
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 goedgekeur 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 rakleef tyd 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 rakleef tydperiode dek. Stabiliteitsstoets 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. Bemaking 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: 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: 07/3.1.1/19
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: BENZYL PENICILLIN 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, RANDJES PARK, 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, RANDJES PARK, 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: BENZYLAMINE 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:	41/28/0158
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	
Registration number:	41/28/0157
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

F 15	
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 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	
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 XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, RSA
	FPRR:
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	
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

F 15	
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		MRF15		MRF 15	
Registration number:	42/7.1.3/0766	Registration number:	42/7.1/0790	Registration number:	42/15.4/0835
Name of medicine:	CO MICARDIS 80/25 mg TABLETS	Name of medicine:	DYNA INDAPAMIDE SR	Name of medicine:	ALLERGAN BIMATOPROST 0,01 %
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	SOLUTION
Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 80,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Active ingredients:	EACH TABLET CONTAINS: INDAPAMIDE 1,5 mg	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: BIMATOPROST 0,1 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co.KG, INGELHEIM am RHEIN, GERMANY	Manufacturer:	KRKA, d.d. NOVO MESTO, NOVO MESTO, SLOVENIA	Manufacturer:	ALLERGAN, INC., WACO, TEXAS, USA
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co.KG, INGELHEIM am RHEIN, GERMANY	Packer:	KRKA, d.d. NOVO MESTO, NOVO MESTO, SLOVENIA	Packer:	ALLERGAN, INC., WACO, TEXAS, USA
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	Laboratory: FPRC:	KRKA, d.d. NOVO MESTO, NOVO MESTO, CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	ALLERGAN, INC., WACO, TEXAS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, RANDBURG, GAUTENG, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	FPRR:	ALLERGAN PHARMACEUTICALS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months (Provisional)
Date of registration:	25 NOVEMBER 2011	Date of registration:	25 NOVEMBER 2011	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 °C
24 hours stored at 2-8 °C

Date of registration: 25 NOVEMBER 2011

MRF 15

Registration number: 43/26/0348

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 °C
24 hours stored at 2-8 °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 Pte., TANCICS 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 Pte., TANCICS 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 Co, HILTON, KWA-ZULU
NATAL, RSA

FPRR: BAYER (PTY) LTD, ISANDO, GAUTENG,
RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2011

MRF 15

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
Pantoprazole 20,0 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) (PTY) 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) (PTY) 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) (PTY)
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

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 % <i>m/v</i>
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 % <i>m/v</i>
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

*SEE AT END OF BOOK FOR ADDITIONAL CONDITIONS

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: DANO VET 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, ONDERSTEEPOORT,
PRETORIA, RSA

FPRR: NTP RADIOISOTOPES (PTY) LTD, PELINDABA, PRETORIA, RSA

Shelf-life: 12 months
6 hours reconstituted product
stored at 25°C

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

MRF 15	
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	
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

F 15	
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

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

F 15

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 GENERIC 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 GENERIC 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		MRF15		RF 15	
Registration number:	42/2.5/0355	Registration number:	42/11.4.1/0390	Registration number:	42/2.6.5/0456
Name of medicine:	MYLAN OXCARBAZEPINE 300	Name of medicine:	MAALOX POCKET PACK	Name of medicine:	ZYDUS RISPERIDONE 1 TABLETS
Dosage form:	TABLET	Dosage form:	SUSPENSION	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXCARBAZEPINE 300,0 mg	Active ingredients:	EACH SACHET CONTAINS: ALUMINIUM OXIDE HYDRATED EQUIVALENT TO ALUMINIUM OXIDE 230,0 mg MAGNESIUM HYDROXIDE 400,0 mg	Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD	Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD	Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA	Manufacturer:	BK GIULINI GmbH, LUDWIGSHAFEN, GERMANY SANOFI-AVENTIS S.p.A., ORIGGIO, ITALY	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICUS UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UK MCDERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA	Packer:	VARIOPACK LOHNFERTIGUNGEN GmbH, NIDDA-HARB, GERMANY SANOFI-AVENTIS S.p.A., ORIGGIO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICUS 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	Laboratory: FPRC:	A NATTERMANN & CIE GmbH, COLOGNE, GERMANY SANOFI-AVENTIS S.p.A., ORIGGIO, ITALY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA	FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (Provisional)	Shelf-life:	36 months	Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012	Date of registration:	2 MARCH 2012	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