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GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 455 OF 2012

MEDICINES CONTROL COUNCIL

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

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

KENNISGEWING 455 VAN 2012

MEDISYNEBEHEERRAAD

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

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goekgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleeftyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleeftydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemarking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:	03/21.1/8
Name of medicine:	QUINABIC 15 %
Dosage form:	ORAL SOLUTION
Active ingredients:	EACH 1,0 ml CONTAINS: NORFLOXACIN NICOTINATE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:	PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL
Packer:	PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL
Laboratory: FPRC:	TEVA PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT (PTY) LTD, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TEVA PHARMACEUTICALS (PTY) LTD, RUIMSIG, ROODEPOORT, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	07/3.1.1/18
Name of medicine:	ONSIOR 5 mg TABLETS FOR DOGS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROBENACOXIB 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTS SA (PTY) LTD
Manufacturer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Packer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Laboratory: FPRC:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	07/3.1.1/19
Name of medicine:	ONSIOR 10 mg TABLETS FOR DOGS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROBENACOXIB 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Packer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Laboratory: FPRC:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	07/3.1.1/20
Name of medicine:	ONSIOR 20 mg TABLETS FOR DOGS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROBENACOXIB 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Packer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Laboratory: FPRC:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	07/3.1.1/21
Name of medicine:	ONSIOR 40 mg TABLETS FOR DOGS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROBENACOXIB 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Packer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Laboratory: FPRC:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	07/3.1.1/22
Name of medicine:	ONSIOR 6 mg TABLETS FOR CATS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROBENACOXIB 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Packer:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
Laboratory: FPRC:	NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	36/20.1.2/0399
Name of medicine:	NORBROOK PENICILLIN G FOR INJECTION
Dosage form:	STERILE POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: BENZYLPENICILLIN 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NORBROOK LABORATORIES SA (PTY) LTD
Manufacturer:	NORBROOK LABORATORIES LIMITED, STATION WORKS, NEWRY, NORTHERN IRELAND
Packer:	NORBROOK LABORATORIES LIMITED, STATION WORKS, NEWRY, NORTHERN IRELAND
Laboratory: FPRC:	NORBROOK LABORATORIES LIMITED, STATION WORKS, NEWRY, NORTHERN IRELAND
FPRR:	NORBROOK LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	37/20.1.2/0223
Name of medicine:	NORBROOK AMPICILLIN FOR INJECTION
Dosage form:	STERILE 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:	NORBROOK LABORATORIES SA (PTY) LTD
Manufacturer:	NORBROOK LABORATORIES LIMITED, STATION WORKS, NEWRY, NORTHERN IRELAND
Packer:	NORBROOK LABORATORIES LIMITED, STATION WORKS, NEWRY, NORTHERN IRELAND
Laboratory: FPRC:	NORBROOK LABORATORIES LIMITED, STATION WORKS, NEWRY, NORTHERN IRELAND
FPRR:	NORBROOK LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	A39/5.7.1/0220
Name of medicine:	HISTADEX
Dosage form:	DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DEXCHLORPHENIRAMINE MALEATE 0,4 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Laboratory: FPRC:	PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
FPRR:	EQUITY PHARMACEUTICALS, IRENE, CENTURION
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	A40/16.5/0065
Name of medicine:	CEPACOL ANTI-INFLAMMATORY THROAT SPRAY
Dosage form:	SPRAY
Active ingredients:	EACH 15,0 ml CONTAINS: BENZYDAMINE HCl 22,5 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	A40/4/0182
Name of medicine:	MACAINE VIAFLEX 0,1 %
Dosage form:	INFUSION SOLUTION
Active ingredients:	EACH 1000,0 ml CONTAINS: BUPIVACAINE HCl 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Packer:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Laboratory: FPRC:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	A40/10.2.2/0243
Name of medicine:	LIPOSURF
Dosage form:	SUSPENSION
Active ingredients:	EACH 1,0 ml CONTAINS: PHOSPHOLIPIDS 27,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	BLES BIOCHEMICALS INC., LONDON, ONTARIO, CANADA
Packer:	BLES BIOCHEMICALS INC., LONDON, ONTARIO, CANADA
Laboratory: FPRC:	BLES BIOCHEMICALS INC., LONDON, ONTARIO, CANADA SGS LABORATORIES, MISSISSAUGA, ONTARIO, CANADA NUCRO-TECHNICS, SCARBOROUGH, ONTARIO, CANADA
FPRR	CIPLA MEDPRO (PTY) LTD, ROSEN PARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	41/26/0156
Name of medicine:	KEMOPLAT 10
Dosage form:	INJECTION
Active ingredients:	EACH 20,0 ml VIAL CONTAINS: CISPLATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC :	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF15 F 15

Registration number:	41/26/0157
Name of medicine:	KEMOPLAT 50
Dosage form:	INJECTION
Active ingredients:	EACH 50,0 ml VIAL CONTAINS: CISPLATIN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR	CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

Registration number:	41/2.6.5/0951
Name of medicine:	MYLAN QUETIAPINE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Packer:	GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARDLABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Laboratory: FPRC	GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARDLABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING(PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:		41/2.6.5/0952
Name of medicine:		MYLAN QUETIAPINE 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Packer:		GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARDLABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Laboratory:	FPRC:	GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
	FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		25 NOVEMBER 2011

MRF15

Registration number:		41/2.6.5/0953
Name of medicine:		MYLAN QUETIAPINE 150
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 150,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Packer:		GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Laboratory: FPRC:		GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:		XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		25 NOVEMBER 2011

MRF 15

Registration number:		41/2.6.5/0954
Name of medicine:		MYLAN QUETIAPINE 200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Packer:		GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Laboratory::FPRC		GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR		XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		25 NOVEMBER 2011

MRF 15

Registration number:	41/2.6.5/0955
Name of medicine:	MYLAN QUETIAPINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Packer:	GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN
Laboratory: FPRC:	GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, ETOBICOKE, ONTARIO CANADA MERCK FARMA y QUIMICA S.A., BARCELONA, SPAIN RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF15 F 15

Registration number:	41/5.3/0989
Name of medicine:	ASPEN GALANTAMINE 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA
Packer:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, MIDRAND, GAUTENG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

Registration number:	42/26/0044
Name of medicine:	ASPEN DACARBAZINE
Dosage form:	INJECTION
Active ingredients:	EACH 20,0 ml VIAL CONTAINS: DACARBAZINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	42/21.2/0249
Name of medicine:	DYNA GLICLAZIDE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	KRKA, D.D., NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA HERSOL MANUFACTURING LABORATORIES (PTY) LTD, JEPPESTOWN, JOHANNESBURG, RSA
Packer:	KRKA, D.D., NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA HERSOL MANUFACTURING LABORATORIES (PTY) LTD, JEPPESTOWN, JOHANNESBURG, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA
Laboratory: FPRC:	KRKA, D.D., NOVO MESTO, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA HERSOL MANUFACTURING LABORATORIES (PTY) LTD, JEPPESTOWN, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	42/21.5.1/0309
Name of medicine:	MYLAN-METHYLPREDNISOLONE 40
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: Methylprednisolone hemisuccinate equivalent to Methylprednisolone 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA – PLANT C, PALLINI-ATTICA, GREECE
Packer:	BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA – PLANT C, PALLINI-ATTICA, GREECE PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA- PLANT C, PALLINI-ATTICA, GREECE
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

F 15

Registration number:	42/3.1/0321
Name of medicine:	GLENMARK MELOXICAM TABLETS 7,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA GLENMARK PHARMACEUTICAL SA (PTY) LTD, VORNA VALLEY, MIDRAND, RSA
FPRR:	GLENMARK PHARMACEUTICAL SA (PTY) LTD, VORNA VALLEY, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	42/3.1/0322
Name of medicine:	GLENMARK MELOXICAM TABLETS 15 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Laboratory: FPRC	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA GLENMARK PHARMACEUTICAL SA (PTY) LTD, VORNA VALLEY, MIDRAND, RSA
FPRR:	GLENMARK PHARMACEUTICAL SA (PTY) LTD, VORNA VALLEY, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	42/20.2.8/0661
Name of medicine:	NEVIR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DEZZO TRADING 392 (PTY) LIMITED, T/A INDO PHARMA
Manufacturer:	EMCURE PHARMACEUTICALS LIMITED, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LIMITED, PUNE, INDIA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS LIMITED, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING 392 (PTY) LIMITED, T/A INDO PHARMA, LENASIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	42/18.10/0722
Name of medicine:	ZYDUS TAMSULOSIN SR
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TAMSULOSIN HCl 0,4 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	42/7.1.3/0766
Name of medicine:	CO MICARDIS 80/25 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 80,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co.KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co.KG, INGELHEIM am RHEIN, GERMANY
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & Co.KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY A & M STABTEST, MAINZ, GERMANY SGS INSTITUT FRESENIUS GmbH, TAUNUSSTEIN, GERMANY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, RANDBURG, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	42/7.1/0790
Name of medicine:	DYNA INDAPAMIDE SR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: INDAPAMIDE 1,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	KRKA, d.d. NOVO MESTO, NOVO MESTO, SLOVENIA
Packer:	KRKA, d.d. NOVO MESTO, NOVO MESTO, SLOVENIA
Laboratory: FPRC:	KRKA, d.d. NOVO MESTO, NOVO MESTO, CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	42/15.4/0835
Name of medicine:	ALLERGAN BIMATOPROST 0,01 %
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: BIMATOPROST 0,1 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALLERGAN, INC., WACO, TEXAS, USA
Packer:	ALLERGAN, INC., WACO, TEXAS, USA
Laboratory: FPRC:	ALLERGAN, INC., WACO, TEXAS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ALLERGAN PHARMACEUTICALS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	42/1.2/1009
Name of medicine:	BIO CITALOPRAM 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, MIDRAND, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	42/1.2/1010
Name of medicine:	BIO CITALOPRAM 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 20,0 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, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, MIDRAND, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	42/1.2/1067
Name of medicine:	BIO CITALOPRAM 30
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 30,0 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, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, MIDRAND, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	42/7.5/1092
Name of medicine:	TREDAPTIVE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NIACIN 1 000,0 mg LAROPIPRANT 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME TECNOLOGY LTD, SINGAPORE PATHEON PHARMACEUTICALS INC., CINCINNATI, OHIO, USA
Packer:	MERCK SHARP & DOHME BV, HAARLEM, NETHERLANDS MSD FROSST IBERICA S.A, MADRID, SPAIN MERCK SHARP & DOHME LTD, CRAMLINGTON, NORTHUMBERLAND, ENGLAND MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	MERCK SHARP & DOHME TECNOLOGY LTD, SINGAPORE MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/2.6.5/0159
Name of medicine:	TRUVALIN 25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK BRECON PHARMACEUTICALS LTD, FOREST ROAD, HAY-ON-WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BRECON ROAD, HAY-ON-WYE, HEREFORD, UK
Laboratory: FPRC:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

Registration number:	43/2.6.5/0160
Name of medicine:	TRUVALIN 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK BRECON PHARMACEUTICALS LTD, FOREST ROAD, HAY-ON-WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BRECON ROAD, HAY-ON-WYE, HEREFORD, UK
Laboratory: FPRC:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/2.6.5/0161
Name of medicine:	TRUVALIN 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK BRECON PHARMACEUTICALS LTD, FOREST ROAD, HAY-ON-WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BRECON ROAD, HAY-ON-WYE, HEREFORD, UK
Laboratory: FPRC:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	43/2.6.5/0162
Name of medicine:	TRUVALIN 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA
Packer:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK BRECON PHARMACEUTICALS LTD, FOREST ROAD, HAY-ON-WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BRECON ROAD, HAY-ON-WYE, HEREFORD, UK
Laboratory: FPRC:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/2.5/0288
Name of medicine:	BINRONTIN 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 LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/2.5/0289
Name of medicine:	BINRONTIN 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 LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	43/26/0348
Name of medicine:	MYLAN IRINOTECAN 100 mg/5 ml
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: Irinotecan Hydrochloride Trihydrate equivalent to Irinotecan 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GP PHARM, S.A., SANT QUINTI DE MEDIONA, BARCELONA, SPAIN
Packer:	GP PHARM, S.A., SANT QUINTI DE MEDIONA, BARCELONA, SPAIN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, INDUSTRIA JOHANNESBURG, RSA
Laboratory: FPRC:	GP PHARM, S.A., SANT QUINTI DE MEDIONA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:	36 months if manufactured by GP Pharm Spain with API manufactured by Fermion Oy Oulu Plant Finland 6 hours stored at 25 ^{0}C 24 hours stored at 2-8 ^{0}C
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/26/0349
Name of medicine:	MYLAN IRINOTECAN 40 mg/2 ml
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: Irinotecan Hydrochloride Trihydrate equivalent to Irinotecan 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GP PHARM, S.A., SANT QUINTI DE MEDIONA, BARCELONA, SPAIN
Packer:	GP PHARM, S.A., SANT QUINTI DE MEDIONA, BARCELONA, SPAIN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, INDUSTRIA JOHANNESBURG, RSA
Laboratory: FPRC	GP PHARM, S.A., SANT QUINTI DE MEDIONA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:	36 months if manufactured by GP Pharm Spain with API manufactured by Fermion Oy Oulu Plant Finland 6 hours stored at 25 ^{0}C 24 hours stored at 2-8 ^{0}C
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/2.5/0452
Name of medicine:	BINRONTIN 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 LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	43/21.2/0608
Name of medicine:	ONGLYZA 2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SAXAGLIPTIN 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB COMPANY, MOUNT VERNON, INDIANA, USA
Packer:	BRISTOL-MYERS SQUIBB S.r.l., ANAGNI, ITALY
Laboratory: FPRC:	BRISTOL-MYERS SQUIBB COMPANY, MOUNT VERNON, INDIANA, USA BRISTOL-MYERS SQUIBB S.r.l., ANAGNI, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	BRISTOL-MYERS SQUIBB (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/21.2/0609
Name of medicine:	ONGLYZA 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SAXAGLIPTIN 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB COMPANY, MOUNT VERNON, INDIANA, USA
Packer:	BRISTOL-MYERS SQUIBB S.r.l., ANAGNI, ITALY
Laboratory: FPRC	BRISTOL-MYERS SQUIBB COMPANY, MOUNT VERNON, INDIANA, USA BRISTOL-MYERS SQUIBB S.r.l., ANAGNI, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	BRISTOL-MYERS SQUIBB (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/20.1.1/0656
Name of medicine:	ARROW NORFLOXACIN 400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NORFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA, (PTY) LTD WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	43/20.1.1/0657
Name of medicine:	UTIFLOXA 400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NORFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA, (PTY) LTD WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/31/0745
Name of medicine:	MYOZYME
Dosage form:	LYOPHILIZED POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: RECOMBINANT HUMAN ACID ALPHA-GLUCOSIDASE (rhGAA) 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENZYME BIOPHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA IDA INDUSTRIAL PARK, WATERFORD, IRELAND
Packer:	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA IDA INDUSTRIAL PARK, WATERFORD, IRELAND
Laboratory: FPRC	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA IDA INDUSTRIAL PARK, WATERFORD, IRELAND GENZYME CORPORATION, 45 & 76 NEW YORK AVENUE, FRAMINGHAM, MASSACHUSETTS, USA INTERNATIONAL LABORATORY SERVICES, SHARDLOW, DERBYSHIRE, UNITED KINGDOM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	GENZYME BIOPHARMACEUTICALS SA (PTY) LTD, BRYANSTON, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/21.12/0764
Name of medicine:	TEVA BICALUTAMIDE 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL
Packer:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL TEVA PHARMACEUTICAL WORKS Plc., TANCSICS MIHALY, HUNGARY
Laboratory: FPRC:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SIVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	TEVA PHARMACEUTICALS (PTY) LTD, ROODEPORT, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	43/21.12/0765
Name of medicine:	TEVA 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:	TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL
Packer:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL TEVA PHARMACEUTICAL WORKS Plc., TANCSICS MIHALY, HUNGARY
Laboratory: FPRC:	TEVA PHARMACEUTICAL INDUSTRIES LTD, KFAR SAVA, ISRAEL CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SIVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	TEVA PHARMACEUTICALS (PTY) LTD, ROODEPORT, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

RF 15

Registration number:	43/21.13/0781
Name of medicine:	VICTOZA
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml CONTAINS: LIRAGLUTIDE 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVO NORDISK (PTY) LTD
Manufacturer:	NOVO NORDISK A/S, BAGSVAERD, DENMARK
Packer:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK PHARMACEUTICAL INDUSTRY, INC., CLAYTON, NORTH CAROLINA, USA
Laboratory: FPRC	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, FREDERIKSBERG, DENMARK NOVO NORDISK A/S, HILLEROED, DENMARK
FPRR:	NOVO NORDISK (PTY) LTD, SANDTON, JOHANNESBURG, RSA
Shelf-life:	30 months (2 – 8 °C)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/18.8/0782
Name of medicine:	JARINA
Dosage form:	TABLET
Active ingredients:	EACH TABLET (21) CONTAINS: DROSPIRENONE 3,0 mg ETHINYLESTRADIOL 0,03 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 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA BIOCHEMICAL AND SCIENTIFIC CONSULTANTS Cc, HILTON, KWA-ZULU NATAL, RSA
FPRR:	BAYER (PTY) LTD, ISANDO, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	43/11.4.3/0843
Name of medicine:	MYLAN PANTOPRAZOLE 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pantoprazole sodium sesquihydrate equivalent to Pantoprazole20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIOS DR ESTEVE S.A, BARCELONA, SPAIN PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
Packer:	LABORATORIOS DR ESTEVE S.A, BARCELONA, SPAIN PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA MC DERMOTT LABORATORIES LTD (T/A GERARD LABORATORIES), DUBLIN, IRELAND
Laboratory: FPRC:	LABORATORIOS DR ESTEVE S.A, BARCELONA, SPAIN PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA MC DERMOTT LABORATORIES LTD (T/A GERARD LABORATORIES), DUBLIN, IRELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

RF 15

Registration number:	43/11.4.3/0844
Name of medicine:	MYLAN PANTOPRAZOLE 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pantoprazole sodium sesquihydrate equivalent to Pantoprazole 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIOS DR ESTEVE S.A, BARCELONA, SPAIN PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
Packer:	LABORATORIOS DR ESTEVE S.A, BARCELONA, SPAIN PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA MC DERMOTT LABORATORIES LTD (T/A GERARD LABORATORIES), DUBLIN, IRELAND
Laboratory: FPRC	LABORATORIOS DR ESTEVE S.A, BARCELONA, SPAIN PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA MC DERMOTT LABORATORIES LTD (T/A GERARD LABORATORIES), DUBLIN, IRELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/7.1.5/0886
Name of medicine:	AVIGRA 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:	PHARMACIA SOUTH AFRICA (PTY) LTD
Manufacturer:	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA
Packer:	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA
Laboratory: FPRC:	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA PFIZER GLOBAL MANUFACTURING (Division of Pfizer Laboratories) (PTY0 LTD, RETREAT, CAPE TOWN, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA LAB & BIOLOGICAL SERVICES (PTY) LTD, BRACKENHURST, ALBERTON, RSA
FPRR:	PHARMACIA SOUTH AFRICA (PTY) LTD, SANDTON, GAUTENG, RSA
Shelf-life:	60 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	43/7.1.5/0887
Name of medicine:	AVIGRA 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:	PHARMACIA SOUTH AFRICA (PTY) LTD
Manufacturer:	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA
Packer:	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA
Laboratory: FPRC:	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA PFIZER GLOBAL MANUFACTURING (Division of Pfizer Laboratories) (PTY0 LTD, RETREAT, CAPE TOWN, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG,RSA LAB & BIOLOGICAL SERVICES (PTY) LTD, BRACKENHURST, ALBERTON, RSA
FPRR:	PHARMACIA SOUTH AFRICA (PTY) LTD, SANDTON, GAUTENG, RSA
Shelf-life:	60 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/7.1.5/0888
Name of medicine:	AVIGRA 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:	PHARMACIA SOUTH AFRICA (PTY) LTD
Manufacturer:	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA
Packer:	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA
Laboratory: FPRC	PFIZER PGM AMBOISE, POCE sur CISSE, FRANCE PFIZER MANUFACTURING DEUTSCHLAND GmbH, ILLERTISSEN, GERMANY PFIZER PGM DALIAN, DETDZ, DALIAN, CHINA PFIZER GLOBAL MANUFACTURING (Division of Pfizer Laboratories) (PTY0 LTD, RETREAT, CAPE TOWN, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (TY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA LAB & BIOLOGICAL SERVICES (PTY) LTD, BRACKENHURST, ALBERTON, RSA
FPRR:	PHARMACIA SOUTH AFRICA (PTY) LTD, SANDTON, GAUTENG, RSA
Shelf-life:	60 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/8.3/0941
Name of medicine:	MIRCERA 30 µg/0,3 ml
Dosage form:	INJECTION
Active ingredients:	EACH SYRINGE CONTAINS: METHOXY POLYETHYTHYLENE GLYCOL EPOETIN BETA 30,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
Packer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY VETTER PHARM-FERTIGUNG GmbH & Co. KG, RAVENSBURG, GERMANY AKACIA HEALTH CARE, ISANDO GAUTENG, RSA
Laboratory: FPRC:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY AKACIA HEALTH CARE, ISANDO GAUTENG, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	43/8.3/0942
Name of medicine:	MIRCERA 120 µg/0,3 ml
Dosage form:	INJECTION
Active ingredients:	EACH SYRINGE CONTAINS: METHOXY POLYETHYTHYLENE GLYCOL EPOETIN BETA IN 120,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
Packer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY VETTER PHARM-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY AKACIA HEALTH CARE, ISANDO GAUTENG, RSA
Laboratory: FPRC:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY AKACIA HEALTH CARE, ISANDO GAUTENG, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	43/8.3/0943
Name of medicine:	MIRCERA 360 µg/0,6 ml
Dosage form:	INJECTION
Active ingredients:	EACH SYRINGE CONTAINS: METHOXY POLYETHYTHYLENE GLYCOL EPOETIN BETA IN 360,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY
Packer:	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY VETTER PHARM-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY AKACIA HEALTH CARE, ISANDO GAUTENG, RSA
Laboratory: FPRC	ROCHE DIAGNOSTICS, MANNHEIM, GERMANY AKACIA HEALTH CARE, ISANDO GAUTENG, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	44/20.2.8/0385
Name of medicine:	ASPEN EFAVIRENZ 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7 *
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA ASPEN PORT ELIZABETH, GIBAUD ROAD, KORSTEN, PORT ELIZABETH
Packer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA ASPEN PORT ELIZABETH, GIBAUD ROAD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRC/FPRR:	ASPEN PORT ELIZABETH, GIBAUD ROAD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

*SEE AT END OF BOOK FOR ADDITIONAL CONDITIONS

MRF15

Registration number:	44/32.2/0393
Name of medicine:	SOLVENT FOR CIPLA DOCETAXEL 20
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ETHANOL 13,0 % *m/v*
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA
Shelf-life:	24 months (2- 8 °C)
Date of registration:	25 NOVEMBER 2011

RF 15

Registration number:	44/32.2/0394
Name of medicine:	SOLVENT FOR CIPLA DOCETAXEL 80
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ETHANOL 13,0 % *m/v*
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA
Shelf-life:	24 months (2 – 8 °C)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	44/7.1.3/0504
Name of medicine:	ZYDUS PERINDOPRIL 4 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ERBUMINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	44/20.2.8/0919
Name of medicine:	BACATAC
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Abacavir sulfate equivalent to Abacavir 300,0 mg Lamivudine 150,0 mg Zidovudine 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	MATRIX LABORATORIES LIMITED, VZIANAGARAM DISTRICT, ANDHRA PRADESH, INDIA
Packer:	MATRIX LABORATORIES LIMITED, VZIANAGARAM DISTRICT, ANDHRA PRADESH, INDIA ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, VZIANAGARAM DISTRICT, ANDHRA PRADESH, INDIA ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	44/20.2.8/0980
Name of medicine:	TRIBUSS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Tenofovir disoproxil fumarate 300,0 mg Efavirenz 600,0 mg Emtricitabine 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA STATE, INDIA ASPEN PORT ELIZABETH, CNR FAIRCLOUGH AND GIVAUD ROADS, KORSTEN, PORT ELIZABETH, RSA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA STATE, INDIA ASPEN PORT ELIZABETH, CNR FAIRCLOUGH AND GIVAUD ROADS, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRC/FPRR:	ASPEN PORT ELIZABETH, CNR FAIRCLOUGH AND GIVAUD ROADS,KORSTEN, PORT ELIZABETH, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	44/10.2.2/0847
Name of medicine:	KULAIR 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND
Packer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND CONFARMA FRANCE S.A.R.L., HOMBOURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF15

Registration number:	44/10.2.2/0848
Name of medicine:	KULAIR 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND
Packer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND CONFARMA FRANCE S.A.R.L., HOMBOURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

RF 15

Registration number:	44/10.2.2/0849
Name of medicine:	KULAIR 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND
Packer:	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC	SIEGFRIED LTD, ZOFINGEN, SWITZERLAND CONFARMA FRANCE S.A.R.L., HOMBOURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011

MRF 15

Registration number:	07/21.9/02
Name of medicine:	DANOVET 2,5 %
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DANOFLOXACIN MESYLATE EQUIVALENT TO DANOFLOXACIN 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, HOSUR, TAMIL NADU, INDIA
Packer:	CIPLA LTD, HOSUR, TAMIL NADU, INDIA
Laboratory: FPRC:	CIPLA LTD, HOSUR, TAMIL NADU, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELVILLE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	09/11.2/03
Name of medicine:	CERENIA 16 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MAROPITANT CITRATE EQUIVALENT TO MAROPITANT 16,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE PFIZER GLOBAL MANUFACTURING, LINCOLN, NEBRASKA, USA
Packer:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE
Laboratory: FPRC:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	09/11.2/04
Name of medicine:	CERENIA 24 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MAROPITANT CITRATE EQUIVALENT TO MAROPITANT 24,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE PFIZER GLOBAL MANUFACTURING, LINCOLN, NEBRASKA, USA
Packer:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE
Laboratory: FPRC:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	2 March 2012

MRF 15

Registration number:	09/11.2/05
Name of medicine:	CERENIA 60 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MAROPITANT CITRATE EQUIVALENT TO MAROPITANT 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE PFIZER GLOBAL MANUFACTURING, LINCOLN, NEBRASKA, USA
Packer:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE
Laboratory: FPRC:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF15

Registration number:	09/11.2/06
Name of medicine:	CERENIA 160 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MAROPITANT CITRATE EQUIVALENT TO MAROPITANT 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE PFIZER GLOBAL MANUFACTURING, LINCOLN, NEBRASKA, USA
Packer:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE
Laboratory: FPRC:	PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	31/35/0528
Name of medicine:	RENATEK
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CALCIUM TRISODIUM PENTETATE 5,0 mg TIN DICHLORIDE-2 HYDRATE 0,27 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NTP RADIOISOTOPES (PTY) LTD
Manufacturer:	NTP RADIOISOTOPES (PTY) LTD, PELINDABA, PRETORIA, RSA
Packer:	NTP RADIOISOTOPES (PTY) LTD, PELINDABA, PRETORIA, RSA
Laboratory: FPRC:	NTP RADIOISOTOPES (PTY) LTD, PELINDABA, PRETORIA, RSA BIOMEDICAL RESEARCH CENTRE, UNIVERSITY OF PRETORIA, ONDERSTEPOORT, PRETORIA, RSA
FPRR:	NTP RADIOISOTOPES (PTY) LTD, PELINDABA, PRETORIA, RSA
Shelf-life:	12 months 6 hours reconstituted product stored at 25^0C
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	32/20.2.2/0041
Name of medicine:	GLENMARK CLOTRIMAZOLE 6 VAGINAL TABLET
Dosage form:	TABLETS
Active ingredients:	EACH TABLET CONTAINS: CLOTRIMAZOLE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MEDIVISION (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LTD, SATPUR, NASIK, INDIA GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LTD, SATPUR, NASIK, INDIA GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LTD, SATPUR, NASIK, INDIA GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA CONSULTING CHEMICAL LABORATORIES,ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WSET UNIVERSITY, POTCHEFSTROOM, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	MEDIVISION (PTY) LTD, SPARTAN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	32/20.2.2/0042
Name of medicine:	GLENMARK CLOTRIMAZOLE 1 VAGINAL TABLET
Dosage form:	TABLETS
Active ingredients:	EACH TABLET CONTAINS: CLOTRIMAZOLE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MEDIVISION (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LTD, SATPUR, NASIK, INDIA GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LTD, SATPUR, NASIK, INDIA GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LTD, SATPUR, NASIK, INDIA GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA CONSULTING CHEMICAL LABORATORIES,ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WSET UNIVERSITY, POTCHEFSTROOM, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA
FPRR:	MEDIVISION (PTY) LTD, SPARTAN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	37/6.2/0198
Name of medicine:	TAMBOCOR CR 50
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLECAINIDE ACETATE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	3M PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
Packer:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
Laboratory: FPRC:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
FPRR:	3M PHARMACEUTICALS SA (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	37/6.2/0199
Name of medicine:	TAMBOCOR CR 100
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLECAINIDE ACETATE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	3M PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
Packer:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
Laboratory: FPRC:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
FPRR:	3M PHARMACEUTICALS SA (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF15

Registration number:	37/6.2/0200
Name of medicine:	TAMBOCOR CR 150
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLECAINIDE ACETATE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	3M PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
Packer:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
Laboratory: FPRC:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
FPRR:	3M PHARMACEUTICALS SA (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	37/6.2/0201
Name of medicine:	TAMBOCOR CR 200
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLECAINIDE ACETATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	3M PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
Packer:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
Laboratory: FPRC:	3M HEALTH CARE LTD, LOUGHBOROUGH, LEICESTERSHIRE, ENGLAND, UK
FPRR	3M PHARMACEUTICALS SA (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	37/20.1.2/0452
Name of medicine:	ADIPEN S
Dosage form:	POWDER FOR SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 125,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 31,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY d.d, PREVALJE, SLOVENIA
Packer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY d.d, PREVALJE, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC :	LEK PHARMACEUTICAL & CHEMICAL COMPANY d.d, PREVALJE, SLOVENIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF15 :F 15

Registration number:	37/20.1.2/0453
Name of medicine:	ADIPEN SF
Dosage form:	POWDER FOR SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 250,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 62,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY d.d, PREVALJE, SLOVENIA
Packer:	LEK PHARMACEUTICAL & CHEMICAL COMPANY d.d, PREVALJE, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC:	LEK PHARMACEUTICAL & CHEMICAL COMPANY d.d, PREVALJE, SLOVENIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR	BIOTECH LABORATORIES (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

Registration number:	A39/11.5/0058
Name of medicine:	PICOLAX
Dosage form:	POWDER FOR ORAL SOLUTION
Active ingredients:	EACH SACHET CONTAINS: SODIUM PICOSULPHATE 10,0 mg MAGNESIUM OXIDE 3,5 g CITRIC ACID (ANHYDROUS) 12,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FERRING (PTY) LTD
Manufacturer:	PHARMASERVE LTD, SWINTON, MANCHESTER, UNITED KINGDOM
Packer:	PHARMASERVE LTD, SWINTON, MANCHESTER, UNITED KINGDOM
Laboratory: FPRC	PHARMASERVE LTD, SWINTON, MANCHESTER, UNITED KINGDOM CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING (PTY) LTD, IRENE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	A40/20.1.1/0394
Name of medicine:	STRIDES CEFTRIAXONE 1 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	STRIDES SA PHARMACEUTICALS (PTY) LTD
Manufacturer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Laboratory: FPRC:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR:	STRIDES S.A. PHARMACEUTICALS, ARCADIA, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	A40/20.1.1/0395
Name of medicine:	STRIDES CEFTRIAXONE 500 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	STRIDES SA PHARMACEUTICALS (PTY) LTD
Manufacturer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Laboratory: FPRC:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR:	STRIDES S.A. PHARMACEUTICALS, ARCADIA, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	41/2.2/0294
Name of medicine:	B. BRAUN ETOMIDATE 2 mg/ml
Dosage form:	EMULSION FOR INJECTION
Active ingredients:	EACH 1,0 ml CONTAINS: ETOMIDATE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B. BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B. BRAUN MELSUNGEN AG, BERLIN, GERMANY
Packer:	B. BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B. BRAUN MELSUNGEN AG, BERLIN, GERMANY
Laboratory::FPRC	B. BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA COSY PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR	B BRAUN MEDICAL (PTY) LTD, LASER PARK, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	41/21.12/0703
Name of medicine:	MYLAN BICALUTAMIDE 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GENPHARM INC., ONCOLOGY UNIT, MISSISSAUGA, ONTARIO, CANADA
Packer:	GENPHARM INC., ONCOLOGY UNIT, MISSISSAUGA, ONTARIO, CANADA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	GENPHARM INC., ONCOLOGY UNIT, MISSISSAUGA, ONTARIO, CANADA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF15 F 15

Registration number:	41/21.12/0745
Name of medicine:	XIXIA BICALUTAMIDE 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GENPHARM INC., ONCOLOGY UNIT, MISSISSAUGA, ONTARIO, CANADA
Packer:	GENPHARM INC., ONCOLOGY UNIT, MISSISSAUGA, ONTARIO, CANADA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	GENPHARM INC., ONCOLOGY UNIT, MISSISSAUGA, ONTARIO, CANADA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

Registration number:	41/11.4.3/0761
Name of medicine:	PEPLOC IV
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: PANTOPRAZOLE SODIUM EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	SOFARIMEX, INDUSTRIA QUIMICA e FARMACEUTICA, AGUALVA, CACEM, PORTUGAL
Packer:	SOFARIMEX, INDUSTRIA QUIMICA e FARMACEUTICA, AGUALVA, CACEM, PORTUGAL TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMACEUTICAL ENTERPRISES N'DABENI DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	SOFARIMEX, INDUSTRIA QUIMICA e FARMACEUTICA, AGUALVA, CACEM, PORTUGAL TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA
FPRR:	PHARMA DYNAMICS, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	41/18.10/0828
Name of medicine:	ALFATAM SR 0,4 mg CAPSULES
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 0,4 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	42/1.2/0208
Name of medicine:	AURO PAROXETINE 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

F 15

Registration number:	42/1.2/0209
Name of medicine:	AURO PAROXETINE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/1.2/0210
Name of medicine:	TEXINE 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	42/1.2/0211
Name of medicine:	TEXINE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/2.5/0354
Name of medicine:	MYLAN OXCARBAZEPINE 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXCARBAZEPINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA
Packer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UK MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UK MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/2.5/0355
Name of medicine:	MYLAN OXCARBAZEPINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXCARBAZEPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA
Packer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UK MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UK MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	42/11.4.1/0390
Name of medicine:	MAALOX POCKET PACK
Dosage form:	SUSPENSION
Active ingredients:	EACH SACHET CONTAINS: ALUMINIUM OXIDE HYDRATED EQUIVALENT TO ALUMINIUM OXIDE 230,0 mg MAGNESIUM HYDROXIDE 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	BK GIULINI GmbH, LUDWIGSHAFEN, GERMANY SANOFI-AVENTIS S.p.A., ORIGGIO, ITALY
Packer:	VARIOPACK LOHNFERTIGUNGEN GmbH, NIDDA-HARB, GERMANY SANOFI-AVENTIS S.p.A., ORIGGIO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	A NATTERMANN & CIE GmbH, COLOGNE, GERMANY SANOFI-AVENTIS S.p.A., ORIGGIO, ITALY 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:	2 MARCH 2012

RF 15

Registration number:	42/2.6.5/0456
Name of medicine:	ZYDUS RISPERIDONE 1 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/2.6.5/0457
Name of medicine:	ZYDUS RISPERIDONE 2 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	42/2.6.5/0458
Name of medicine:	ZYDUS RISPERIDONE 3 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/2.6.5/0459
Name of medicine:	ZYDUS RISPERIDONE 4 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/34/0496
Name of medicine:	IMAVEC
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: IMATINIB MESYLATE EQUIVALENT TO IMATINIB 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT VI, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT VI, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT VI, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/20.2.2/0566
Name of medicine:	BIO FLUCONAZOLE 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FLUCONAZOLE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA
Laboratory: FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	2 MARCH 2012

Registration number:	42/20.2.2/0684
Name of medicine:	BIO FLUCONAZOLE 150 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FLUCONAZOLE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA
Laboratory: FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	*42/35/0689*
Name of medicine:	ULTRA-TECHNEKOW FM
Dosage form:	RADIONUCLIDE GENERATOR
Active ingredients:	EACH GENERATOR CONTAINS: SODIUM MOLYBDATE 2,15 GBq SODIUM PERTECHNETATE 2,08 GBq
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	COVIDIEN (PTY) LTD
Manufacturer:	MALLINCKRODT MEDICAL B.V., PETTEN, NETHERLANDS
Packer:	MALLINCKRODT MEDICAL B.V., PETTEN, NETHERLANDS
Laboratory: FPRC:	MALLINCKRODT MEDICAL B.V., PETTEN, NETHERLANDS PET LABS PHARMACEUTICAL (PTY) LTD, GROENKLOOF, PRETORIA, RSA
FPRR:	PET LABS PHARMACEUTICAL (PTY) LTD, GROENKLOOF, PRETORIA, RSA COVIDIEN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	*42/20.2.2/0690*
Name of medicine:	BIO FLUCONAZOLE 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FLUCONAZOLE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA
Laboratory: FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES (DIVISION OF J.B.CHEMICALS & PHARMACEUTICALS), PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	2 MARCH 2012

RF 15

Registration number:	*42/30.1/0765*
Name of medicine:	TYSABRI
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml CONCENTRATE CONTAINS: NATALIZUMAB 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	TEVA PARENTERAL MEDICINES INC, IRVINE, CALIFORNIA, USA HOSPIRA INC, MCPHERSON, KANSAS, USA VETTER PHARMA-FERTIGUNG GmbH & Co, MOOSWIESEN, RAVENSBURG, GERMANY
Packer:	TEVA PARENTERAL MEDICINES INC, IRVINE, CALIFORNIA, USA HOSPIRA INC, MCPHERSON, KANSAS, USA VETTER PHARMA-FERTIGUNG GmbH & Co, MOOSWIESEN, RAVENSBURG, GERMANY BIOGEN IDEC DENMARK MANUFACTURING, HILLEROD, DENMARK ELAN PHARMA INTERNATIONAL LTD, ATHLONE, WESTMEATH, IRELAND
Laboratory: FPRC	VETTER PHARMA-FERTIGUNG GmbH & Co, MOOSWIESEN, RAVENSBURG, GERMANY BIOGEN IDEC DENMARK MANUFACTURING, HILLEROD, DENMARK BIOGEN IDEC B.V., HOOFDDORP, THE NETHERLANDS ELAN PHARMA INTERNATIONAL LTD, ATHLONE, WESTMEATH, IRELAND VETTER PHARMA-FERTIGUNG GmbH & Co, SCHUETZENSTRASSE, RAVENSBURG, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co, HOLBEINSTRASSE, RAVENSBURG, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co, LANGENARGEN, GERMANY
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/20.1.1/0915
Name of medicine:	VANCOMYCIN SAFELINE INJECTION 500 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: VANCOMYCIN HYDROCHLORIDE EQUIVALENT TO VANCOMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A., PALINI ATTICI, GREECE
Packer:	VIANEX S.A., PALINI ATTICI, GREECE
Laboratory: FPRC:	VIANEX S.A., PALINI ATTICI, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF15

Registration number:	42/20.2.8/0943
Name of medicine:	DEZZO TRIVIR
Dosage form:	TABLET
Active ingredients:	EACH TABLETS CONTAINS: STAVUDINE 30,0 mg LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
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 (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING 392 (PTY) LTD, T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/5.7.1/0985
Name of medicine:	DYNA DESLORATADINE 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DESLORATADINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA
Packer:	PENDOPHARM INC, MONTREAL, QUEBEC, CANADA ROPACK INC, MONTREAL, QUEBEC, CANADA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMACEUTICAL ENTERPRISES N'DABENI DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA PENDOPHARM INC, MONTREAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	42/32.2/0988
Name of medicine:	ASPENCEPT 250 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LTD
Manufacturer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	PHARMACARE LTD, KORSTEN PORT ELIZABETH, RSA PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	42/34/0996
Name of medicine:	ASPEN WATER FOR INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTIONS 2,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB POLSKA SP, WARSZAWA, POLAND
Packer:	STRIDES ARCOLAB POLSKA SP, WARSZAWA, POLAND PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	STRIDES ARCOLAB POLSKA SP, WARSZAWA, POLAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Date of registration:	24 months 2 MARCH 2012

RF 15

Registration number:	43/3.2/0266
Name of medicine:	DYNA ALENDRONATE 70 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE TRIHYDRATE MONOSODIUM EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS BELMAC, S.A., ZARAGOZA, SPAIN
Packer:	LABORATORIOS BELMAC, S.A., ZARAGOZA, SPAIN
Laboratory: FPRC	LABORATORIOS BELMAC, S.A., ZARAGOZA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/11.4.3/0439
Name of medicine:	VIAPAN
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: PANTOPRAZOLE SODIUM EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A., PALINI ATTICI, GREECE
Packer:	VIANEX S.A., PALINI ATTICI, GREECE
Laboratory: FPRC:	VIANEX S.A., PALINI ATTICI, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	43/34/0613
Name of medicine:	ZOMEDRON
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ZOLEDRONIC ACID 4,0 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 LTD, UNIT IX, VERNA, GOA, INDIA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/5.7.1/0643
Name of medicine:	AURO CETIRIZINE TABLETS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, 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:	2 MARCH 2012

MRF 15

Registration number:	43/5.7.1/0644
Name of medicine:	AURO CETIRIZINE TABLETS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 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, LIMBRO BUSINESS PARK, SANDTON, 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:	2 MARCH 2012

MRF15

Registration number:	43/5.7.1/0645
Name of medicine:	TRANTRIN TABLETS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, 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:	2 MARCH 2012

RF 15

Registration number:	43/5.7.1/0646
Name of medicine:	TRANTRIN TABLETS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 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, LIMBRO BUSINESS PARK, SANDTON, 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:	2 MARCH 2012

MRF 15

Registration number:	43/34/0731
Name of medicine:	CIPLA ZOLEDRONIC ACID
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ZOLEDRONIC ACID 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	43/20.2.8/0831
Name of medicine:	HETLAM
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BLISS PHARMACEUTICALS cc
Manufacturer:	HETERO DRUG LTD, JEEDIMETLA HYDERABAD, INDIA
Packer:	HETERO DRUG LTD, JEEDIMETLA HYDERABAD, INDIA
Laboratory: FPRC:	HETERO DRUG LTD, JEEDIMETLA HYDERABAD, INDIA
FPRR:	BLISS PHARMACEUTICALS, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/26/0913
Name of medicine:	IXEMPRA 15 mg
Dosage form:	*POWDER AND DILUENT* FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: IXABEPILONE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY
Packer:	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY BRISTOL-MYERS SQUIBB S.r.l., SERMONETA, LATINA, ITALY
Laboratory: FPRC	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY BRISTOL-MYERS SQUIBB S.r.l., SERMONETA, LATINA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA MERCK PHARMACEUTICAL MANUFACTURER (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:	BRISTOL-MYERS SQUIBB (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/26/0914
Name of medicine:	IXEMPRA 45 mg
Dosage form:	POWDER AND DILUENT FOR SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: IXABEPILONE 45,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY
Packer:	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY BRISTOL-MYERS SQUIBB S.r.l., SERMONETA, LATINA, ITALY
Laboratory: FPRC:	BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY BRISTOL-MYERS SQUIBB S.r.l., SERMONETA, LATINA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA MERCK PHARMACEUTICAL MANUFACTURER (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:	BRISTOL-MYERS SQUIBB (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	43/7.1.3/1094
Name of medicine:	CO-TEKTURNA 150 mg/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALISKIREN HEMIFUMARATE EQUIVALENT TO ALISKIREN 150,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK GROUP AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP SAN PROSPERO S.p.A., SAN PROSPERO, ITALY MIPHARM S.p.A., MILANO, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMANALYTICA S.A., LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/7.1.3/1095
Name of medicine:	CO=TEKTURNA 150 mg/25 mg
Dosage form:	TABLE
Active ingredients:	EACH TABLET CONTAINS: ALISKIREN HEMIFUMARATE EQUIVALENT TO ALISKIREN 150,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK GROUP AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP SAN PROSPERO S.p.A., SAN PROSPERO, ITALY MIPHARM S.p.A., MILANO, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMANALYTICA S.A., LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/7.1.3/1096
Name of medicine:	CO-TEKTURNA 300 mg/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALISKIREN HEMIFUMARATE EQUIVALENT TO ALISKIREN 300,0 mg HYDROCHLOROTHIAZIDE 12,50 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK GROUP AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP SAN PROSPERO S.p.A., SAN PROSPERO, ITALY MIPHARM S.p.A., MILANO, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMANALYTICA S.A., LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	43/7.1.3/1097
Name of medicine:	CO-TEKTURNA 300 mg/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALISKIREN HEMIFUMARATE EQUIVALENT TO ALISKIREN 300,0 m HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK GROUP AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP SAN PROSPERO S.p.A., SAN PROSPERO, ITALY MIPHARM S.p.A., MILANO, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMANALYTICA S.A., LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/7.1.3/1098
Name of medicine:	CO-RASILEZ 150 mg/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALISKIREN HEMIFUMARATE EQUIVALENT TO ALISKIREN 150,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK GROUP AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP SAN PROSPERO S.p.A., SAN PROSPERO, ITALY MIPHARM S.p.A., MILANO, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMANALYTICA S.A., LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/7.1.3/1099
Name of medicine:	CO-RASILEZ 150 mg/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALISKIREN HEMIFUMARATE EQUIVALENT TO ALISKIREN 150,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK GROUP AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP SAN PROSPERO S.p.A., SAN PROSPERO, ITALY MIPHARM S.p.A., MILANO, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMANALYTICA S.A., LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	43/7.1.3/1100
Name of medicine:	CO-RASILEZ 300 mg/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALISKIREN HEMIFUMARATE EQUIVALENT TO ALISKIREN 300,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK GROUP AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP SAN PROSPERO S.p.A., SAN PROSPERO, ITALY MIPHARM S.p.A., MILANO, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMANALYTICA S.A., LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

RF 15

Registration number:	43/7.1.3/1101
Name of medicine:	CO-RASILEZ 300 mg/25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALISKIREN HEMIFUMARATE EQUIVALENT TO ALISKIREN 300,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK GROUP AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP SAN PROSPERO S.p.A., SAN PROSPERO, ITALY MIPHARM S.p.A., MILANO, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC	NOVARTIS PHARMA PRODUKTIONS GmbH, WEHR, GERMANY NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMANALYTICA S.A., LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/20.1.6/1103
Name of medicine:	ALTARGO
Dosage form:	OINTMENT
Active ingredients:	EACH 1,0 g OF OINTMENT CONTAINS: RETAPAMULIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LIMITED, BARNARD CASTLE, DURHAM, UNITED KINGDOM
Packer:	GLAXO OPERATIONS UK LIMITED, BARNARD CASTLE, DURHAM, UNITED KINGDOM GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
Laboratory: FPRC:	GLAXO OPERATIONS UK LIMITED, BARNARD CASTLE, DURHAM, UNITED KINGDOM GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA
FPRR:	GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA GLAXOSMITHKLINE SA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF15

Registration number:	43/13.1/1104
Name of medicine:	GAVISCON TROPICAL GRANULES
Dosage form:	ORAL POWDER
Active ingredients:	EACH SACHET CONTAINS: SODIUM ALGINATE 500,0 mg SODIUM BICARBONATE 267,0 mg CALCIUM CARBONATE 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD
Manufacturer:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD, NOTTINGHAM, UNITED KINGDOM
Packer:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD, NOTTINGHAM, UNITED KINGDOM CARDINAL HEALTH GERMANY GmbH, SCHORNDORF, GERMANY PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA
Laboratory: FPRC:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD, NOTTINGHAM, UNITED KINGDOM CARDINAL HEALTH GERMANY GmbH, SCHORNDORF, GERMANY PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA
FPRR:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/13.1/1105
Name of medicine:	GAVISCON PEPPERMINT GRANULES
Dosage form:	ORAL POWDER
Active ingredients:	EACH SACHET CONTAINS: SODIUM ALGINATE 500,0 mg SODIUM BICARBONATE 267,0 mg CALCIUM CARBONATE 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD
Manufacturer:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD, NOTTINGHAM, UNITED KINGDOM
Packer:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD, NOTTINGHAM, UNITED KINGDOM CARDINAL HEALTH GERMANY GmbH, SCHORNDORF, GERMANY PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA
Laboratory: FPRC	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD, NOTTINGHAM, UNITED KINGDOM CARDINAL HEALTH GERMANY GmbH, SCHORNDORF, GERMANY PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA
FPRC/FPRR:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	44/15.4/0046
Name of medicine:	AZARGA
Dosage form:	EYE DROP SUSPENSION
Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: BRINZOLAMIDE 10,0 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ALCON LABORATORIES SA (PTY) LTD
Manufacturer:	S.A. ALCON-COUVREUR N.V, PUURS, BELGIUM
Packer:	S.A. ALCON-COUVREUR N.V, PUURS, BELGIUM
Laboratory: FPRC:	S.A. ALCON-COUVREUR N.V, PUURS, BELGIUM RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	ALCON LABORATORIES SA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	44/21.12/0260
Name of medicine:	LETROZOLE BRIMPHARM
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LETROZOLE2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	KERN PHARMA S.L, TERRASSA BARCELONA, SPAIN
Packer:	KERN PHARMA S.L, TERRASSA BARCELONA, SPAIN
Laboratory: FPRC:	KERN PHARMA S.L, TERRASSA BARCELONA, SPAIN DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA (PTY) LTD, ATHLONE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 MARCH 2012

RF 15

Registration number:	44/21.12/0261
Name of medicine:	TROZOLT
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LETROZOLE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	KERN PHARMA S.L, TERRASSA BARCELONA, SPAIN
Packer:	KERN PHARMA S.L, TERRASSA BARCELONA, SPAIN
Laboratory: FPRC	KERN PHARMA S.L, TERRASSA BARCELONA, SPAIN DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA (PTY) LTD, ATHLONE, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	44/26/0374
Name of medicine:	PAXITAS 30
Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH 5,0 ml CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF15

Registration number:	44/26/0375
Name of medicine:	PAXITAS 100
Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH 16,7 ml CONTAINS: PACLITAXEL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

RF 15

Registration number:	44/26/0376
Name of medicine:	PAXITAS 300
Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH 50,0 ml CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	44/26/0377
Name of medicine:	ACCORD PACLITAXEL 30
Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH 5,0 ml CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF15

Registration number:	44/26/0378
Name of medicine:	ACCORD PACLITAXEL 100
Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH 16,7 ml CONTAINS: PACLITAXEL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

RF 15

Registration number:	44/26/0379
Name of medicine:	ACCORD PACLITAXEL 300
Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH 50,0 ml CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, GUJARAT, INDIA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	44/21.12/0439
Name of medicine:	ACROVIC 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, UNIT VII, VISHAKAPATNAM, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, UNIT VII, VISHAKAPATNAM, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, UNIT VII, VISHAKAPATNAM, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	2 MARCH 2012

MRF15

Registration number:	44/21.12/0440
Name of medicine:	DRL ANASTROZOLE 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, UNIT VII, VISHAKAPATNAM, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, UNIT VII, VISHAKAPATNAM, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, UNIT VII, VISHAKAPATNAM, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	36 months
Date of registration:	2 MARCH 2012

RF 15

Registration number:	44/7.1.3/0503
Name of medicine:	ZYDUS PERINDOPRIL CO TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 4,0 mg INDAPAMIDE 1,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	44/20.2.8/0779
Name of medicine:	*ODIMUNE
Dosage form:	TAB;ET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1,2,3,4,5,6,7,8,9,10**
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, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	09 February 2012

MRF15

Registration number:	44/20.2.8/0780
Name of medicine:	*CIPLA EFAVIRENZ 600 mg/TENOFOVIR 300 mg/EMTRICITABINE 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1,2,3,4,5,6,7,8,9,10**
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, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	09 February 2012

MMRF 15

Registration number:	44/21.10/0781
Name of medicine:	PERGOVERIS 150 I.U /75 I.U
Dosage form:	POWDER FOR SOLUTION
Active ingredients:	EACH VIAL CONTAINS: FOLLITROPIN ALFA (r-hFSH) 150,0 I.U LUTROPIN ALFA (r-hLH) 75,0 I.U
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK SERONO S.A., AUBONNE, SWITZERLAND
Packer:	MERCK SERONO S.A., AUBONNE, SWITZERLAND MERCK SERONO S.A., COINSINS, SWITZERLAND
Laboratory: FPRC	MERCK SERONO S.A., AUBONNE, SWITZERLAND MERCK SERONO S.p.A., GUIDONIA MONTECELIO, ITALY
FPRR:	MERCK (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	44/2.6.5/0973
Name of medicine:	SEROQUEL XR 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LIMITED
Manufacturer:	ASTRAZENECA AB, SODERTALJE, SWEDEN ASTRAZENECA UK LIMITED, MACCLESFIELD, CHESHIRE, UK
Packer:	ASTRAZENECA AB, SODERTALJE, SWEDEN ASTRAZENECA UK LIMITED, CHESHIRE, UK AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALBERTON, SOUTH AFRICA
Laboratory: FPRC:	ASTRAZENECA AB, SODERTALJE, SWEDEN ASTRAZENECA UK LIMITED, CHESHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ASTRAZENECA PHARMACEUTICALS (PTY) LIMITED, SUNNINGHILL, RSA
Shelf-life:	36 months
Date of registration:	2 MARCH 2012

MRF15

Registration number:	45/20.2.8/0078
Name of medicine:	RAOLIN 100/25 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 100,0 mg RITONAVIR 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT 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, LIMBRO BUSINESS PARK, SANDTON, 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:	2 MARCH 2012

MRF 15

Registration number:	45/20.2.8/0079
Name of medicine:	RAOLIN 200/50 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 200,0 mg RITONAVIR 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT 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, LIMBRO BUSINESS PARK, SANDTON, 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:	2 MARCH 2012

MRF 15

45/20.2.8/0080

MECOTRIL 100/25 mg TABLETS

TABLET

EACH TABLET CONTAINS:
LOPINAVIR 100,0 mg
RITONAVIR 25,0 mg

1, 2, 3, 4, 5, 6, 7, 8

AUROBINDO PHARMA (PTY) LTD

AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA

AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA

AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA

AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA

24 months (Provisional)

2 MARCH 2012

MRF 15

Registration number:	45/20.2.8/0081
Name of medicine:	MECOTRIL 200/50 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 200,0 mg RITONAVIR 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT 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, LIMBRO BUSINESS PARK, SANDTON, 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:	2 MARCH 2012

MRF 15

Registration number:	08/3.1.2/14
Name of medicine:	METACAM 20 mg/ml FOR CATTLE, PIGS AND HORSES
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: MELOXICAM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABIANA LIFE SCIENCES S.A., LES FONTS DE TERRASSA, BARCELONA, SPAIN
Packer:	LABIANA LIFE SCIENCES S.A., LES FONTS DE TERRASSA, BARCELONA, SPAIN
Laboratory: FPRC:	LABIANA LIFE SCIENCES S.A., LES FONTS DE TERRASSA, BARCELONA, SPAIN WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	INGELHEIM PHARMACEUTICALS, FERNDALE, RANDBURG
Shelf-life:	36 months
Date of registration:	20 APRIL 2012

MRF15

Registration number:	A39/34/0605
Name of medicine:	NICOTINELL FRUIT 2 mg COATED CHEWING GUM
Dosage form:	CHEWING GUM
Active ingredients:	EACH CHEWING GUM CONTAINS: NICOTINE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK
Packer:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK SANDOZ SA, SPARTAN, KEMPTON PARK
FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	A39/34/0606
Name of medicine:	NICOTINELL FRUIT 4 mg COATED CHEWING GUM
Dosage form:	CHEWING GUM
Active ingredients:	EACH CHEWING GUM CONTAINS: NICOTINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK
Packer:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK SANDOZ SA, SPARTAN, KEMPTON PARK
FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	A39/34/0607
Name of medicine:	NICOTINELL MINT 2 mg COATED CHEWING GUM
Dosage form:	CHEWING GUM
Active ingredients:	EACH CHEWING GUM CONTAINS: NICOTINE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK
Packer:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK SANDOZ SA, SPARTAN, KEMPTON PARK
FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF15

Registration number:	A39/34/0608
Name of medicine:	NICOTINELL MINT 4 mg COATED CHEWING GUM
Dosage form:	CHEWING GUM
Active ingredients:	EACH CHEWING GUM CONTAINS: NICOTINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK
Packer:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	FERTIN A/S, DANDYVEJ, VEJLE, DENMARK SANDOZ SA, SPARTAN, KEMPTON PARK
FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	41/11.10/0215
Name of medicine:	GAVISCON LIQUISHOT
Dosage form:	SUSPENSION
Active ingredients:	EACH SACHET CONTAINS: SODIUM ALGINATE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD
Manufacturer:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM
Packer:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM
Laboratory: FPRC:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UNITED KINGDOM RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD, ELANDSFONTEIN, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD, ELANDSFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	41/21.10/0523
Name of medicine:	OVITRELLE 250 µg/0,5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: Choriogonadotropin alfa 250,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERONO SA (PTY) LTD
Manufacturer:	INDUSTRIA FARMACEUTICA SERONO SpA, BARI, ITALY
Packer:	INDUSTRIA FARMACEUTICA SERONO SpA, BARI, ITALY LABORATOIRES SERONO SA, COINSINS, SWITZERLAND
Laboratory: FPRC:	INDUSTRIA FARMACEUTICA SERONO SpA, BARI, ITALY LABORATOIRES SERONO SA, COINSINS, SWITZERLAND
FPRR:	SERONO SA (PTY) LTD, FOURWAYS, SANDTON, RSA
Shelf-life:	24 months at 2-8 ^{0}C
Date of registration:	20 APRIL 2012

MRF15

Registration number:	41/26/0608
Name of medicine:	ASPEN CARBOPLATIN 50 mg
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 5,0 ml VIAL CONTAINS: CARBOPLATIN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional) at 2-8 ^{0}C
Date of registration:	20 APRIL 2012

F 15

Registration number:	41/26/0609
Name of medicine:	ASPEN CARBOPLATIN 150 mg
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 15,0 ml VIAL CONTAINS: CARBOPLATIN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional) at 2-8 ^{0}C
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	41/26/0610
Name of medicine:	ASPEN CARBOPLATIN 450 mg
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 45,0 ml VIAL CONTAINS: CARBOPLATIN 450,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	S.C. SINDAN-PHARMA S.R.L, BUCHAREST, ROMANIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional) at 2-8 ^{0}C
Date of registration:	20 APRIL 2012

MRF15

Registration number:	42/20.1.1/0247
Name of medicine:	ASPEN AZITHROMYCIN IV
Dosage form:	POWDER FORSOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: AZITHROMYCIN MONOHYDRATE EQUIVALENT TO AZITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LTD
Manufacturer:	STRIDES ARCOLAB LIMITED (STERILE PRODUCTS DIVISION), BANNERGHATTA ROAD, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

F 15

Registration number:	42/21.5.1/0310
Name of medicine:	MYLAN-METHYLPREDNISOLONE 120
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: Methylprednisolone hemisuccinate equivalent to Methylprednisolone 120,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA – PLANT C, PALLINI-ATTICA, GREECE
Packer:	BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA – PLANT C, PALLINI-ATTICA, GREECE PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA- PLANT C, PALLINI-ATTICA, GREECE
FPRR	XIXIA PHARMACEUTICALS, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/21.5.1/0311
Name of medicine:	MYLAN METHYLPREDNISOLONE 500
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: Methylprednisolone hemisuccinate equivalent to Methylprednisolone 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA – PLANT C, PALLINI-ATTICA, GREECE
Packer:	BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA – PLANT C, PALLINI-ATTICA, GREECE PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC :	MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA- PLANT C, PALLINI-ATTICA, GREECE
FPRR:	XIXI PHARMACEUTICALS, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF15

Registration number:	42/21.5.1/0312
Name of medicine:	MYLAN-METHYLPREDNISOLONE 1 000
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: Methylprednisolone hemisuccinate equivalent to Methylprednisolone 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA – PLANT C, PALLINI-ATTICA, GREECE
Packer:	BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA – PLANT C, PALLINI-ATTICA, GREECE PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA PHARMA-Q, INDUSTRIA, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA BIOLOGICI ITALIA LABORATORIES S.R.L., MASATE (MILANO), ITALY VIANEX SA- PLANT C, PALLINI-ATTICA, GREECE
FPRR	XIXI PHARMACEUTICALS, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

F 15

Registration number:	42/7.1.3/0352
Name of medicine:	TRANDOPRESS 0,5 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TRANDOLAPRIL 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATEN S.A, PALLINI, ATTIKIS, GREECE
Packer:	PHARMATEN S.A, PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE ESAT LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC	PHARMATEN S.A, PALLINI, ATTIKIS, GREECE PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, ESAT LONDON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE ESAT LONDON, WILSONIA, ESAT LONDON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/20.1.1/0641
Name of medicine:	GULF CEFOTAXIME 2 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 2,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN
Packer:	LABORATORIO REIG JOFRE, TOLEOO, SPAIN
Laboratory: FPRC:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORY, BEYERSPARK, BOKSBURG
FPRR:	GULF DRUG COMPANY, MOUNT EDGECOMBE
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF15 .F 15

Registration number:	42/7.5/0805
Name of medicine:	VATICOL XL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FLUVASTATIN SODIUM EQUIVALENT TO FLUVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., SCHIMATARI, ATHENS, GREECE
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

Registration number:	42/7.1.3/0947
Name of medicine:	IRBELO 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:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory::FPRC	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/7.1.3/0948
Name of medicine:	IRBELO 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:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	42/7.1.3/0949
Name of medicine:	IRBELO 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:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/7.1.3/0950
Name of medicine:	RAN 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:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/7.1.3/0951
Name of medicine:	RAN 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:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	42/7.1.3/0952
Name of medicine:	RAN 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:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/26/0965
Name of medicine:	MYLAN CARBOPLATIN 150
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CARBOPLATIN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A., PALLINI, ATTICA, GREECE
Packer:	VIANEX S.A., PALLINI, ATTICA, GREECE
Laboratory: FPRC:	VIANEX S.A., PALLINI, ATTICA, GREECE GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/26/0965
Name of medicine:	MYLAN CARBOPLATIN 450
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CARBOPLATIN 450,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	VIANEX S.A., PALLINI, ATTICA, GREECE
Packer:	VIANEX S.A., PALLINI, ATTICA, GREECE
Laboratory: FPRC	VIANEX S.A., PALLINI, ATTICA, GREECE GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15 F 15

Registration number:	42/2.9/0967
Name of medicine:	TRAMASPEN 50 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Tramadol Hydrochloride 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	FAMAR ITALIA S.p.A, BARANZATE DI BOLLATE, ITALY
Packer:	FAMAR ITALIA S.p.A, BARANZATE DI BOLLATE, ITALY PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	FAMAR ITALIA S.p.A, BARANZATE DI BOLLATE, ITALY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:	PHARMACARE LTD, KORTSEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

Registration number:	42/21.12/1096
Name of medicine:	EVERDEX 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA
Packer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Laboratory: FPRC:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA CARDINAL HEALTH UK 417 LIMITED, STOCKPOT, CHESHIRE, UK AFRIKA BIOPHARMA (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG
Shelf-life:	60 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/2.6.5/0039
Name of medicine:	RISPEVON 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	43/2.6.5/0040
Name of medicine:	RISPEVON 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/2.6.5/0041
Name of medicine:	RISPEVON 3
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/2.6.5/0042
Name of medicine:	RISPEVON 4
Dosage *form*:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	43/26/0046
Name of medicine:	MYLAN GEMCITABINE 1 g
Dosage *form*:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: GEMCITABINE EQUIVALENT TO GEMCITABINE 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, SANAND, DISTRICT AHMEDABAD, GUJURAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, SANAND, DISTRICT AHMEDABAD, GUJURAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, SANAND, DISTRICT AHMEDABAD, GUJURAT, INDIA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD,MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/20.1.1/0062
Name of medicine:	ORCHID CEFUROXIME 250 mg
Dosage *form*:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ORCHID PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	ORCHID HEALTHCARE, SRIPERUMBUDUR, KANCHEEPURAM, INDIA
Packer:	ORCHID HEALTHCARE, SRIPERUMBUDUR, KANCHEEPURAM, INDIA
Laboratory: FPRC	ORCHID HEALTHCARE, SRIPERUMBUDUR, KANCHEEPURAM, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ORCHID PHARMACEUTICALS, SA, NOORBRUG, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/20.1.1/0063
Name of medicine:	ORCHID CEFUROXIME 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ORCHID PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	ORCHID HEALTHCARE, SRIPERUMBUDUR, KANCHEEPURAM, INDIA
Packer:	ORCHID HEALTHCARE, SRIPERUMBUDUR, KANCHEEPURAM, INDIA
Laboratory: FPRC:	ORCHID HEALTHCARE, SRIPERUMBUDUR, KANCHEEPURAM, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ORCHID PHARMACEUTICALS, SA, NOORBRUG, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/26/0068
Name of medicine:	MYLAN GEMCITABINE 200 mg
Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: GEMCITABINE EQUIVALENT TO GEMCITABINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, SANAND, DISTRICT AHMEDABAD, GUJURAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, SANAND, DISTRICT AHMEDABAD, GUJURAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, SANAND, DISTRICT AHMEDABAD, GUJURAT, INDIA GENERICS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

Registration number:	43/20.1.1/0221
Name of medicine:	ZEEMIDE 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Azithromycin dehydrate equivalent to Azithromycin 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	KERN PHARMA S.L., VENUS, TERRASSA-BARCELONA, SPAIN
Packer:	KERN PHARMA S.L., VENUS, TERRASSA-BARCELONA, SPAIN
Laboratory: FPRC:	KERN PHARMA S.L., VENUS, TERRASSA-BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPHARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/11.4.3/0545
Name of medicine:	ASPEN PANTOPRAZOLE 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	ACTAVIS Hf., ICELAND ACTAVIS LTD., ZEJTUN, MALTA
Packer:	ACTAVIS Hf., ICELAND ACTAVIS LTD., ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS Hf., ICELAND ACTAVIS LTD., ZEJTUN, MALTA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	43/11.4.3/0546
Name of medicine:	ASPEN PANTOPRAZOLE 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	ACTAVIS Hf., ICELAND ACTAVIS LTD., ZEJTUN, MALTA
Packer:	ACTAVIS Hf., ICELAND ACTAVIS LTD., ZEJTUN, MALTA
Laboratory: FPRC:	ACTAVIS Hf., ICELAND ACTAVIS LTD., ZEJTUN, MALTA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/20.2.8/0570
Name of medicine:	VUDERIT 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg STAVUDINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/20.2.8/0571
Name of medicine:	VUDERIT 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg STAVUDINE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF15

Registration number:	43/2.5/0823
Name of medicine:	EPIMATE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, MURRAYFEILD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/2.5/0824
Name of medicine:	EPIMATE 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA
Laboratory: FPRC	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, MURRAYFEILD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/2.5/0825
Name of medicine:	EPIMATE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, MURRAYFEILD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	43/2.5/0826
Name of medicine:	EPIMATE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, DISTRICT MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TRINITY PHARMA (PTY) LTD, MURRAYFEILD, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

RF 15

Registration number:	43/11.4.3/1001
Name of medicine:	PANTOLOC OTC
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NYCOMED (PTY) LTD
Manufacturer:	NYCOMED GmbH, ORANIENBURG, GERMANY ADAVANCE PHARMA GmbH, BERLIN, GERMANY
Packer:	NYCOMED GmbH, ORANIENBURG, GERMANY
Laboratory: FPRC	NYCOMED GmbH, ORANIENBURG, GERMANY
FPRR:	NYCOMED (PTY) LTD, BRYANSTON, RSA
Shelf-life:	36 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/1.2/1015
Name of medicine:	ZYDUS ESCITALOPRAM 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF15

Registration number:	43/7.1.3/1044
Name of medicine:	BIQURETIC 10/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quinapril Hydrochloride equivalent to Quinapril 10,0 mg Hydrochlorothiazide 12,5 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, LIMBRO BUSINESS PARK, SANDTON, 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:	20 APRIL 2012

MRF 15

Registration number:	43/7.1.3/1045
Name of medicine:	BIQURETIC 20/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quinapril Hydrochloride equivalent to Quinapril 20,0 mg Hydrochlorothiazide 12,5 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, LIMBRO BUSINESS PARK, SANDTON, 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:	20 APRIL 2012

MRF 15

Registration number:	43/7.1.3/1046
Name of medicine:	AURO QUINAPRIL CO 10/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quinapril Hydrochloride equivalent to Quinapril 10,0 mg Hydrochlorothiazide 12,5 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, LIMBRO BUSINESS PARK, SANDTON, 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:	20 APRIL 2012

MRF15

Registration number:	43/7.1.3/1047
Name of medicine:	AURO QUINAPRIL CO 20/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quinapril Hydrochloride equivalent to Quinapril 20,0 mg Hydrochlorothiazide 12,5 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, LIMBRO BUSINESS PARK, SANDTON, 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:	20 APRIL 2012

RF 15

Registration number:	44/20.1.1/0316
Name of medicine:	KANAMYCIN 1 g BIOTECH
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: KANAMYCIN SULPHATE EQUIVALENT TO KANAMYCIN1000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF JB CHEMICALS & PHARMACEUTICALS LIMITED), PANOLI, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF JB CHEMICALS & PHARMACEUTICALS LIMITED), PANOLI, INDIA PHARMA-Q (PTY) LTD TRADING AS COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA
Laboratory: FPRC	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF JB CHEMICALS & PHARMACEUTICALS LIMITED), PANOLI, INDIA PHARMA-Q (PTY) LTD TRADING AS COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	44/34/0391
Name of medicine:	SOLVENT FOR DOCELEX 20
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ETHANOL 13,0 % m/v
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF15

Registration number:	44/34/0392
Name of medicine:	SOLVENT FOR DOCELEX 80
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ETHANOL 13,0 % m/v
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	44/8.1/0550
Name of medicine:	NOVOSEVEN 1 mg
Dosage form:	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Activated Recobinant Coagulation Factor VIIa (rFVIIa) 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVO NORDISK (PTY) LTD
Manufacturer:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
Packer:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
Laboratory: FPRC	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
FPRR:	NOVO NORDISK (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	44/8.1/0551
Name of medicine:	NOVOSEVEN 2 mg
Dosage form:	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Activated Recobinant Coagulation Factor VIIa (rFVIIa) 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVO NORDISK (PTY) LTD
Manufacturer:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
Packer:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
Laboratory: FPRC:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
FPRR:	NOVO NORDISK (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF15

Registration number:	44/8.1/0552
Name of medicine:	NOVOSEVEN 5 mg
Dosage form:	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: Activated Recobinant Coagulation Factor VIIa (rFVIIa) 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVO NORDISK (PTY) LTD
Manufacturer:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
Packer:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
Laboratory: FPRC:	NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK NOVO NORDISK A/S, BROGAARDSVEJ, DENMARK
FPRR:	NOVO NORDISK (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	44/13.9.1/0632
Name of medicine:	XAMIOL GEL
Dosage form:	GEL
Active ingredients:	EACH GRAM CONTAINS: Calcipotriol hydrate equivalent to Calcipotriol 50,0 ug Betamethasone dipropionate equivalent to Betamethasone 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK
Packer:	LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK
Laboratory: FPRC	LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIORAND, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	45/20.2.8/0111
Name of medicine:	RILOVIA 200/50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 200,0 mg RITONAVIR 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF15

Registration number:	45/20.2.8/0169
Name of medicine:	EFRIN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	45/20.2.8/0336
Name of medicine:	RILOVIA 100/25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 100,0 mg RITONAVIR 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	45/20.2.8/0538
Name of medicine:	MACLEODS LAMIVUDINE 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA
Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	20 APRIL 2012

*ADDITIONAL CONDITIONS OF REGISTRATION

Due to the non discriminating nature of the dissolution method (2 % SLS in water, at 100 fpm) used for release and stability testing of Efavirenz containing products, the following must be complied with:

Develop an appropriate (discriminating) dissolution method for release and stability testing and submit for evaluation.

As an interim measure, continue to use the current dissolution medium (2 % SLS in water, at 100 rpm) for a maximum period of twelve months from the date of registration or until implementation of the new method, whichever is sooner.

Provide periodic progress reports on the method development and data.

**ADDITIONAL CONDITIONS OF REGISTRATION

Develop an appropriate (discriminating) dissolution method for release and stability testing and submit for evaluation.

As an interim measure, continue to use the current dissolution medium (2 % SLS in water, at 100 rpm) for a maximum period of twelve months from the date of registration or until implementation of the new method, whichever is sooner.

Provide periodic progress reports on the method development and data.

A new bioequivalence study in support of the safety and efficacy of this product must be submitted within 12 months (by 03 February 2013).

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