Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 579 Pretoria, 27 September 2013 No. 36879

AIDS HELPLINE: 0800-0123-22 Prevention is the cure

CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 963 OF 2013

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 963 VAN 2013

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:	36/7.1.5/0385
Name of medicine:	LILLY TADALAFIL 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TADALAFIL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY & Co, LILY TECHNOLOGY CENTER, INDIANAPOLIS, INDIANA, USA
Packer:	LILLY SA, ALCOBENDAS, MADRID, SPAIN ELI LILLY & Co LTD, BASINGSTOKE, HAMPSHIRE, UK
Laboratory: FPRC:	ELI LILLY & Co, LILY TECHNOLOGY CENTER, INDIANAPOLIS, INDIANA, USA ELI LILLY & Co, LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA, USA ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	ELI LILLY (S.A.) (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF15	
Registration number:	A39/32.11/0158
Name of medicine:	REN-ACID SK-F 209
Dosage form:	DIALYSATE
Active ingredients:	EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 7,718 g SODIUM CHLORIDE 214,8 g ACETIC ACID 4,207 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, RSA FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15	
Registration number:	A39/32.11/0159
Name of medicine:	REN-ACID SK-F 207 LOW Ca^{++}
Dosage form:	DIALYSATE
Active ingredients:	EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 6,431 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, RSA FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	A39/32.11/0160
Name of medicine:	REN-ACID SK-F 203
Dosage form:	DIALYSATE
Active ingredients:	EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 9,004 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, RSA FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	A39/32.11/0404
Name of medicine:	REN-ACID SK-F 213
Dosage form:	DIALYSATE
Active ingredients:	EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 9,004 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g DEXTROSE MONOHYDRATE EQUIVALENT TO DEXTROSE ANHYDROUS 38,5 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD INDUSTRIA PARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	A39/32.11/0405
Name of medicine:	REN-ACID SK-F 219 LOW Ca^{++}/GLUCOSE
Dosage form:	DIALYSATE
Active ingredients:	EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 6,431 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g DEXTROSE MONOHYDRATE EQUIVALENT TO DEXTROSE ANHYDROUS 38,5 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD INDUSTRIA PARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	41/11.4.3/0099
Name of medicine:	PEPTAZOL 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACO DISTRIBUTION (PTY) LTD
Manufacturer:	QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA
Packer:	QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA
Laboratory: FPRC:	QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA
FPRR:	PHARMACO DISTRIBUTION (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	42/7.1.3/0115
Name of medicine:	COIRBESARTAN WINTHROP 300/25 (TABLET)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE & WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE & WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	24 Months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	42/7.1.3/0116
Name of medicine:	SARBEN HCTZ 300/25 (TABLET)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE & WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA
Laboratory: FPRC	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE & WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	24 Months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	42/7.1.3/0117
Name of medicine:	COAPROVEL 300/25 (TABLET)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE & WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE & WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	24 Months
Date of registration:	15 AUGUST 2013

MRF15 F 15

Registration number:	42/3.2/0222
Name of medicine:	ARROW ALENDRONATE 70
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM TRIHYDRATE EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SA (PTY) LTD
Manufacturer:	ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA ARROW LABORATORIES LTD, CROYDEN SOUTH, VICTORIA, AUSTRALIA
Packer:	ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA ARROW LABORATORIES LTD, CROYDEN SOUTH, VICTORIA, AUSTRALIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA ARROW LABORATORIES LTD, CROYDEN SOUTH, VICTORIA, AUSTRALIA SELAMINE LTD t/a ARROW GENERICS LTD, CLONSHAUGH, DUBLIN, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

Registration number:	42/34/0377
Name of medicine:	IMMUNOLATE 250 CAPSULE
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	42/5.10/0577
Name of medicine:	VOMIZ D 4 mg
Dosage form:	DISPERSIBLE TABLET
Active ingredients:	EACH DISPERSIBLE TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC :	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	42/5.10/0578
Name of medicine:	VOMIZ D 8 mg
Dosage form:	DISPERSIBLE TABLET
Active ingredients:	EACH DISPERSIBLE TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	42/1.2/0850
Name of medicine:	AURO CITALOPRAM 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	42/1.2/0851
Name of medicine:	AURO CITALOPRAM 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	42/20.1.1/0999
Name of medicine:	DEPUY CMW 2 GENTAMICIN BONE CEMENT
Dosage form:	POWDER/LIQUID MIX
Active ingredients:	EACH 40 g UNIT CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ORTHOMEDICS PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEPUY INTERNATIONAL LTD, BLACKPOOL, LANCASHIRE, UK
Packer:	DEPUY INTERNATIONAL LTD, BLACKPOOL, LANCASHIRE, UK
Laboratory: FPRC:	DEPUY INTERNATIONAL LTD, BLACKPOOL, LANCASHIRE, UK JOHNSON & JOHNSON MEDICAL LTD, SKIPTON, NORTH YORKSHIRE, UK ISOTRON Plc, EUROWAY TRADING ESTATE, BRADFORD, UK STERIGENICS UK LTD, SOMERCOTES, DERBYSHIRE, UK
FPRR:	ORTHOMEDICS PHARMACEUTICALS (PTY) LTD, SYBRAND PARK, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	42/2.5/1017
Name of medicine:	TORCETAM 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory::FPRC	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, CNR SLOANE & MEADOWBROOK CLOSE, BRYANSTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	42/2.5/1018
Name of medicine:	TORCETAM 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, CNR SLOANE & MEADOWBROOK CLOSE, BRYANSTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	42/2.5/1019
Name of medicine:	TORCETAM 750
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, CNR SLOANE & MEADOWBROOK CLOSE, BRYANSTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/11.4.3/0090
Name of medicine:	PEPTAZOL 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACO DISTRIBUTION (PTY) LTD
Manufacturer:	QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA
Packer:	QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA PHARMA-Q, INDUSTIRA WEST, JOHANNESBURG, RSA
Laboratory: FPRC:	QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA PHARMA-Q, INDUSTIRA WEST, JOHANNESBURG, RSA
FPRR:	PHARMACO DISTRIBUTION (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/26/0237
Name of medicine:	PACLITAXEL FRESENIUS 6 mg/ml (30 mg/5 ml)
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 5,0 ml CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Packer:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Laboratory: FPRC:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	FRESENIUS KABI SA (PTY) LTD, INDUSTRIA PARK, MIDRAND, RSA
Shelf-life:	24 months stored at or below 25 ^{0}C 28 days in-use stored at 2-8 ^{0}C for undiluted but opened product
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	43/26/0239
Name of medicine:	PACLITAXEL FRESENIUS 6 mg/ml (300 mg/50 ml)
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 50,0 ml CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Packer:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Laboratory: FPRC:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	FRESENIUS KABI SA (PTY) LTD, INDUSTRIA PARK, MIDRAND, RSA
Shelf-life:	24 months stored at or below 25 ^{0}C 28 days in-use stored at 2-8 ^{0}C for undiluted but opened product
Date of registration:	15 AUGUST 2013

F 15

Registration number:	43/26/0244
Name of medicine:	PACLITAXEL FRESENIUS 6 mg/ml (100 mg/16,7 ml)
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 16,7 ml CONTAINS: PACLITAXEL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Packer:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Laboratory: FPRC:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	FRESENIUS KABI SA (PTY) LTD, INDUSTRIA PARK, MIDRAND, RSA
Shelf-life:	24 months stored at or below 25 ^{0}C 28 days in-use stored at 2-8 ^{0}C for undiluted but opened product
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/32.16/0352
Name of medicine:	PROMUS ELEMENT MONORAIL EVEROLIMUS ELUTING CORONARY STENT SYSTEM
Dosage form:	STENT
Active ingredients:	EACH STENT CONTAINS: EVEROLIMUS 100,0 µg per cm^2
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BOSTON SCIENTIFIC SOUTH AFRICA (PTY) LTD
Manufacturer:	BOSTON SCIENTIFIC IRELAND LTD, GALWAY, IRELAND BOSTON SCIENTIFIC SCIMED, INC., MAPLE GROVE, MINNESOTA, USA ISOTRON IRELAND LTD, TULLAMORE, OFFALY, IRELAND BOSTON SCIENTIFIC CORPORATION COVENTRY, COVENTRY, USA
Packer:	BOSTON SCIENTIFIC IRELAND LTD, GALWAY, IRELAND BOSTON SCIENTIFIC SCIMED, INC., MAPLE GROVE, MINNESOTA, USA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC	BOSTON SCIENTIFIC IRELAND LTD, GALWAY, IRELAND
FPRR:	BOSTON SCIENTIFIC SOUTH AFRICA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	43/5.7.1/0358
Name of medicine:	DEZZO CETIRIZINE 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DEZZO TRADING 392 (PTY) LTD
Manufacturer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA
Packer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA
Laboratory: FPRC:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/5.7.1/0359
Name of medicine:	ZINALLERG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DEZZO TRADING 392 (PTY) LTD
Manufacturer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA
Packer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA
Laboratory: FPRC:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/20.1.1/0389
Name of medicine:	PIPERACILLIN AND TAZOBACTAM 4 g/0,5 g ADCO
Dosage form:	LYOPHILIZED POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACCILIN 4,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 0,5 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA
Packer:	ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA
Laboratory: FPRC:	ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	43/20.1.1/0553
Name of medicine:	FRESENIUS CEFTAZIDIME 500 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTAZIDIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL
Packer:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL
Laboratory: FPRC:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	FRESENIUS KABI SA (PTY) LTD, INDUSTRIA PARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional
Date of registration:	15 AUGUST 2013

RF 15

Registration number:	43/20.1.1/0554
Name of medicine:	FRESENIUS CEFTAZIDIME 1 000 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTAZIDIME 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL
Packer:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL
Laboratory: FPRC:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	FRESENIUS KABI SA (PTY) LTD, INDUSTRIA PARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/20.1.1/0555
Name of medicine:	FRESENIUS CEFTAZIDIME 2 000 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTAZIDIME 2 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL
Packer:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL
Laboratory: FPRC:	LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	FRESENIUS KABI SA (PTY) LTD, INDUSTRIA PARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/2.5/0597
Name of medicine:	EPLEPTIN 600
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GABAPENTIN 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

Registration number:	43/2.5/0598
Name of medicine:	EPLEPTIN 800
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GABAPENTIN 800,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/26/0793
Name of medicine:	DOCEFREZ 20
Dosage form:	POWDER FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL ANHYDROUS 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	43/26/0794
Name of medicine:	DOCEFREZ 80
Dosage form:	POWDER FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL ANHYDROUS 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/26/0795
Name of medicine:	DOCEFREZ DILUENT
Dosage form:	SOLVENT FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS:ETHANOL IN POLYSORBATE 80 26,76 % *m/m*
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/30.1/0808
Name of medicine:	SIMPONI
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: GOLIMUMAB 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA
Packer:	BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA CILAG AG, SCHAFFHAUSEN, SWITZERLAND
Laboratory: FPRC:	BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA CENTOCOR B.V., LEIDEN, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA CILAG AG, SCHAFFHAUSEN, SWITZERLAND
FPRR:	JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	43/2.6.5/0870
Name of medicine:	ZYPOGEN 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/2.6.5/0871
Name of medicine:	ZYPOGEN 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/2.6.5/0872
Name of medicine:	ZYPOGEN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

0

MRF15

Registration number:	43/2.6.5/0873
Name of medicine:	RAN OLANZAPINE 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/2.6.5/0874
Name of medicine:	RAN OLANZAPINE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	43/2.6.5/0875
Name of medicine:	RAN OLANZAPINE 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	43/2.6.5/1016
Name of medicine:	CLOMENT ORAL SUSPENSION 50 mg/ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: CLOZAPINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory: FPRC:	DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	19 APRIL 2013

MRF 15

Registration number:	44/2.6.5/0003
Name of medicine:	PERIDA 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR::	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/2.6.5/0004
Name of medicine:	PERIDA 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR::	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/2.6.5/0005
Name of medicine:	PERIDA 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC/FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/2.6.5/0006
Name of medicine:	PERIDA 3 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/2.6.5/0007
Name of medicine:	PERIDA 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/2.6.5/0008
Name of medicine:	PERIDA 6 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/5.2/0047
Name of medicine:	ALFUZOSIN SANOFI-AVENTIS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALFUZOSIN HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, GUSTAV EIFFEL, TOURS, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, GUSTAV EIFFEL, TOURS, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	SANOFI WINTHROP INDUSTRIE, GUSTAV EIFFEL, TOURS, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0443
Name of medicine:	ASPEN 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
Applicant:	PHARMACARE LIMITED
Manufacturer:	ACTAVIS Hf, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	ACTAVIS Hf, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	ACTAVIS Hf, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/7.1.3/0444
Name of medicine:	ASPEN 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
Applicant:	PHARMACARE LIMITED
Manufacturer:	ACTAVIS Hf, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	ACTAVIS Hf, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	ACTAVIS Hf, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/32.11/0489
Name of medicine:	ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 192A
Dosage form:	SOLUTION
Active ingredients:	EACH 1 000,0 ml OF SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE DIHYDRATE 7,72 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g ACETIC ACID, GLACIAL 6,31 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
Packer:	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
Laboratory: FPRC	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL (PTY) LTD, NORTHRIDING, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/32.11/0490
Name of medicine:	ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 196A
Dosage form:	SOLUTION
Active ingredients:	EACH 1 000,0 ml OF SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE DIHYDRATE 6,43 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g ACETIC ACID, GLACIAL 6,31 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
Packer:	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
Laboratory: FPRC:	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL (PTY) LTD, NORTHRIDING, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/32.11/0491
Name of medicine:	ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 380A
Dosage form:	SOLUTION
Active ingredients:	EACH 1 000,0 ml OF SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE DIHYDRATE 7,72 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g ACETIC ACID, GLACIAL 6,31 g GLUCOSE MONOHYDRATE 30,50 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
Packer:	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
Laboratory: FPRC:	B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL (PTY) LTD, NORTHRIDING, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0508
Name of medicine:	ADCOTAN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0509
Name of medicine:	ADCOTAN 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/7.1.3/0510
Name of medicine:	ADCOTAN 160
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MMRF 15

Registration number:	44/7.1.3/0514
Name of medicine:	PROPAN VALSARTAN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0515
Name of medicine:	PROPAN VALSARTAN 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/7.1.3/0516
Name of medicine:	PROPAN VALSARTAN 160
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0517
Name of medicine:	COVAN VALSARTAN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0518
Name of medicine:	COVAN VALSARTAN 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/7.1.3/0519
Name of medicine:	COVAN VALSARTAN 160
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0520
Name of medicine:	ADCO VALSARTAN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0521
Name of medicine:	ADCO VALSARTAN 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/7.1.3/0522
Name of medicine:	ADCO VALSARTAN 160
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0523
Name of medicine:	RESTAN VALSARTAN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0524
Name of medicine:	RESTAN VALSARTAN 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/7.1.3/0525
Name of medicine:	RESTAN VALSARTAN 160
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
Laboratory: FPRC:	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/0609
Name of medicine:	LEPITRIN CO 100/25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND
Packer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC	ACTAVIS HF, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional) manufactured with hydrochlorothiazide sourced from Cambrex and losartan potassium sourced from Dr Reddy's
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/2.9/0931
Name of medicine:	ULTRACET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 37,5 mg PARACETAMOL 325,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN-CILAG SpA, BORGO S MICHELE, LATINA, ITALY
Packer:	JANSSEN-CILAG SpA, BORGO S MICHELE, LATINA, ITALY
Laboratory: FPRC:	JANSSEN-CILAG SpA, BORGO S MICHELE, LATINA, ITALY SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/20.2.8/0941
Name of medicine:	SEBIVO ORAL SOLUTION
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml OF SOLUTION CONTAINS: TELBIVUDINE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA SAS, HUNINGUE, FRANCE
Packer:	NOVARTIS PHARMA SAS, HUNINGUE, FRANCE DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	NOVARTIS PHARMA SAS, HUNINGUE, FRANCE SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA PHARMANALYTICA S.A., LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	36 months manufactured by Novartis, France, stored at or below 30 ^{0}C
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/5.3/0944
Name of medicine:	ZEPANALZ 5 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/5.3/0945
Name of medicine:	ZEPANALZ 10 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/7.1.3/1010
Name of medicine:	BILOCOR CO 2,5/6,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 2,5 mg HYDROCHLOROTHIAZIDE 6,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA
Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months manufactured by Lupin, Aurangabad, India with Bisoprolol fumarate sourced from Urictem and Hydrochlorothiazide sourced from IPCA
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/1011
Name of medicine:	BILOCOR CO 5/6,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 5,0 mg HYDROCHLOROTHIAZIDE 6,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA
Laboratory: FPRC	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months manufactured by Lupin, Aurangabad, India with Bisoprolol fumarate sourced from Urictem and Hydrochlorothiazide sourced from IPCA
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/7.1.3/1012
Name of medicine:	BILOCOR CO 10/6,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg HYDROCHLOROTHIAZIDE 6,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA
Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months manufactured by Lupin, Aurangabad, India with Bisoprolol fumarate sourced from Urictem and Hydrochlorothiazide sourced from IPCA
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/20.1.1/1045
Name of medicine:	SANDOZ 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
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA
Laboratory: FPRC:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months manufactured by Lek, Slovenia with Teicoplanin sourced from Dong Kook
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/34/1046
Name of medicine:	WATER FOR INJECTION FOR SANDOZ TEICOPLANIN 200
Dosage form:	SOLVENT FOR SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA
Laboratory: FPRC	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional) manufactured by Lek, Slovenia.
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	44/20.1.1/1082
Name of medicine:	PLANITEC 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
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA
Laboratory: FPRC:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months manufactured by Lek, Slovenia.
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	44/34/1083
Name of medicine:	PLANITEC WATER FOR INJECTION
Dosage form:	SOLVENT FOR SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA
Laboratory: FPRC:	LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional) manufactured by Lek, Slovenia.
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/21.2/0173
Name of medicine:	DIAGLUMED 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DEZZO TRADING 392 (PTY) LTD
Manufacturer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA
Packer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA
Laboratory: FPRC	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/21.2/0174
Name of medicine:	GLICLAZIDE DEZZO 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DEZZO TRADING 392 (PTY) LTD
Manufacturer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA
Packer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA
Laboratory: FPRC:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	45/21.12/0180
Name of medicine:	FEMONC 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LETROZOLE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/21.12/0181
Name of medicine:	FEMOLET 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LETROZOLE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC	RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/7.1.3/0301
Name of medicine:	MYLACAND 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN
Laboratory: FPRC:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	45/7.1.3/0302
Name of medicine:	MYLACAND 16 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN
Laboratory: FPRC:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/11/0463
Name of medicine:	MEZAVANT
Dosage form:	PROLONGED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: MESALAZINE 1 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	COSMO SpA, COLOMBO, LAINATE-MILAN, ITALY
Packer:	COSMO SpA, COLOMBO, LAINATE-MILAN, ITALY
Laboratory: FPRC	COSMO SpA, COLOMBO, LAINATE-MILAN, ITALY ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD – RESEARCH & DEVELOPMENT, AEROTON, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD – RESEARCH & DEVELOPMENT, AEROTON RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/7.5/0502
Name of medicine:	STORWIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC
Packer:	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months manufactured with Rosuvastatin sourced from MSN.
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	45/7.5/0503
Name of medicine:	STORWIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC
Packer:	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months manufactured with Rosuvastatin sourced from MSN.
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/7.5/0504
Name of medicine:	STORWIN 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC
Packer:	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months manufactured with Rosuvastatin sourced from MSN
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/21.2/0557
Name of medicine:	TRAJENTA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LINAGLIPTIN 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, OAK STREET, COLUMBUS, OHIO, USA
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, OAK STREET, COLUMBUS, OHIO, USA SIXARP, LLC-PRAXIS PACKAGING SOLUTIONS, CATERPILLAR DRIVE, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC-PRAXIS PACKAGING SOLUTIONS, WILSON ROAD, COLUMBUS, OHIO, USA
Laboratory: FPRC:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	45/20.2.8/0586
Name of medicine:	VOLIRET 500 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO VALACICLOVIR 500,0,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer.	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/20.2.8/0587
Name of medicine:	VOLIRET 1 g TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO VALACICLOVIR 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/20.2.8/0590
Name of medicine:	SHILOVA 500 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO VALACICLOVIR 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	45/20.2.8/0591
Name of medicine:	SHILOVA 1 g TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO VALACICLOVIR 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/15.4/0710
Name of medicine:	SAFLUTAN
Dosage form:	OPHTHALMIC SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: TAFLUPROST 15,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	SANTEN OY, TAMPERE, FINLAND LABORATOIRE UNITHER, COUTANCES CEDEX, FRANCE
Packer:	SANTEN OY, TAMPERE, FINLAND LABORATOIRE UNITHER, COUTANCES CEDEX, FRANCE MERCK SHARP & DOHME BV. HAARLEM, THE NETHERLANDS
Laboratory: FPRC	SANTEN OY, TAMPERE, FINLAND LABORATOIRE UNITHER, COUTANCES CEDEX, FRANCE MERCK SHARP & DOHME BV. HAARLEM, THE NETHERLANDS MERCK SHARP & DOHME LTD, CRAMLINGTON, NORTHUMBERLAND, UK MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	45/20.2.8/0723
Name of medicine:	ACTIPREZ 1 000
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACYCLOVIR HYDROCHLORIDE EQUIVALENT TO VALACYCLOVIR 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	45/20.2.8/0924
Name of medicine:	RINAVO
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RITONAVIR 100,0 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, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	46/20.2.6/0025
Name of medicine:	FALCIRONE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATOVAQUONE 250,0 mg PROGUANIL HYDROCHLORIDE 100,0mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC	CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	46/20.2.6/0027
Name of medicine:	NUMAL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATOVAQUONE 250,0 mg PROGUANIL HYDROCHLORIDE 100,0mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

MRF15

Registration number:	47/20.2.8/0118
Name of medicine:	EFTENEM
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	HETERO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA
Packer:	HETERO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA SPECPHARM HOLDING (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	HETERO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA SPECPHARM HOLDING (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional) manufactured by Hetero Laboratories Ltd, India.
Date of registration:	15 AUGUST 2013

MRF 15

Registration number:	47/20.2.8/0304
Name of medicine:	EMTEWIN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	HETERO DRUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Packer:	HETERO DRUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	HETERO DRUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	15 AUGUST 2013

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737
Kaapstad-tak: Tel: (021) 465-7531