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

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INHOUD

GOVERNMENT NOTICE
GOEWERMENTSKENNISGEWING

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. 74 **6 February 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.

No. 74 **6 Februarie 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:	07/13.3.1/24
Name of medicine:	CORTAVANCE
Dosage form:	CUTANEOUS SPRAY SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: Hydrocortisone aceponate 0,584 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	VIRBAC RSA (PTY) LTD
Manufacturer:	VIRBAC S.A, CARROS, CEDEX, FRANCE
Packer:	VIRBAC S.A, CARROS, CEDEX, FRANCE VIRBAC RSA, CENTURION, RSA
Laboratory: FPRC:	VIRBAC S.A, CARROS, CEDEX, FRANCE M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	VIRBAC RSA (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months In-use shelf life of 6 months stored at or below 25 °C or between 2 – 8 °C
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	A39/20.2.2/0589
Name of medicine:	CANESTEN 3VC
Dosage form:	VAGINAL CREAM
Active ingredients:	EACH 1,0 g CREAM CONTAINS: CLOTRIMAZOLE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BAYER (PTY) LTD
Manufacturer:	KERN PHARMA SL, TERASSA, BARCELONA, SPAIN
Packer:	KERN PHARMA SL, TERASSA, BARCELONA, SPAIN AKACIA PHARMACEUTICALS, ISANDO, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA PHARMACEUTICAL CONTRACTORS, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	KERN PHARMA SL, TERASSA, BARCELONA, SPAIN AKACIA PHARMACEUTICALS, ISANDO, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA PHARMACEUTICAL CONTRACTORS, ISANDO, JOHANNESBURG, RSA
FPRR:	BAYER (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

F 15

Registration number:	A39/7.1/0590
Name of medicine:	ASPEN NIMODIPINE IV
Dosage form:	INFUSION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: NIMODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	LABORATORIO REIG JOFRE, S.A, BARCELONA, SPAIN STRIDES ARCOLAB LIMITED, BANNERGHATTA, BANGALORE, INDIA
Packer:	LABORATORIO REIG JOFRE, S.A, BARCELONA, SPAIN STRIDES ARCOLAB LIMITED, BANNERGHATTA, BANGALORE, INDIA
Laboratory: FPRC:	LABORATORIO REIG JOFRE, S.A, BARCELONA, SPAIN STRIDES ARCOLAB LIMITED, BANNERGHATTA, BANGALORE, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	A40/11.4.3/0153
Name of medicine:	COVAN LANSOPRAZOLE 15
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: LANSOPRAZOLE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LICONSA S.A., GUADALAJARA, SPAIN
Packer:	LICONSA S.A., GUADALAJARA, SPAIN
Laboratory: FPRC:	LICONSA S.A., GUADALAJARA, SPAIN
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	41/3.1/0252
Name of medicine:	MEDOXICAM 7,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Packer:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Laboratory: FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

F 15

Registration number:	41/3.1/0253
Name of medicine:	MEDOXICAM 15
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Packer:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Laboratory: FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	41/7.1.3/0770
Name of medicine:	EXFORGE 5/320 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 5,0 mg Valsartan 320,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	41/7.1.3/0771
Name of medicine:	EXFORGE 10/320 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 10,0 mg Valsartan 320,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	42/8.2/0193
Name of medicine:	ENOXAPARIN SODIUM 20 WINTHROP
Dosage form:	INJECTION
Active ingredients:	EACH 0,2 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months
Date of registration	26 OCTOBER 2012

MRF 15

Registration number:	42/8.2/0194
Name of medicine:	ENOXAPARIN SODIUM 40 WINTHROP
Dosage form:	INJECTION
Active ingredients:	EACH 0,4 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	42/8.2/0195
Name of medicine:	ENOXAPARIN SODIUM 60 WINTHROP
Dosage form:	INJECTION
Active ingredients:	EACH 0,6 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	42/8.2/0196
Name of medicine:	ENOXAPARIN SODIUM 80 WINTHROP
Dosage form:	INJECTION
Active ingredients:	EACH 0,8 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRC/FPRR	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	42/8.2/0197
Name of medicine:	ENOXAPARIN SODIUM 100 WINTHROP
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory: FPRC :	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15 F 15

Registration number:	42/8.2/0198
Name of medicine:	ENOXAPARIN SODIUM 300 WINTHROP
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRC/FPRR	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

Registration number:	42/20.1.2/0212
Name of medicine:	CLAMGEN IV 0,6
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMOXICILLIN SODIUM EQUIVALENT TO AMOXICILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK
Packer:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK
Laboratory: FPRC	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	42/20.1.2/0213
Name of medicine:	CLAMGEN IV 1,2
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMOXICILLIN SODIUM EQUIVALENT TO AMOXICILLIN 1 000,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK
Packer:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK
Laboratory: FPRC:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	42/20.1.1/0251
Name of medicine:	LITHA PIPERACILLIN CO 2/0,250
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 2,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 0,250 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	MITIM S.r.L, BRESCIA, ITALY
Packer:	MITIM S.r.L, BRESCIA, ITALY
Laboratory: FPRC:	MITIM S.r.L, BRESCIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	LITHA PHARMA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	42/20.1.1/0252
Name of medicine:	LITHA PIPERACILLIN CO 3/0,375
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 3,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 0,375 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	MITIM S.r.L, BRESCIA, ITALY
Packer:	MITIM S.r.L, BRESCIA, ITALY
Laboratory::FPRC	MITIM S.r.L, BRESCIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR	LITHA PHARMA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	42/20.1.1/0253
Name of medicine:	LITHA PIPERACILLIN CO 4/0,5
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 4,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 0,5 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	MITIM S.r.L, BRESCIA, ITALY
Packer:	MITIM S.r.L, BRESCIA, ITALY
Laboratory: FPRC:	MITIM S.r.L, BRESCIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	LITHA PHARMA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	42/3.1/0831
Name of medicine:	VOLTAREN ACTI-GO SOFT GEL CAPSULE
Dosage form:	SOFT GEL CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: DICLOFENAC POTASSIUM 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	RP SCHERER GmbH & Co. KG, EBERBACH/BADEN, GERMANY
Packer:	CARDINAL HEALTH GERMANY 405 GmbH, STEINBEISSTRASSE, SCHORNDORF, GERMANY
Laboratory: FPRC:	RP SCHERER GmbH & Co. KG, EBERBACH/BADEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	42/26/0961
Name of medicine:	TEMODAL 140 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 140,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SCHERING-PLOUGH (PTY) LTD
Manufacturer:	ORION CORPORATION, TURKU, FINLAND
Packer:	ORION CORPORATION, TURKU, FINLAND SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM
Laboratory: FPRC:	ORION CORPORATION, TURKU, FINLAND SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM SGS LAB SIMON SA, WAVRE, BELGIUM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	SCHERING-PLOUGH, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	42/26/0962
Name of medicine:	TEMODAL 180 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 180,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SCHERING-PLOUGH (PTY) LTD
Manufacturer:	ORION CORPORATION, TURKU, FINLAND
Packer:	ORION CORPORATION, TURKU, FINLAND SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM
Laboratory: FPRC:	ORION CORPORATION, TURKU, FINLAND SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM SGS LAB SIMON SA, WAVRE, BELGIUM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	SCHERING-PLOUGH, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/5.4.1/0133
Name of medicine:	GULF PRAMIPEXOLE 0,25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

F 15

Registration number:	43/5.4.1/0134
Name of medicine:	GULF PRAMIPEXOLE 0,125 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0,125 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/5.4.1/0135
Name of medicine:	GULF PRAMIPEXOLE 1,0 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/2.2/0171
Name of medicine:	MIDAZOLAM B.BRAUN 1 mg/ml
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: MIDAZOLAM 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN
Packer:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN
Laboratory: FPRC:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
FPRR:	B BRAUN MEDICAL (PTY) LTD, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

F 15

Registration number:	43/2.2/0172
Name of medicine:	MIDAZOLAM B.BRAUN 5 mg/ml
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: MIDAZOLAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN
Packer:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN
Laboratory: FPRC:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
FPRR:	B BRAUN MEDICAL (PTY) LTD, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/20.1.1/0190
Name of medicine:	DRL LEVOFLOXACIN 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Levofloxacin 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/20.1.1/0191
Name of medicine:	DRL LEVOFLOXACIN 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Levofloxacin 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	43/26/0246
Name of medicine:	GENEXOL 300 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACORP cc
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA-SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA-SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA-SANAND, AHMEDABAD, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG, RSA
FPRR:	PHARMACORP cc, ARCADIA, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/7.1.3/0301
Name of medicine:	VALANT 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA
Packer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA ROPACK MIRABEAU, MONTREAL, QUEBEC, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/7.1.3/0302
Name of medicine:	VALANT 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA
Packer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA ROPACK MIRABEAU, MONTREAL, QUEBEC, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/7.1.3/0303
Name of medicine:	VALANT 160
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	PHARMASCIENCE INC, ROYALMOUNT, AVENUE, MONTREAL, QUEBEC, CANADA
Packer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA ROPACK MIRABEAU, MONTREAL, QUEBEC, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/2.6.5/0446
Name of medicine:	PSYQUET 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ. SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/2.6.5/0447
Name of medicine:	SANDOZ QUETIAPINE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7,8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

Registration number:	43/5.7.1/0451
Name of medicine:	SIBELIUM T 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FLUNARIZINE HYDROCHLORIDE EQUIVALENT TO FLUNARIZINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN-CILAG S.P.A, LATINA, ITALY
Packer:	JANSSEN-CILAG S.P.A, LATINA, ITALY SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	JANSSEN-CILAG S.P.A, LATINA, ITALY SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/5.4.1/0505
Name of medicine:	ACCORD ROPINIROLE 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HCl 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/5.4.1/0506
Name of medicine:	ACCORD ROPINIROLE 0,25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HCl 0,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/5.4.1/0507
Name of medicine:	ACCORD ROPINIROLE 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HCl 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/5.4.1/0508
Name of medicine:	ACCORD ROPINIROLE 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HCl 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/5.4.1/0509
Name of medicine:	ACCORD ROPINIROLE 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROPINIROLE HCl 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/26/0540
Name of medicine:	TEMODAL 100 mg/ml POWDER FOR INJECTION
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEMOZOLOMIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCHERING-PLOUGH (PTY) LTD
Manufacturer:	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY
Packer:	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM
Laboratory: FPRC	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	SCHERING-PLOUGH, WOODMEAD, SANDTON, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/18.3/0701
Name of medicine:	SORBISTERIT POWDER FOR ORAL SUSPENSION
Dosage form:	POWDER FOR ORAL SUSPENSION
Active ingredients:	EACH 1,0 g POWDER CONTAINS: CALCIUM POLYSTYRENE SULPHONATE 7,59 – 9,49 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, ST. WENDEL, GERMANY
Packer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, ST. WENDEL, GERMANY
Laboratory: FPRC:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, ST. WENDEL, GERMANY BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA
FPRR:	FRESENIUS KABI SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/21.12/0726
Name of medicine:	LETOZ 2,5 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LETROZOLE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/2.6.5/0849
Name of medicine:	PSYQUET 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (FTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/2.6.5/0850
Name of medicine:	PSYQUET 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/2.6.5/0851
Name of medicine:	PSYQUET 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	43/2.6.5/0852
Name of medicine:	SANDOZ QUETIAPINE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/2.6.5/0853
Name of medicine:	SANDOZ QUETIAPINE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/2.6.5/0854
Name of medicine:	SANDOZ QUETIAPINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/21.3/0869
Name of medicine:	THYROTROPIN ALFA GENZYME 0,9 mg/ml
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml CONTAINS: THYROTROPIN ALFA 0,9 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENZYME BIOPHARMACEUTICALS SA (PTY)
Manufacturer:	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA
Packer:	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA
Laboratory: FPRC	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA GENZYME CORPORATION, 45 NEW YORK AVENUE, FRAMINGHAM, MASSACHUSETTS, USA GENZYME CORPORATION, 76 NEW YORK AVENUE, FRAMINGHAM, MASSACHUSETTS, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	GENZYME BIOPHARMACEUTICALS SA (PTY) LTD, BRYANSTON, GAUTENG, RSA
Shelf-life:	36 months In-use shelf life of 24 hours stored at 2 – 8 °C
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/11.4.3/1089
Name of medicine:	WATSON RANITIDINE 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RANITIDINE HCl EQUIVALENT TO RANITIDINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	Rx MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	Rx MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD WOODMEAD, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/11.4.3/1090
Name of medicine:	WATSON RANITIDINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RANITIDINE HCl EQUIVALENT TO RANITIDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	Rx MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	Rx MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD WOODMEAD, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/7.5/1107
Name of medicine:	PROPAN ATORVASTATIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/7.5/1108
Name of medicine:	PROPAN ATORVASTATIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRC:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/7.5/1109
Name of medicine:	PROPAN ATORVASTATIN 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/ FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MMRF 15

Registration number:	43/7.5/1110
Name of medicine:	COVAN ATORVASTATIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/7.5/1111
Name of medicine:	COVAN ATORVASTATIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/7.5/1112
Name of medicine:	COVAN ATORVASTATIN 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/7.5/1113
Name of medicine:	RESTAN ATORVASTATIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15	
Registration number:	43/7.5/1114
Name of medicine:	RESTAN ATORVASTATIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15	
Registration number:	43/7.5/1115
Name of medicine:	RESTAN ATORVASTATIN 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MMRF 15	
Registration number:	43/7.5/1116
Name of medicine:	ADCO ATORVASTATIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/7.5/1117
Name of medicine:	ADCO ATORVASTATIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/7.5/1118
Name of medicine:	ADCO ATORVASTATIN 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/ FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	43/7.5/1119
Name of medicine:	ALCHOLTIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/7.5/1120
Name of medicine:	ALCHOLTIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/7.5/1121
Name of medicine:	ALCHOLTIN 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/13.4.1/0095
Name of medicine:	MOMATE OINTMENT
Dosage form:	OINTMENT
Active ingredients:	EACH 1,0 g OINTMENT CONTAINS: MOMETASONE FUROATE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA
Packer:	GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA
Laboratory: FPRC	GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/26/0098
Name of medicine:	DOCETAXEL WINTHROP 20 mg/1 ml RTU
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Laboratory: FPRC:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/26/0099
Name of medicine:	DOCETAXEL WINTHROP 80 mg/4 ml RTU
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 4,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Laboratory: FPRC:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/26/0100
Name of medicine:	TAXOTERE 20 mg/1 ml RTU
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SA (PTY) LTD
Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Laboratory: FPRC	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	SANOFI-AVENTIS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/26/0101
Name of medicine:	TAXOTERE 80 mg/4 ml RTU
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 4,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SA (PTY) LTD
Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Laboratory: FPRC:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	SANOFI-AVENTIS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/24/0102
Name of medicine:	PHOSPHOSORB 660
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CALCIUM ACETATE 660,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, BAD HOMBURG, GERMANY
Packer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, BAD HOMBURG, GERMANY
Laboratory: FPRC:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, BAD HOMBURG, GERMANY
FPRR:	FRESENIUS KABI SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months In-use shelf life of 5 weeks stored at or below 25 °C
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	44/13.12/0109
Name of medicine:	EPIDUO 0,1 %/2,5 %
Dosage form:	GEL
Active ingredients:	EACH 1,0 g GEL CONTAINS: ADAPALENE 1,0 mg BENZOYL PEROXIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GALDERMA LABORATORIES S.A. (PTY) LTD
Manufacturer:	LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE
Packer:	LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE
Laboratory: FPRC	LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
FPRR:	GALDERMA LABORATORIES S.A., BRYANSTON, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/3.1/0298
Name of medicine:	VOLTAREN ACTI-GO SOFT GEL CAPSULE 25 mg
Dosage form:	SOFT GEL CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: DICLOFENAC POTASSIUM 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	RP SCHERER GmbH & Co. KG, EBERBACH/BADEN, GERMANY
Packer:	CATALENT GERMANY SCHORNDORF GmbH, STEINBEISSTRASSE, SCHORNDORF, GERMANY
Laboratory: FPRC:	RP SCHERER GmbH & Co. KG, EBERBACH/BADEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/32.2/0546
Name of medicine:	MOZOBIL
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: PLERIXAFOR 20 mg/ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENZYME BIOPHARMACEUTICALS SOUTH AFRICA (PTY) LTD
Manufacturer:	PATHEON UK LTD, SWINDON, WILTSHIRE, UNITED KINGDOM
Packer:	PATHEON UK LTD, SWINDON, WILTSHIRE, UNITED KINGDOM GENZYME LTD, HAVERHILL, SUFFOLK, UNITED KINGDOM
Laboratory: FPRC:	PATHEON UK LTD, SWINDON, WILTSHIRE, UNITED KINGDOM GENZYME LTD, HAVERHILL, SUFFOLK, UNITED KINGDOM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	GENZYME BIOPHARMACEUTICALS, BRYANSTON, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	44/10.3/0670
Name of medicine:	DAXAS 500 µg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROFLUMILAST 500,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NYCOMED (PTY) LTD
Manufacturer:	NYCOMED GmbH, ORANIENBURG, GERMANY
Packer:	NYCOMED GmbH, ORANIENBURG, GERMANY
Laboratory: FPRC	NYCOMED GmbH, ORANIENBURG, GERMANY
FPRR:	NYCOMED (PTY) LTD, BRYANSTON, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/10.2.2/0829
Name of medicine:	SINTAIR 4 mg
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD,ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/10.2.2/0830
Name of medicine:	SINTAIR 5 mg
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD,ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	44/10.2.2/0831
Name of medicine:	SINTAIR 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA
Laboratory: FPRC	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD,ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/20.2.3/0863
Name of medicine:	CIPLA CAPREOMYCIN
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CAPREOMYCIN SULPHATE EQUIVALENT TO CAPREOMYCIN 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA
Packer:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/20.2.3/0864
Name of medicine:	MEDPRO CAPREOMYCIN
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CAPREOMYCIN SULPHATE EQUIVALENT TO CAPREOMYCIN 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA
Packer:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/10.2.2/0912
Name of medicine:	GLENMONT 4
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH CHEWABLE TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Laboratory: FPRC	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA
FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/10.2.2/0913
Name of medicine:	GLENMONT 5
Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH CHEWABLE TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA
FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/10.2.2/0914
Name of medicine:	GLENMONT 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA
FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/10.1/0925
Name of medicine:	MUCO GO 200 EFFERVESCENT TABLETS
Dosage form:	EFFERVESCENT TABLET
Active ingredients:	EACH TABLET CONTAINS: ACETYLCYSTEINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACTOR PHARMA (PTY) LTD
Manufacturer:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY
Packer:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE EXTENSION, FLORIDA, RSA
FPRR:	ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	60 months (Aluminium tubes) 36 months (Polyproylene containers)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/10.1/0927
Name of medicine:	MUCATAK 200 EFFERVESCENT TABLETS
Dosage form:	EFFERVESCENT TABLET
Active ingredients:	EACH TABLET CONTAINS: ACETYLCYSTEINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACTOR PHARMA (PTY) LTD
Manufacturer:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY
Packer:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE EXTENSION, FLORIDA, RSA
FPRR:	ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	60 months (Aluminium tubes) 36 months (Polyproylene containers)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	46/20.2.8/0760
Name of medicine:	LAMIVUDINE WINTHROP 150 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg
Conditions of registration:	1,2,3,4,5,6,7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Packer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

Registration number:	46/20.2.8/0682
Name of medicine:	ATAZOR 300
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 300,0 mg
Conditions of registration:	1,2,3,4,5,6,7
Applicant:	EMCURE PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRIKEM cc, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	EMCURE PHARMACEUTICALS SA (PTY) LTD, MONDEOR, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/26/0960
Name of medicine:	ACCORD TEMOZOLOMIDE 5
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/26/0961
Name of medicine:	ACCORD TEMOZOLOMIDE 20
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/26/0962
Name of medicine:	ACCORD TEMOZOLOMIDE 100
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/26/0963
Name of medicine:	ACCORD TEMOZOLOMIDE 250
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/26/0964
Name of medicine:	TEMINTAS 5
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/26/0965
Name of medicine:	TEMINTAS 20
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/26/0966
Name of medicine:	TEMINTAS 100
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	44/26/0967
Name of medicine:	TEMINTAS 250
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	44/7.1.5/1049
Name of medicine:	LEVITRA ODT 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VARDENAFIL HYDROCHLORIDE EQUIVALENT TO VARDENAFIL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
Packer:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY BRECON PHARMACEUTICAL LTD, HAY-ON-WYE, HEREFORD, UNITED KINGDOM
Laboratory: FPRC	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	BAYER (PTY) LTD, ISANDO, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	45/1.3.2/0224
Name of medicine:	ACCORD NALTREXONE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NALTREXONE HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	45/1.3.2/0225
Name of medicine:	NALTIMA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NALTREXONE HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	45/2.6.5/0361
Name of medicine:	QUETIPINE MEDPRO 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	45/2.6.5/0362
Name of medicine:	QUETIPINE MEDPRO 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	45/2.6.5/0363
Name of medicine:	QUETIPINE MEDPRO 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	45/2.6.5/0364
Name of medicine:	QUETIPINE MEDPRO 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	45/2.6.5/0365
Name of medicine:	QUETIAPINE MEDPRO 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	45/2.6.5/0366
Name of medicine:	CIPLA QUETIAPINE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	45/2.6.5/0367
Name of medicine:	CIPLA QUETIAPINE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer.	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	45/2.6.5/0368
Name of medicine:	CIPLA QUETIAPINE 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	45/2.6.5/0369
Name of medicine:	CIPLA QUETIAPINE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	45/2.6.5/0370
Name of medicine:	CIPLA QUETIAPINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	45/26/0383
Name of medicine:	IRINOTECAN SAFELINE 40 mg/2 ml
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: Irinotecan hydrochloride trihydrate 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A, PALINI ATTICI, GREECE
Packer:	VIANEX S.A, PALINI ATTICI, GREECE
Laboratory: FPRC:	VIANEX S.A, PALINI ATTICI, GREECE M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	45/26/0384
Name of medicine:	IRINOTECAN SAFELINE 100 mg/5 ml
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: Irinotecan hydrochloride trihydrate 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A, PALINI ATTICI, GREECE
Packer:	VIANEX S.A, PALINI ATTICI, GREECE
Laboratory: FPRC:	VIANEX S.A, PALINI ATTICI, GREECE M&L LABORATORY SERCICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	45/26/0511
Name of medicine:	JEVTAMA
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION AND SOLVENT FOR DILUTION
Active ingredients:	EACH VIAL CONTAINS: CABAZITAXEL 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UK
Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UK
Laboratory: FPRC	AVENTIS PHARMA DAGENHAM, ESSEX, UK WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	46/20.2.8/0005
Name of medicine:	ACRIPTAZ 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg
Conditions of registration:	1,2,3,4,5,6,7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	60 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	46/20.2.8/0010
Name of medicine:	LAZENA 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg
Conditions of registration:	1,2,3,4,5,6,7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	48 months
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	46/20.2.8/0011
Name of medicine:	LAZENA 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 300 mg
Conditions of registration:	1,2,3,4,5,6,7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	48 months
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	46/20.2.8/0012
Name of medicine:	DUMIVA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 600,0 mg LAMIVUDINE 300,0 mg
Conditions of registration:	1,2,3,4,5,6,7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC SONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	46/20.2.8/0019
Name of medicine:	HETERO TENOFOVIR 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS:TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1,2,3,4,5,6,7
Applicant:	HETERO DRUGS SA
Manufacturer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
Laboratory: FPRC:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA
FPRR:	HETERO DRUGS SA, JEAN PARK CHAMBERS, CENTURION, RSA
Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012

RF 15

Registration number:	46/20.2.8/0680
Name of medicine:	DIVUWIN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg
Conditions of registration:	1,2,3,4,5,6,7,8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Packer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	08/1.4.2/17
Name of medicine:	DEXDOMITOR
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DEXMEDETOMIDINE HCl 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	ORION CORPORATION ORION PHARMA, TURKU, FINLAND
Packer:	ORION CORPORATION ORION PHARMA, TURKU, FINLAND
Laboratory: FPRC:	ORION CORPORATION ORION PHARMA, TURKU, FINLAND SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	36/20.2.2/0233
Name of medicine:	VARI MICONAZOLE 2 % *m/m* ORAL GEL
Dosage form:	ORAL GEL
Active ingredients:	EACH 1,0 g GEL CONTAINS: MICONAZOLE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LEBASI PHARMCEUTICALS CC
Manufacturer:	VARICHEM LABORATORIES, HARARE, ZIMBABWE
Packer:	VARICHEM LABORATORIES, HARARE, ZIMBABWE
Laboratory: FPRC:	VARICHEM LABORATORIES, HARARE, ZIMBABWE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA
FPRR:	LEBASI PHARMACEUTICALS CC, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

F 15

Registration number:	37/15.4/0341
Name of medicine:	ALLERCHROM EYE DROPS
Dosage form:	EYEDROPS
Active ingredients:	EACH 1,0 ml CONTAINS: SODIUM CROMOGLICATE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	FDC LIMITED, WALUJ, AURANGABAD, INDIA
Packer:	FDC LIMITED, WALUJ, AURANGABAD, INDIA
Laboratory: FPRC:	FDC LIMITED, WALUJ, AURANGABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	38/11.5/0338
Name of medicine:	SUPERTABS NEW FORMULATION
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISACODYL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER2012

MRF15

Registration number:	A40/2.5/0342
Name of medicine:	EPIPROATE 400 mg/4 ml
Dosage form:	POWDER AND SOLVENT FOR INJECTABLE SOLUTION
Active ingredients:	EACH VIAL CONTAINS: SODIUM VALPROATE 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7,8
Applicant:	PHARMACARE LIMITED
Manufacturer:	LABORATORIO REIG JOFRE S.A., SAN JOAN DESPI, BARCELONA, SPAIN
Packer:	LABORATORIO REIG JOFRE S.A., SAN JOAN DESPI, BARCELONA, SPAIN
Laboratory: FPRC:	LABORATORIO REIG JOFRE S.A., SAN JOAN DESPI, BARCELONA, SPAIN RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER2012

MRF 15

Registration number:	A40/5.7.1/0375
Name of medicine:	ALLERCHLOR 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CHLORPHENIRAMINE MALEATE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER2012

MRF 15

Registration number:	A40/20.1.1/0390
Name of medicine:	SPEC-CIPROFLOXACIN 400 IV
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	ELPEN PHARMACEUTICAL CO. INC, PIKERMI-ATTICA, GREECE
Packer:	ELPEN PHARMACEUTICAL CO. INC, PIKERMI-ATTICA, GREECE
Laboratory: FPRC:	ELPEN PHARMACEUTICAL CO. INC, PIKERMI-ATTICA, GREECE
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	A40/10.2/0624
Name of medicine:	FENOVENT
Dosage form:	LIQUID
Active ingredients:	EACH 5,0 ml CONTAINS: FENOTEROL HYDROBROMIDE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	41/7.3/0477
Name of medicine:	AUSTIGRAN 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Laboratory: FPRC	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration	07 DECEMBER 2012

MRF 15

Registration number:	41/7.3/0478
Name of medicine:	AUSTIGRAN 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Laboratory: FPRC:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	41/7.3/0479
Name of medicine:	AUSTELL SUMATRIPTAN 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Laboratory: FPRC:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, FRETORIA, RSA
FPRR:	AUSTELL LABORATORIES (PTY) LTD,CROWN X3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	41/7.3/0480
Name of medicine:	AUSTELL SUMATRIPTAN 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Laboratory: FPRC:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR	AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	41/7.3/0481
Name of medicine:	SUMAGRAN 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Laboratory: FPRC :	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	AUSTELL LABORATORIES (PTY) LTD,CROWN X3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF15 .F 15

Registration number:	41/7.3/0482
Name of medicine:	SUMAGRAN 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Laboratory: FPRC:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	AUSTELL LABORATORIES (PTY) LTD,CROWN X3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

Registration number:	41/21.5.1/0814
Name of medicine:	MYLAN DEXAMETHASONE 4 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml CONTAINS: DEXAMETHASONE SODIUM PHOSPHATE 4 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A (PLANT A), ATHENS-LAMIA, METAMORPHOSSIS-ATTICA, GREECE
Packer:	VIANEX S.A (PTY) LTD, ATHENS-LAMIA, METAMORPHOSSIS-ATTICA, GREECE PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC	VIANEX SA (PLANT A), ATHENS-LAMIA, METAMORPHOSSIS-ATTICA, GREECE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	41/10.2.1/0908
Name of medicine:	DUOLIN HFA INHALER
Dosage form:	METERED DOSE INHALER
Active ingredients:	EACH METERED DOSE CONTAINS: IPRATROPIUM BROMIDE MONOHYDRATE EQUIVALENT TO IPRATROPIUM BROMIDE 20,0 µg SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 100,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LIMITED GOA, UNIT (II), VERNA , SALCETTE,GOA, INDIA
Packer:	CIPLA LIMITED GOA, UNIT (II), VERNA , SALCETTE,GOA, INDIA
Laboratory: FPRC:	CIPLA LIMITED GOA, UNIT (II), VERNA , SALCETTE,GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	42/20.1.1/0280
Name of medicine:	MEROJECT 500 mg (POWDER FOR INJECTION)
Dosage form:	STERILE POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM ANHYDROUS 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE
Packer:	DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE
Laboratory: FPRC:	DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	42/20.1.1/0281
Name of medicine:	MEROJECT 1 g (POWDER FOR INJECTION)
Dosage form:	STERILE POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM ANHYDROUS 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE
Packer:	DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE
Laboratory::FPRC	DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	42/2.9/0283
Name of medicine:	TRAMAL SR 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HCl 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	FAMACEUTICI FORMENTI ITALY, ORIGGIO, ITALY GRUNENTHAL GmbH, STOLBERG, GERMANY
Packer:	GRUNENTHAL GmbH, STOLBERG, GERMANY GRUNENTHAL GmbH, AACHEN, GERMANY SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	GRUNENTHAL GmbH, STOLBERG, GERMANY SPECPHARM HOLDINGS (PTY) LTD. HALFWAY HOUSE, MIDRAND, RSA
FPRR:	JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER2012

MRF15 F 15

Registration number:	42/20.1.1/0388
Name of medicine:	ASPEN CEFPODOXIME 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFPODOXIME PROXETIL EQUIVALENT TO CEFPODOXIME 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (provisional)
Date of registration:	07 DECEMBER2012

Registration number:	42/20.1.1/0389
Name of medicine:	ASPEN CEFPODOXIME 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFPODOXIME PROXETIL EQUIVALENT TO CEFPODOXIME 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Shelf-life:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Date of registration:	24 months (provisional) 07 DECEMBER2012

MRF 15

Registration number:	45/11.4.3/0515
Name of medicine:	OMEPRAZOLE SAFELINE INJECTION 40 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OMEPRAZOLE SODIUM EQUIVALENT TO OMEPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A, PALINI ATTICI, GREECE
Packer:	VIANEX S.A, PALINI ATTICI, GREECE
Laboratory: FPRC:	VIANEX S.A, PALINI ATTICI, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	42/18.10/0538
Name of medicine:	OMSAL CAPSULES
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 0,4 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	GEDEON RICHTER ROMANIA S.A, TARGU-MURES, ROMANIA
Packer:	GEDEON RICHTER ROMANIA S.A, TARGU-MURES, ROMANIA
Laboratory: FPRC:	GEDEON RICHTER ROMANIA S.A, TARGU-MURES, ROMANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

F 15

Registration number:	42/20.1.1/0737
Name of medicine:	FKSA CEFUROXIME 750 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BODENE (PTY) LTD (TRADING AS INTRAMED)
Manufacturer:	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL
Packer:	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL
Laboratory: FPRC:	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL BODENE (PTY) LTD (TRADING AS INTRAMED), KORSTEN, PORT ELIZABETH, RSA
FPRR:	BODENE (PTY) LTD (TRADING AS INTRAMED), KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	42/21.12/0760
Name of medicine:	TEVA ANASTROZOLE 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL
Packer:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL TEVA PHARMACEUTICAL WORKS PRIVATE, LIMITED COMPANY, GODOLLO, HUNGARY
Laboratory: FPRC	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SIVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	TEVA PHARMACEUTICALS (PTY) LTD, RUIMSIG, ROODEPORT, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	42/20.1.1/0986
Name of medicine:	FKSA CEFUROXIME 1 500 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BODENE (PTY) LTD (TRADING AS INTRAMED)
Manufacturer:	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL
Packer:	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL
Laboratory: FPRC:	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL BODENE (PTY) LTD (TRADING AS INTRAMED), KORSTEN, PORT ELIZABETH, RSA
FPRR:	BODENE (PTY) LTD (TRADING AS INTRAMED), KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/7.5/0167
Name of medicine:	DYNATOR 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/7.5/0168
Name of medicine:	DYNATOR 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/7.5/0169
Name of medicine:	DYNATOR 40 mg
Dosage form:	TABLE
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/7.5/0170
Name of medicine:	DYNATOR 80 mg
Dosage form:	TABLE
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/7.5/0186
Name of medicine:	DYNA ATORVASTATIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/7.5/0187
Name of medicine:	DYNA ATORVASTATIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/7.5/0188
Name of medicine:	DYNA ATORVASTATIN 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory: FPRC	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/7.5/0189
Name of medicine:	DYNA ATORVASTATIN 80 mg
Dosage form:	TABLE
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRC/FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/32.2/0240
Name of medicine:	MYCOPHENOLATE HEXAL 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

Registration number:	43/32.2/0241
Name of medicine:	MYCOCEPT 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA 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)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/2.6.5/0317
Name of medicine:	SEROMIND 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/2.6.5/0318
Name of medicine:	RAN QUETIAPINE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/2.6.5/0319
Name of medicine:	RAN QUETIAPINE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/2.6.5/0320
Name of medicine:	SEROMIND 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/2.6.5/0321
Name of medicine:	RAN QUETIAPINE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/2.6.5/0322
Name of medicine:	SEROMIND 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/2.6.5/0323
Name of medicine:	SEROMIND 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/20.1.1/0632
Name of medicine:	REFOBACIN PLUS BONE CEMENT 20
Dosage form:	BONE CEMENT
Active ingredients:	EACH 22,4 g OF POWDER CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 0,3 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS
Packer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJOBO, SWEDEN
Laboratory: FPRC:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJOBO, SWEDEN BIOMET ORTHOPAEDICS SWITZERLAND, KEZERS, SWITZERLAND ROSE MEDIZIN-UND STERILISIERTECHNIK GmbH, TRIER, GERMANY STERIGENICS, ZOETERMEER, THE NETHERLANDS LABOR L&S AG, BAD BOCKLET-GROSSENBRACH GERMANY ACILAR AG, MORFELDEN-WALLDORF, GERMANY FARMALYSE BV, ZAANDAM, THE NETHERLANDS MAINSITE SERVICES GmbH & CO KG, OBERNBURG, GERMANY BACTIMM BV, NIJMEGEN, THE NETHERLANDS
FPRR:	MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

RF 15

Registration number:	43/2.6.5/0684
Name of medicine:	RAN QUETIAPINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (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 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRC/FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/20.1.1/0702
Name of medicine:	REFOBACIN PLUS BONE CEMENT 40
Dosage form:	BONE CEMENT
Active ingredients:	EACH 44,9 g OF POWDER CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 0,6 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS
Packer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJOBO, SWEDEN
Laboratory: FPRC:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJOBO, SWEDEN BIOMET ORTHOPAEDICS SWITZERLAND, KEZERS, SWITZERLAND ROSE MEDIZIN-UND STERILISIERTECHNIK GmbH, TRIER, GERMANY STERIGENICS, ZOETERMEER, THE NETHERLANDS LABOR L&S AG, BAD BOCKLET-GROSSENBRACH GERMANY ACILAR AG, MORFELDEN-WALLDORF, GERMANY FARMALYSE BV, ZAANDAM, THE NETHERLANDS MAINSITE SERVICES GmbH & CO KG, OBERNBURG, GERMANY BACTIMM BV, NIJMEGEN, THE NETHERLANDS
FPRC/FPRR:	MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/20.1.1/0703
Name of medicine:	REFOBACIN PLUS BONE CEMENT 60
Dosage form:	BONE CEMENT
Active ingredients:	EACH 67,4 g OF POWDER CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 0,8 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS
Packer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJOBO, SWEDEN
Laboratory: FPRC:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V, NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJOBO, SWEDEN BIOMET ORTHOPAEDICS SWITZERLAND, KEZERS, SWITZERLAND ROSE MEDIZIN-UND STERILISIERTECHNIK GmbH, TRIER, GERMANY STERIGENICS, ZOETERMEER, THE NETHERLANDS LABOR L&S AG, BAD BOCKLET-GROSSENBRACH GERMANY ACILAR AG, MORFELDEN-WALLDORF, GERMANY FARMALYSE BV, ZAANDAM, THE NETHERLANDS MAINSITE SERVICES GmbH & CO KG, OBERNBURG, GERMANY BACTIMM BV, NIJMEGEN, THE NETHERLANDS
FPRC/FPRR:	MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

RF 15

Registration number:	43/21.2/0957
Name of medicine:	DIAMICRON MR 60 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SERVIER LABORATORIES SA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND MILLMOUNT HEALTHCARE LTD, NAVAN, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC	LES LABORATOIRES SERVIER INDUSTRIE, GIDIE, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR::	SERVIER LABORATORIES SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/21.2/0958
Name of medicine:	GLUCTAM MR 60 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	EGIS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND MILLMOUNT HEALTHCARE LTD, NAVAN, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDIE, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	EGIS PHARMACEUTICALS SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/21.2/0959
Name of medicine:	DIASTAL MR 60 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND MILLMOUNT HEALTHCARE LTD, NAVAN, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDIE, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	BIOGARAN SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/21.2/0960
Name of medicine:	DIAGLUCIDE MR 60 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND MILLMOUNT HEALTHCARE LTD, NAVAN, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC	LES LABORATOIRES SERVIER INDUSTRIE, GIDIE, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	BIOGARAN SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/26/1019
Name of medicine:	ACCORD CISPLATIN 10
Dosage form:	INFUSION SOLUTION
Active ingredients:	EACH VIAL CONTAINS: CISPLATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/26/1021
Name of medicine:	ACCORD CISPLATIN 50
Dosage form:	INFUSION SOLUTION
Active ingredients:	EACH VIAL CONTAINS: CISPLATIN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/5.4.1/1062
Name of medicine:	PEXOLA ER 0,375 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 0,375 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory: FPRC	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/5.4.1/1063
Name of medicine:	PEXOLA ER 0,75 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 0,75 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/5.4.1/1064
Name of medicine:	PEXOLA ER 1,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 1,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MMRF 15

Registration number:	43/5.4.1/1065
Name of medicine:	PEXOLA ER 3,0 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory: FPRC	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/5.4.1/1066
Name of medicine:	PEXOLA ER 4,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 4,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FENDALE, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	44/15.2/0045
Name of medicine:	OZURDEX
Dosage form:	INTRAVITREAL IMPLANT
Active ingredients:	EACH IMPLANT CONTAINS: DEXAMETHASONE 700,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALLERGAN PHARMACEUTICALS IRELAND, WESTPORT, COUNTY MAYO, IRELAND
Packer:	ALLERGAN PHARMACEUTICALS IRELAND, WESTPORT, COUNTY MAYO, IRELAND
Laboratory: FPRC:	ALLERGAN PHARMACEUTICALS IRELAND, WESTPORT, COUNTY MAYO, IRELAND INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ALLERGAN PHARMACEUTICALS (PTY) LTD, RANDJESPARK EXT. 11, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	44/1.2/0114
Name of medicine:	YELATE 30
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	44/1.2/0115
Name of medicine:	YELATE 60
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	44/1.2/0116
Name of medicine:	DRL DULOXETINE 30
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MMRF 15

Registration number:	44/1.2/0117
Name of medicine:	DRL DULOXETINE 60
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	44/26/0205
Name of medicine:	SPRYCEL 100 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DASATINIB 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB COMPANY, MT VERNON, INDIANA, USA
Packer:	BRISTOL-MYERS SQUIBB COMPANY, MT VERNON, INDIANA, USA BRISTOL-MYERS SQUIBB COMPANY, EPERNON, FRANCE BRISTOL-MYERS SQUIBB S.R.L, ANAGNI, ITALY
Laboratory: FPRC:	BRISTOL-MYERS SQUIBB COMPANY, EPERNON, FRANCE BRISTOL-MYERS SQUIBB S.R.L, ANAGNI, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA NKUNZI PHARMACEUTICALS (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:	BRISTOL-MYERS SQUIBB (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	44/26/0556
Name of medicine:	AXTERE 20
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

RF 15

Registration number:	44/26/0557
Name of medicine:	AXTERE 80
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	44/26/0558
Name of medicine:	ACCORD DOCETAXEL 20
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	44/26/0559
Name of medicine:	ACCORD DOCETAXEL 80
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	44/26/0728
Name of medicine:	ACCORD DOCETAXEL DILUENT
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTION q.s 1,0 ml POLYETHYLENE GLYCOL 400 130,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	44/26/0729
Name of medicine:	AXTERE DILUENT
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTION q.s 1,0 ml POLYETHYLENE GLYCOL 400 130,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	44/1.2/0851
Name of medicine:	ACCORD ESCITALOPRAM 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	44/1.2/0852
Name of medicine:	ACCORD ESCITALOPRAM 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0085
Name of medicine:	DIZOVIN 100
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, DEGRAS ROAD, SILVERTON, PRETORIA, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	45/20.2.8/0086
Name of medicine:	DIZOVIN 300
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, DEGRAS ROAD, SILVERTON, PRETORIA, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

RF 15

Registration number:	45/8.2/0175
Name of medicine:	NPLATE 250 µg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: ROMIPLOSTIM 250,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	PATHEON S.p.A, MONZA, ITALY
Packer:	AMGEN EUROPE BV (ABR), BREDA, THE NETHERLANDS
Laboratory: FPRC	AMGEN EUROPE BV (ABR), BREDA, THE NETHERLANDS
FPRR:	BATSWADI PHARMACEUTICALS (PTY) LTD, PETER PLACE, BRYANSTON, RSA
Shelf-life:	60 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/8.2/0176
Name of medicine:	NPLATE 500 µg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ROMIPLOSTIM 500,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	PATHEON S.p.A, MONZA, ITALY
Packer:	AMGEN EUROPE BV (ABR), BREDA, THE NETHERLANDS
Laboratory: FPRC:	AMGEN EUROPE BV (ABR), BREDA, THE NETHERLANDS
FPRR:	BATSWADI PHARMACEUTICALS (PTY) LTD, PETER PLACE, BRYANSTON, RSA
Shelf-life:	60 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	45/2.6.5/0694
Name of medicine:	SIZONORM 25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SUN PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Packer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

RF 15

Registration number:	45/2.6.5/0695
Name of medicine:	SIZONORM 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SUN PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Packer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/2.6.5/0696
Name of medicine:	SIZONORM 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SUN PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Packer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	45/2.6.5/0697
Name of medicine:	SIZONORM 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SUN PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Packer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0768
Name of medicine:	VIRAMUNE XR 50 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 50 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
Laboratory: FPRC	BOEHRINGER INGELHEIM ROXANE INC., WILSON RD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC., OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0769
Name of medicine:	VIRAMUNE XR 100 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 100 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
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, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	45/20.2.8/0770
Name of medicine:	VIRAMUNE XR 400 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 400 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
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, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0771
Name of medicine:	ALVIR XR 50 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 50 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
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, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0772
Name of medicine:	ALVIR XR 100 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 100 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
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, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	45/20.2.8/0773
Name of medicine:	ALVIR XR 400 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 400 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
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, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0774
Name of medicine:	NEVIRAPINE XR IP 50 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 50 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
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, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0775
Name of medicine:	NEVIRAPINE XR IP 100 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 100 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
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, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	45/20.2.8/0776
Name of medicine:	NEVIRAPINE XR IP 400 mg
Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 400 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
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
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, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0825
Name of medicine:	RICOVIR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Tenofovir disoproxil fumarate 300,0mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	45/20.2.8/0886
Name of medicine:	MACLEODS NEVIRAPINE 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg
Conditions of registration:	1,2,3,4,5,6,7,8
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES ([TY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, DEGRAS ROAD, SILVERTON, PRETORIA, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	46/20.2.8/0020
Name of medicine:	EFAMAT 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECENBER 2012

MRF 15

Registration number:	46/20.2.8/0021
Name of medicine:	EFAMAT 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECENBER 2012

MRF 15

Registration number:	46/20.2.8/0022
Name of medicine:	EFAMAT 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR,NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECENBER 2012

MRF15

Registration number:	46/26/0866
Name of medicine:	HERCLON
Dosage form:	POWDER FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: TRASTUZUMAB 440,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA GENENTECH INC., VACAVILLE, CALIFORNIA, USA
Packer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA GENENTECH INC., VACAVILLE, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	46/32.4/0867
Name of medicine:	HERCLON BWFI
Dosage form:	DILUENT FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Bacteriostatic water for injection 20,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND
Packer:	F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND GP GRENZACH PRODUCTIONS, GRENZACH-WYHLEN, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC	F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO, JOHANNESBURG, RSA
Shelf-life:	48 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	46/26/0868
Name of medicine:	RISTOVA 100
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: RITUXIMAB 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY
Packer.	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO, JOHANNESBURG, RSA
Shelf-life:	30 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	46/26/0869
Name of medicine:	RISTOVA 500
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: RITUXIMAB 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY
Packer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO, JOHANNESBURG, RSA
Shelf-life:	30 months
Date of registration:	07 DECEMBER 2012

RF 15

Registration number:	47/20.2.8/0188
Name of medicine:	MACLEODS EMTRICITABINE AND TENOFOVIR 200 mg/300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LIMITED, KACHIGAM, DAMAN, INDIA MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Packer:	MACLEODS PHARMACEUTICALS LIMITED, KACHIGAM, DAMAN, INDIA MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Laboratory: FPRC	MACLEODS PHARMACEUTICALS LIMITED, KACHIGAM, DAMAN, INDIA MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, DEGRAS ROAD, SILVERTONDALE, PRETORIA, RSA KHULULEKANI LABORATORY SERVICES CC, COVENTRY PARK, MIDRAND, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

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