15

Registration number:	41/8.4/0211
Name of medicine:	VOLUVEN 6 % BALANCED
Dosage form:	INFUSION
Active ingredients:	EACH 1 000,0 ml SOLUTION CONTAINS: METASTARCH 60,0 g SODIUM ACETATE TRIHYDRATE 4,63 g SODIUM CHLORIDE 6,02 g POTASSIUM CHLORIDE 0,30 g MAGNESIUM CHLORIDE 0,30 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA
Packer:	FRESENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA
Laboratory: FPRC:	FRESENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA BODENE 1/2 INTRAMED, KORSTEN, PORT ELIZABETH KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	FRESENIUS KABI SA, HALFWAY HOUSE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 NOVEMBER 2010

MRF15

Registration number:	41/5.7.2/0295
Name of medicine:	GRANITRIL INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	41/11.4.3/0344
Name of medicine:	HEXAL PANTOPRAZOLE IV
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	LEK D.D., VEROVSKOVA, LJUBLJANA, SLOVENIA
Packer:	LEK D.D., VEROVSKOVA, LJUBLJANA, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	LEK D.D., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG NOVARTIS, SPARTAN, KEMPTON PARK
FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number: 41/11.4.3/0345
Name of medicine: TOPRALOCIV

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
PANTOPRAZOLE SODIUM
SESQUIHYDRATE
EQUIVALENT TO
PANTOPRAZOLE 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD

Manufacturer: LEK D.D., VEROVSKOVA,
LJUBLJANA, SLOVENIA

Packer: LEK D.D., VEROVSKOVA,
LJUBLJANA, SLOVENIA
DIVPHARM
MANUFACTURING &
PACKAGING, LONGDALE,
JOHANNESBURG
TECHNIKON
LABORATORIES,
ROBERTVILLE, FLORIDA
NOVARTIS, SPARTAN,
KEMPTON PARK

Laboratory:FPRC : LEK D.D., VEROVSKOVA,
LJUBLJANA, SLOVENIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG
NOVARTIS, SPARTAN,
KEMPTON PARK

FPRR: SANDOZ S.A., SPARTAN,
KEMPTON PARK

Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 41/5.7.2/0364
Name of medicine: GRANITRIL 1 mg TABLET

Dosage form: TABLET

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA

Packer: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA

Laboratory: FPRC: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR PHARMAPLAN, MIDRAND,
RSA

Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 41/5.7.1/0420
Name of medicine: SINUTAB SINUS
ALLERGY
EFFERVESCENT

Dosage form: TABLET

Active ingredients: EACH TABLET
CONTAINS:
CETIRIZINE
DIHYDROCHLORIDE
10,0 mg

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

Manufacturer: HOCHLAND PHARMA
GmbH,
WOLFRATSHAUSEN,
GERMANY

Packer: HOCHLAND PHARMA
GmbH,
WOLFRATSHAUSEN,
GERMANY

Laboratory: FPRC HOCHLAND PHARMA
GmbH,
WOLFRATSHAUSEN,
GERMANY
SABS
PHARMACEUTICAL
CHEMISTRY
LABORATORY,
GROENKLOOF,
PRETORIA

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

Shelf-life: 36 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 41/34/0573
Name of medicine: CHAMPIX 0,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VARENICLINE TARTRATE
EQUIVALENT TO
VARENICLINE 0,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PFIZER LABORATORIES
(PTY) LTD
Manufacturer: PFIZER MANUFACTURING
DEUTSCHLAND,ILLERTISSEN,
GERMANY
Packer: PFIZER MANUFACTURING
DEUTSCHLAND,ILLERTISSEN,
GERMANY

Laboratory: PFIZER MANUFACTURING
FPRC: DEUTSCHLAND,ILLERTISSEN,
GERMANY
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
KHULULEKANI LABORATORY
SERVICES, COVENTRY PARK,
MIDRAND

FPRC/FPRR: PFIZER LABORATORIES,
RETREAT, CAPE TOWN

Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 41/34/0574
Name of medicine: CHAMPIX 1 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VARENICLINE TARTRATE
EQUIVALENT TO
VARENICLINE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PFIZER LABORATORIES
(PTY) LTD
Manufacturer: PFIZER MANUFACTURING
DEUTSCHLAND,ILLERTISSEN,
GERMANY
Packer: PFIZER MANUFACTURING
DEUTSCHLAND,ILLERTISSEN,
GERMANY

Laboratory: PFIZER MANUFACTURING
FPRC: DEUTSCHLAND,ILLERTISSEN,
GERMANY
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
KHULULEKANI LABORATORY
SERVICES, COVENTRY PARK,
MIDRAND

FPRR: PFIZER LABORATORIES,
RETREAT, CAPE TOWN

Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 41/10.2.1/0618
Name of medicine: SALBU-NEB 5
Dosage form: SOLUTION
Active ingredients: EACH 2,5 ml SOLUTION
CONTAINS:
SALBUTAMOL SULPHATE
EQUIVALENT TO
SALBUTAMOL 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ARROW PHARMA SOUTH
AFRICA (PTY) LTD
Manufacturer: LABORATOIRE UNITHER,
ZI LONGPRE, AMIENS,
FRANCE
Packer: LABORATOIRE UNITHER,
ZI LONGPRE, AMIENS,
FRANCE
TECHNIKON
LABORATORIES,
ROBERTVILLE, FLORIDA
DIVPHARM
MANUFACTURING &
PACKAGING, LONGDALE,
JOHANNESBURG

Laboratory: LABORATOIRE UNITHER,
FPRC: ZI LONGPRE, AMIENS,
FRANCE
TECHNIKON
LABORATORIES,
ROBERTVILLE, FLORIDA
M&L LABORATORY
SERVICES, ORMONDE,
JOHANNESBURG

FPRR: ARROW PHARMA S.A.,
WOODMEAD,
JOHANNESBURG

Shelf-life: 36 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number:	41/10.2.1/0619
Name of medicine:	SALBU-NEB 2,5
Dosage form:	SOLUTION
Active ingredients:	EACH 2,5 ml SOLUTION CONTAINS: SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	LABORATOIRE UNITHER, ZI LONGPRE, AMIENS, FRANCE
Packer:	LABORATOIRE UNITHER, ZI LONGPRE, AMIENS, FRANCE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	LABORATOIRE UNITHER, ZI LONGPRE, AMIENS, FRANCE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	ARROW PHARMA S.A., WOODMEAD, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	26 NOVEMBER 2010

MRF15

Registration number:	41/10.2.1/0699
Name of medicine:	TROPIVENT
Dosage form:	INHALER
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: IPRATROPIUM BROMIDE 250,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	LABORATOIRE UNITHER, ZI LONGPRE, AMIENS, FRANCE
Packer:	LABORATOIRE UNITHER, ZI LONGPRE, AMIENS, FRANCE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	LABORATOIRE UNITHER, ZI LONGPRE, AMIENS, FRANCE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	ARROW PHARMA SA, SANDOWN, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	41/2.1/0807
Name of medicine:	PE-ISOFBURANE
Dosage form:	LIQUID
Active ingredients:	EACH 1,0 ml LIQUID CONTAINS: ISOFLURANE 1,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACEUTICAL ENTERPRISES (PTY) LTD
Manufacturer:	HALOCARBON LABORATORIES, NORTH AUGUSTA, SOUTH CAROLINA, USA
Packer:	HALOCARBON LABORATORIES, NORTH AUGUSTA, SOUTH CAROLINA, USA PHARMACEUTICAL ENTERPRISES, N'DABENI, PINELANDS
Laboratory: FPRC:	HALOCARBON LABORATORIES, NORTH AUGUSTA, SOUTH CAROLINA, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	PHARMACEUTICAL ENTERPRISES, N'DABENI, PINELANDS
Shelf-life:	60 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number: 42/20.2.8/0069
 Name of medicine: MYLAN ACICLOVIR 250
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 ACICLOVIR SODIUM
 EQUIVALENT TO
 ACICLOVIR 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: XIXIA PHARMACEUTICALS
 (PTY) LTD
 Manufacturer: REIG JOFRE S.A., SAN JOAN
 DESPI, BARCELONA, SPAIN
 Packer: REIG JOFRE S.A., SAN JOAN
 DESPI, BARCELONA, SPAIN
 PHARMA-Q, INDUSTRIA-WEST,
 JOHANNESBURG
 Laboratory: FPRC: REIG JOFRE S.A., SAN JOAN
 DESPI, BARCELONA, SPAIN
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: XIXIA PHARMACEUTICALS,
 MODDERFONTEIN, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/20.2.8/0070
 Name of medicine: MYLAN ACICLOVIR 500
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 ACICLOVIR SODIUM
 EQUIVALENT TO
 ACICLOVIR 500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: XIXIA PHARMACEUTICALS
 (PTY) LTD
 Manufacturer: REIG JOFRE S.A., SAN JOAN
 DESPI, BARCELONA, SPAIN
 Packer: REIG JOFRE S.A., SAN JOAN
 DESPI, BARCELONA, SPAIN
 PHARMA-Q, INDUSTRIA-WEST,
 JOHANNESBURG
 Laboratory: FPRC: REIG JOFRE S.A., SAN JOAN
 DESPI, BARCELONA, SPAIN
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: XIXIA PHARMACEUTICALS,
 MODDERFONTEIN, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/34/0173
 Name of medicine: JMS BLOOD BAG CPD-
 SAGM
 Dosage form: BAG
 Active ingredients: EACH 100,0 ml
 SOLUTION CONTAINS:
 CPD SOLUTION:
 CITRIC ACID 0,299 g
 SODIUM CITRATE
 2,630 g
 MONOBASIC SODIUM
 PHOSPHATE 0,222 g
 DEXTROSE 2,550 g
 SAGM SOLUTION:
 DEXTROSE 0,900 g
 SODIUM CHLORIDE
 0,877 g
 MANNITOL 0,525 g
 ADENINE 0,0169 g

Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: MEDICINE DEVELOPERS
 INTERNATIONAL cc
 Manufacturer: JMS SINGAPORE PTE
 LTD, SINGAPORE
 Packer: JMS SINGAPORE PTE
 LTD, SINGAPORE
 Laboratory: FPRC: JMS SINGAPORE PTE
 LTD, SINGAPORE
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE,
 BOKSBURG
 FPRR: MEDICINE DEVELOPERS
 INTERNATIONAL,
 MENLO PARK,
 PRETORIA
 Shelf-life: 36 months
 Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/34/0174
 Name of medicine: JMS BLOOD BAG CPDA-1
 Dosage form: BAG
 Active ingredients: EACH 100,0 ml SOLUTION
 CONTAINS:
 CITRIC ACID 0,299 g
 SODIUM CITRATE 2,830 g
 MONOBASIC SODIUM
 PHOSPHATE 0,222 g
 DEXTROSE 3,190 g
 ADENINE 0,0275 g

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

Applicant: MEDICINE DEVELOPERS INTERNATIONAL cc

Manufacturer: JMS SINGAPORE PTE LTD, SINGAPORE

Packer: JMS SINGAPORE PTE LTD, SINGAPORE

Laboratory: FPRC: JMS SINGAPORE PTE LTD, SINGAPORE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: MEDICINE DEVELOPERS INTERNATIONAL, MENLO PARK, PRETORIA

Shelf-life: 36 months

Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/3.2/0235
 Name of medicine: OSTEONATE 70 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TRIHYDRATE
 MONOSODIUM
 ALENDRONATE
 EQUIVALENT TO
 ALENDRONIC ACID 70,0 mg

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: LABORATORIOS BELMAC SA, ZARAGOZA, SPAIN

Packer: LABORATORIOS BELMAC SA, ZARAGOZA, SPAIN

Laboratory: FPRC: LABORATORIOS BELMAC SA, ZARAGOZA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE BOKSBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA

FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 26 November 2010

MRF 15

Registration number: 42/21.5.4/0238
 Name of medicine: SALMEFLUT 25/50 INHALER
 Dosage form: INHALER
 Active ingredients: EACH ACTUATION PROVIDES:
 SALMETEROL XINAFOATE
 EQUIVALENT TO
 SALMETEROL 25,0 ug
 FLUTICASONE PROPIONATE 50,0 ug

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

Applicant: GROUP LABORATORIES SOUTH AFRICA (PTY) LTD

Manufacturer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE

Packer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
 GLAXOSMITHKLINE SA, EPPING, CAPE TOWN

Laboratory: FPRC: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE

FPRC/FPRR: GLAXOSMITHKLINE SA, EPPING, CAPE TOWN

FPRR: GROUP LABORATORIES SA, EPPING, CAPE TOWN

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/21.5.4/0239
Name of medicine: SALMEFLUT 25/125 INHALER
Dosage form: INHALER
Active ingredients: EACH ACTUATION PROVIDES: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 ug FLUTICASON PROPRIONATE 125,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
Packer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
Laboratory: FPRC: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
FPRC/FPRR: GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
FPRR: GROUP LABORATORIES SA, EPPING, CAPE TOWN
Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/21.5.4/0240
Name of medicine: SALMEFLUT 25/250 INHALER
Dosage form: INHALER
Active ingredients: EACH ACTUATION PROVIDES: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 ug FLUTICASON PROPRIONATE 250,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
Packer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
Laboratory: FPRC: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
FPRC/FPRR: GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
FPRR: GROUP LABORATORIES SA, EPPING, CAPE TOWN
Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/21.5.4/0244
Name of medicine: FOXAIR 25/50 INHALER
Dosage form: INHALER
Active ingredients: EACH ACTUATION PROVIDES: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 ug FLUTICASON PROPRIONATE 50,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GROUP LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
Packer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
Laboratory: FPRC: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
FPRC/FPRR: GLAXOSMITHKLINE SA, EPPING, CAPE TOWN
FPRR: GROUP LABORATORIES SA, EPPING, CAPE TOWN
Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/21.5.4/0245

Name of medicine: FOXAIR 25/125 INHALER

Dosage form: INHALER

Active ingredients: EACH ACTUATION PROVIDES: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 ug FLUTICASON PROPIONATE 125,0 ug

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

Applicant: GROUP LABORATORIES SOUTH AFRICA (PTY) LTD

Manufacturer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE

Packer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
GLAXOSMITHKLINE SA, EPPING, CAPE TOWN

Laboratory: FPRC: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE

FPRC/FPRR: GLAXOSMITHKLINE SA, EPPING, CAPE TOWN

FPRR: GROUP LABORATORIES SA, EPPING, CAPE TOWN

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/21.5.4/0246

Name of medicine: FOXAIR 25/250 INHALER

Dosage form: INHALER

Active ingredients: EACH ACTUATION PROVIDES: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 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 WELLCOME PRODUCTION, EVREUX, FRANCE

Packer: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE
GLAXOSMITHKLINE SA, EPPING, CAPE TOWN

Laboratory: FPRC: GLAXO WELLCOME PRODUCTION, EVREUX, FRANCE

FPRC/FPRR: GLAXOSMITHKLINE SA, EPPING, CAPE TOWN

FPRR: GROUP LABORATORIES SA, EPPING, CAPE TOWN

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/21.12/0259

Name of medicine: ACCORD-ANASTROZOLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg

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

Applicant: ACCORD HEALTHCARE (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA

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

Laboratory: FPRC INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: ACCORD HEALTHCARE, RIVONIA, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number:	42/21.12/0260
Name of medicine:	WINTHROP-ANASTROZOLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 NOVEMBER 2010

MRF15

Registration number:	42/2.6.5/0314
Name of medicine:	SCHIZOROL 0,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC:	SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
FPRC/FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	42/2.6.5/0315
Name of medicine:	SCHIZOROL 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC:	SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
FPRC/FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number: 42/2.6.5/0316

Name of medicine: SCHIZOROL 2

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 2,0 mg

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

Applicant: THEBE MEDICARE (PTY) LTD

Manufacturer: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE

Packer: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE

Laboratory: FPRC: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON

FPRC/FP RR: THEBE MEDICARE, NORTHRIDING, RANDBURG

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/2.6.5/0317

Name of medicine: SCHIZOROL 3

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 3,0 mg

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

Applicant: THEBE MEDICARE (PTY) LTD

Manufacturer: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE

Packer: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE

Laboratory: FPRC: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON

FPRC/FP RR: THEBE MEDICARE, NORTHRIDING, RANDBURG

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.6.5/0318

Name of medicine: SCHIZOROL 4

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 4,0 mg

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

Applicant: THEBE MEDICARE (PTY) LTD

Manufacturer: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE

Packer: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE

Laboratory: FPRC: SPECIFAR PHARMACEUTICALS S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON

FPRC/FP RR: THEBE MEDICARE, NORTHRIDING, RANDBURG

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.6.5/0319

Name of medicine: SCHIZOROL 6

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 6,0 mg

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

Applicant: THEBE MEDICARE (PTY) LTD

Manufacturer: SPECIFAR PHARMACEUTICALS S.A.,
VARVARA, ATHENS, GREECE

Packer: SPECIFAR PHARMACEUTICALS S.A.,
VARVARA, ATHENS, GREECE

Laboratory: FPRC: SPECIFAR PHARMACEUTICALS S.A.,
VARVARA, ATHENS, GREECE
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
LABORATORY & BIOLOGICAL
SERVICES, BRACKENHURST,
ALBERTON

FPRC/FPRR: THEBE MEDICARE, NORTHRIDING,
RANDBURG

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/2.6.5/0320

Name of medicine: SCHIZOROL 8

Dosage form: TABLET

Active ingredients: EACH TABLET
CONTAINS:
RISPERIDONE 8,0 mg

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

Applicant: THEBE MEDICARE
(PTY) LTD

Manufacturer: SPECIFAR
PHARMACEUTICALS
S.A., VARVARA,
ATHENS, GREECE

Packer: SPECIFAR
PHARMACEUTICALS
S.A., VARVARA,
ATHENS, GREECE

Laboratory: FPRC: SPECIFAR
PHARMACEUTICALS
S.A., VARVARA,
ATHENS, GREECE
CONSULTING
CHEMICAL
LABORATORIES,
ATLASVILLE,
BOKSBURG
LABORATORY &
BIOLOGICAL SERVICES,
BRACKENHURST,
ALBERTON

FPRC/FPRR: THEBE MEDICARE,
NORTHRIDING,
RANDBURG

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/21.12/0323

Name of medicine: ACCORD LETROZOLE 2,5
mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LETROZOLE 2,5 mg

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

Applicant: ACCORD HEALTHCARE
(PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS
LTD, MATODA, SANAND,
AHMEDABAD, INDIA

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

Laboratory: FPRC: INTAS PHARMACEUTICALS
LTD, MATODA, SANAND,
AHMEDABAD, INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: ACCORD HEALTHCARE,
RIVONIA, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/21.12/0324
Name of medicine: WINTHROP LETROZOLE 2,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: LETROZOLE 2,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ACCORD HEALTHCARE (PTY) LTD
Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/7.3/0356
Name of medicine: ACCORD SUMATRIPTAN 50 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ACCORD HEALTHCARE (PTY) LTD
Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/7.3/0357
Name of medicine: ACCORD SUMATRIPTAN 100 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ACCORD HEALTHCARE (PTY) LTD
Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/7.5/0358
 Name of medicine: PRAVACOR 40 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PRAVASTATIN SODIUM 40,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Laboratory: INTAS PHARMACEUTICALS LTD, MATODA, AHMEDABAD, INDIA
 FPRC: CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 26 November 2010

MRF15

Registration number: 42/7.5/0372
 Name of medicine: PRAVACOR 10 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PRAVASTATIN SODIUM 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, AHMEDABAD, INDIA
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 26 November 2010

MRF 15

Registration number: 42/7.5/0373
 Name of medicine: PRAVACOR 20 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 PRAVASTATIN SODIUM 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, AHMEDABAD, INDIA
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 26 November 2010

MRF 15

Registration number: 42/21.12/0430
 Name of medicine: WINTHROP BICALUTAMIDE 50 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 26 November 2010

MRF15

Registration number: 42/21.12/0431
 Name of medicine: ACCORD BICALUTAMIDE 50 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 26 November 2010

MRF 15

Registration number: 42/20.2.8/0563
 Name of medicine: VIRTRIUM 30/150/200
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg STAVUDINE 30,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: PHARMACARE LIMITED
 Manufacturer: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 Packer: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 Laboratory: FPRC: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA 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: 26 NOVEMBER 2010

MRF 15

Registration number:	42/20.2.8/0564
Name of medicine:	VIRTRIUM 40/150/200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg STAVUDINE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA 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:	26 NOVEMBER 2010

MRF15

Registration number:	42/10.2.1/0569
Name of medicine:	CIPLA-IPRATROPIUM 20 HFA
Dosage form:	INHALER
Active ingredients:	EACH ACTUATION CONTAINS: IPRATROPIUM BROMIDE 20,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT II, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT II, VERNA, GOA, INDIA
Laboratory:	FPRC: CIPLA LTD, UNIT II, VERNA, GOA, INDIA
	FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	42/7.1.3/0579
Name of medicine:	LOZAAN CO 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
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, VILLAGE MAIN, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number: 42/7.1.3/0580
Name of medicine: LOZAAN CO 100 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM
 100,0 mg
 HYDROCHLOROTHIAZIDE
 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: THEBE MEDICARE (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA,
 ATHENS, GREECE

Packer: SPECIFAR S.A., VARVARA,
 ATHENS, GREECE

Laboratory: SPECIFAR S.A., VARVARA,
 ATHENS, GREECE
FPRC: CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 LABORATORY &
 BIOLOGICAL SERVICES,
 BRACKENHURST,
 ALBERTON

FPRR: THEBE MEDICARE, VILLAGE
 MAIN, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/2.9/0748
Name of medicine: GSK REMIFENTANIL 1 mg
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 REMIFENTANIL
 HYDROCHLORIDE
 EQUIVALENT TO
 REMIFENTANIL 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GROUP LABORATORIES
 SOUTH AFRICA (PTY) LTD
Manufacturer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA. ITALY

Packer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA. ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN

Laboratory: FPRC: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA. ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN

FPRR: GROUP LABORATORIES
 S.A., EPPING, CAPE TOWN

Shelf-life: 18 months

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.9/0749
Name of medicine: GSK REMIFENTANIL 2 mg
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 REMIFENTANIL
 HYDROCHLORIDE
 EQUIVALENT TO
 REMIFENTANIL 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GROUP LABORATORIES
 SOUTH AFRICA (PTY) LTD
Manufacturer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA.
 ITALY

Packer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA.
 ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN

Laboratory: FPRC: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA.
 ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN

FPRR: GROUP LABORATORIES S.A.,
 EPPING, CAPE TOWN

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.9/0750
 Name of medicine: GSK REMIFENTANIL 5 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 REMIFENTANIL
 HYDROCHLORIDE
 EQUIVALENT TO
 REMIFENTANIL 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GROUP LABORATORIES
 SOUTH AFRICA (PTY) LTD
 Manufacturer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA, ITALY
 Packer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA, ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN
 Laboratory: FPRC: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA, ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN
 FPRR: GROUP LABORATORIES
 S.A., EPPING, CAPE TOWN
 Shelf-life: 36 months
 Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/2.9/0751
 Name of medicine: FORTIVA 1 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 REMIFENTANIL
 HYDROCHLORIDE
 EQUIVALENT TO
 REMIFENTANIL 1,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GROUP LABORATORIES
 SOUTH AFRICA (PTY) LTD
 Manufacturer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA, ITALY
 Packer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA, ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN
 Laboratory: FPRC: GLAXOSMITHKLINE
 MANUFACTURING S.p.A.,
 SAN POLO DI TORRILE,
 PARMA, ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN
 FPRR: GROUP LABORATORIES
 S.A., EPPING, CAPE TOWN
 Shelf-life: 18 months
 Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.9/0752
 Name of medicine: FORTIVA 2 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 REMIFENTANIL
 HYDROCHLORIDE
 EQUIVALENT TO
 REMIFENTANIL 2,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GROUP LABORATORIES
 SOUTH AFRICA (PTY) LTD
 Manufacturer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA,
 ITALY
 Packer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA,
 ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN
 Laboratory: FPRC: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA,
 ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN
 FPRR: GROUP LABORATORIES S.A.,
 EPPING, CAPE TOWN
 Shelf-life: 24 months
 Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.9/0753
 Name of medicine: FORTIVA 5 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 REMIFENTANIL
 HYDROCHLORIDE EQUIVALENT
 TO REMIFENTANIL 5,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: GROUP LABORATORIES SOUTH
 AFRICA (PTY) LTD
 Manufacturer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA,
 ITALY
 Packer: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA,
 ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN
 Laboratory: FPRC: GLAXOSMITHKLINE
 MANUFACTURING S.p.A., SAN
 POLO DI TORRILE, PARMA,
 ITALY
 GLAXOSMITHKLINE S.A.,
 EPPING, CAPE TOWN

 FPRR: GROUP LABORATORIES S.A.,
 EPPING, CAPE TOWN
 Shelf-life: 36 months
 Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/2.5/0827
 Name of medicine: PAMIRAM 25
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TOPIRAMATE 25,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: THEBE MEDICARE (PTY) LTD
 Manufacturer: PHARMATHEN S.A., PALLINI,
 ATTIKIS, GREECE
 Packer: PHARMATHEN S.A., PALLINI,
 ATTIKIS, GREECE
 Laboratory: FPRC: PHARMATHEN S.A., PALLINI,
 ATTIKIS, GREECE
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 SABS PHARMACEUTICAL
 CHEMICAL LABORATORY,
 GROENKLOOF, PRETORIA
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 CONSULTING
 MICROBIOLOGICAL
 LABORATORIES, MOREHILL,
 BENONI
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG

 FPRR: THEBE MEDICARE,
 NORTHRIDING, RANDBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.5/0828
 Name of medicine: PAMIRAM 50
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TOPIRAMATE 50,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: THEBE MEDICARE (PTY) LTD
 Manufacturer: PHARMATHEN S.A., PALLINI,
 ATTIKIS, GREECE
 Packer: PHARMATHEN S.A., PALLINI,
 ATTIKIS, GREECE
 Laboratory: FPRC: PHARMATHEN S.A., PALLINI,
 ATTIKIS, GREECE
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 SABS PHARMACEUTICAL
 CHEMICAL LABORATORY,
 GROENKLOOF, PRETORIA
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY, NORTH-
 WEST UNIVERSITY,
 POTCHEFSTROOM
 CONSULTING MICROBIOLOGICAL
 LABORATORIES, MOREHILL,
 BENONI
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG

 FPRR: THEBE MEDICARE, NORTHRIDING,
 RANDBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.5/0829
Name of medicine: PAMIRAM 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TOPIRAMATE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: THEBE MEDICARE (PTY)
LTD
Manufacturer: PHARMATHEN S.A.,
PALLINI, ATTIKIS, GREECE
Packer: PHARMATHEN S.A.,
PALLINI, ATTIKIS, GREECE
Laboratory: PHARMATHEN S.A.,
FPRC: PALLINI, ATTIKIS, GREECE
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG
SABS PHARMACEUTICAL
CHEMICAL LABORATORY,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
CONSULTING
MICROBIOLOGICAL
LABORATORIES,
MOREHILL, BENONI
M&L LABORATORY
SERVICES, ORMONDE,
JOHANNESBURG
FPRR: THEBE MEDICARE,
NORTHRIDING, RANDBURG
Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/2.5/0830
Name of medicine: PAMIRAM 200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TOPIRAMATE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: THEBE MEDICARE (PTY)
LTD
Manufacturer: PHARMATHEN S.A.,
PALLINI, ATTIKIS, GREECE
Packer: PHARMATHEN S.A.,
PALLINI, ATTIKIS, GREECE
Laboratory: PHARMATHEN S.A.,
FPRC: PALLINI, ATTIKIS, GREECE
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG
SABS PHARMACEUTICAL
CHEMICAL LABORATORY,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE
FOR INDUSTRIAL
PHARMACY, NORTH-WEST
UNIVERSITY,
POTCHEFSTROOM
CONSULTING
MICROBIOLOGICAL
LABORATORIES,
MOREHILL, BENONI
M&L LABORATORY
SERVICES, ORMONDE,
JOHANNESBURG
FPRR: THEBE MEDICARE,
NORTHRIDING,
RANDBURG
Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/5.7.2/0838
Name of medicine: BIQ DOMPERIDONE 10
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
DOMPERIDONE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BIOTECH LABORATORIES (PTY) LTD
Manufacturer: RIVOPHARM SA, MANNO,
SWITZERLAND
Packer: RIVOPHARM SA, MANNO,
SWITZERLAND
Laboratory: RIVOPHARM SA, MANNO,
FPRC: SWITZERLAND
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY, NORTH-
WEST UNIVERSITY, POTCHEFSTROOM
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
FPRR: BIOTECH LABORATORIES,
RANDJESPAK, MIDRAND
Shelf-life: 36 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/5.7.1/0849

Name of medicine: POLLENTYME ND

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DESLOMATADINE 5,0 mg

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: PHARMASCIENCE INC, MONTREAL,
QUEBEC, CANADA

Packer: PENDOPHARM INC, MONTREAL,
QUEBEC, CANADA
ROPACK INC, MONTREAL, QUEBEC,
CANADA
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE,
JOHANNESBURG
TECHNIKON LABORATORIES,
ROBERTVILLE, FLORIDA
PHARMACEUTICAL ENTERPRISES,
N'DABENI, KZN

Laboratory: FPRC: PHARMASCIENCE INC, MONTREAL,
QUEBEC, CANADA
PENDOPHARM INC, MONTREAL,
QUEBEC, CANADA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG

FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE

Shelf-life: 24 months

Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 42/3.2/1013

Name of medicine: ACCORD
ALENDRONATE 10

Dosage form: TABLET

Active ingredients: EACH TABLET
CONTAINS:
ALENDRONATE
SODIUM
EQUIVALENT TO
ALENDRONIC ACID
10,0 mg

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

Applicant: ACCORD
HEALTHCARE (PTY)
LTD

Manufacturer: INTAS
PHARMACEUTICALS
LTD, MATODA,
SANAND,
AHMEDABAD, INDIA

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

Laboratory: FPRC: INTAS
PHARMACEUTICALS
LTD, MATODA,
SANAND,
AHMEDABAD, INDIA
CONSULTING
CHEMICAL
LABORATORIES,
ATLASVILLE,
BOKSBURG

FPRR: ACCORD
HEALTHCARE,
RIVONIA, RSA

Shelf-life: 24 months
(Provisional)

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/3.2/1014

Name of medicine: ACCORD ALENDRONATE
70

Dosage form: TABLET

Active ingredients: EACH TABLET
CONTAINS:
ALENDRONATE SODIUM
EQUIVALENT TO
ALENDRONIC ACID 70,0
mg

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

Applicant: ACCORD HEALTHCARE
(PTY) LTD

Manufacturer: INTAS
PHARMACEUTICALS
LTD, MATODA, SANAND,
AHMEDABAD, INDIA

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

Laboratory: FPRC: INTAS
PHARMACEUTICALS
LTD, MATODA, SANAND,
AHMEDABAD, INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: ACCORD HEALTHCARE,
RIVONIA, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number:	42/3.2/1015
Name of medicine:	OSTENA 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONIC ACID 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 NOVEMBER 2010

MRF15

Registration number:	42/3.2/1018
Name of medicine:	OSTENA 70
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	42/20.2.8/1020
Name of medicine:	TAMIFLU 30 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: OSELTAMIVIR 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	F. HOFFMAN-LA ROCHE LTD, BASEL, SWITZERLAND
Packer:	F. HOFFMAN-LA ROCHE LTD, BASEL, SWITZERLAND F. HOFFMAN-LA ROCHE LTD, KAISERAUGST, SWITZERLAND ROCHE PRODUCTS, ISANDO, RSA DIVPHARM MANUFACTURING & PACKAGING LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC: F. HOFFMAN-LA ROCHE LTD, BASEL, SWITZERLAND
	FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	60 months
Date of registration:	26 November 2010

MRF 15

Registration number: 42/20.2.8/1021
Name of medicine: TAMIFLU 45 mg

Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
 OSELTAMIVIR 45,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ROCHE PRODUCTS (PTY) LTD
Manufacturer: F. HOFFMAN-LA ROCHE LTD, BASEL, SWITZERLAND
Packer: F. HOFFMAN-LA ROCHE LTD, BASEL, SWITZERLAND
 F. HOFFMAN-LA ROCHE LTD, KAISERAUGST, SWITZERLAND
 ROCHE PRODUCTS, ISANDO, RSA
 DIVPHARM MANUFACTURING & PACKAGING LONGDALE, JOHANNESBURG, RSA

Laboratory: F. HOFFMAN-LA ROCHE LTD, BASEL, SWITZERLAND
FPRC:

FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA

Shelf-life: 60 months
Date of registration: 26 November 2010

MRF15

Registration number: 43/5.7.2/0001
Name of medicine: IVEMEND

Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 FOSAPREPITANT
 DIMEGLUMINE
 EQUIVALENT TO FOSAPREPITANT 115,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: MSD (PTY) LTD
Manufacturer: DSM PHARMACEUTICALS, GREENVILLE, NORTH CAROLINA, USA
 DSM PHARMACEUTICALS, GREENVILLE, NORTH CAROLINA, USA
 MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS
 MERCK & CO INC, WEST POINT, PENNSYLVANIA, USA
 MSD, HALFWAY HOUSE, RSA

Laboratory: FPRC: DSM PHARMACEUTICALS, GREENVILLE, NORTH CAROLINA, USA
 MERCK & CO INC, WEST POINT, PENNSYLVANIA, USA

FPRC/FPRR: MSD, HALFWAY HOUSE, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 43/20.2.6/0225
Name of medicine: COARTEM 20 mg/120 mg DISPERSIBLE TABLETS

Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 ARTEMETHER 20,0 mg
 LUMEFANTRINE 120,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer: NOVARTIS PHARMACEUTICALS, SUFFERN, NEW YORK, USA
Packer: NOVARTIS PHARMACEUTICALS, SUFFERN, NEW YORK, USA
 BEIJING NOVARTIS PHARMA LTD, BEIJING, CHINA
 CATALENT PHARMA SOLUTIONS, PHILADELPHIA, PA, USA
 ANDERSON PACKAGING INC, ROCKFORD, ILLINOIS, USA
 SHARP CORPORATION, CONSHOHOKEN, PA, USA
 NOVARTIS SA, SPARTAN, KEMPTON PARK

Laboratory: FPRC: NOVARTIS PHARMACEUTICALS, SUFFERN, NEW YORK, USA
 BEIJING NOVARTIS PHARMA LTD, BEIJING, CHINA
 M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG

FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK

Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 43/31/0309
Name of medicine: REPLAGAL
Dosage form: INFUSION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 AGALSIDASE ALFA 1,0 mg

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

Manufacturer: CHESAPEAKE BIOLOGICAL
 LABORATORIES, BALTIMORE,
 MARYLAND, USA
 BAXTER PHARMACEUTICAL
 SOLUTIONS, BLOOMINGTON, INDIANA,
 USA

Packer: CHESAPEAKE BIOLOGICAL
 LABORATORIES, BALTIMORE,
 MARYLAND, USA
 BAXTER PHARMACEUTICAL
 SOLUTIONS, BLOOMINGTON, INDIANA,
 USA
 EMINENT SERVICES CORPORATION,
 FREDERICK, MARYLAND, USA
 INPAC AB, LUND, SWEDEN

Laboratory: FPRC: CHESAPEAKE BIOLOGICAL
 LABORATORIES, BALTIMORE,
 MARYLAND, USA
 BAXTER PHARMACEUTICAL
 SOLUTIONS, BLOOMINGTON, INDIANA,
 USA
 SHIRE, CAMBRIDGE, MASSACHUSETS,
 USA
 SHIRE, LEXINGTON, MASSACHUSETS,
 USA

FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 43/3.2/0751
Name of medicine: DRL ALENDRONATE 70
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 ALENDRONATE SODIUM
 EQUIVALENT TO
 ALENDRONIC ACID 70,0
 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 DISTRICT,
 ANDHRA PRADESH, INDIA

Packer: DR REDDY'S
 LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT,
 ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS,
 IRENE, CENTURION
 TECHNIKON
 LABORATORIES,
 ROBERTVILLE, FLORIDA
 DIVPHARM
 MANUFACTURING &
 PACKAGING, LONGDALE,
 JOHANNESBURG

Laboratory: FPRC: DR REDDY'S
 LABORATORIES LTD,
 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
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 43/3.2/0752
Name of medicine: DENFOS 70
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 ALENDRONATE SODIUM
 EQUIVALENT TO
 ALENDRONIC ACID 70,0 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
 DISTRICT, ANDHRA
 PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES
 LTD, QUTHUBULLAPUR
 MANDAL, RANGA REDDY
 DISTRICT, ANDHRA
 PRADESH, INDIA
 DRA PHARMACEUTICALS,
 IRENE, CENTURION
 TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 DIVPHARM MANUFACTURING
 & PACKAGING, LONGDALE,
 JOHANNESBURG

Laboratory: FPRC: DR REDDY'S LABORATORIES
 LTD, 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
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number:	44/30.1/0002
Name of medicine:	PREVENAR 13
Dosage form:	SUSPENSION FOR INJECTION
Active ingredients:	EACH 0.5 ml DOSE CONTAINS: SACCHARIDE FOR SEROTYPES 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F 2.2 µg SACCHARIDE FOR SEROTYP 6B 4.4 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	WYETH PHARMACEUTICALS INC, PEARL RIVER, NEW YORK, USA BAXTER BIOPHARMA SOLUTIONS LLC, BLOOMINGTON, USA
Packer:	WYETH PHARMACEUTICALS, HAVANT, NEW HAMPSHIRE, UK
Packer (secondary):	WYETH PHARMACEUTICALS INC, PEARL RIVER, NEW YORK, USA BAXTER PHARMACEUTICAL SOLUTIONS LLC, BLOOMINGTON, USA
FPRC:	WYETH PHARMACEUTICALS, HAVANT, NEW HAMPSHIRE, UK NATIONAL CONTROL LABORATORY, UNIVERSITY OF THE ORANGE FREE STATE, BLOEMFONTEIN WYETH PHARMACEUTICALS INC, PEARL RIVER, NEW YORK, USA WYETH MEDICA IRELAND, DUBLIN, IRELAND BAXTER PHARMACEUTICAL SOLUTIONS LLC, BLOOMINGTON, USA
FPRR:	PFIZER LABORATORIES, SANDTON RSA
Shelf-life:	24 months (provisional) at 2 - 8 °C
Date of registration:	26 NOVEMBER 2010

MRF15

Registration number:	44/20.2.8/0210
Name of medicine:	TRILAMSTAN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150.0 mg STAVUDINE 30.0 mg NEVIRAPINE 200.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	44/20.2.8/0211
Name of medicine:	ADCO LAMIVUDINE, STAVUDINE & NEVIRAPINE 150 mg/40 mg/200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150.0 mg STAVUDINE 40.0 mg NEVIRAPINE 200.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number: 44/20.2.8/0212
Name of medicine: TRI-NESTLAM 150/30/200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LAMIVUDINE 150,0 mg
 STAVUDINE 30,0 mg
 NEVIRAPINE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
 ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
 ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
FPRC:
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
 ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF15

Registration number: 44/20.2.8/0213
Name of medicine: TRI-NESTLAM 150/40/200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LAMIVUDINE 150,0 mg
 STAVUDINE 40,0 mg
 NEVIRAPINE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
 ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
 ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
FPRC:
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
 ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 44/20.2.8/0214
Name of medicine: TRI-STARIELAM 150/30/200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LAMIVUDINE 150,0 mg
 STAVUDINE 30,0 mg
 NEVIRAPINE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
 ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
 ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
FPRC:
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
 ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number:	44/20.2.8/0215
Name of medicine:	TRI-STARIELAM 150/40/200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg STAVUDINE 40,0 mg NEVIRAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory:	FPRC: HETERO DUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
	FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
	FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number: 44/20.2.8/0215
Name of medicine: TRI-STARIELAM 150/40/200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LAMIVUDINE 150,0 mg
 STAVUDINE 40,0 mg
 NEVIRAPINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: HETERO DUGS LTD, UNIT III,
 JEEDIMETLA, HYDERABAD,
 INDIA
 ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
Packer: HETERO DUGS LTD, UNIT III,
 JEEDIMETLA, HYDERABAD,
 INDIA
 ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON

Laboratory: HETERO DUGS LTD, UNIT III,
 JEEDIMETLA, HYDERABAD,
 INDIA
FPRC:

FPRC/FPRR: ADCOCK INGRAM
 HEALTHCARE, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM LTD,
 AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD,
 ERAND GARDENS, MIDRAND

Shelf-life: 24 months
Date of registration: 26 NOVEMBER 2010

MRF 15

Registration number: 42/2.5/0840
Name of medicine: ZEPTOL 200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 CARBAMAZEPINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL
 INDUSTRIES LTD, SILVASSA, DADRA
 & NAGAR HAVELI, INDIA

Packer: SUN PHARMACEUTICAL
 INDUSTRIES LTD, SILVASSA, DADRA
 & NAGAR HAVELI, INDIA

Laboratory: FPRC: SUN PHARMACEUTICAL
 INDUSTRIES LTD, SILVASSA, DADRA
 & NAGAR HAVELI, INDIA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG

FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 26 NOVEMBER 2010

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