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CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 915 OF 2012

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 915 VAN 2012

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 goekgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleeftyd 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 rakleeftydperiode 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. Bemarking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:	41/10.2.1/0765
Name of medicine:	CO-IPRASAL SOLUTION
Dosage form:	SOLUTION FOR INHALATION
Active ingredients:	EACH 2,5 ml VIAL CONTAINS: IPRATROPIUM BROMIDE 0,5 mg SALBUTAMOL SULPHATE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA (PTY) LTD
Manufacturer:	LABORATOIRE UNITHER, AMIENS, FRANCE
Packer:	LABORATOIRE UNITHER, AMIENS, FRANCE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LABORATOIRE UNITHER, AMIENS, FRANCE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	ARROW PHARMA (PTY) LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	36 months
Date of registration:	18 MAY 2012

MRF15

Registration number:	42/21.12/0461
Name of medicine:	FINIDE 5 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FINASTERIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	18 MAY 2012

MRF 15

Registration number:	44/10.2.2/0203
Name of medicine:	SINTRINE 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 MAY 2012

MRF 15

Registration number:	44/10.2.2/0204
Name of medicine:	SANDOZ MONTELUKAST 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 MAY 2012

MRF15

Registration number:	44/10.2.2/0485
Name of medicine:	SINTRINE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 MAY 2012

MRF 15

Registration number:	44/10.2.2/0486
Name of medicine:	SINTRINE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	18 MAY 2012

MRF 15

Registration number:	44/10.2.2/0487
Name of medicine:	SANDOZ MONTELUKAST 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	18 MAY 2012

MRF15

Registration number:	44/10.2.2/0488
Name of medicine:	SANDOZ MONTELUKAST 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, RETORIA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	18 MAY 2012

MRF 15

Registration number:	38/21.12/0173
Name of medicine:	ASPEN FLUTAMIDE 250 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FLUTAMIDE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENERICS (UK) LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM GERARD LABORATORIES, GRANGE ROAD, DUBLIN, IRELAND PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA
Packer:	GENERICS (UK) LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM GERARD LABORATORIES, GRANGE ROAD, DUBLIN, IRELAND PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA
Laboratory: FPRC	GENERICS (UK) LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM GERARD LABORATORIES, GRANGE ROAD, DUBLIN, IRELAND SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration	07 JUNE 2012

MRF 15

Registration number:	A38/7.5/0729
Name of medicine:	OMACOR
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Eicosapent (EPA) ethyl esters 46,0 % Doconexent (DHA) ethyl esters 38,0 %
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ABBOTT LABORATORIES SA (PTY) LTD
Manufacturer:	CARDINAL HEALTH UK, SWINDON, WILTSHIRE, UNITED KINGDOM
Packer:	CARDINAL HEALTH UK, SWINDON, WILTSHIRE, UNITED KINGDOM GMPACK, HADSUND, DENMARK
Laboratory: FPRC:	CARDINAL HEALTH UK, SWINDON, WILTSHIRE, UNITED KINGDOM PRONOVA BIOCARE A.S, LYSAKER, NORWAY SOLVAY PHARMACEUTICALS GmbH, NEUSTADT, GERMANY
FPRC/FPRR:	ABBOTT LABORATORIES (PTY) LTD, CONSTANTIA KLOOF, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	A40/15.1/0048
Name of medicine:	CEPROLEN EYE DROPS
Dosage form:	EYE DROP SOLUTION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin 0,3 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MEDIVISION (PTY) LTD
Manufacturer:	INDOCO REMEDIES, VERNA INDUSTRIAL ESTATE, GOA, INDIA
Packer:	INDOCO REMEDIES, VERNA INDUSTRIAL ESTATE, GOA, INDIA
Laboratory: FPRC:	INDOCO REMEDIES, VERNA INDUSTRIAL ESTATE, GOA, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	MEDIVISION (PTY) LTD, KRAMERVILLE, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	A40/2.9/0355
Name of medicine:	SABAX TRAMADOL 100 mg/2 ml
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml CONTAINS: TRAMADOL HYDROCHLORIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
Packer:	PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
FPRR	PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	A40/21.5.1/0748
Name of medicine:	FRESENIUS DEXAMETHASONE 4 mg/1 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml CONTAINS: Dexamethasone sodium phosphate equivalent to Dexamethasone phosphate 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BODENE (PTY) LIMITED TRADING AS INTRAMED
Manufacturer:	BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA
Packer:	BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC :	BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA
FPRR:	BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF15

Registration number:	42/2.2/0045
Name of medicine:	MIDAZOLAM SAFELINE 15 mg
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml AMPOULE CONTAINS: MIDAZOLAM HYDROCHLORIDE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEMO S.A., PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	DEMO S.A., PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Laboratory: FPRC:	DEMO S.A., PHARMACEUTICAL INDUSTRY, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

F 15

Registration number:	42/2.2/0046
Name of medicine:	MIDAZOLAM SAFELINE 50 mg
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml AMPOULE CONTAINS: MIDAZOLAM HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEMO S.A., PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	DEMO S.A., PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Laboratory: FPRC	DEMO S.A., PHARMACEUTICAL INDUSTRY, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/20.1.1/0511
Name of medicine:	ASPEN TEICOPLANIN 200
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 3,2 ml CONTAINS: TEICOPLANIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN
Packer:	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORTSEN, PORT ELIZABETH,RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LTD, KORTSEN, PORT ELIZABETH,RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (provisional)
Date of registration:	07 JUNE 2012

MRF15 F 15

Registration number:	42/20.1.1/0512
Name of medicine:	ASPEN TEICOPLANIN 400
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 3,2 ml CONTAINS: TEICOPLANIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN
Packer:	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (provisional)
Date of registration:	07 JUNE 2012

Registration number:	42/34/0513
Name of medicine:	ASPEN DILUENT FOR TEICOPLANIN
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 3,2 ml CONTAINS: WATER FOR INJECTION 3,2 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN
Packer:	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory::FPRC	LABIANA PHARMACEUTICALS, S.L.U, BARBERA DEL VALLES, BARCELONA, SPAIN PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA M & L LABORATORY SERVICES (PTY) LTD,LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR	PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/24/0518
Name of medicine:	RINGERFUNDIN
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH PLASTIC INFUSION BAG CONTAINS: Calcium Chloride Dihydrate 0,37 g Magnesium Chloride 0,20 g Malic Acid 0,67 g Potassium Chloride 0,30 g Sodium Acetate 3,27 g Sodium Chloride 6,80 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, GERMANY PRODUCTION PHARMA PFIEFFEWIESEN, GERMANY B BRAUN MEDICAL S.A., BARCELONA, SPAIN B BRAUN MEDICAL S.A., SWITZERLAND
Packer:	B BRAUN MELSUNGEN AG, GERMANY PRODUCTION PHARMA PFIEFFEWIESEN, GERMANY B BRAUN MEDICAL S.A., BARCELONA, SPAIN B BRAUN MEDICAL S.A., SWITZERLAND
Laboratory: FPRC:	B BRAUN MELSUNGEN AG, GERMANY M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL (PTY) LTD, FOURWAYS, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF15

Registration number:	42/20.1.1/0617
Name of medicine:	AURO CEFUROXIME 250 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/20.1.1/0618
Name of medicine:	AURO CEFUROXIME 750 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/20.1.1/0619
Name of medicine:	AURO CEFUROXIME 1500 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF15

Registration number:	42/26/0739
Name of medicine:	HYCAMTIN 0,25 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Topotecan Hydrochloride equivalent to Topotecan 0,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GLAXOSMITHKLINE SA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE MANUFACTURING S.p.A,PARMA, ITALY
Packer:	GLAXOSMITHKLINE MANUFACTURING S.p.A,PARMA, ITALY GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
Laboratory: FPRC:	GLAXOSMITHKLINE MANUFACTURING S.p.A,PARMA, ITALY GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
FPRR:	GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/26/0740
Name of medicine:	HYCAMTIN 1,0 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Topotecan Hydrochloride equivalent to Topotecan 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GLAXOSMITHKLINE SA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE MANUFACTURING S.p.A, PARMA, ITALY
Packer:	GLAXOSMITHKLINE MANUFACTURING S.p.A, PARMA, ITALY GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
Laboratory: FPRC:	GLAXOSMITHKLINE MANUFACTURING S.p.A, PARMA, ITALY GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
FPRR:	GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/2.6.5/0792
Name of medicine:	RISNIA 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	42/2.6.5/0793
Name of medicine:	RISNIA 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

F 15

Registration number:	42/2.6.5/0794
Name of medicine:	RISNIA 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/2.6.5/0795
Name of medicine:	RISNIA 3 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	42/2.6.5/0796
Name of medicine:	RISNIA 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/2.6.5/0797
Name of medicine:	RISNIA 6 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/2.6.5/0798
Name of medicine:	CIPLA RISPERIDONE 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	42/2.6.5/0799
Name of medicine:	CIPLA RISPERIDONE 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/2.6.5/0800
Name of medicine:	CIPLA RISPERIDONE 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/2.6.5/0801
Name of medicine:	CIPLA RISPERIDONE 3 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/2.6.5/0802
Name of medicine:	CIPLA RISPERIDONE 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

Registration number:	42/2.6.5/0803
Name of medicine:	CIPLA RISPERIDONE 6 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSEN HEIGHTS, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/20.1.1/0888
Name of medicine:	SPEC TEICOPLANIN 200
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	SIRTON, VILLA GUARDIA, ITALY
Packer:	SIRTON, VILLA GUARDIA, ITALY
Laboratory: FPRC:	SIRTON, VILLA GUARDIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)*
Date of registration:	07 JUNE 2012

MRF15

Registration number:	42/20.1.1/0889
Name of medicine:	SPEC TEICOPLANIN 400
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	SIRTON, VILLA GUARDIA, ITALY
Packer:	SIRTON, VILLA GUARDIA, ITALY
Laboratory: FPRC:	SIRTON, VILLA GUARDIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)*
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	42/34/1056
Name of medicine:	SPEC TEICOPLANIN SOLVENT
Dosage form:	LIQUID
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	SIRTON, VILLA GUARDIA, ITALY
Packer:	SIRTON, VILLA GUARDIA, ITALY
Laboratory: FPRC	SIRTON, VILLA GUARDIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

*A provisional shelf-life of 24 months is approved for this product manufactured by Sirton with API manufactured by Zhejiang Medicine. A shelf-life of 24 hours at 2-8 ^{0}C is approved for the reconstituted and diluted product.

MRF 15

Registration number:	43/5.3/0251
Name of medicine:	DONESPES 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HCl 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	SPECIFAR S.A, VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A, VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS (PTY) LTD, MIDRAND, RSA
Laboratory: FPRC:	SPECIFAR S.A, VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS (PTY) LTD, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months (Provisional)*
Date of registration:	07 JUNE 2012

MRF15

Registration number:	43/5.3/0252
Name of medicine:	DONESPES 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HCl 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	SPECIFAR S.A, VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A, VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS (PTY) LTD, MIDRAND, RSA
Laboratory: FPRC:	SPECIFAR S.A, VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS (PTY) LTD, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months (Provisional)*
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/5.3/0253
Name of medicine:	DONERIN 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HCl 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	SPECIFAR S.A, VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A, VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS (PTY) LTD, MIDRAND, RSA
Laboratory: FPRC	SPECIFAR S.A, VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS (PTY) LTD, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months (Provisional)*
Date of registration:	07 JUNE 2012

*A provisional shelf-life of 24 months is approved for this product manufactured with API from Jubilant Oranosys and Ranbaxy Laboratories Limited

MRF 15

Registration number:	43/5.3/0254
Name of medicine:	DONERIN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HCl 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	SPECIFAR S.A, VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A, VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS (PTY) LTD, MIDRAND, RSA
Laboratory: FPRC:	SPECIFAR S.A, VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS (PTY) LTD, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months (Provisional)*
Date of registration:	07 JUNE 2012

MRF15

Registration number:	43/8.3/0675
Name of medicine:	FERROUS GLUCONATE SYRUP BARRS
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml CONTAINS: FERROUS GLUCONATE 350,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BARRS PHARMACEUTICAL INDUSTRIES cc
Manufacturer:	BARRS PHARMACEUTICAL INDUSTRIES cc, NDABENI, CAPE TOWN, RSA
Packer:	BARRS PHARMACEUTICAL INDUSTRIES cc, NDABENI, CAPE TOWN, RSA
Laboratory: FPRC:	BARRS PHARMACEUTICAL INDUSTRIES cc, NDABENI, CAPE TOWN, RSA
FPRR:	BARRS PHARMACEUTICAL INDUSTRIES cc, NDABENI, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/7.1.3/0716
Name of medicine:	DYNA IRBESARTAN 75 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN LABORATORIOS ECHEVARNE, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

A provisional shelf-life of 24 months is approved for this product manufactured with API from Jubilant Oranosys and Ranbaxy Laboratories Limited

MRF 15

Registration number:	43/7.1.3/0717
Name of medicine:	DYNA IRBESARTAN 150 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN LABORATORIOS ECHEVARNE, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF15

Registration number:	43/7.1.3/0718
Name of medicine:	DYNA IRBESARTAN 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN LABORATORIOS ECHEVARNE, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/7.1.3/0719
Name of medicine:	DYNARB 75 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN LABORATORIOS ECHEVARNE, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/7.1.3/0720
Name of medicine:	DYNARB 150 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN LABORATORIOS ECHEVARNE, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF15

Registration number:	43/7.1.3/0721
Name of medicine:	DYNARB 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	LABORATORIOS CINFA, S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN LABORATORIOS ECHEVARNE, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

RF 15

Registration number:	43/20.1.1/1026
Name of medicine:	AURO CEFTAZIDIME 250 mg
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Ceftazidime Pentahydrate equivalent to Ceftazidime 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/20.1.1/1027
Name of medicine:	AURO CEFTAZIDIME 500 mg
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Ceftazidime Pentahydrate equivalent to Ceftazidime 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	43/20.1.1/1028
Name of medicine:	AURO CEFTAZIDIME 1,0 g
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Ceftazidime Pentahydrate equivalent to Ceftazidime 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/20.1.1/1029
Name of medicine:	AURO CEFTAZIDIME 2,0 g
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Ceftazidime Pentahydrate equivalent to Ceftazidime 2,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/20.1.1/1035
Name of medicine:	AURIZEF 250 mg
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Ceftazidime Pentahydrate equivalent to Ceftazidime 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	43/20.1.1/1036
Name of medicine:	AURIZEF 500 mg
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Ceftazidime Pentahydrate equivalent to Ceftazidime 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/20.1.1/1037
Name of medicine:	AURIZEF 1,0 g
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Ceftazidime Pentahydrate equivalent to Ceftazidime 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	43/20.1.1/1038
Name of medicine:	AURIZEF 2,0 g
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Ceftazidime Pentahydrate equivalent to Ceftazidime 2,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	44/30.1/0039
Name of medicine:	MENCEVAX ACW$_{135}$Y MULTIDOSE
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: NEISSERIA MENINGITIDIS GROUP A 50,0 µg NEISSERIA MENINGITIDIS GROUP C 50,0 µg NEISSERIA MENINGITIDIS GROUP Y 50,0 µg NEISSERIA MENINGITIDIS GROUP W135 50,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS, DRESDEN, GERMANY
Packer:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS S.A., WAVRE, BELGIUM GLAXOSMITHKLINE BIOLOGICALS, DRESDEN, GERMANY GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM
FPRC/FPRR:	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:	36 months at 2 – 8 °C (Lyophilised vaccine) 8 hours at 2 – 8 °C (Reconstituted vaccine) 60 months at 2 – 25 °C (Diluent)
Date of registration:	07 JUNE 2012

RF 15

Registration number:	44/10.2.2/0059
Name of medicine:	MONTE-AIR 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK
Packer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, HAARLEM, THE NETHERLANDS
FPRC/FPRR:	MSD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	44/10.2.2/0060
Name of medicine:	MONTE-AIR 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK
Packer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, HAARLEM, THE NETHERLANDS
FPRR:	MSD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	44/10.2.2/0061
Name of medicine:	MONTE-AIR 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK
Packer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, HAARLEM, THE NETHERLANDS
FPRR:	MSD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	44/10.2.2/0062
Name of medicine:	MONTE-AIR SPRINKLES
Dosage form:	GRANULES
Active ingredients:	EACH SACHET OF GRANULES CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK MANUFACTURING DIVISION, WEST POINT, PENNSYLVANIA, USA
Packer:	MERCK MANUFACTURING DIVISION, WILSON, NORTH CAROLINA, USA ANDERSON PACKAGING INC, ROCKFORD, ILLINOIS, USA MMD HAARLEM, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	MERCK MANUFACTURING DIVISION, WEST POINT, PENNSYLVANIA, USA MERCK MANUFACTURING DIVISION, WILSON, NORTH CAROLINA, USA MMD HAARLEM, HAARLEM, THE NETHERLANDS
FPRC/FPRR:	MSD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	44/10.2.1/0544
Name of medicine:	ONBREZ BREEZHALER 150 µg
Dosage form:	DRY POWDER INHALATION CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: INDACATEROL MALEATE EQUIVALENT TO INDACATEROL 150,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	07 JUNE 2012

MRF15

Registration number:	44/10.2.2/0791
Name of medicine:	MONTELUKAST ZYDUS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE (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 INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRC/ FPRR:	ZYDUS HEALHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	44/10.2.2/0792
Name of medicine:	LUMONT 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE (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 INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRC/FPRR:	ZYDUS HEALHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	44/10.2.2/0821
Name of medicine:	MONTELUKAST ZYDUS 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE (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 INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRC/FPRR:	ZYDUS HEALHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF15

Registration number:	44/10.2.2/0822
Name of medicine:	MONTELUKAST ZYDUS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE (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 INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRC/FPRR:	ZYDUS HEALHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

RF 15

Registration number:	44/10.2.2/0823
Name of medicine:	LUMONT 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE (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 INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRC/FPRR:	ZYDUS HEALHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	44/10.2.2/0824
Name of medicine:	LUMONT 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE (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 INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRC/FPRR:	ZYDUS HEALHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF15

Registration number:	44/7.1.3/0857
Name of medicine:	TWYNSTA 40/5 mg TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 40,0 mg AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA PHAST GmbH, HOMBURG/SAAR, GERMANY A&M STABTEST, MAINZ, GERMANY LABOR L + S AG, BAD BOCKLET-GROSSENBRACH, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

RF 15

Registration number:	44/7.1.3/0858
Name of medicine:	TWYNSTA 40/10 mg TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 40,0 mg AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA
Laboratory: FPRC	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA PHAST GmbH, HOMBURG/SAAR, GERMANY A&M STABTEST, MAINZ, GERMANY LABOR L + S AG, BAD BOCKLET-GROSSENBRACH, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	44/7.1.3/0859
Name of medicine:	TWYNSTA 80/5 mg TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 80,0 mg AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA PHAST GmbH, HOMBURG/SAAR, GERMANY A&M STABTEST, MAINZ, GERMANY LABOR L + S AG, BAD BOCKLET-GROSSENBRACH, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF15

Registration number:	44/7.1.3/0860
Name of medicine:	TWYNSTA 80/10 mg TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 80,0 mg AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG, INGELHEIM AM RHEIN, GERMANY CIPLA LIMITED (Unit IV), VERNA, GOA, INDIA PHAST GmbH, HOMBURG/SAAR, GERMANY A&M STABTEST, MAINZ, GERMANY LABOR L + S AG, BAD BOCKLET-GROSSENBRACH, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

RF 15

Registration number:	45/20.2.8/0171
Name of medicine:	EFLATEN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TENOFOVIR DISOPROXIL FUMARATE 300,0 mg LAMIVUDINE 300,0 mg EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8*
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	45/20.2.8/0172
Name of medicine:	ATROIZA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TENOFOVIR DISOPROXIL FUMARATE 300,0 mg EFAVIRENZ 600,0 mg EMTRICITABINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8*
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 JUNE 2012

MRF 15

Registration number:	07/3.1.2.2/23
Name of medicine:	ONSIOR INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ROBENACOXIB 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Packer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Laboratory: FPRC:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months stored at 2-8 °C In-use shelf life of 28 days stored at 2-8 °C
Date of registration:	27 JULY 2012

MRF15

Registration number:	37/15.4/0224
Name of medicine:	LIPOSIC EYE GEL
Dosage form:	EYE GEL
Active ingredients:	EACH 1,0 g GEL CONTAINS: CARBOMER 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SOFLENS (PTY) LTD
Manufacturer:	Dr MANN PHARMA, CHEM-PHARM FABRIK GmbH, BERLIN, GERMANY
Packer:	Dr MANN PHARMA, CHEM-PHARM FABRIK GmbH, BERLIN, GERMANY COLUMBIA PHARMACEUTICALS (PTY) LTD, MIDDEL RD, BARDENE, BOKSBURG, RSA
Laboratory: FPRC:	Dr MANN PHARMA, CHEM-PHARM FABRIK GmbH, BERLIN, GERMANY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SOFLENS (PTY) LTD, RIVONIA, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	37/15.2/0588
Name of medicine:	LOTEMAX OPHTHALMIC SUSPENSION
Dosage form:	EYE DROPS
Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: LOTEPREDNOL ETABONATE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SOFLENS (PTY) LTD
Manufacturer:	BAUSCH & LOMB INC, HIDDEN RIVER PARKWAY, TAMPA, FLORIDA, USA
Packer:	BAUSCH & LOMB INC, HIDDEN RIVER PARKWAY, TAMPA, FLORIDA, USA. COLUMBIA PHARMACEUTICALS (PTY) LTD, MIDDEL RD, BARDENE, BOKSBURG, RSA
Laboratory: FPRC:	BAUSCH & LOMB INC, HIDDEN RIVER PARKWAY, TAMPA, FLORIDA, USA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SOFLENS (PTY) LTD, RIVONIA, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	A39/7.1/0419
Name of medicine:	APEX TERAZOSIN 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Terazosin hydrochloride equivalent to Terazosin 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	A39/7.1/0420
Name of medicine:	APEX TERAZOSIN 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Terazosin hydrochloride equivalent to Terazosin 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	A39/7.1/0421
Name of medicine:	APEX TERAZOSIN 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Terazosin hydrochloride equivalent to Terazosin 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	A39/7.1/0422
Name of medicine:	APEX TERAZOSIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Terazosin hydrochloride equivalent to Terazosin 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	A39/7.1/0423
Name of medicine:	APEX TERAZOSIN BPH STARTER PACK
Dosage form:	TABLET
Active ingredients:	EACH PACK CONTAINS 3 x Apex Terazosin 1 mg tablets containing Terazosin hydrochloride equivalent to Terazosin 1,0 mg 11 x Apex Terazosin 2 mg tablets containing Terazosin hydrochloride equivalent to Terazosin 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	A39/7.1/0424
Name of medicine:	TERAPRESS BPH STARTER PACK
Dosage form:	TABLET
Active ingredients:	EACH PACK CONTAINS 3 x Terapress 1 mg tablets containing Terazosin hydrochloride equivalent to Terazosin 1,0 mg 11 x Terapress 2 mg tablets containing Terazosin hydrochloride equivalent to Terazosin 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration	27 JULY 2012

MRF 15

Registration number:	A39/7.1/0425
Name of medicine:	TERAPRESS 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Terazosin hydrochloride equivalent to Terazosin 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	A39/7.1/0426
Name of medicine:	TERAPRESS 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Terazosin hydrochloride equivalent to Terazosin 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	A39/7.1/0427
Name of medicine:	TERAPRESS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Terazosin hydrochloride equivalent to Terazosin 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	A39/7.1/0428
Name of medicine:	TERAPRESS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Terazosin hydrochloride equivalent to Terazosin 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory: FPRC :	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXTENSION 3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	A40/4/0214
Name of medicine:	SABAX BUPIVACAINE 0,1 % VIAFLEX
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH 1 000,0 ml CONTAINS BUPIVACAINE HYDROCHLORIDE 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Packer:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Laboratory. FPRC:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
FPRR	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

F 15

Registration number:	41/26/0034
Name of medicine:	CIPLA DOXORUBICIN 10
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: DOXORUBICIN HYDROCHLORIDE 10,0 mg
Conditions of registration.	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	41/26/0035
Name of medicine:	CIPLA DOXORUBICIN 50
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: DOXORUBICIN HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, (UNIT V), VERNA, GOA, INDIA
Packer:	CIPLA LTD, (UNIT V), VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, (UNIT V), VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15 F 15

Registration number:	41/5.10/0241
Name of medicine:	ONDANSETRON SAFELINE 4 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: Ondansetron hydrochloride dihydrate equivalent to Ondansetron 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEMO S.A., ATHENS-LAMIA, ATHENS, GREECE
Packer:	DEMO S.A., ATHENS-LAMIA, ATHENS, GREECE
Laboratory: FPRC:	DEMO S.A., ATHENS-LAMIA, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA
Shelf-life:	24 months (Provisional) for product stored at or below 25 °C 24 hours for diluted solutions stored at 2 – 8 °C
Date of registration:	27 JULY 2012

Registration number:	41/5.10/0242
Name of medicine:	ONDANSETRON SAFELINE 8 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: Ondansetron hydrochloride dihydrate equivalent to Ondansetron 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEMO S.A., ATHENS-LAMIA, ATHENS, GREECE
Packer:	DEMO S.A., ATHENS-LAMIA, ATHENS, GREECE
Laboratory::FPRC	DEMO S.A., ATHENS-LAMIA, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA
Shelf-life:	24 months (Provisional) for product stored at or below 25 °C 24 hours for diluted solutions stored at 2 – 8 °C
Date of registration:	27 JULY 2012

MRF 15

Registration number:	41/20.1.1/0947
Name of medicine:	TEICOPLANIN WINTHROP 200
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY
Packer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACAEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	41/20.1.1/0948
Name of medicine:	TEICOPLANIN WINTHROP 400
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY
Packer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACAEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	41/20.1.1/0949
Name of medicine:	TEICOPLANIN SANOFI-AVENTIS 200
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY
Packer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACAEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	41/20.1.1/0950
Name of medicine:	TEICOPLANIN SANOFI-AVENTIS 400
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY
Packer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACAEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	41/34/1134
Name of medicine:	TEICOPLANIN WINTHROP SOLVENT
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY
Packer:	GRUPPO LEPETIT Srl,ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACAEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	41/34/1135
Name of medicine:	TEICOPLANIN SANOFI-AVENTIS SOLVENT
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY
Packer:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	GRUPPO LEPETIT Srl, ANAGNI, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACAEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/28/0102
Name of medicine:	OPTIMARK 10
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 10,0 ml CONTAINS: GADOVERSETAMIDE 3 309,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	COVIDIEN (PTY) LTD
Manufacturer:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Packer:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Laboratory: FPRC	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA PETLABS PHARMACEUTICALS (PTY) LTD, GROENKLOOF, PRETORIA, RSA BIOCHEMICAL AND SCIENTIFIC cc, HILTON, KWA-ZULU NATAL, RSA
FPRR:	COVIDIEN (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months (Glass vials) 36 months (Pre-filled syringes)
Date of registration:	27 JULY 2012

MRF15

Registration number:	42/28/0103
Name of medicine:	OPTIMARK 15
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 15,0 ml CONTAINS: GADOVERSETAMIDE 4963,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	COVIDIEN (PTY) LTD
Manufacturer:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Packer:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Laboratory: FPRC:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA PETLABS PHARMACEUTICALS (PTY) LTD, GROENKLOOF, PRETORIA, RSA BIOCHEMICAL AND SCIENTIFIC cc, HILTON, KWA-ZULU NATAL, RSA
FPRR:	COVIDIEN (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months (Glass vials) 36 months (Pre-filled syringes)
Date of registration:	27 JULY 2012

F 15

Registration number:	42/28/0104
Name of medicine:	OPTIMARK 20
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 20,0 ml CONTAINS: GADOVERSETAMIDE 6618,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	COVIDIEN (PTY) LTD
Manufacturer:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Packer:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Laboratory: FPRC:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA PETLABS PHARMACEUTICALS (PTY) LTD, GROENKLOOF, PRETORIA, RSA BIOCHEMICAL AND SCIENTIFIC cc, HILTON, KWA-ZULU NATAL, RSA
FPRR:	COVIDIEN (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months (Glass vials) 36 months (Pre-filled syringes)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/28/0105
Name of medicine:	OPTIMARK 30
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 30,0 ml CONTAINS: GADOVERSETAMIDE 9927,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	COVIDIEN (PTY) LTD
Manufacturer:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Packer:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Laboratory: FPRC:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA PETLABS PHARMACEUTICALS (PTY) LTD, GROENKLOOF, PRETORIA, RSA BIOCHEMICAL AND SCIENTIFIC cc, HILTON, KWA-ZULU NATAL, RSA
FPRR:	COVIDIEN (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months (Glass vials) 36 months (Pre-filled syringes)
Date of registration:	27 JULY 2012

MRF15

Registration number:	42/7.1.3/0262
Name of medicine:	TRANDOPRESS 2 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TRANDOLAPRIL 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE
Packer:	PHARMATEN S.A, PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	PHARMATEN S.A, PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/20.1.1/0427
Name of medicine:	LEVOFLOXACIN SPECPHARM 250 IV
Dosage form:	SOLUTION FOR IV INFUSION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN
Packer:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN
Laboratory: FPRC:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/20.1.1/0428
Name of medicine:	SPEC LEVOFLOXACIN 500 IV
Dosage form:	SOLUTION FOR IV INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN
Packer:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN
Laboratory: FPRC:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	42/20.1.1/0439
Name of medicine:	LEVOFLOXACIN SPECPHARM 500 IV
Dosage form:	SOLUTION FOR IV INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN
Packer:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN
Laboratory: FPRC:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/20.1.1/0440
Name of medicine:	SPEC LEVOFLOXACIN 250 IV
Dosage form:	SOLUTION FOR IV INFUSION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN
Packer:	BIOMENDI S.A, BERNEDO, ALVA, SPAIN
Laboratory: FPRC	BIOMENDI S.A, BERNEDO, ALVA, SPAIN SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/20.1.1/0505
Name of medicine:	ZITRO 500 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Azithromycin dihydrate equivalent to Azithromycin 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, SOUTH AFRICA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/20.1.2/0771
Name of medicine:	ADCO AMOXYCLAV BD
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	MEDREICH LTD, UNIT 1, VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH LTD, UNIT 1, VIRGONAGAR, BANGALORE, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	MEDREICH LTD, UNIT 1, VIRGONAGAR, BANGALORE, INDIA ADCOCK INGRAM LIMITED, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

Registration number:	42/34/0786
Name of medicine:	ADVAGRAF 0,5 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TACROLIMUS 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ASTELLAS PHARMA (PTY) LTD
Manufacturer:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND
Packer:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND
Laboratory: FPRC:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTELLAS PHARMA (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/34/0787
Name of medicine:	ADVAGRAF 1 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TACROLIMUS 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ASTELLAS PHARMA (PTY) LTD
Manufacturer:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND
Packer:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND
Laboratory: FPRC:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTELLAS PHARMA (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	42/34/0788
Name of medicine:	ADVAGRAF 5 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TACROLIMUS 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ASTELLAS PHARMA (PTY) LTD
Manufacturer:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND
Packer:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND
Laboratory: FPRC:	ASTELLAS IRELAND CO. LTD, KILLORGLIN, KERRY, IRELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTELLAS PHARMA (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/2.5/0810
Name of medicine:	RESTAN TOPIRAMATE 25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Laboratory: FPRC	ACTAVIS hf, HAFNARFJORDUR, ICELAND
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/2.5/0811
Name of medicine:	RESTAN TOPIRAMATE 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	42/2.5/0812
Name of medicine:	RESTAN TOPIRAMATE 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
FPRC/ FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/2.5/0813
Name of medicine:	RESTAN TOPIRAMATE 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND
Laboratory: FPRC	ACTAVIS hf, HAFNARFJORDUR, ICELAND
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	42/21.12/0995
Name of medicine:	CASTRA 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA PHARMASPEC LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ZYDUS HEALHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	42/21.12/1037
Name of medicine:	ASPEN ANASTROZOLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	HAUPT PHARMA MUNSTER GmbH, MUNSTER, GERMANY PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	HAUPT PHARMA MUNSTER GmbH, MUNSTER, GERMANY PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	48 months
Date of registration:	27 JULY 2012

RF 15

Registration number:	43/21.2/0002
Name of medicine:	GLAMARYL COMBI 1/250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg METFORMIN HYDROCHLORIDE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA
Packer:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA WINTHROP PHARMACEUTICALS, (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, (PTY) LTD WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS, (PTY) LTD MIDRAND, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/21.2/0003
Name of medicine:	GLAMARYL COMBI 2/500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA
Packer:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA WINTHROP PHARMACEUTICALS, (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, (PTY) LTD WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS, (PTY) LTD MIDRAND, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/21.2/0004
Name of medicine:	AMARYL COMBI 1/250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg METFORMIN HYDROCHLORIDE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA
Packer:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA WINTHROP PHARMACEUTICALS, (PTY) LTD WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, (PTY) LTD WALTLOO, PRETORIA, RSA
FPRR:	SANOFI-AVENTIS S.A. (PTY) LTD, MIDRAND, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/21.2/0005
Name of medicine:	AMARYL COMBI 2/500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA
Packer:	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA WINTHROP PHARMACEUTICALS, (PTY) LTD WALTLOO, PRETORIA, RSA
Laboratory: FPRC	HANDOK PHARMACEUTICALS Co LTD, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, (PTY) LTD WALTLOO, PRETORIA, RSA
FPRR:	SANOFI-AVENTIS S.A. (PTY) LTD, MIDRAND, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/21.12/0074
Name of medicine:	ANAMAST 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTRAZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/5.7.1/0079
Name of medicine:	ADCO DESLORATADINE SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: DESLORATADINE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
Packer:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR;	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/26/0102
Name of medicine:	OXALIPLATIN PCH 50
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 10,0 ml VIAL CONTAINS: OXALIPLATIN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant"	PHARMACHEMIE (PTY) LTD
Manufacturer:	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS
Packer:	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS
Laboratory: FPRC	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	PHARMACHEMIE (PTY) LTD, RUIMSIG, ROODEPOORT, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/26/0103
Name of medicine:	OXALIPLATIN PCH 100
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 20,0 ml VIAL CONTAINS: OXALIPLATIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACHEMIE (PTY) LTD
Manufacturer:	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS
Packer:	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS
Laboratory: FPRC:	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	PHARMACHEMIE (PTY) LTD, RUIMSIG, ROODEPOORT, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/30.1/0127
Name of medicine:	PRIORIX TETRA
Dosage form:	POWDER AND DILUENT FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 0,5 ml CONTAINS: Live attenuated measles virus (Schwarz strain) $\geq 10^{3.0}$ $CCID_{50}$ Live attenuated mumps virus (RIT4385 strain) $\geq 10^{4.4}$ $CCID_{50}$ Live attenuated rubella virus (Wistar RA 27/3 strain) $\geq 10^{3.0}$ $CCID_{50}$ Live attenuated varicella virus (OKA strain) $\geq 10^{3.3}$ PFU
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS S.A, RIXENSART, BELGIUM SACHSISCHES SERUWERK DRESDEN, NI der SMITHKLINE BEECHAM PHARMA GmbH, DRESDEN, GERMANY
Packer:	GLAXOSMITHKLINE BIOLOGICALS S.A, WAVRE, BELGIUM SACHSISCHES SERUWERK DRESDEN, NI der SMITHKLINE BEECHAM PHARMA GmbH, DRESDEN, GERMANY GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
Laboratory: FPRC:	GLAXOSMITHKLINE BIOLOGICALS S.A, RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS S.A, WAVRE, BELGIUM
FPRC/FPRR:	GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
Shelf-life:	60 months (Diluent stored at or below 25 °C) 24 months (Product stored at -20 °C 18 months (Product stored at 2 – 8 °C In-use shelf-life of 24 hours for product stored at 2 – 8 °C
Date of registration:	27 JULY 2012

RF 15

Registration number:	43/21.2/0140
Name of medicine:	ACCORD PIOGLITAZONE 15 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PIOGLITAZONE HYDROCHLORIDE EQUIVALENT TO PIOGLITAZONE15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/21.2/0141
Name of medicine:	ACCORD PIOGLITAZONE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PIOGLITAZONE HYDROCHLORIDE EQUIVALENT TO PIOGLITAZONE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/21.2/0142
Name of medicine:	ACCORD PIOGLITAZONE 45 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PIOGLITAZONE HYDROCHLORIDE EQUIVALENT TO PIOGLITAZONE 45,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/20.1.1/0310
Name of medicine:	BACTRICEF 1 g
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME HYDROCHLORIDE EQUIVALENT TO CEFEPIME 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/20.2.8/0433
Name of medicine:	VALCYTE 50 mg/ml
Dosage form:	POWDER FOR ORAL SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: Valganciclovir hydrochloride equivalent to Valganciclovir 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	PANTHEON INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA ROCHE PHARMA AG, GRENZACH-WYHLEN, GERMANY AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/5.10/0542
Name of medicine:	ONDANSETRON FRESENIUS 2 mg/ml (4 mg/2 ml)
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSENTRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	LABESFAL, LABORATORIOS ALIRO S.A, FRESENIUS KABI GROUP, SANTIAGO DE BESTEIROS, PORTUGAL
Packer:	LABESFAL, LABORATORIOS ALIRO S.A, FRESENIUS KABI GROUP, SANTIAGO DE BESTEIROS, PORTUGAL
Laboratory: FPRC:	LABESFAL, LABORATORIOS ALIRO S.A, FRESENIUS KABI GROUP, SANTIAGO DE BESTEIROS, PORTUGAL SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA KHULULEKANI LABORATORY SERVICES, RANDJESPARK, MIDRAND, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/5.10/0543
Name of medicine:	ONDANSETRON FRESENIUS 2 mg/ml (8 mg/4 ml)
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSENTRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	LABESFAL, LABORATORIOS ALIRO S.A, FRESENIUS KABI GROUP, SANTIAGO DE BESTEIROS, PORTUGAL
Packer:	LABESFAL, LABORATORIOS ALIRO S.A, FRESENIUS KABI GROUP, SANTIAGO DE BESTEIROS, PORTUGAL
Laboratory: FPRC	LABESFAL, LABORATORIOS ALIRO S.A, FRESENIUS KABI GROUP, SANTIAGO DE BESTEIROS, PORTUGAL SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA KHULULEKANI LABORATORY SERVICES, RANDJESPARK, MIDRAND, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/5.4.1/0622
Name of medicine:	PRAMEX 0,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS-LAMIA HIGHWAY, SCHIMATRI, ATHENS, GREECE
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/5.4.1/0623
Name of medicine:	PRAMEX 0,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE 0,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS-LAMIA HIGHWAY, SCHIMATRI, ATHENS, GREECE
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MMRF 15

Registration number:	43/5.4.1/0624
Name of medicine:	PRAMEX 0,125
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE 0,125 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS-LAMIA HIGHWAY, SCHIMATRI, ATHENS, GREECE
Laboratory: FPRC	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC/FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/5.4.1/0625
Name of medicine:	PRAMEX 1,0
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS-LAMIA HIGHWAY, SCHIMATRI, ATHENS, GREECE
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/5.4.1/0626
Name of medicine:	PRAMEX 1,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE 1,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS-LAMIA HIGHWAY, SCHIMATRI, ATHENS, GREECE
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC/ FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

RF 15

Registration number:	43/7.1.3/0652
Name of medicine:	PERIPREX 2/0,625
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 2,0 mg INDAPAMIDE 0,625 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA
Packer:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/7.1.3/0653
Name of medicine:	PERIPREX 4/1,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 4,0 mg INDAPAMIDE 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA
Packer:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/7.1.3/0654
Name of medicine:	ARIPREL PLUS 2/0,625
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 2,0 mg INDAPAMIDE 0,625 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA
Packer:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

RF 15

Registration number:	43/7.1.3/0655
Name of medicine:	ARIPREL PLUS 4/1,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 4,0 mg INDAPAMIDE 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA
Packer:	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC	ARROW LABORATORIES LIMITED, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, HAL FAR INDUSTRIAL ESTATE, BIRZEBBUGIA, MALTA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/32.16/0681
Name of medicine:	SEQUENT PLEASE
Dosage form:	PTCA BALLOON CATHETER
Active ingredients:	EACH mm^2 SURFACE CONTAINS: PACLITAXEL 3,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B. BRAUN MELSUNGEN AG – VASCULAR SYSTEMS, BERLIN, GERMANY B. BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY HEMOTEQ GmbH, WURSELEN, GERMANY
Packer:	B. BRAUN MELSUNGEN AG – VASCULAR SYSTEMS, BERLIN, GERMANY B. BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY HEMOTEQ GmbH, WURSELEN, GERMANY
Laboratory: FPRC:	BIOPROOF AG, MUNCHEN, GERMANY MEDICAL DEVICE SERVICES – Dr ROSSBERGER GmbH, GILCHING, GERMANY M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL (PTY) LTD, FOURWAYS, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/30.1/0727
Name of medicine:	STELARA 45 mg
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: USTEKINUMAB 45,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	CILAG AG, SCHAFFHAUSEN, SWITZERLAND BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA
Packer:	CILAG AG, SCHAFFHAUSEN, SWITZERLAND BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA
Laboratory: FPRC:	CILAG AG, SCHAFFHAUSEN, SWITZERLAND CENTOR B.V, LEIDEN, THE NETHERLANDS
FPRR:	JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, RSA
Shelf-life:	12 months (Vial) 18 months (Pre-filled syringe)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/30.1/0728
Name of medicine:	STELARA 90 mg
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: USTEKINUMAB 90,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	CILAG AG, SCHAFFHAUSEN, SWITZERLAND BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA
Packer:	CILAG AG, SCHAFFHAUSEN, SWITZERLAND BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA
Laboratory: FPRC	CILAG AG, SCHAFFHAUSEN, SWITZERLAND CENTOR B.V, LEIDEN, THE NETHERLANDS
FPRR:	JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, RSA
Shelf-life:	12 months (Vial) 18 months (Pre-filled syringe)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/20.1.1/0783
Name of medicine:	LEVOTAV IV 250
Dosage form:	INFUSION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Laboratory: FPRC:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED - RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/20.1.1/0784
Name of medicine:	LEVOTAV IV 500
Dosage form:	INFUSION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Laboratory: FPRC:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED - RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

RF 15

Registration number:	43/5.7.1/0814
Name of medicine:	CETLEV 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Levocetirizine dihydrochloride 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, SOUTH WING, THE PLACE, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/5.7.1/0815
Name of medicine:	DRL LEVOCETIRIZINE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Levocetirizine dihydrochloride 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
aboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, SOUTH WING, THE PLACE, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/2.5/0840
Name of medicine:	GULF CARBAMAZEPINE 200
Dosage form:	TABLETS
Active ingredients:	EACH TABLET CONTAINS: CARBAMAZEPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCMAHALS, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA SWIFT MICRO LABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/20.1.1/0859
Name of medicine:	CLARIHEXAL 500 XL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d.d, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d.d, LJUBLJANA, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC	LEK PHARMACEUTICALS d.d, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/20.1.1/0860
Name of medicine:	SANDOX CLARITHROMYCIN 500 XL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d.d, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d.d, LJUBLJANA, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	LEK PHARMACEUTICALS d.d, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/20.1.1/0955
Name of medicine:	MYLAN CIPROFLOXACIN 200 mg/100 ml
Dosage form:	INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: CIPROFLOXACIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCP PHARMACEUTICALS (PTY) LTD
Manufacturer:	MACO PRODUCTIONS SAS, MOUVAUX, FRANCE
Packer:	MACO PRODUCTIONS SAS, MOUVAUX, FRANCE
Laboratory: FPRC:	MACO PRODUCTIONS SAS, MOUVAUX, FRANCE MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA
FPRR:	SCP PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/20.1.1/0956
Name of medicine:	MYLAN CIPROFLOXACIN 400 mg/200 ml
Dosage form:	INFUSION
Active ingredients:	EACH 200,0 ml SOLUTION CONTAINS: CIPROFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCP PHARMACEUTICALS (PTY) LTD
Manufacturer:	MACO PRODUCTIONS SAS, MOUVAUX, FRANCE
Packer:	MACO PRODUCTIONS SAS, MOUVAUX, FRANCE
Laboratory: FPRC	MACO PRODUCTIONS SAS, MOUVAUX, FRANCE MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA
FPRR:	SCP PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/21.2/1055
Name of medicine:	GALVUS MET 50 mg/850 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VILDAGLIPTIN 50,0 mg METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND SANDOZSA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	43/21.2/1056
Name of medicine:	GALVUS MET 50 mg/1 000 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VILDAGLIPTIN 50,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND SANDOZSA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	43/7.1/1127
Name of medicine:	TRITACE PLUS 2,5/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 2,5 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY
Packer:	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	27 July 2012

MRF 15

Registration number:	43/7.1/1128
Name of medicine:	TRITACE PLUS 5/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 5,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY
Packer:	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	27 July 2012

MRF15

Registration number:	43/7.1/1129
Name of medicine:	TRITACE PLUS 10/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY
Packer:	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	27 July 2012

MRF 15

Registration number:	43/7.1/1130
Name of medicine:	TRITACE PLUS 5/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 5,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY
Packer:	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	27 July 2012

MRF 15

Registration number:	43/7.1/1131
Name of medicine:	TRITACE PLUS 10/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 10,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY
Packer:	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	SANOFI-AVENTIS S.p.A., SCOPPITO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	27 July 2012

MRF15

Registration number:	44/7.1.3/0075
Name of medicine:	CO EXFORGE 5 mg/160 mg/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 5,0 mg Valsartan 160,0 mg Hydrochlorothiazide 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/7.1.3/0076
Name of medicine:	CO EXFORGE 5 mg/160 mg/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 5,0 mg Valsartan 160,0 mg Hydrochlorothiazide 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/7.1.3/0077
Name of medicine:	CO EXFORGE 10 mg/160 mg/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 10,0 mg Valsartan 160,0 mg Hydrochlorothiazide 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/7.1.3/0078
Name of medicine:	CO EXFORGE 10 mg/160 mg/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 10,0 mg Valsartan 160,0 mg Hydrochlorothiazide 25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/7.1.3/0079
Name of medicine:	CO EXFORGE 10 mg/320 mg/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 10,0 mg Valsartan 320,0 mg Hydrochlorothiazide 25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0200
Name of medicine:	MONTEWIN 5 mg
Dosage form:	CHEWABLE TABLETS
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	NYCOMED, LYSZKOWICE, POLAND
Packer:	NYCOMED, LYSZKOWICE, POLAND WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	NYCOMED, LYSZKOWICE, POLAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/10.2.2/0201
Name of medicine:	MONTEWIN 10 mg
Dosage form:	TABLETS
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	NYCOMED, LYSZKOWICE, POLAND
Packer:	NYCOMED, LYSZKOWICE, POLAND WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	NYCOMED, LYSZKOWICE, POLAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/20.1.1/0220
Name of medicine:	PROPAN LEVOFLOXACIN IV 250
Dosage form:	INFUSION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Laboratory: FPRC	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED - RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/20.1.1/0221
Name of medicine:	PROPAN LEVOFLOXACIN IV 500
Dosage form:	INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Laboratory: FPRC:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED - RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/20.1.1/0222
Name of medicine:	RESTAN LEVOFLOXACIN IV 250
Dosage form:	INFUSION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Laboratory: FPRC:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED - RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/20.1.1/0223
Name of medicine:	RESTAN LEVOFLOXACIN IV 500
Dosage form:	INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Laboratory: FPRC	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED - RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/20.1.1/0224
Name of medicine:	COVAN LEVOFLOXACIN IV 250
Dosage form:	INFUSION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Laboratory: FPRC:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED - RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/20.1.1/0225
Name of medicine:	COVAN LEVOFLOXACIN IV 500
Dosage form:	INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
Laboratory: FPRC:	ACS DOBFAR INFO SA, CAMPASCIO, SWITZERLAND
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED - RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0257
Name of medicine:	MONTEFLO 4
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA SA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA
Laboratory: FPRC	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA SA (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0262
Name of medicine:	MONTEFLO 5
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA SA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA SA (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/10.2.2/0286
Name of medicine:	MONTEFLO 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA SA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA SA (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/1.3.2/0339
Name of medicine:	ALTREX
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NALTREXONE HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	MALLINCKRODT INC, HOBART, NEW YORK, USA
Packer:	MALLINCKRODT INC, HOBART, NEW YORK, USA
Laboratory: FPRC	MALLINCKRODT INC, HOBART, NEW YORK, USA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0384
Name of medicine:	MONTEWIN 4 mg
Dosage form:	CHEWABLE TABLETS
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	NYCOMED, LYSZKOWICE, POLAND
Packer:	NYCOMED, LYSZKOWICE, POLAND WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	NYCOMED, LYSZKOWICE, POLAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Date of registration:	24 months (Provisional) 27 JULY 2012

MRF15

Registration number:	44/10.2.2/0431
Name of medicine:	LEUKOBLOC 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	ABDI IBRAHIM ILAÇ SAN, VE TIC. A.S, HADIMKÖY/ ISTANBUL, TURKEY PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	ABDI IBRAHIM ILAÇ SAN, VE TIC. A.S, HADIMKÖY/ ISTANBUL, TURKEY PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

RF 15

Registration number:	44/10.2.2/0493
Name of medicine:	MINAIR 4
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE FAMAR S.A, ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A, ATHENS-LAMIA HIGHWAY, SCHIMATRI, ATHENS, GREECE
Laboratory: FPRC	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0494
Name of medicine:	MINAIR 5
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE FAMAR S.A, ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A, ATHENS-LAMIA HIGHWAY, SCHIMATRI, ATHENS, GREECE
Laboratory: FPRC:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/10.2.2/0495
Name of medicine:	MINAIR 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE FAMAR S.A, ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A, ATHENS-LAMIA HIGHWAY, SCHIMATRI, ATHENS, GREECE
Laboratory: FPRC:	PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

RF 15

Registration number:	44/20.1.1/0582
Name of medicine:	ZOCEF 250 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALKEM LABORATORIES (PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA
Packer:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA
Laboratory: FPRC	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/20.1.1/0583
Name of medicine:	ZOCEF 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALKEM LABORATORIES (PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA
Packer:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA
Laboratory: FPRC:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/10.2.2/0666
Name of medicine:	MSD MONTELUKAST 4 mg
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK
Packer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, PC HAARLEM, THE NETHERLANDS MSD (PTY) LTD, HALFWAY HOUSE, RSA
Laboratory: FPRC:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, PC HAARLEM, THE NETHERLANDS
FPRR:	MSD (PTY) LTD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0667
Name of medicine:	MSD MONTELUKAST 5 mg
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK
Packer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, PC HAARLEM, THE NETHERLANDS MSD (PTY) LTD, HALFWAY HOUSE, RSA
Laboratory: FPRC	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, PC HAARLEM, THE NETHERLANDS
FPRR:	MSD (PTY) LTD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0668
Name of medicine:	MSD MONTELUKAST 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK
Packer:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, PC HAARLEM, THE NETHERLANDS MSD (PTY) LTD, HALFWAY HOUSE, RSA
Laboratory: FPRC:	MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MMD HAARLEM, PC HAARLEM, THE NETHERLANDS
FPRR:	MSD (PTY) LTD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/10.2.2/0669
Name of medicine:	MSD MONTELUKAST SPRINKLES
Dosage form:	GRANULES
Active ingredients:	EACH PACKET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK MANUFACTURING DIVISION, WEST POINT, PENNSYLVANIA, USA
Packer:	MERCK MANUFACTURING DIVISION, WILSON, NORTH CAROLINA, USA MMD HAARLEM, PC HAARLEM, THE NETHERLANDS MSD (PTY) LTD, HALFWAY HOUSE, RSA
Laboratory: FPRC:	MERCK MANUFACTURING DIVISION, WEST POINT, PENNSYLVANIA, USA MERCK MANUFACTURING DIVISION, WILSON, NORTH CAROLINA, USA MMD HAARLEM, PC HAARLEM, THE NETHERLANDS
FPRC/FPRR:	MSD (PTY) LTD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0844
Name of medicine:	MONTELUKAST BRIMPHARM 4
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA
Packer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR,MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA CONFARMA FRANCE S.A.R.L., HOMBOURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0845
Name of medicine:	MONTELUKAST BRIMPHARM 5
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA
Packer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR,MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA CONFARMA FRANCE S.A.R.L., HOMBOURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/10.2.2/0846
Name of medicine:	MONTELUKAST BRIMPHARM 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA
Packer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR,MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA CONFARMA FRANCE S.A.R.L., HOMBOURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0889
Name of medicine:	MONTELUKAST SPECPHARM 4
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	44/10.2.2/0890
Name of medicine:	MONTELUKAST SPECPHARM 5
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	44/10.2.2/0891
Name of medicine:	MONTELUKAST SPECPHARM 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

RF 15

Registration number:	44/2.5/0924
Name of medicine:	GDC CARBAMAZEPINE 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:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCMAHALS, GUJARAT, INDIA
Laboratory: FPRC	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCMAHALS, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA SWIFT MICRO LABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/10.2.2/0058
Name of medicine:	DILAIR 4
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	45/10.2.2/0059
Name of medicine:	DILAIR 5
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/10.2.2/0060
Name of medicine:	DILAIR 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES, (PTY) LTD, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/20.2.8/0082
Name of medicine:	COTIRAL 100/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 100,0 mg RITONAVIR 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT 111, QUTHUBULLAPUR MANDAL, RANGA RADDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT 111, QUTHUBULLAPUR MANDAL, RANGA RADDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT 111, QUTHUBULLAPUR MANDAL, RANGA RADDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	45/20.2.8/0083
Name of medicine:	COTIRAL 200/50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 200,0 mg RITONAVIR 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT 111, QUTHUBULLAPUR MANDAL, RANGA RADDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT 111, QUTHUBULLAPUR MANDAL, RANGA RADDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT 111, QUTHUBULLAPUR MANDAL, RANGA RADDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/20.1.1/0216
Name of medicine:	CEFUROXIME ALKEM 250 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALKEM LABORATORIES (PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA
Packer:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA
Laboratory: FPRC	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/20.1.1/0217
Name of medicine:	CEFUROXIME ALKEM 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALKEM LABORATORIES (PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA
Packer:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA
Laboratory: FPRC:	ALKEM LABORATORIES LIMITED, AMALIYA, DAMAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	45/30.2/0431
Name of medicine:	GSK PNEUMOCOCCAL VACCINE
Dosage form:	SUSPENSION FOR INJECTION
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: Polysaccharide for Serotype 1 1,0 µg Polysaccharide for Serotype 5 1,0 µg Polysaccharide for Serotype 6B 1,0 µg Polysaccharide for Serotype 7F 1,0 µg Polysaccharide for Serotype 9V 1,0 µg Polysaccharide for Serotype 14 1,0 µg Polysaccharide for Serotype 23F 1,0 µg Polysaccharide for Serotype 4 3,0 µg Polysaccharide for Serotype 18C 3,0 µg Polysaccharide for Serotype 19F 3,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS S.A, RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS S.A, WAVRE, BELGIUM
Packer:	GLAXOSMITHKLINE BIOLOGICALS S.A. WAVRE, BELGIUM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING, CAPE TOWN, RSA
Laboratory: FPRC:	GLAXOSMITHKLINE BIOLOGICALS S.A, RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS S.A, WAVRE, BELGIUM
FPRC/FPRR:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING, CAPE TOWN, RSA
Shelf-life:	36 months stored at 2 – 8 °C
Date of registration:	27 JULY 2012

RF 15

Registration number:	45/20.2.8/0537
Name of medicine:	MACLEODS EFAVIRENZ 600 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Laboratory: FPRC	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/20.2.8/0766
Name of medicine:	CIPLA LAMIVUDINE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IV, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT IV, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IV, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	45/20.2.8/0767
Name of medicine:	MEDPRO LAMIVUDINE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MEDPRO PHARMACEUTICA (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IV, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT IV, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IV, VERNA, GOA, INDIA
FPRR:	MEDPRO PHARMACEUTICA (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/20.2.8/0815
Name of medicine:	NEVIRAPINE MEDPRO 50 mg TABLETS FOR ORAL SUSPENSION
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/20.2.8/0816
Name of medicine:	NEVIRAPINE MEDPRO 100 mg TABLETS FOR ORAL SUSPENSION
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF15

Registration number:	45/20.2.8/0817
Name of medicine:	NEVIMUNE 50 mg TABLETS FOR ORAL SUSPENSION
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	45/20.2.8/0818
Name of medicine:	NEVIMUNE 100 mg TABLETS FOR ORAL SUSPENSION
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC	CIPLA LTD, UNIT II, PATALGANGA DISTRICT RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	27 JULY 2012

MRF 15

Registration number:	46/20.2.8/0039
Name of medicine:	EFAVIRENZ WINTHROP
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Packer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

MRF15

Registration number:	46/20.2.8/0040
Name of medicine:	TENOFOVIR WINTHROP
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Packer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	27 JULY 2012

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