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CONTENTS • INHOUD

GENERAL NOTICES
ALGEMENE KENNISGEWINGS

NOTICE 405 OF 2014

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 405 VAN 2014

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 voldoën 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:	06/17.1.6/07
Name of medicine:	MARBOCYL 10 %
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: MARBOFLOXACIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AFRIVET LOGISTICS (PTY) LTD
Manufacturer:	VETOQUINOL, LURE, CEDEX, FRANCE
Packer:	VETOQUINOL, LURE, CEDEX, FRANCE
Laboratory: FPRC:	VETOQUINOL, LURE, CEDEX, FRANCE BIOINDUSTRIAL SERVICES, KEMPTON PARK, JOHANNESBURG, RSA
FPRR:	AFRIVET LOGISTICS (PTY) LTD, KEMPTON PARK, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	08/3.1.2/03
Name of medicine:	PETCAM INJECTION 0,5%
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: MELOXICAM 5,0 mg
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 (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	09/3.1.2/19
Name of medicine:	CANIFLAM
Dosage form:	ORAL SUSPENSION
Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: MELOXICAM 1,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CEVA ANIMAL HEALTH (PTY) LTD
Manufacturer:	CEVA SANTE ANIMALE, TRES LE BOIS, LOUDEAC, FRANCE
Packer:	CEVA SANTE ANIMALE, TRES LE BOIS, LOUDEAC, FRANCE
Laboratory: FPRC:	CEVA SANTE ANIMALE, TRES LE BOIS, LOUDEAC, FRANCE BIOINDUSTRIAL SERVICES, KEMPTON PARK, JOHANNESBURG, RSA
FPRR:	CEVA ANIMAL HEALTH (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	10/5.3.2/11
Name of medicine:	BREXACE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BENAZEPRIL HYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	10/5.3.2/12
Name of medicine:	PETACE 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BENAZEPRIL HYDROCHLORIDE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	10/5.3.2/13
Name of medicine:	BREXACE 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BENAZEPRIL HYDROCHLORIDE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	10/5.3.2/14
Name of medicine:	PETACE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BENAZEPRIL HYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	37/21.5.1/0013
Name of medicine:	PULMAX 100 MDI
Dosage form:	DRY POWDER FOR INHALATION
Active ingredients:	EACH ACTUATION CONTAINS: BUDESONIDE 100,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND
Packer:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	37/21.5.1/0014
Name of medicine:	PULMAX 200 MDI
Dosage form:	DRY POWDER FOR INHALATION
Active ingredients:	EACH ACTUATION CONTAINS: BUDESONIDE 200,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND
Packer:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR	BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	37/21.5.1/0015
Name of medicine:	PULMAX 400 MDI
Dosage form:	DRY POWDER FOR INHALATION
Active ingredients:	EACH ACTUATION CONTAINS: BUDESONIDE 400,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND
Packer:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC :	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	41/11.4.3/0449
Name of medicine:	RENNIE DUO
Dosage form:	SUSPENSION
Active ingredients:	EACH 10,0 ml SUSPENSION CONTAINS: CALCIUM CARBONATE 1 200,0 mg MAGNESIUM CARBONATE 140,0 mg SODIUM ALGINATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER SANTE FAMILIE, GAILLARD, FRANCE
Packer:	BAYER SANTE FAMILIE, GAILLARD, FRANCE
Laboratory: FPRC:	BAYER SANTE FAMILIE, GAILLARD, FRANCE ROCHE PRODUCTS (PTY) LTD, NORTHLANDS, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA BIOCHEMICAL AND SCIENTIFIC CONSULTANTS, HILTON, KWAZULU NATAL, RSA
FPRR:	BAYER (PTY) LTD, ISANDO, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	41/5.7.1/0555
Name of medicine:	GULF CETIRIZINE 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ALEMBIC LIMITED, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:	ALEMBIC LIMITED, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC	ALEMBIC LIMITED, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, DURBAN, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15	
Registration number:	41/20.1.1/0586
Name of medicine:	LIZORP 250 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEPROZIL MONOHYDRATE EQUIVALENT TO ANHYDROUS CEFPROZIL 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICK, ANDHRA PRADESH, INDA
Packer:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICK, ANDHRA PRADESH, INDA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICK, ANDHRA PRADESH, INDA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15	
Registration number:	41/20.1.1/0587
Name of medicine:	LIZORP 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEPROZIL MONOHYDRATE EQUIVALENT TO ANHYDROUS CEFPROZIL 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICK, ANDHRA PRADESH, INDA
Packer:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICK. ANDHRA PRADESH, INDA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICK, ANDHRA PRADESH, INDA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15	
Registration number:	42/3.2/0410
Name of medicine:	ASTERIX ALENDRONATE 70
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM TRIHYDRATE EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	PHARMACEUTICAL WORKS POLPHARMA SA, STAROGARD, GDANSKI, POLAND
Packer:	PHARMACEUTICAL WORKS POLPHARMA SA, STAROGARD, GDANSKI, POLAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory::FPRC	PHARMACEUTICAL WORKS POLPHARMA SA, STAROGARD, GDANSKI, POLAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	LITHA PHARMA (PTY) LTD, EDENVALE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	42/2.7/0543
Name of medicine:	PARAFIZZ 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, TALUKA DAUND, POONA DISTRICT, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, TALUKA DAUND, POONA DISTRICT, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, TALUKA DAUND, POONA DISTRICT, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	42/26/0742
Name of medicine:	CANOTEC
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: IRINOTECAN HYDROCHLORIDE TRIHYDRATE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, JOHANNESBURG, RSA
Shelf-life:	24 months – Product 24 hours stored at 2-8 °C – Diluted product 12 hours stored at or below 25 °C – Diluted product
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	42/3.2/0767
Name of medicine:	DYNA RISEDRONATE 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISEDRONATE SODIUM HEMIPENTAHYDTRATE EQUIVALENT TO RISEDRONATE SODIUM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS, GREECE
Laboratory: FPRC:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, RSA
Shelf-life:	60 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	42/3.2/0768
Name of medicine:	DYNA RISEDRONATE 35 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISEDRONATE SODIUM HEMIPENTAHYDTRATE EQUIVALENT TO RISEDRONATE SODIUM 35,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS, GREECE
Laboratory: FPRC:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, RSA
Shelf-life:	60 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	42/20.1./0998
Name of medicine:	LEVONIC IV 500
Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	PHARMACEUTICAL WORKS POLPHARMA S.A., STAROGARD GDANSKI, POLAND
Packer:	PHARMACEUTICAL WORKS POLPHARMA S.A., STAROGARD GDANSKI, POLAND
Laboratory: FPRC:	PHARMACEUTICAL WORKS POLPHARMA S.A., STAROGARD GDANSKI, POLAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/26/0018
Name of medicine:	DOXOLIP
Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOXORUBICIN HYDROCHLORIDE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	43/5.3/0099
Name of medicine:	ARICEPT ODT 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIE (PTY) LTD
Manufacturer:	EISAI Co LTD, MISATO PLANT, KODAMA-GUM, SAITAM-KEN, JAPAN
Packer:	PFIZER PGM, POCE-SUR-CISSE, AMBOISE PLANT, FRANCE
Laboratory: FPRC	PFIZER PGM, POCE-SUR-CISSE, AMBOISE PLANT, FRANCE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	43/5.3/0100
Name of medicine:	ARICEPT ODT 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIE (PTY) LTD
Manufacturer:	EISAI Co LTD, MISATO PLANT, KODAMA-GUM, SAITAM-KEN, JAPAN
Packer:	EISAI Co LTD, MISATO PLANT, KODAMA-GUM, SAITAM-KEN, JAPAN
Laboratory: FPRC:	PFIZER PGM, POCE-SUR-CISSE, AMBOISE PLANT, FRANCE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/1.2/0339
Name of medicine:	DYNA SERTRALINE 50l
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LEBASI PHARMACEUTICALS cc
Manufacturer:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	LEBASI PHARMACEUTICAL cc, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	43/1.2/0340
Name of medicine:	DYNA SERTRALINE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LEBASI PHARMACEUTICALS cc
Manufacturer:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA
Laboratory: FPRC:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	LEBASI PHARMACEUTICAL cc, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	43/26/0467
Name of medicine:	PLIXEL
Dosage form:	CONCENTRATE FOR DILUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A., PALLINI, ATTICI, GREECE
Packer:	VIANEX S.A., PALLINI, ATTICI, GREECE
Laboratory: FPRC:	VIANEX S.A., PALLINI, ATTICI, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/5.3/0668
Name of medicine:	ARIMER 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/5.3/0669
Name of medicine:	ARIMER 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/7.5/0837
Name of medicine:	ASPAVOR 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACIA SOUTH AFIRCA (PTY) LTD
Manufacturer:	PFIZER PHARMACEUTICALS LLS, VEGA BAJA, PUERTO RICO, USA PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY, COUNTY CORK, IRELAND
Packer:	GODECKE GmbH, FREIBURG, GERMANY
Laboratory: FPRC:	PFIZER PHARMACEUTICALS LLS, VEGA BAJA, PUERTO RICO, USA PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY, COUNTY CORK, IRELAND GODECKE GmbH, FREIBURG, GERMANY JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA LAB & BIOLOGICAL SERVICES (PTY) LTD, BRACKENHURST, ALBERTON, RSA
FPRR:	PHARMACIA SOUTH AFRICA (PTY) LTD, SANDTON, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

Registration number:	43/7.5/0839
Name of medicine:	ATORVASTATIN PHARMACIA 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACIA SOUTH AFIRCA (PTY) LTD
Manufacturer:	PFIZER PHARMACEUTICALS LLS, VEGA BAJA, PUERTO RICO, USA PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY, COUNTY CORK, IRELAND
Packer:	GODECKE GmbH, FREIBURG, GERMANY
Laboratory: FPRC:	PFIZER PHARMACEUTICALS LLS, VEGA BAJA, PUERTO RICO, USA PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY, COUNTY CORK, IRELAND GODECKE GmbH, FREIBURG, GERMANY JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA LAB & BIOLOGICAL SERVICES (PTY) LTD, BRACKENHURST, ALBERTON, RSA
FPRR:	PHARMACIA SOUTH AFRICA (PTY) LTD, SANDTON, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	43/7.1.3/0925
Name of medicine:	FLAMIPAX 5/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	43/7.1.3/0926
Name of medicine:	FLAMIPAX 5/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/7.1.3/0927
Name of medicine:	FLAMIPAX 10/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	43/7.1.3/0928
Name of medicine:	FLAMIPAX 10/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	43/7.1.3/0929
Name of medicine:	REAPTAN 5/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/7.1.3/0930
Name of medicine:	REAPTAN 5/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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Registration number:	43/7.1.3/0931
Name of medicine:	REAPTAN 10/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	43/7.1.3/0932
Name of medicine:	REAPTAN 10/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	43/7.1.3/0933
Name of medicine:	COVERAM 5/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	SERVIER LABORATORIES SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	43/7.1.3/0934
Name of medicine:	COVERAM 5/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	SERVIER LABORATORIES SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	43/7.1.3/0935
Name of medicine:	COVERAM 10/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	SERVIER LABORATORIES SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/7.1.3/0936
Name of medicine:	COVERAM 10/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR::	SERVIER LABORATORIES SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	43/7.1.3/0937
Name of medicine:	MIXANVAL 5/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	EGIS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR::	EGIS PHARMACEUTICALS SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	43/7.1.3/0938
Name of medicine:	MIXANVAL 5/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	EGIS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRC/FPRR:	EGIS PHARMACEUTICALS SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	43/7.1.3/0939
Name of medicine:	MIXANVAL 10/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
	EGIS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
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Laboratory: FPRC	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	EGIS PHARMACEUTICALS SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	43/7.1.3/0940
Name of medicine:	MIXANVAL 10/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	EGIS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IREALND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEALTH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND
Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOSTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	EGIS PHARMACEUTICALS SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15 ?F 15

Registration number:	43/20.1/0954
Name of medicine:	CUBICIN
Dosage form:	POWDER FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DAPTOMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	HOSPIRA INC., MCPHERSON, KANSA, USA
Packer:	HOSPIRA INC., MCPHERSON, KANSA, USA ASTRAZENECA UK LIMITED, MACCLESFIELD, CHESSHIRE, UK AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA
Laboratory: FPRC:	CUBIST PHARMACEUTICALS INC, LEXINGTON, MASSACHUSETS, USA PPD DEVELOPMENT, MIDDLETON, WISCONSIN, USA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, RSA
Shelf-life:	36 months at 2-8 °C – Product 48 hours at 2-8 °C – Reconstituted solution 12 hours at or below 25 °C – Reconstituted solution
Date of registration:	05 DECEMBER 2013

Registration number:	43/20.1.1/1025
Name of medicine:	ADCO CIPROFLOXACIN 2 mg/ml
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR INFO S.A., CAMPASCIO, SWITZERLAND
Packer:	ACS DOBFAR INFO S.A., CAMPASCIO, SWITZERLAND
Laboratory: FPRC	ACS DOBFAR INFO S.A., CAMPASCIO, SWITZERLAND ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/8.2/0041
Name of medicine:	CLOPIDOGREL SANOFI-AVENTIS 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL HYDRGEN SULPHATE EQUIVALENT TO CLOPIDOGREL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE
Packer:	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/8.2/0042
Name of medicine:	CLOPIWIN 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL HYDRGEN SULPHATE EQUIVALENT TO CLOPIDOGREL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE
Packer:	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MMRF 15

Registration number:	44/8.2/0043
Name of medicine:	PLAVIX 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL HYDRGEN SULPHATE EQUIVALENT TO CLOPIDOGREL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE
Packer:	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC	SANOFI WINTHROP INDUSTIRE, CARBON BLANC, CEDEX, FRANCE M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/2.5/0065
Name of medicine:	SODIUM VALPROATE PROPAIN 300 CR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND
Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/2.5/0066
Name of medicine:	SODIUM VALPROATE PROPAIN 500 CR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND
Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
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Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	44/2.5/0067
Name of medicine:	VANAPRO 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND
Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/2.5/0068
Name of medicine:	VANAPRO 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND
Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/2.5/0069
Name of medicine:	ADCO SODIUM VALPROATE 300 CR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND
Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MMRF 15

Registration number:	44/2.5/0070
Name of medicine:	ADCO SODIUM VALPROATE 500 CR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND
Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	44/2.5/0120
Name of medicine:	KEPRACET 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/2.5/0121
Name of medicine:	KEPRACET 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	44/2.5/0122
Name of medicine:	KEPRACET 750
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/2.5/0123
Name of medicine:	KEPRACET 1 000
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/2.5/0124
Name of medicine:	ADCO LEVETIRACETAM 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	44/2.5/0125
Name of medicine:	ADCO LEVETIRACETAM 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/2.5/0126
Name of medicine:	ADCO LEVETIRACETAM 750
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Laboratory. FPRC:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/2.5/0127
Name of medicine:	ADCO LEVETIRACETAM 1 000
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	44/11.4.3/0208
Name of medicine:	NEXIUM 2,5 mg SACHETS
Dosage form:	GRANULES
Active ingredients:	EACH SACHET CONTAINS: ESOMEPRAZOLE MAGNESIUM TRIHYDRATE EQUIVALENT TO ESOMEPRAZOLE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA AB, SODERTALJE, SWEDEN
Packer:	ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA
Laboratory: FPRC:	ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/11.4.3/0209
Name of medicine:	NEXIUM 5 mg SACHETS
Dosage form:	GRANULES
Active ingredients:	EACH SACHET CONTAINS: ESOMEPRAZOLE MAGNESIUM TRIHYDRATE EQUIVALENT TO ESOMEPRAZOLE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA AB, SODERTALJE, SWEDEN
Packer:	ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA
Laboratory: FPRC:	ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/3.2/0258
Name of medicine:	SANDOZ IBANDRONATE 2 mg/2 ml
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: IBANDRONATE SODIUM MOHOHYDRATE EQUIVALENT TO IBANDRONIC ACID 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY
Packer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY 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
Date of registration:	05 DECEMBER 2013

Registration number:	44/3.2/0259
Name of medicine:	SANDOZ IBANDRONATE 6 mg/6 ml
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: IBANDRONATE SODIUM MOHOHYDRATE EQUIVALENT TO IBANDRONIC ACID 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY
Packer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY 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
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	44/7.1.3/0265
Name of medicine:	CANDESARTAN RAN 8
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/7.1.3/0266
Name of medicine:	CANDESARTAN RAN 16
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7,8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

Registration number:	44/7.1.3/0267
Name of medicine:	CANDAGEN 8
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/7.1.3/0268
Name of medicine:	CANDAGEN 16
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/3.2/0319
Name of medicine:	BONATE 2 mg/2 ml
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: IBANDRONATE SODIUM MONOHYDRATE EQUIVALENT TO IBANDRONIC ACID 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY
Packer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY 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
Date of registration:	05 DECEMBER 2013

Registration number:	44/3.2/0320
Name of medicine:	BONATE 6 mg/6 ml
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: IBANDRONATE SODIUM MONOHYDRATE EQUIVALENT TO IBANDRONIC ACID 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY
Packer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY 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
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	44/20.1.1/0421
Name of medicine:	LEVOFLOXACIN TRINITY 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/20.1.1/0422
Name of medicine:	LEVOFLOXACIN TRINITY 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	44/32.2/0631
Name of medicine:	MYCOKEM 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALKEM LABORATORIES (PTY) LTD
Manufacturer:	ALKEM LABORATORIES LTD, NALAGARH, DISTT-SOLAN (HP), INDIA
Packer:	ALKEM LABORATORIES LTD, NALAGARH, DISTT-SOLAN (HP), INDIA
Laboratory: FPRC:	ALKEM LABORATORIES LTD, NALAGARH, DISTT-SOLAN (HP), INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/21.10/0763
Name of medicine:	BRAVELLE 75 I.U.
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: UROFOLLITROPIN 75,0 I.U.
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	FERRING (PTY) LTD
Manufacturer:	FERRING GmbH, KIEL, GERMANY
Packer:	FERRING GmbH, KIEL, GERMANY FERRING INTERNATIONLA CENTER SA, VERGOGNAUSAZ, ST-PREX, SWITZERLAND DRA PHARMACEUTICALS cc, IRENE, CENTURION, RSA
Laboratory: FPRC:	FERRING GmbH, KIEL, GERMANY LABOR L+S AG, BAD BOCKLET-GROBENBACH, GERMANY LPT, HAMBURG, GERMANY PIPELINE BIOTECH A/S. TRIGE, DENMARK INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING (PTY) LTD, IRENE, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/21.10/0764
Name of medicine:	BRAVELLE SOLVENT
Dosage form:	SOLVENT FOR SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: SODIUM CHLORIDE (0,9%) AND 1,0 ml WATER FOR INJECTION.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FERRING (PTY) LTD
Manufacturer:	HAUPT PHARMA WULFING GmbH, GRONAU, GERMANY WEIMER PHARMA, KIEL, GERMANY
Packer:	HAUPT PHARMA WULFING GmbH, GRONAU, GERMANY WEIMER PHARMA, KIEL, GERMANY FERRING PHARMA, KIEL, GERMANY FERRING INTERNATIONAL CENTER SA, VERGOGNAUSAZ, ST-PREX, SWITZERLAND DRA PHARMACEUTICALS cc, IRENE, CENTURION, RSA
Laboratory: FPRC:	FERRING GmbH, KIEL, GERMANY INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA
FPRR:	FERRING (PTY) LTD, IRENE, CENTURION, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

Registration number:	44/26/0886
Name of medicine:	IMALEK 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IMATINIB MESILATE EQUIVALENT TO IMTINIB 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	44/26/0887
Name of medicine:	IMALEK 400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IMATINIB MESILATE EQUIVALENT TO IMTINIB 400,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/1.2/0948
Name of medicine:	PRATALOPRAM 5 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

Registration number:	44/1.2/0949
Name of medicine:	PRATALOPRAM 10 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/1.2/0950
Name of medicine:	PRATALOPRAM 20 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/1.2/0951
Name of medicine:	DOLIN 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

Registration number:	44/1.2/0952
Name of medicine:	DOLIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	44/1.2/0953
Name of medicine:	DOLIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/1.2/0954
Name of medicine:	MARPREM 5 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

Registration number:	44/1.2/0955
Name of medicine:	MARPREM 10 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	44/1.2/0956
Name of medicine:	MARPREM 20 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	44/11.4.3/0981
Name of medicine:	ADCO PANTOPRAZOLE IV
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN
Packer:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Laboratory: FPRC:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	44/11.4.3/0982
Name of medicine:	PANTOPRAZOLE COVAN INJECTION
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN
Packer:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Laboratory: FPRC:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
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MRF 15

Registration number:	44/21.12/1009
Name of medicine:	ANABREZ 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/15.1/0034
Name of medicine:	FOXIN
Dosage form:	EYE DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	MERCK BIOSCIENCES LIMITED, TALUKA, MATAR DISTRICT, KHEDA, GUJARAT, INDIA
Packer:	MERCK BIOSCIENCES LIMITED, TALUKA, MATAR DISTRICT, KHEDA, GUJARAT, INDIA
Laboratory: FPRC:	MERCK BIOSCIENCES LIMITED, TALUKA, MATAR DISTRICT, KHEDA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SWIFT MICRO LABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, DURBAN, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	45/26/0038
Name of medicine:	LILLY PEMETREXED 100 mg
Dosage form:	POWDER FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: PEMETREXED 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA
Packer:	LILLY FRANCE, FEGERSHEIM, FRANCE
Laboratory: FPRC:	LILLY FRANCE, FEGERSHEIM, FRANCE ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	ELI LILLY (S.A.) (PTY) LTD, BRYANSTON, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	45/26/0039
Name of medicine:	LILLY PEMETREXED 500 mg
Dosage form:	POWDER FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: PEMETREXED 500,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (S.A.) (PTY) LTD
Manufacturer:	ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA
Packer:	LILLY FRANCE, FEGERSHEIM, FRANCE
Laboratory: FPRC:	LILLY FRANCE, FEGERSHEIM, FRANCE ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	ELI LILLY (S.A.) (PTY) LTD, BRYANSTON, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/20.1.1/0100
Name of medicine:	TARBACT 200
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN
Packer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN
Laboratory: FPRC:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product
Date of registration:	05 DECEMBER 2013

Registration number:	45/20.1.1/0101
Name of medicine:	TARBACT 400
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN
Packer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN
Laboratory: FPRC:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	45/20.1.1/0102
Name of medicine:	TARBACT SOLVENT
Dosage form:	SOLUTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN
Packer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN
Laboratory: FPRC:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	60 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/26/0184
Name of medicine:	BLEOCIP
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: BLEOMYCIN SULPHATE EQUIVALENT TO BLEOMYCIN
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
Packer:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
Laboratory: FPRC:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

Registration number:	45/26/0185
Name of medicine:	CIPLA BLEOCIP
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: BLEOMYCIN SULPHATE EQUIVALENT TO BLEOMYCIN
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
Packer:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
Laboratory: FPRC:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	45/32.2/0219
Name of medicine:	MYCOPHENOLATE ALKEM 250 mg
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	ALKEM LABORATORIES PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA
Packer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA
Laboratory: FPRC:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/32.2/0220
Name of medicine:	MYCOPHENOLATE ALKEM 500 mg
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ALKEM LABORATORIES PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA
Packer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA
Laboratory: FPRC:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

Registration number:	45/32.2/0221
Name of medicine:	MYCOKEM 250
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALKEM LABORATORIES PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA
Packer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA
Laboratory: FPRC:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	45/8.3/0335
Name of medicine:	EQUIFER
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: IRON (III)-HYDROXIDE SUCROSE COMPLEX EQUIVALENT TO IRON 20,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:	RAFARM S.A., PEANIA-ATTIKI, GREECE
Packer:	RAFARM S.A., PEANIA-ATTIKI, GREECE
Laboratory: FPRC:	RAFARM S.A., PEANIA-ATTIKI, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	EQUITY PHARMACEUTICALS (PTY) LTD, IRENE, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/21.12/0425
Name of medicine:	EXERAN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EXEMESTANE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) PTY) LTD
Manufacturer:	EIRGEN PHARMA LTD, WATERFORD, IRELAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA
Packer:	EIRGEN PHARMA LTD, WATERFORD, IRELAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA MILLMOUNT HEALTHCARE LTD, STAMULLEN, COUNTY MEALTH, IRELAND, MILLMOUNT HEALTHCARE LTD, TRIM ROAD, COUNTY MEALTH, IRELAND
Laboratory: FPRC:	EIRGEN PHARMA LTD, WATERFORD, IRELAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

Registration number:	45/21.12/0487
Name of medicine:	ANASTRAZOLE WATSON
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTRAZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	REMEDICA LTD, LIMASSOL, CYPRUS
Packer:	REMEDICA LTD, LIMASSOL, CYPRUS DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, INDUSTRIA, LONGDALE, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	REMEDICA LTD, LIMASSOL, CYPRUS TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	45/2.7/0531
Name of medicine:	PARACETAMIL FRESENIUS 10 mg/ml (50 ml)
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: PARACETAMOL 10,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA
Packer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AUSTRIA GmbH, LINZ, AUSTRIA
Laboratory: FPRC:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA BODENE (PTY) LTD TRADING AS INTRAMED, PORT ELIZABETH, RSA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	42/20.1.1/0554
Name of medicine:	TEICOPLANIN LITHA 200
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE
Packer:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE PHARMATHEN S.A., ATTIKIS, GREECE
Laboratory: FPRC:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE PHARMATHEN S.A., ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	LITHA PHARMA (PTY) LTD, EDENVALE, RSA
Shelf-life:	36 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product
Date of registration:	05 DECEMBER 2013

Registration number:	42/20.1.1/0555
Name of medicine:	TEICOPLANIN LITHA 400
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE
Packer:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE PHARMATHEN S.A., ATTIKIS, GREECE
Laboratory: FPRC:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE PHARMATHEN S.A., ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	LITHA PHARMA (PTY) LTD, EDENVALE, RSA
Shelf-life:	36 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	45/34/0556
Name of medicine:	SOLVENT FOR TEICOPLANIN LITHA
Dosage form:	SOLUTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE
Packer:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE PHARMATHEN S.A., ATTIKIS, GREECE
Laboratory: FPRC:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE PHARMATHEN S.A., ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	LITHA PHARMA (PTY) LTD, EDENVALE, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/20.2.8/0588
Name of medicine:	VALZOFT 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO CALACICLOVIR 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSPARK, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisonal)
Date of registration:	05 DECEMBER 2013

Registration number:	45/20.2.8/0589
Name of medicine:	VALZOFT 1 g
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO CALACICLOVIR 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSPARK, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	45/2.5/0711
Name of medicine:	LEVETIRACETAM 250 BIOTECH
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA
Laboratory: FPRC:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA
FPRR:	BIOTECH LABORATORIES PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/2.5/0712
Name of medicine:	LEVETIRACETAM 750 BIOTECH
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA
Laboratory: FPRC:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA
FPRR:	BIOTECH LABORATORIES PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	45/2.5/0713
Name of medicine:	LEVETIRACETAM 1 000 BIOTECH
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA
Laboratory: FPRC:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA
FPRR:	BIOTECH LABORATORIES PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	45/5.3/0939
Name of medicine:	ALZIDO 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ZYDUS HEALTHCARE SA PTY) LTD, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/5.3/0940
Name of medicine:	ALZIDO 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ZYDUS HEALTHCARE SA PTY) LTD, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

Registration number:	45/5.3/0941
Name of medicine:	DONEPEZIL ZYDUS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ZYDUS HEALTHCARE SA PTY) LTD, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	45/5.3/0942
Name of medicine:	DONEPEZIL ZYDUS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ZYDUS HEALTHCARE SA PTY) LTD, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	45/2.7/11881
Name of medicine:	PARACETAMIL FRESENIUS 10 mg/ml (100 ml)
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: PARACETAMOL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA
Packer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AUSTRIA GmbH, LINZ, AUSTRIA
Laboratory: FPRC:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA BODENE (PTY) LTD TRADING AS INTRAMED, PORT ELIZABETH, RSA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

Registration number:	46/8.2/0111
Name of medicine:	ARELTO 15
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RIVAROXABAN 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
Packer:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY STEGEMANN LOHNVERPACKUNG & LOGISTISCHER SERVICES e.K., GREVEN, GERMANY
Laboratory: FPRC:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	BAYER (PTY) LTD, ISANDO, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	46/20.2.8/0793
Name of medicine:	ENDURANT
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RILPIVIRINE HYDROCHLORIDE EQUIVALENT TO RILPIVIRINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	JANSSEN CILAG SpA, LATINA, ITLAY
Packer:	JANSSEN CILAG SpA, LATINA, ITLAY
Laboratory: FPRC:	JANSSEN CILAG SpA, LATINA, ITLAY ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	46/8.3/0849
Name of medicine:	RAUTEVENE
Dosage form:	SOLUTION FOR INJECTION/CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH AMPOULE CONTAINS: IRON (III)-HYDROCHLORIDE SUCROSE COMPLEX EQUIVALENT TO IRON 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACTOR PHARMA (PTY) LTD
Manufacturer:	RAFARM S.A., PEANIA, ARRIKI, GREECE
Packer:	RAFARM S.A., PEANIA, ARRIKI, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, INDUSTRIA, LONGDALE, RSA
Laboratory: FPRC:	RAFARM S.A., PEANIA, ARRIKI, GREECE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

Registration number:	47/20.1.8/0327
Name of medicine:	RIZENE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg EMTRICITABINE 200,0 mg FUMARATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HETETO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA
Packer:	HETETO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	HETETO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA ADCOCK INGRAM LIMITED, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

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MRF 15

Registration number:	47/20.2.8/0740
Name of medicine:	TENEMCOM
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	HETETO LABS LIMITED, UNIT II, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETETO LABS LIMITED, UNIT II, JEEDIMETLA, HYDERABAD, INDIA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	HETETO LABS LIMITED, UNIT V, JEEDIMETLA, HYDERAB, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ADCOCK INGRAM LIMITED, WADEVILLE, GERMISTON, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	A40/34/0520
Name of medicine:	NICORETTE FRESHMINT 2 mg
Dosage form:	GUM
Active ingredients:	EACH PIECE OF GUM CONTAINS: NICORETTE RESINATE 20 % EQUIVALENT TO NICOTINE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JOHNSON & JOHNSON (PTY) LTD
Manufacturer:	MCNEIL AB, HELSINGBORG, SWEDEN
Packer:	MCNEIL AB, HELSINGBORG, SWEDEN
Laboratory: FPRC:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA MCNEIL AB, HELSINGBORG, SWEDEN SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

Registration number:	A40/34/0523
Name of medicine:	NICORETTE FRESHMINT 4 mg
Dosage form:	GUM
Active ingredients:	EACH PIECE OF GUM CONTAINS: NICORETTE RESINATE 20 % EQUIVALENT TO NICOTINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JOHNSON & JOHNSON (PTY) LTD
Manufacturer:	MCNEIL AB, HELSINGBORG, SWEDEN
Packer:	MCNEIL AB, HELSINGBORG, SWEDEN
Laboratory: FPRC:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA MCNEIL AB, HELSINGBORG, SWEDEN SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	A40/34/0565
Name of medicine:	NICORETTE ICE MINT 2 mg
Dosage form:	GUM
Active ingredients:	EACH PIECE OF GUM CONTAINS: NICORETTE RESINATE 20 % EQUIVALENT TO NICOTINE 2,0 mg
Conditions of registration :	1, 2, 3, 4, 5, 6, 7
Applicant:	JOHNSON & JOHNSON (PTY) LTD
Manufacturer:	MCNEIL AB, HELSINGBORG, SWEDEN
Packer:	MCNEIL AB, HELSINGBORG, SWEDEN
Laboratory: FPRC:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA MCNEIL AB, HELSINGBORG, SWEDEN SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

MRF15

Registration number:	A40/34/0566
Name of medicine:	NICORETTE ICE MINT 4 mg
Dosage form:	GUM
Active ingredients:	EACH PIECE OF GUM CONTAINS: NICORETTE RESINATE 20 % EQUIVALENT TO NICOTINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JOHNSON & JOHNSON (PTY) LTD
Manufacturer:	MCNEIL AB, HELSINGBORG, SWEDEN
Packer:	MCNEIL AB, HELSINGBORG, SWEDEN
Laboratory: FPRC:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA MCNEIL AB, HELSINGBORG, SWEDEN SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013

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NOTICE 406 OF 2014

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 406 VAN 2014

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 voldoën 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.

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MRF 15	
Registration number:	37/7.1.3/0564
Name of medicine:	ZIABETA 2,5/6,25 mg
Dosage form:	TABLETS
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 2,5 mg HYDROCHLOROTHIAZIDE6,25 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK KGaA, DARMSTADT, GERMANY
Packer:	MERCK KGaA, DARMSTADT, GERMANY
Laboratory: FPRC:	MERCK KGaA, DARMSTADT, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	37/7.1.3/0610
Name of medicine:	ZIABETA 5/6,25 mg
Dosage form:	TABLETS
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 5,0 mg HYDROCHLOROTHIAZIDE6,25 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK KGaA, DARMSTADT, GERMANY
Packer:	MERCK KGaA, DARMSTADT, GERMANY
Laboratory: FPRC:	MERCK KGaA, DARMSTADT, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	37/7.1.3/0611
Name of medicine:	ZIABETA 10/6,25 mg
Dosage form:	TABLET
Active ingredients:	EACHTABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg HYDROCHLOROTHIAZIDE6,25 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK KGaA, DARMSTADT, GERMANY
Packer:	MERCK KGaA, DARMSTADT, GERMANY
Laboratory: FPRC:	MERCK KGaA, DARMSTADT, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	41/20.2.8/0045
Name of medicine:	AURO ZILAVIRENZ
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg EFAVIRENZ 600,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	41/20.2.8/0182
Name of medicine:	TRIDEX
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: STAVUDINE 40,0 mg LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	DEZZO TRADING 392 (PTY) LTD, T/A INDO PHARMA
Manufacturer:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	41/26/0247
Name of medicine:	ACCORD-FLUOROURACIL 50 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FLUOROURACIL 50,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHAMACEUTICALS LTD, MATODA, TALUKA, SANAND, DIST AHMEDABAD, INDIA
Packer:	INTAS PHAMACEUTICALS LTD, MATODA, TALUKA, SANAND, DIST AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHAMACEUTICALS LTD, MATODA, TALUKA, SANAND, DIST AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	41/2.6.5/0332
Name of medicine:	SPARID 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND SELAMINE LTD t/a ARROW GENERICS LIMITED, CLONSHAUGH, DUBLIN, IRELAND M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTDWOODMEAD RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	41/2.6.5/0333
Name of medicine:	SPARID 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND SELAMINE LTD t/a ARROW GENERICS LIMITED, CLONSHAUGH, DUBLIN, IRELAND M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, WOODMEAD RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	41/2.6.5/0334
Name of medicine:	SPARID 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND SELAMINE LTD t/a ARROW GENERICS LIMITED, CLONSHAUGH, DUBLIN, IRELAND M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD , WOODMEAD RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	41/2.6.5/0335
Name of medicine:	SPARID 3 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND SELAMINE LTD t/a ARROW GENERICS LIMITED, CLONSHAUGH, DUBLIN, IRELAND M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, WOODMEAD RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	41/2.6.5/0336
Name of medicine:	SPARID 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	DOUGLAS PHARMACEUTICALS LTD, LINCOLN, AUCKLAND, NEW ZEALAND SELAMINE LTD t/a ARROW GENERICS LIMITED, CLONSHAUGH, DUBLIN, IRELAND M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, WOODMEAD RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	41/1.2/0427
Name of medicine:	EXSIRA 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESVENLAFAXINE SUCCINATE EQUIVALENT TO DESVENLAFAXINE 100,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	WYETH PHAMACEUTICALS Co, GUAYAMA, PUERTO RICO
Packer:	WYETH PHAMACEUTICAL Co, GUAYAMA, PUERTO RICO WYETH MEDICA IRELAND, KILDARE, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	WYETH PHAMACEUTICAL Co, GUAYAMA, PUERTO RICO WYETH MEDICA IRELAND, KILDARE, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORY (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PFIZER LABORATORY (PTY) LTD, SANDTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	41/5.8/0995
Name of medicine:	DIMETAPP PAEDIATRIC COLD & ALLERGY
Dosage form:	LIQUID
Active ingredients:	EACH 5,0 ml LIQUID CONTAINS: BROMPHENIRAMINE MALEATE 2,0 mg PHENYLEPHRINE HCl 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	WYETH PHARMACEUTICALS, SAINT-LAURENT, QUEBEC, CANADA
Packer:	WYETH PHARMACEUTICALS, SAINT-LAURENT, QUEBEC, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	WYETH PHARMACEUTICALS, SAINT-LAURENT, QUEBEC, CANADA CONSULTING CHEMICALS LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	42/7.1.3/0165
Name of medicine:	PRETERAX 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 2,5 mg INDAPAMIDE 0,625 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND
Packer:	QUALITI (Burnley) LIMITED, BRIERCLIFFE, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	42/7.1.3/0166
Name of medicine:	COVERSYL 2,5 mg PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 2,5 mg INDAPAMIDE 0,625 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND
Packer:	QUALITI (Burnley) LIMITED, BRIERCLIFFE, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	42/7.1.3/0167
Name of medicine:	COVERSYL 5 mg PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg INDAPAMIDE 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND
Packer:	QUALITI (Burnley) LIMITED, BRIERCLIFFE, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD,
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/7.1.3/0168
Name of medicine:	PREXUM 5 mg PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg INDAPAMIDE 1,25 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND
Packer:	QUALITI (Burnley) LIMITED, BRIERCLIFFE, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SOUTH AFRICA (PTY) LTD, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/7.1.3/0169
Name of medicine:	CIRCATOR 5 mg PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg INDAPAMIDE 1,25 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	EGIS PHARMACEUTICALS SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND
Packer:	QUALITI (Burnley) LIMITED, BRIERCLIFFE, BURNLEY, CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	EGIS PHARMACEUTICALS SOUTH AFRICA (PTY) LTD, RIVONIA, RSA
Shelf-life:	36months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	42/7.1.3/0170
Name of medicine:	COVERON 5 mg PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg INDAPAMIDE 1,25 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	EGIS PHARMACEUTICALS SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND
Packer:	QUALITI (Burnley) LIMITED, BRIERCLIFFE, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR.	EGIS PHARMACEUTICALS SOUTH RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number	: 42/7.1.3/0171
Name of medicine:	VECTORYL 5 mg PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg INDAPAMIDE 1,25 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND
Packer:	QUALITI (Burnley) LIMITED, BRIERCLIFFE, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SOUTH AFRICA (PTY) LTD, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/7.1.3/0172
Name of medicine:	BiPRETERAX 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5,0 mg INDAPAMIDE 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND
Packer:	QUALITI (Burnley) LIMITED, BRIERCLIFFE, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (Ireland) INDUSTRIES LTD, WICKLOW, ARKLOW, IRELAND M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	SERVIER LABOARATORIES SOUTH AFRICA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/18.2/0345
Name of medicine:	MINIRIN MELT 60 µg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESMOPRESSIN ACETATE 60,0 µg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	FERRING (PTY) LTD
Manufacturer:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK
Packer:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK CARDINAL HEALTH UK 417, SEDGE CLOSE, CORBY NORTHANTS, UK
Laboratory: FPRC:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK FERRING GmbH, KIEL, GERMANY FERRING A/S, VANLOSE, DENMARK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING (PTY) LIMITED, IRENE, CENTURION, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/18.2/0346
Name of medicine:	MINIRIN MELT 120 µg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESMOPRESSIN ACETATE 120,0 µg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	FERRING (PTY) LTD
Manufacturer:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK
Packer:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK CARDINAL HEALTH UK 417, SEDGE CLOSE, CORBY NORTHANTS, UK
Laboratory: FPRC:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK FERRING GmbH, KIEL, GERMANY FERRING A/S, VANLOSE, DENMARK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING (PTY) LIMITED, IRENE, CENTURION, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/18.2/0347
Name of medicine:	MINIRIN MELT 240 µg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESMOPRESSIN ACETATE 240,0 µg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	FERRING (PTY) LTD
Manufacturer:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK
Packer:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK CARDINAL HEALTH UK 417, SEDGE CLOSE, CORBY NORTHANTS, UK
Laboratory: FPRC:	CARDINAL HEALTH UK 416 LIMITED, BLAGROVE, SWINDON, WILTSHIRE, UK FERRING GmbH, KIEL, GERMANY FERRING A/S, VANLOSE, DENMARK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING (PTY) LIMITED, IRENE, CENTURION, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	42/26/0448
Name of medicine:	ALIMTA 100 mg
Dosage form:	POWDER FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: PEMETREXED SODIUM EQUIVALENT TO PEMETREXED 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ELI LILLY (SA) (PTY) LTD
Manufacturer:	ELI LILLY & COMPANY, LILLY TECHNOLOGY CENTRE, INDIANA, USA
Packer:	ELI LILLY & COMPANY, LILLY TECHNOLOGY CENTRE, INDIANA, USA LILLY FRANCE S.A.S., FEGERSHEIM, FRANCE
Laboratory:FPRC:	LILLY FRANCE S.A.S., FEGERSHEIM, FRANCE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	EL LILLY SOUTH AFRICA (PTY) LTD, BRYANSTON, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/22.2/0783
Name of medicine:	ROPEN 250MG
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMPICILLIN SODIUM EQUIVALENT TO 250,0MG AMPICILLIN
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Laboratory:FPRC:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA M&L LABORATORY SERVICES ORMONDE JOHANNESBURG RSA KHULULEKANI LABORATORY SERVICES MIDRAND RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/20.1.2/0784
Name of medicine:	ROPEN 500 mg
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	42/20.1.2/0785
Name of medicine:	ROPEN 1 g
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/1.2/0935
Name of medicine:	EXSIRA 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESVENLAFAXINE SUCCINATE EQUIVALENT TO DESVENLAFAXINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	WYETH PHAMACEUTICALS Co, GUAYAMA, PUERTO RICO
Packer:	WYETH PHAMACEUTICAL Co, GUAYAMA, PUERTO RICO WYETH MEDICA IRELAND, KILDARE, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	WYETH PHAMACEUTICAL Co, GUAYAMA, PUERTO RICO WYETH MEDICA IRELAND, KILDARE, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORY (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PFIZER LABORATORY (PTY) LTD, SANDTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/1.2/0935
Name of medicine:	EXSIRA 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESVENLAFAXINE SUCCINATE EQUIVALENT TO DESVENLAFAXINE 50,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	WYETH PHAMACEUTICALS Co, GUAYAMA, PUERTO RICO
Packer:	WYETH PHAMACEUTICAL Co, GUAYAMA, PUERTO RICO WYETH MEDICA IRELAND, KILDARE, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	WYETH PHAMACEUTICAL Co, GUAYAMA, PUERTO RICO WYETH MEDICA IRELAND, KILDARE, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORY (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PFIZER LABORATORY (PTY) LTD,SANDTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	42/2.6.5/0968
Name of medicine:	RISPLAN 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory: FPRC:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months (HDPE) 48 months (Blister)
Date of registration.	06 MARCH 2014

MRF 15	
Registration number:	42/2.6.5/0969
Name of medicine:	RISPLAN 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory: FPRC:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months (HDPE) 48 months (Blister)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/2.6.5/0970
Name of medicine:	RISPLAN 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory: FPRC:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months (HDPE) 48 months (Blister)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/2.6.5/0982
Name of medicine:	RISPLAN 3 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory: FPRC:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months (HDPE) 48 months (Blister)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/2.6.5/0983
Name of medicine:	RISPLAN 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory: FPRC:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months (HDPE) 48 months (Blister)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	42/2.6.5/0984
Name of medicine:	RISPLAN 6 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory: FPRC:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months (HDPE) 48 months (Blister)
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	A42/20.1.1/1073
Name of medicine:	ORCHID-CEFOXITIN 1G
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFOXITIN SODIUM EQUIVALENT TO 1G CEFOXITIN
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ORCHID, PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	ORCHID HEALTHCARE
Packer:	ORCHID HEALTHCARE
Laboratory:FPRC:	ORCHID HEALTHCARE SA PTY LTD, KANCHEEPURAM INDIA CONSULTING CHEMICAL LABORATERIES (PTY) LTD BOKSBURG RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY NORTHWEST UNIVERSITY POTCHEFSTROOM RSA INSTITUTE FOR PHARMACEUTICAL SERVICES SILVERTONDALE RSA
FPRR:	ORCHID PHARMACEUTICAL (PTY) LTD, , RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	43/2.5/0284
Name of medicine:	AURO GABAPENTIN 100 mg CAPSULES
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	M/S AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKA LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	43/2.5/0285
Name of medicine:	AURO GABAPENTIN 300 mg CAPSULES
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	M/S AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKA LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	43/2.5/0286
Name of medicine:	AURO GABAPENTIN 400 mg CAPSULES
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	M/S AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKA LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	43/20.1.1/0492
Name of medicine:	CLARIDE INJECTION
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CLARITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB LIMITED, BILEKAHALLI, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LIMITED, BILEKAHALLI, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	STRIDES ARCOLAB LIMITED, BILEKAHALLI, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	43/11.4.3/0502
Name of medicine:	CORPOCID 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OMEPRAZOLE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACORP CC
Manufacturer:	SMB TECHNOLOGY S.A., MAECHE-EN-FAMENNE, BELGIUM
Packer:	SMB TECHNOLOGY S.A., MAECHE-EN-FAMENNE, BELGIUM
Laboratory: FPRC:	SMB TECHNOLOGY S.A, MAECHE-EN-FAMENNE, BELGIUM INSTITUTE FOR PHARMACEUTICAL SERVICES SILVERTONDALE, PRETORIA, RSA
FPRR:	PHARMACORP CC, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	43/21.12/0620
Name of medicine:	SPEC BICALUTAMIDE 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	GENEPHARM S.A., PALLINI, ATTIKIS, GREECE
Packer:	GENEPHARM S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	GENEPHARM S.A., PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAYHOUSE, MIDRAND, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	43/2.6.5./0908
Name of medicine:	PREXOLAN 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ATHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE
Laboratory:FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	43/2.6.5./0909
Name of medicine:	PREXOLAN 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ATHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE
Laboratory:FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	43/2.6.5./0910
Name of medicine:	PREXOLAN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ATHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE
Laboratory:FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	43/2.6.5/0911
Name of medicine:	PREXOLAN IM
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: OLANZAPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	ANFARM HELLAS S.A., SCHIMATARI, VIOTIAS, GREECE STRIDES ARCOLAB POLSKA Sp.zo.o, WARSAW, POLAND
Packer:	ANFARM HELLAS S.A., SCHIMATARI, VIOTIAS, GREECE STRIDES ARCOLAB POLSKA Sp.zo.o, WARSAW, POLAND PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Laboratory: FPRC:	ANFARM HELLAS S.A., SCHIMATARI, VIOTIAS, GREECE STRIDES ARCOLAB POLSKA Sp.zo.o, WARSAW, POLAND SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	43/5.7.1/1149
Name of medicine:	CIPLA DESLORATADINE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESLORATADINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LIMITED, UNIT III, VERNA, GOA, INDIA
Packer:	CIPLA LIMITED, UNIT III, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LIMITED, UNIT III, VERNA, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	43/5.7.1/1150
Name of medicine:	LORALEX
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESLORATADINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LIMITED, UNIT III, VERNA, GOA, INDIA
Packer:	CIPLA LIMITED, UNIT III, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LIMITED, UNIT III, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	44/2.2/0001
Name of medicine:	CIRCADIN 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLETS CONTAINS: MELATONIN 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACORP CC
Manufacturer:	SWISSCO SERVICES AG, SISSELN, SWITZERLAND CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY
Packer:	SWISSCO SERVICES AG, SISSELN, SWITZERLAND CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY
Laboratory:FPRC:	SWISSCO SERVICES AG, SISSELN, SWITZERLAND CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY PENN PHARMACEUTICAL SERVICES LTD, GWENT, UNITED KINGDOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	PHARMACORP CC, MORELETA PARK, PRETORIA,RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	44/20.1.1/0206
Name of medicine:	ADCO-MEROPENEM 500 MG IV
Dosage form:	POWDER FOR SOLUTION FOR INTRAVENOUS INJECTION
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT 500 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LTD (PTY) LTD MIDRAND RSA
Manufacturer:	ACS DOBFAR S.P.A) MELANO ITALY FACTA FARMACEUTICI S.P.A TERAMO ITALY
Packer:	FACTA FARMACEUTICI S.P.A TERAMO ITALY ADCOCK INGRAM CRITICAL CARE (PTY) LTD JOHANNESBURG RSA
Laboratory: FPRC:	FACTA FARMACEUTICI S.P.A TERAMO ITALY ADCOCK INGRAM CRITICAL CARE (PTY) LTD WADEVILLE RSA ADCOCK INGRAM (RESEARCH AND DEVELOPEMENT) SABAX RSA
FPRR:	ADCOCK INGRAM LIMITED MIDRAND RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD JOHANNESBURG RSA ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPEMENT) SABAX RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	44/20.1.1/0207
Name of medicine:	COVAN MEROPENEM 500 mg IV
Dosage form:	POWDER FOR SOLUTION FOR INTRAVENOUS INJECTION
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR S.p.A., TRIBIANO, MILANO, ITALY FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY
Packer:	FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Laboratory: FPRC:	FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	44/20.1.1/0303
Name of medicine:	ADCO MEROPENEM 1 000 mg IV
Dosage form:	POWDER FOR SOLUTION FOR INTRAVENOUS INJECTION
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR S.p.A., TRIBIANO, MILANO, ITALY FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY
Packer:	FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Laboratory: FPRC:	FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	44/20.1.1/0304
Name of medicine:	COVAN MEROPENEM 1 000 mg IV
Dosage form:	POWDER FOR SOLUTION FOR INTRAVENOUS INJECTION
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 1 000,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACS DOBFAR S.p.A., TRIBIANO, MILANO, ITALY FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY
Packer:	FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Laboratory: FPRC:	FACTA FARMACEUTICI S.p.A., TRIBIANO, TERAMO, ITALY ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	44/20.1.1/0328
Name of medicine:	TAZOGEN
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 4,0g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 0,5g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	LABORATORY REIG JOFRE S.A., TOLEDO, SPAIN
Packer:	LABORATORY REIG JOFRE S.A., TOLEDO, SPAIN
Laboratory: FPRC:	LABORATORY REIG JOFRE S.A., TOLEDO, SPAIN KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/10.2.2/0487
Name of medicine:	SANDOZ MONTELUKAST 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:	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 (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE- KOCAELI, TURKEY CONSULTING CHEMICALS LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/10.2.2/0488
Name of medicine:	SANDOZ MONTELUKAST 5
Dosage form:	CHEABLE 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:	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 (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S., GEBZE- KOCAELI, TURKEY CONSULTING CHEMICALS LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/21.12/0499
Name of medicine:	ANASTA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Packer:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory: FPRC:	DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/20.2.8/0636
Name of medicine:	TRAYROCA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg ZIDOVUDINE 300,0 mg
Conditions of: Registration	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ACROLAB LIMITED, INDLAWADI CROSS, ANEKAL TALUK, BANGALORE, INDIA ASPEN OSD (PTY) LTD, PORT ELIZABETH, RSA
Packer:	STRIDES ACROLAB LIMITED, INDLAWADI CROSS, ANEKAL TALUK, BANGALORE, INDIA ASPEN OSD (PTY) LTD PORT ELIZABETH, RSA
Laboratory: FPRC:	STRIDES ACROLAB LIMITED, INDLAWADI CROSS, ANEKAL TALUK, BANGALORE, INDIA ASPEN OSD (PTY) LTD, PORT ELIZABETH, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ASPEN OSD (PTY) LTD, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/13.1.2/0765
Name of medicine:	DERIVA MICROSPHERES GEL
Dosage form:	GEL
Active ingredients:	EACH GEL CONTAINS: ADAPALENE 0.1 % w/w
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GLENMARK PHARMACEUTICAL SA (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, NASIK, INDIA
Packer:	GLENMARK PHARMACEUTICAL LIMITED, NASIK, INDIA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, NASIK, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	GLENMARK PHARMACEUTICAL SOUTH AFRICA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	44/20.1.2/0816
Name of medicine:	MEDREICH FLUCLOXACILLIN 250 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCLOXACILLIN SODIUM EQUIVALENT TO FLUCLOXACILLIN 250,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDREICH SA (PTY) LTD
Manufacturer:	MEDREICH LIMITED (UNIT 1), VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH LIMITED (UNIT 1), VIRGONAGAR, BANGALORE, INDIA
Laboratory: FPRC:	MEDREICH LIMITED (UNIT 1), VIRGONAGAR, BANGALORE, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	MEDREICH SA (PTY) LTD, ROBERTSHAM, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number: 44/3.2/0818

Name of medicine:	ASPEN BANDRONATE 1 mg IV
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: (IBANDRONIC ACID) EQUIVALENT TO IBANDRONATE SODIUM MONOHYDRATE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE,JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY I NCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number: 44/3.2/0819

Name of medicine:	ASPEN BANDRONATE 2 mg IV
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: (IBANDRONIC ACID) EQUIVALENT TO IBANDRONATE SODIUM MONOHYDRATE
Conditions of: Registration	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN SA ATIIKIS GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15

Registration number: 44/3.2/0820

Name of medicine:	ASPEN IBANDRONATE 6 mg IV
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: (IBANDRONIC ACID) EQUIVALENT TO IBANDRONATE SODIUM MONOHYDRATE
Conditions of: Registration	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN SA ATIIKIS GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/20.1.2/0838
Name of medicine:	ADCO FLUCLOXACILLIN 250 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCLOXACILLIN SODIUM EQUIVALENT TO FLUCLOXACILLIN 250,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	MEDREICH LIMITED (UNIT 1), VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH LIMITED (UNIT 1), VIRGONAGAR, BANGALORE, INDIA
Laboratory: FPRC:	MEDREICH LIMITED (UNIT 1), VIRGONAGAR, BANGALORE, INDIA ADCOCK INGRAM HEALTHCARE (PTY) LTD WADEVILLE, GERMISTON, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD WADEVILLE, GERMISTON, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, RSA ADCOCK INGRAM, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/17.1/0904
Name of medicine:	MYPROCAM 15
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: CYCLOBENZAPRINE HYDROCHLORIDE 15,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	EURAND INC, VANDALIA, OHIO, USA
Packer:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	EURAND INC, VANDALIA, OHIO, USA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM - RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM LIMITED - RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	48 months
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	44/2.7/1048
Name of medicine:	TORAKET 30 mg INJECTION
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: KETOROLAC TROMETAMOL 30,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	LABORATORIES LESVI, S.L., JOAN DESPI (BARCELONA), SPAIN
Packer:	LABORATORIES LESVI, S.L., JOAN DESPI (BARCELONA), SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	LABORATORIES LESVI, S.L JOAN DESPI (BARCELONA), SPAIN CONSULTING CHEMICAL LABORATORIES ATLASVILLE, BOKSBURG RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/30.1/1064
Name of medicine:	MENACTRA
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: GROUP A MENINGOCOCCAL POLYSACCHARIDE 4,0 µg GROUP C MENINGOCOCCAL POLYSACCHARIDE 4,0 µg GROUP Y MENINGOCOCCAL POLYSACCHARIDE 4,0 µg GROUP W-135 MENINGOCOCCAL POLYSACCHARIDE 4,0 µg DIPTHERIA TOXOID PROTEIN approx 48,0 µg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI PASTEUR INC, SWIFTWATER, PENNSYLVANIA, USA
Packer:	SANOFI PASTEUR INC, SWIFTWATER, PENNSYLVANIA, USA
Laboratory: FPRC:	SANOFI PASTEUR INC, SWIFTWATER, PENNSYLVANIA, USA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA
Shelf-life:	18 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	44/7.5/1065
Name of medicine:	CRESAGEN 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 5, 0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A., KSAWEROW, POLAND ADAMED Sp zo.o, CZOSNOW, POLAND
Packer:	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A., KSAWEROW, POLAND ADAMED Sp zo.o, CZOSNOW, POLAND
Laboratory: FPRC:	KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	44/7.5/1066
Name of medicine:	CRESAGEN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10, 0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A., KSAWEROW, POLAND ADAMED Sp zo.o, CZOSNOW, POLAND
Packer:	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A., KSAWEROW, POLAND ADAMED Sp zo.o, CZOSNOW, POLAND
Laboratory: FPRC:	KHULULEKANI LABORATORY SERVICES, CONVETRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	44/7.5/1067
Name of medicine:	CRESAGEN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20, 0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A., KSAWEROW, POLAND ADAMED Sp zo.o, CZOSNOW, POLAND
Packer:	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A., KSAWEROW, POLAND ADAMED Sp zo.o, CZOSNOW, POLAND
Laboratory: FPRC:	KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	44/7.5/1068
Name of medicine:	CRESAGEN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40, 0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A., KSAWEROW, POLAND ADAMED Sp zo.o, CZOSNOW, POLAND
Packer:	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A., KSAWEROW, POLAND ADAMED Sp zo.o, CZOSNOW, POLAND
Laboratory: FPRC:	KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	45/26/0095
Name of medicine:	DOCETAXEL SANOFI-AVENTIS 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 ANHYDROUS 20,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (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, ORMONDE, JOHANNESBRG, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/26/0096
Name of medicine:	DOCETAXEL SANOFI-AVENTIS 80 mg/1 ml RTU
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 4,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL ANHYDROUS 80,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (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, ORMONDE, JOHANNESBRG, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	A40/5.8/0218
Name of medicine:	IBUMAX COLD & FLU (TABS)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 200,0 mg PSEUDOEPHEDRINE HYDROCHLORIDE 30,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Packer:	PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN PARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	19 APRIL 2013

MRF 15	
Registration number:	45/26/0211
Name of medicine:	CIPLA FLUOROURACIL
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FLUOROURACIL 50,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LIMITED, UNIT V, VERNA SALCETTE, GOA, INDIA
Packer:	CIPLA LIMITED, UNIT V, VERNA SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LIMITED, UNIT V, VERNA SALCETTE, GOA INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/8.3/0252
Name of medicine:	SUCROFER
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml CONTAINS: FERRIC HYDROXIDE SUCROSE EQUIVALENT TO COMPLEX IRON 20,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA
Packer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life.	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/21.8.2/0534
Name of medicine:	YAZ PLUS
Dosage form:	TABLETS
Active ingredients:	EACH PINK TABLET CONTAINS: DROSPIRENONE 3,0 mg ETHINYLESTRADIOL 0,02 mg LEVOMEFOLATE CALCIUM 0,451 mg EACH LIGHT ORANGE TABLET CONTAINS: LEVOMEFOLATE CALCIUM 0,451 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	SCHERING GmbH UND Co PRODUKTIONS KG, WEIMAR, GERMANY
Packer:	SCHERING GmbH UND Co PRODUKTIONS KG, WEIMAR, GERMANY BAYER SCHERING PHARMA AG, BERLIN, GERMANY
Laboratory:FPRC:	SCHERING GmbH UND Co PRODUKTIONS KG, WEIMAR, GERMANY BAYER SCHERING PHARMA AG, BERLIN, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	BAYER (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	45/3.2./0571
Name of medicine:	HIDRIST 8MG TABLETS
Dosage form:	TABLET
Active ingredients:	EACH UNCOATED TABLET CONTAINS: BETAHISTINE DIHYDROCHLORIDE TO 8, 0MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD DURBAN RSA
Manufacturer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Laboratory:FPRC:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA M&L LABORATORY SERVICES (PTY) LTD ORMONDE JOHANNESBURG RSA KHULULEKANI LABORATORY SERVICES CC COVENTRY MIDRAND RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.6/0572
Name of medicine:	HIDRIST 16 MG TABLETS
Dosage form:	TABLET
Active ingredients:	EACH UNCOATED TABLET CONTAINS: BETAHISTINE DIHYDROCHLORIDE TO 16, 0MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD DURBAN RSA
Manufacturer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Laboratory:FPRC:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA M&L LABORATORY SERVICES (PTY) LTD ORMONDE JOHANNESBURG RSA KHULULEKANI LABORATORY SERVICES CC COVENTRY MIDRAND RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.6/0573
Name of medicine:	HIDRIST 24 MG TABLETS
Dosage form:	TABLET
Active ingredients:	EACH UNCOATED TABLET CONTAINS:BETAHISTINE DIHYDROCHLORIDE TO 24, 0MG
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD DURBAN RSA
Manufacturer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Laboratory:FPRC:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA M&L LABORATORY SERVICES (PTY) LTD ORMONDE JOHANNESBURG RSA KHULULEKANI LABORATORY SERVICES CC COVENTRY MIDRAND RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.6/0574
Name of medicine:	DAHIDE 8 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BETAHISTINE DIHYDROCHLORIDE 8,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.6/0575
Name of medicine:	DAHIDE 16 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BETAHISTINE DIHYDROCHLORIDE 16,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.6/0576
Name of medicine:	DAHIDE 24 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BETAHISTINE DIHYDROCHLORIDE 24,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	45/5.6/0577
Name of medicine:	TREVIGO 8 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BETAHISTINE DIHYDROCHLORIDE 8,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.6/0578
Name of medicine:	TREVIGO 16 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BETAHISTINE DIHYDROCHLORIDE 16,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.6/0579
Name of medicine:	TREVIGO 24 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BETAHISTINE DIHYDROCHLORIDE 24,0 mg
Conditions: of registration	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/3.2/0582
Name of medicine:	DEPLOVIN 10MG
Dosage form:	SODIUM ALENDRONATE TABLET
Active ingredients:	EACH UNCOATED TABLETS CONTAINS: SODIUM ALEDRONATE EQUIVALENT TO ALENDRONIC ACID 10MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Laboratory:FPRC:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA M&L LABORATORY SERVICES ORMONDE JOHANNESBURG RSA KHULULEKANI LABORATORY SERVICES MIDRAND RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/3.2/0583
Name of medicine:	DEPLOVIN 70MG
Dosage form:	SODIUM ALENDRONATE TABLET
Active ingredients:	EACH UNCOATED TABLETS CONTAINS: SODIUM ALEDRONATE EQUIVALENT TO ALENDRONIC ACID 70MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Packer:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA
Laboratory:FPRC:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA M&L LABORATORY SERVICES MONDE JOHANNESBURG RSA KHULULEKANI LABORATORY SERVICES MIDRAND RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/3.2./0584
Name of medicine:	GENSOF 70MG
Dosage form:	TABLET
Active ingredients:	EACH UNCOATED TABLET CONTAINS: SODIUM ALEDRONATE EQUIVALENT TO ALEDRONIC ACID 70MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	M/S AUROBINDO PHARMA LIMITED
Packer:	M/S AUROBINDO PHARMA LIMITED
Laboratory:FPRC:	M/S AUROBINDO PHARMA LIMITED ANDHRA PRADESH INDIA M&L LABORATORY SERVICES (PTY) LTD ORMONDE JOHANNESBURG RSA KHULULEKANI LABORATORY SERVICES CC COVENTRY MIDRAND RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	45/16.4/0620
Name of medicine:	STREPSILS WARM GINGER
Dosage form:	LOZENGE
Active ingredients:	EACH LOZENGE CONTAINS: AMYLMETACRESOL 0,6 mg 2,4-DICHLOROBENZYL ALCOHOL 1,2 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD
Manufacturer:	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM, UNITED KINGDOM
Packer:	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM, UNITED KINGDOM PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM, UNITED KINGDOM PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, JOHANNESBURG, RSA RECKITT BENCKISER PHARMACEUTICAL (PTY) LTD, ELANDSFONTEIN, RSA
FPRR:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	45/5.3/0682
Name of medicine:	MACLEODS DONEPEZIL TABLETS 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Packer	MACLEODS PHARMACEUTICALS LTD, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA SEDEK AGRIKEM, SILVERTON, PRETORIA, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	45/5.3/0683
Name of medicine:	MACLEODS DONEPEZIL TABLETS 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Packer	MACLEODS PHARMACEUTICALS LTD, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA SEDEK AGRIKEM, SILVERTON, PRETORIA, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.2/0792
Name of medicine:	RETOCAR 2,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 2,5 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.2/0793
Name of medicine:	RETOCAR 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 5,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	45/5.2/0794
Name of medicine:	RETOCAR 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLARPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	46/20.2.8/0863
Name of medicine:	ISENTRESS CHEWABLE TABLETS
Dosage form:	TABLETS
Active ingredients:	EACH 25 MG CHEWABLE TABLET OF ISENTRESS COINTAINS 27.16 MG OF RALTEGRAVIR EQUIVALENT TO 25MG OF RALTEGRAVIR FREE PHENOL
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MSD (PTY) LTD
Manufacturer:	PATHEON PHARMACEUTICAL INC
Packer:	MERCK SHARP & DOHME BV A.HUMA MEDICINE
Laboratory:FPRC:	PATHEON PHARMACEUTICAL INC CINCINNATI USA MSD (PTY) LTD HALFWAY HOUSE RSA MERCK SHARP & DOHME BV HAARLEM NETHERLANDS
FPRR:	MSD (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	46/20.2.8/0864
Name of medicine:	ISENTRESS CHEWABLE 100 mg
Dosage form:	TABLETS
Active ingredients:	EACH CHEWABLE TABLET CONTAINS: RALTEGRAVIR POTASSIUM EQUIVALENT TO RALTEGRAVIR 100,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MSD (PTY) LTD
Manufacturer:	PATHEON PHARMACEUTICAL INC, CINCINNATI, OHIO, USA
Packer:	MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory:FPRC:	PATHEON PHARMACEUTICAL INC, CINCINNATI, OHIO, USA MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS
FPRR:	MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	45/8.3/0948
Name of medicine:	FERINJECT
Dosage form:	SOLUTION FOR INJECTION/INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FERRIC CARBOXYMALTOSE EQUIVALENT TO IRON 50,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	NYCOMED (PTY) LTD
Manufacturer:	NYCOMED GmbH, SINGEN, GERMANY IDT BIOLOGIKA GmbH, DESSAU- ROSSLAU, GERMANY
Packer:	NYCOMED GmbH, SINGEN, GERMANY IDT BIOLOGIKA GmbH, DESSAU- ROSSLAU, GERMANY
Laboratory: FPRC:	NYCOMED GmbH, SINGEN, GERMANY IDT BIOLOGIKA GmbH, DESSAU- ROSSLAU, GERMANY VIFOR (INT) INC, ST GALLEN, SWITZERLAND
FPRR:	NYCOMED (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	46/20.2.8/0979
Name of medicine:	KAVIMUN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ABACAVIR SULFATE QUIVALENT TO ABACAVIR 300,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NISHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NISHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NISHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	48 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	A39/7.1/0316
Name of medicine:	ALFADIL XL 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN 4,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LIMITED
Manufacturer:	PFIZER INC, BROOKLYN, NEW YORK, USA
Packer:	HEINRICH MACK NACHF. GmbH AND Co EIN UNTERNEHMEN DER PFIZER-GRUPPE, ILLERTISSEN, GERMANY
Laboratory: FPRC:	PFIZER INC, ROOKLYN, NEW YORK, USA JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
FPRR:	PFIZER LABORATORIES (PTY) LIMITED, RIVONIA, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	A39/7.1/0317
Name of medicine:	ALFADIL XL 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN 8,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LIMITED
Manufacturer:	PFIZER INC, BROOKLYN, NEW YORK, USA
Packer:	HEINRICH MACK NACHF. GmbH AND Co EIN UNTERNEHMEN DER PFIZER-GRUPPE, ILLERTISSEN, GERMANY
Laboratory: FPRC:	PFIZER INC, BROOKLYN, NEW YORK, USA JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
FPRR:	PFIZER LABORATORIES (PTY) LIMITED, RIVONIA, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15	
Registration number:	A39/18.10/0611
Name of medicine:	FLOMAXTRA 0,4
Dosage form:	PROLONGED RELEASE FILM-COATED TABLET
Active ingredients:	EACH 0.4 TAMSULOSIN HYDROCHLORIDE COINTAINS PER PROLONGED RELEASE FILM-COATED TO TABLET
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	YAMANOUCHI PHARMA (PTY) LTD
Manufacturer:	YAMANOUCHI EUROPE BV
Packer:	YAMANOUCHI EUROPE BV DIVPHARMA MANUFACTUREING AND PACKING CC
Laboratory:FPRC:	YAMANOUCHI EUROPE BV MEPPEL NETHERLANDS CONSULTING CHEMICAL LABORATORY (PTY) LTD ATLASVILLE BOKSBURG RSA
FPRR:	YAMANOUCHI PHARMA (PTY) LTD
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	A40/22.2/0592
Name of medicine:	GULF FOLIC ACID 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: 5, 0 MG FOLIC ACID
Conditions of: registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GULF DRUG COMPANY (PTY) LTD DURBAN RSA
Manufacturer:	ALEMBIC LIMITED GUJARAT INDIA
Packer:	ALEMBIC LIMITED GUJARAT INDIA
Laboratory:FPRC:	ALEMBIC LIMITED GUJARAT INDIA ASBS PHARMACEUTICAL CHEM LAB GROONKLOOF PRETORIA RSA INSTITUTE FOR PHARMACEUTICAL SERVICES SILVERTONDALE PRETORIA RSA CONSULTING CHEMICAL LABORATORY (PTY) LTD ATLASVILLE BOKSBURG ACORN PHARMACEUTICAL (PTY) LTD NORTH RIDING RANDBURG
FPRR.	GULF DRUG COMPANY (PTY) LTD DURBAN RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

MRF 15	
Registration number:	A40/26/0750
Name of medicine:	DOCETAXEL WINTHROP 20 mg
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL ANHYDROUS 20,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	AVENTIS PRINCIPES ACTIFS PHARMACEUTIQUES, VITRY-SUR-SEINE, FRANCE AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Packer:	AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Laboratory: FPRC:	AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

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MRF 15

Registration number:	A40/26/0751
Name of medicine:	DOCETAXEL WINTHROP 80 mg
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL ANHYDROUS 80,0 mg
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	AVENTIS PRINCIPES ACTIFS PHARMACEUTIQUES, VITRY-SUR-SEINE, FRANCE AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Packer:	AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Laboratory: FPRC:	AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	06 MARCH 2014

MRF 15

Registration number:	A40/34/0752
Name of medicine:	DOCETAXEL WINTHROP SOLVENT
Dosage form:	SOLUTION
Active ingredients:	EACH VIAL CONTAINS: ETHANOL 95 % v/v 95,0 mg WATER FOR INJECTION to 1,5 ml
Conditions of: registration	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM
Packer:	AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	AVENTIS PHARMA, DAGENHAM, EAST ESSEX, UNITED KINGDOM WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	06 MARCH 2014

NOTICE 407 OF 2014

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 407 VAN 2014

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 voldoën 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.

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MRF 15

Registration number:	06/17.1.6/07
Name of medicine:	MRCOBYL 10 %l
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: MARBOFLOXSCIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AFRIVET LOGISTICS(PTY) LTD
Manufacturer:	VETOQUINOL. LURE, CEDEX, FRANCE
Packer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY
Laboratory: FPRC:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY SA NATIONAL CONTROL LABORATORY FOR BIOLOGICAL PRODUCTS, BLOENFONTEIN, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA(PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	47/26/0919
Name of medicine:	ZALTRAP 100 mg/4 ml
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: AFLIBERCEPT 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA(PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY
Packer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY
Laboratory: FPRC:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY SA NATIONAL CONTROL LABORATORY FOR BIOLOGICAL PRODUCTS, BLOENFONTEIN, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA(PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	47/26/0918
Name of medicine:	ZALZEN 200 mg/8 ml
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: AFLIBERCEPT 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS(PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY
Packer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY
Laboratory: FPRC:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY SA NATIONAL CONTROL LABORATORY FOR BIOLOGICAL PRODUCTS, BLOENFONTEIN, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA(PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	47/26/0917
Name of medicine:	ZALZEN 100 mg/4 ml
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: AFLIBERCEPT 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS(PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY
Packer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY
Laboratory: FPRC:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY SA NATIONAL CONTROL LABORATORY FOR BIOLOGICAL PRODUCTS, BLOEMFONTEIN, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA(PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	46/2.6/5/0085
Name of medicine:	SPEC QUETIAPINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	GENEPHARM SA, PALLINI, GREECE
Packer:	GENEPHARM SA, PALLINI, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	GENEPHARM SA, PALLINI, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	46/2.6/5/0084
Name of medicine:	SPEC QUETIAPINE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	GENEPHARM SA, PALLINI, GREECE
Packer:	GENEPHARM SA, PALLINI, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	GENEPHARM SA, PALLINI, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	46/2.6/5/0083
Name of medicine:	SPEC QUETIAPINE 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	GENEPHARM SA, PALLINI, GREECE
Packer:	GENEPHARM SA, PALLINI, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	GENEPHARM SA, PALLINI, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	46/2.6/5/0082
Name of medicine:	SPEC QUETIAPINE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	GENEPHARM SA, PALLINI, GREECE
Packer:	GENEPHARM SA, PALLINI, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	GENEPHARM SA, PALLINI, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	46/2.6/5/0081
Name of medicine:	SPEC QUETIAPINE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	GENEPHARM SA, PALLINI, GREECE
Packer:	GENEPHARM SA, PALLINI, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	GENEPHARM SA, PALLINI, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	43/21.2/0669
Name of medicine:	MYLAN METFORMIN 1 000 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDA
Laboratory: FPRC :	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	MYLAN (PTY) LTD,MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	43/7.1.5/0984
Name of medicine:	VITRIXA 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA ROPACK Inc, MONTREAL, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	43/7.1.5/0983
Name of medicine:	VITRIXA 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA ROPACK Inc, MONTREAL, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

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MRF 15	
Registration number:	43/7.1.5/0982
Name of medicine:	VITRIXA 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA ROPACK Inc, MONTREAL, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF15	
Registration number:	43/7.1.5/0981
Name of medicine:	VIDENA 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA ROPACK Inc, MONTREAL, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF 15	
Registration number:	43/7.1.5/0980
Name of medicine:	VIDENA 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA ROPACK Inc, MONTREAL, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory::FPRC	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	43/7.1.5/0979
Name of medicine:	VIDENA 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA ROPACK Inc, MONTREAL, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	43/5.10/0762
Name of medicine:	ENTRAN INJECTION 4 mg/2 ml1
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN,JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	43/5.10/0761
Name of medicine:	ARROW ONDANSETRON INJECTION 4 mg/2 ml1
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN,JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	43/1.2/0699
Name of medicine:	BIOTECH TRAZODONE 100
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TRAZODONE HYDROCHLORIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	RIVOPHARM SA, MANNO, SWITZERLAND
Packer:	RIVOPHARM SA, MANNO, SWITZERLAND
Laboratory: FPRC:	RIVOPHARM SA, MANNO, SWITZERLAND INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMCAY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	43/1.2/0698
Name of medicine:	BIOTECH TRAZODONE 50
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TRAZODONE HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	RIVOPHARM SA, MANNO, SWITZERLAND
Packer:	RIVOPHARM SA, MANNO, SWITZERLAND
Laboratory: FPRC:	RIVOPHARM SA, MANNO, SWITZERLAND INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMCAY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	43/20.1.1/0238
Name of medicine:	SANDOZ LEVOFLOXACIN 500 mg/100 ml
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA
Packer:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA 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
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	43/20.1.1/0233
Name of medicine:	SANDOZ LEVOFLOXACIN 250 mg/50 ml
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA
Packer:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA 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
Date of registration:	10 APRIL 2014

MRF15

Registration number:	43/20.1.1/0232
Name of medicine:	LEVONIC 500 mg/100 ml
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA
Packer:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA 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
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	43/20.1.1/0231
Name of medicine:	LEVONIC 250 mg/500 ml
Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA
Packer:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA 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
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	36/28/0137
Name of medicine:	ULTRAVIST 240 10 ml
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: IOPROMIDE EQUIVALENT TO IODINE 240,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER SCHERING PHARMA AG, BERLIN, GERMANY
Packer:	BAYER SCHERING PHARMA AG, BERLIN, GERMANY
Laboratory: FPRC:	BAYER SCHERING PHARMA AG, BERLIN, GERMANY
FPRR:	BAYER (PTY) LTD, ISANDO, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	A40/32.5/0648
Name of medicine:	HYLO-MAX EYE DROPS SOLUTION
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: SODIUM HYALURONATE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAFRICA (PTY) LTD
Manufacturer:	URSAPHARM ARZNEIMITTEL GmbH & Co. KG, SARBRUCKEN, GERMANY
Packer:	URSAPHARM ARZNEIMITTEL GmbH & Co. KG, SARBRUCKEN, GERMANY
Laboratory: FPRC:	URSAPHARM ARZNEIMITTEL GmbH & Co. KG, SARBRUCKEN, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAFRICA (PTY) LTD, NEW CENTRE, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	46/20.2.8/0038
Name of medicine:	ALVIR 50 mg/5 ml
Dosage form:	ORAL SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: NEVIRAPINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO
Laboratory: FPRC:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO BOEHRINGER INGELHEIM ROXANE INC, OAK STREET, COLUMBUS, OHIO RESEARCH INSTITUTE FOR INDUSTRIAL PHARMCAY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	46/20.2.8/0037
Name of medicine:	ALVIR 200 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM ELLAS A.E., KOROPI, GREECE BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGEHLHEIM/RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM ELLAS A.E., KOROPI, GREECE BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGEHLHEIM/RHEIN, GERMANY
Laboratory: FPRC:	BOEHRINGER INGELHEIM ELLAS A.E., KOROPI, GREECE BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGEHLHEIM/RHEIN, GERMANY RESEARCH INSTITUTE FOR INDUSTRIAL PHARMCAY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	48 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	45/5.2/0791
Name of medicine:	BISBETA 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

Registration number:	45/5.2/0790
Name of medicine:	BISBETA 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	45/5.2/0789
Name of medicine:	BISBETA 2,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF15

Registration number:	45/20.2.3/0518
Name of medicine:	DYNA ETHAMBUTOL 400 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ETHAMBUTOL HYDROCHLORIDE 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LIMITED, CHIKALTHANA, AURANGABAD, INDIA
Packer:	LUPIN LIMITED, CHIKALTHANA, AURANGABAD, INDIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA
Laboratory: FPRC:	LUPIN LIMITED, CHIKALTHANA, AURANGABAD, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	48 months)
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	44/8.2/1041
Name of medicine:	BRILINTA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TICAGRELOR 90,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA AB, SODERTALJE, SWEDEN
Packer:	ASTRAZENECA AB, SODERTALJE, SWEDEN ASTRAZENECA UK LIMITED, MACCLESFIELD, CHESHIRE, UNITED KINGDOM AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA
Laboratory: FPRC	ASTRAZENECA AB, SODERTALJE, SWEDEN ASTRAZENECA UK LIMITED, MACCLESFIELD, CHESHIRE, UNITED KINGDOM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	43/20.2.8/0355
Name of medicine:	CIPLA EMTRICITABINE
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EMTRICITABINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	43/20.2.8/0353
Name of medicine:	MEDPRO EMTRICITABINE 200 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EMTRICITABINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	43/20.2.8/0226
Name of medicine:	APTIVUS 250 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TIPRANAVIR 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	CATALENT PHARMA SOLUTIONS, ST PETERSBURG, FLORIDA, USA
Packer:	BOEHRINGER INGELHEIM ROXANE Inc, WILSON ROAD, COLUMBUS, OHIO, USA
Laboratory: FPRC	CATALENT PHARMA SOLUTIONS, ST PETERSBURG, FLORIDA, USA CATALENT PHARMA SOLUTIONS, MORRISVILLE, NORTH CAROLINA, USA BOEHRINGER INGELHEIM ROXANE Inc, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE Inc, OAK STREET, COLUMBUS, OHIO, USA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

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Registration number:	41/7.5/0617
Name of medicine:	BIOVAC SIMVASTATIN 80 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARRROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW MANUFACTURING Inc, MISSISSAUGA, ONTARIO, CANADA
Packer:	ARROW MANUFACTURING Inc, MISSISSAUGA, ONTARIO, CANADA CONTRACT PHARMACEUTICALS LTD, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LIMITED, BURNLEY, UNITED KINGDOM
Laboratory: FPRC:	ARROW MANUFACTURING Inc, MISSISSAUGA, ONTARIO, CANADA QUALITY (BURNLEY) LIMITED, BURNLEY, UNITED KINGDOM RESEARCH INSITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	36 months)
Date of registration:	10 APRIL 2014

Registration number:	34/2.7/0290
Name of medicine:	IBUPROFEN RECKITT 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN LYSINE EQUIVALENT TO IBUPROFEN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RECKITT BENCKISER HEALTHCARE (SA) (PTY) LTD
Manufacturer:	RECKITT BENCKISER HEALTHCARE (PTY) LTD, INTERNATIONAL, NOTTINGHAM, ENGLAND
Packer:	RECKITT BENCKISER HEALTHCARE (PTY) LTD, INTERNATIONAL, NOTTINGHAM, ENGLAND
Laboratory: FPRC:	RECKITT BENCKISER HEALTHCARE (PTY) LTD, INTERNATIONAL, NOTTINGHAM, ENGLAND
FPRR:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

Registration number:	A04/2.9/12
Name of medicine:	SEDAXYLAN
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: XYLAZINE HYDROCHLORIDE EQUIVALENT TO XYLAZINE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	VIRBAC RSA (PTY) LTD
Manufacturer:	EUROVET ANIMAL HEALTH B.V., BLADEL, THE NETHERLANDS
Packer:	EUROVET ANIMAL HEALTH B.V., BLADEL, THE NETHERLANDS
Laboratory: FPRC	EUROVET ANIMAL HEALTH B.V., BLADEL, THE NETHERLANDS M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	VIRBAC RSA (PTY) LTD, CENTURION, RSA
Shelf-life:	36 months 28 days (in-use)
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	45/11.4.3/0777
Name of medicine:	TRUSTAN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESOMEPRAZOLE MAGNESIUM TRIHYDRATE EQUIVALENT TO ESOMEPRAZOLE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA AB, SODERTALJE, SWEDEN
Packer:	ASTRAZENECA AB, SODERTALJE, SWEDEN ASTRAZENECA UK LIMITED, MACCLESFIELD, CHESHIRE, UNITED KINGDOM
Laboratory: FPRC:	ASTRAZENECA AB, SODERTALJE, SWEDEN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	45/7.1.3/0626
Name of medicine:	ARROW IRBESARTAN 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	ARROW PHARMA S.A.(PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	45/7.1.3/0625
Name of medicine:	ARROW IRBESARTAN 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG
Laboratory: FPRC	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR::	ARROW PHARMA S.A.(PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	45/7.1.3/0624
Name of medicine:	ARROW IRBESARTAN 75
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR::	ARROW PHARMA S.A.(PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF15

Registration number:	45/7.1.3/0623
Name of medicine:	AROTAN 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRC/FPRR:	ARROW PHARMA S.A.(PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	45/7.1.3/0622
Name of medicine:	AROTAN 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG
Laboratory: FPRC	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	ARROW PHARMA S.A.(PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	45/7.1.3/0621
Name of medicine:	AROTAN 75
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRR:	ARROW PHARMA S.A.(PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF15

Registration number:	44/20.2.8/0016
Name of medicine:	VORIOR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BLISS PHARMACEUTICALS cc
Manufacturer:	HETERO DRUGS LIMITED, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETERO DRUGS LIMITED, JEEDIMETLA, HYDERABAD, INDIA
Laboratory: FPRC:	HETERO DRUGS LIMITED, JEEDIMETLA, HYDERABAD, INDIA
FPRR:	BLISS PHARMACEUTICALS xx, ORMONDE, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	44/20.2.8/0015
Name of medicine:	HEVITREX
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BLISS PHARMACEUTICALS cc
Manufacturer:	HETERO DRUGS LIMITED, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETERO DRUGS LIMITED, JEEDIMETLA, HYDERABAD, INDIA
Laboratory: FPRC	HETERO DRUGS LIMITED, JEEDIMETLA, HYDERABAD, INDIA
FPRR:	BLISS PHARMACEUTICALS xx, ORMONDE, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	43/7.1.3/0445
Name of medicine:	QUINAPRIL ZYDUS 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MRF15

Registration number:	43/7.1.3/0444
Name of medicine:	QUINAPRIL ZYDUS 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

MMRF 15

Registration number:	43/7.1.3/0443
Name of medicine:	QUINAPRIL ZYDUS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	10 APRIL 2014

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MRF 15

Registration number:	43/3.2/0132
Name of medicine:	RISEDRONATE WINTHROP MONTHLY
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISEDRONATE SODIUM EQUIVALENT TO RISEDRONIC ACID 150.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	NORWICH PHARMACEUTICAL INC, NEW YORK, USA PROCTER & GAMBLE PHARMACEUTICALS, PUERTO RICO L.L.C. MANATI, PUERTO RICO
Packer:	PROCTER & GAMBLE PHARMACEUTICALS, GERMANY GmbH, WEITERSTADT, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	PROCTER & GAMBLE PHARMACEUTICALS, GERMANY GmbH, WEITERSTADT, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF15

Registration number:	43/3.2/0131
Name of medicine:	ACTONEL ONCE-A-MONTH
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISEDRONATE SODIUM EQUIVALENT TO RISEDRONIC ACID 150.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NORWICH PHARMACEUTICAL INC, NEW YORK, USA PROCTER & GAMBLE PHARMACEUTICALS, PUERTO RICO L.L.C. MANATI, PUERTO RICO
Packer:	PROCTER & GAMBLE PHARMACEUTICALS, GERMANY GmbH, WEITERSTADT, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	PROCTER & GAMBLE PHARMACEUTICALS, GERMANY GmbH, WEITERSTADT, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF 15

Registration number:	42/7.1.3/0094
Name of medicine:	LOZAAN 12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	SPECIAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIAR S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC	SPECIAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

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MRF 15	
Registration number:	42/7.1.3/0095
Name of medicine:	LOZAAN 25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	SPECIAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIAR S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC:	SPECIAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MRF15	
Registration number:	42/7.1.3/0096
Name of medicine:	LOZAAN 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	SPECIAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIAR S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC:	SPECIAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

MMRF 15	
Registration number:	42/7.1.3/0097
Name of medicine:	LOZAAN 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	SPECIAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIAR S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC	SPECIAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 APRIL 2014

NOTICE – CHANGE OF TELEPHONE NUMBERS: GOVERNMENT PRINTING WORKS

As the mandated government security printer, providing world class security products and services, Government Printing Works has adopted some of the highly innovative technologies to best serve its customers and stakeholders. In line with this task, Government Printing Works has implemented a new telephony system to ensure most effective communication and accessibility. As a result of this development, our telephone numbers will change with effect from 3 February 2014, starting with the Pretoria offices.

The new numbers are as follows:

- Switchboard : 012 748 6001/6002
- Advertising : 012 748 6205/6206/6207/6208/6209/6210/6211/6212
- Publications Enquiries : 012 748 6052/6053/6058 GeneralEnquiries@gpw.gov.za

  Maps : 012 748 6061/6065 BookShop@gpw.gov.za

  Debtors : 012 748 6060/6056/6064 PublicationsDebtors@gpw.gov.za

  Subscription : 012 748 6054/6055/6057 Subscriptions@gpw.gov.za
- SCM : 012 748 6380/6373/6218
- Debtors : 012 748 6236/6242
- Creditors : 012 748 6246/6274

Please consult our website at www.gpwonline.co.za for more contact details.

The numbers for our provincial offices in Polokwane, East London and Mmabatho will not change at this stage.

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Subscriptions: Tel: (012) 748 6054, 748 6055, 748 6057
Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
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