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1105	Wet op Beheer van Medisyne en Verwante Stowwe (101/1965): Medisyne-beheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalinge van artikel 15 (7)	4	32774

GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 1598 OF 2009

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 1598 VAN 2009**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. 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. 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 vrystellingssertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:	06/11.5/2
Name of medicine:	OMEPRACOTE
Dosage form:	PASTE
Active ingredients:	EACH 6,15 g PASTE CONTAINS: OMEPRAZOLE 2,2 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
Laboratory:	FPRC: CIPLA LTD, PLOT A, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
	FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	07/21.9/08
Name of medicine:	CONVENIA IV INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFOVECIN 852,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER INC, CONSHOHOCKEN, PHILLADELPHIA, USA PFIZER INC, KALAMAZOO, MICHGAN, USA
Packer:	PFIZER INC, CONSHOHOCKEN, PHILLADELPHIA, USA PFIZER INC, KALAMAZOO, MICHGAN, USA PFIZER ITALIA S.R.L., SAN MICHELE, LATINA, ITALY
Laboratory:	FPRC: PFIZER INC, KALAMAZOO, MICHGAN, USA PFIZER ITALIA S.R.L., SAN MICHELE, LATINA, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	07/34/09
Name of medicine:	CONVENIA WATER FOR INJECTIONS
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTIONS 10,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PATHEON UK LTD, COVINGHAM, SWINDON, WILTSHIRE, UK
Packer:	PATHEON UK LTD, COVINGHAM, SWINDON, WILTSHIRE, UK PFIZER INC, KALAMAZOO, MICHGAN, USA PFIZER ITALIA S.R.L., SAN MICHELE, LATINA, ITALY
Laboratory:	FPRC: PFIZER INC, KALAMAZOO, MICHGAN, USA PFIZER ITALIA S.R.L., SAN MICHELE, LATINA, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	37/18.3/0073
Name of medicine:	AXIM E-Z-GAS
Dosage form:	GRANULES
Active ingredients:	EACH 1,0 g GRANULES CONTAINS: CITRIC ACID 382,1 mg SODIUM BICARBONATE 551,4 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AXIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	TOWER LABORATORIES, CONNECTICUT, USA
Packer:	TOWER LABORATORIES, CONNECTICUT, USA
Laboratory:	FPRC: TOWER LABORATORIES, CONNECTICUT, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: AXIM PHAMACEUTICALS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	37/5.8/0552
Name of medicine:	CORENZA COLD AND FLU SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: PSEUDOEPHEDRINE HYDROCHLORIDE 5,0 mg CHLORPHENIRAMINE MALEATE 2,0 mg PARACETAMOL 120,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Laboratory:	FPRC: PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	38/5.8/0066
Name of medicine:	CHERICOF SOFTGELS
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: CHLORPHENIRAMINE MALEATE 2,0 mg DEXTROMETHORPHAN HYDROBROMIDE 10,0 mg PHENYLPROPANOLAMINE HYDROCHLORIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	38/5.8/0114
Name of medicine:	REACTYNE PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PSEUDOEPHEDRINE HYDROCHLORIDE 120,0 mg CETIRIZINE DIHYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	UCB FARCHIM S.A., CHEMIN DE CROIX, BULLE, SWITZERLAND
Packer:	UCB PHARMA S.A., PIANEZZA, TURIN, ITALY
Laboratory: FPRC:	UCB FARCHIM S.A., CHEMIN DE CROIX, BULLE, SWITZERLAND
FPRC/FPRR:	PFIZER LABORATORIES, RETREAT, CAPE TOWN
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	38/21.5.1/0125
Name of medicine:	ADCO-PREDNISOLONE SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: PREDNISOLONE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 38/20.2.6/0145
Name of medicine: NOVACLOR
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CHLOROQUINE PHOSPHATE
EQUIVALENT TO
CHLOROQUINE 150,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: MEDICINE DEVELOPERS INTERNATIONAL
cc
Manufacturer: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
Packer: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
Laboratory: FPRC: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE

FPRR MEDICINE DEVELOPERS
INTERNATIONAL, MENLO PARK,
PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 38/2.7/0300
Name of medicine: NOVODOL TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PARACETAMOL 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 8
Applicant: MEDICINE DEVELOPERS INTERNATIONAL
c.c.
Manufacturer: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
Packer: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
Laboratory: FPRC: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE

FPRR: MEDICINE DEVELOPERS INTERNATIONAL
c.c, MENLO PARK, PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	A38/7.1/0654
Name of medicine:	RAMI BLOCK 5/5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 5,0 mg FELODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN
Packer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory: FPRC:	ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
FPRC/FPRR	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	A38/7.1/0655
Name of medicine:	RAMI BLOCK 2,5/2,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RAMIPRIL 2,5 mg FELODIPINE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN
Packer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory: FPRC	ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
FPRC/FPRR	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: A38/2.9/0701
Name of medicine: SABAX PETHIDINE 25
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
PETHIDINE HYDROCHLORIDE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer: PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG

Packer: PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG

Laboratory: FPRC: PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG

FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG

Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A39/21.8.1/0076
Name of medicine: ESTREVA GEL
Dosage form: GEL
Active ingredients: EACH 1,0 g GEL CONTAINS:
OESTRADIOL HEMIHYDRATE EQUIVALENT TO
OESTRADIOL 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK (PTY) LTD
Manufacturer: LABORATOIRE CHEMINEAU, VOUVRAY, FRANCE
LABORATOIRE THERAMEX, CEDEX, MONACO

Packer: LABORATOIRE CHEMINEAU, VOUVRAY, FRANCE
LABORATOIRE THERAMEX, CEDEX, MONACO

Laboratory: FPRC: LABORATOIRE CHEMINEAU, VOUVRAY, FRANCE
LABORATOIRE THERAMEX, CEDEX, MONACO
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON. RSA

FPRR: MERCK, MODDERFONTEIN, RSA

Shelf-life: 36 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A39/5.7.1/0309
 Name of medicine: LAMIFEM 1 % CREAM
 Dosage form: CREAM
 Active ingredients: EACH 1,0 g CREAM CONTAINS:
 TERBINAFINE HYDROCHLORIDE 10,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
 Manufacturer: NOVARTIS CONSUMER HEALTH SA,
 NYON, SWITZERLAND
 NOVARTIS PHARMA GmbH, WEHR,
 GERMANY

 Packer: NOVARTIS CONSUMER HEALTH SA,
 NYON, SWITZERLAND
 NOVARTIS PHARMA GmbH, WEHR,
 GERMANY

 Laboratory: FPRC: NOVARTIS CONSUMER HEALTH SA,
 NYON, SWITZERLAND
 NOVARTIS PHARMA GmbH, WEHR,
 GERMANY

 FPRR: NOVARTIS S.A., SPARTAN, KEMPTON
 PARK

 Shelf-life: 36 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A39/7.1.3/0508
 Name of medicine: TARKA 180/2
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 VERAPAMIL HYDROCHLORIDE 180,0 mg
 TRANDOLAPRIL 2,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ABBOTT LABORATORIES SA (PTY) LTD
 Manufacturer: ABBOTT GmbH & CO, LUDWIGSHAFEN,
 GERMANY

 Packer: ABBOTT GmbH & CO, LUDWIGSHAFEN,
 GERMANY

 Laboratory: FPRC: ABBOTT GmbH & CO, LUDWIGSHAFEN,
 GERMANY

 FPRC/FPRR: ABBOTT LABORATORIES SA,
 CONSTANTIAKLOOF, JOHANNESBURG

 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A39/7.1/0538
Name of medicine: VASCULEX 5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE BESYLATE EQUIVALENT TO
AMLODIPINE 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY
HEXAL A/S, HVIDOVRE, DENMARK
Packer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE, RSA
Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: HEXAL PHARMA, PINETOWN, KZN
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A39/7.1.3/0547
Name of medicine: TARKA 240/4
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VERAPAMIL HYDROCHLORIDE 240,0 mg
TRANOLAPRIL 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ABBOTT LABORATORIES SA (PTY) LTD
Manufacturer: ABBOTT GmbH & CO, LUDWIGSHAFEN,
GERMANY
Packer: ABBOTT GmbH & CO, LUDWIGSHAFEN,
GERMANY
Laboratory: FPRC: ABBOTT GmbH & CO, LUDWIGSHAFEN,
GERMANY
FPRC/FPRR: ABBOTT LABORATORIES SA,
CONSTANTIAKLOOF, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A39/3.1/0564
Name of medicine: CATAFAST SACHETS
Dosage form: POWDER
Active ingredients: EACH SACHET CONTAINS:
DICLOFENAC SODIUM 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer: MIPHARM S.p.A., MILAN, ITALY
Packer: MIPHARM S.p.A., MILAN, ITALY
NOVARTIS S.A., SPARTAN, KEMPTON
PARK
Laboratory: FPRC: MIPHARM S.p.A., MILAN, ITALY
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON
PARK
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A40/7.1.5/0131
Name of medicine: REVATIO
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SILDENAFIL 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PFIZER LABORATORIES (PTY) LTD
Manufacturer: PFIZER PGM, POCE SUR CISSE,
AMBOISE, FRANCE
Packer: PFIZER PGM, POCE SUR CISSE,
AMBOISE, FRANCE
PFIZER Inc, BROOKLYN, NEW YORK, USA
Laboratory: FPRC: PFIZER PGM, POCE SUR CISSE,
AMBOISE, FRANCE
PFIZER Inc, BROOKLYN, NEW YORK, USA
FPRC/FPRR: PFIZER LABORATORIES, RETREAT, CAPE
TOWN
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A40/30.3/0215
Name of medicine: IMMUNATE 250 I.U.
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
HUMAN COAGULATION FACTOR VIII 250,0 I.U.

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer: BAXTER AG, VIENNA, AUSTRIA
BAXTER AG BENATZKYGASSE, VIENNA, AUSTRIA
BAXTER S.p.A., RUFINA, ITALY
BAXTER AG INDUSTRIESTRASSE, VIENNA,
AUSTRIA
BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA

Packer: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG

Laboratory: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA
FPRC: BAXTER VACCINE AG, ORTH/DONAU, AUSTRIA

FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG

Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A40/30.3/0216
Name of medicine: IMMUNATE 500 I.U.
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
HUMAN COAGULATION FACTOR VIII 500,0 I.U.

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer: BAXTER AG, VIENNA, AUSTRIA
BAXTER AG BENATZKYGASSE, VIENNA,
AUSTRIA
BAXTER S.p.A., RUFINA, ITALY
BAXTER AG INDUSTRIESTRASSE, VIENNA,
AUSTRIA
BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA

Packer: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG

Laboratory: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA
FPRC: BAXTER VACCINE AG, ORTH/DONAU, AUSTRIA

FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG

Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A40/30.3/0217
 Name of medicine: IMMUNATE 1 000 I.U.
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 HUMAN COAGULATION FACTOR VIII 1 000,0 I.U.
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD
 Manufacturer: BAXTER AG, VIENNA, AUSTRIA
 BAXTER AG BENATZKYGASSE, VIENNA,
 AUSTRIA
 BAXTER S.p.A., RUFINA, ITALY
 BAXTER AG INDUSTRIESTRASSE, VIENNA,
 AUSTRIA
 BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA
 Packer: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA
 ADCOCK INGRAM CRITICAL CARE, AEROTON,
 JOHANNESBURG
 Laboratory: FPRC: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA
 BAXTER VACCINE AG, ORTH/DONAU, AUSTRIA
 FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
 JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A40/11/0374
 Name of medicine: PENTASA 1 g
 Dosage form: SUPPOSITORY
 Active ingredients: EACH SUPPOSITORY CONTAINS:
 MESALAZINE 1,0 g
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: FERRING (PTY) LTD
 Manufacturer: FERRING A/S, VANLOSE, DENMARK
 EUROFINS DENMARK A/S, VALLENSBAE
 STRAND, DENMARK
 Packer: FERRING A/S, VANLOSE, DENMARK
 Laboratory: FPRC: FERRING A/S, VANLOSE, DENMARK
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 COSI PHARMACEUTICALS, INDUSTRIA-WEST,
 JOHANNESBURG
 FPRR: FERRING, IRENE, CENTURION
 Shelf-life: 36 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	A40/7.1.3/0403
Name of medicine:	OLMETEC 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY
Packer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY BERLIN-CHEMIE, GLIENICKER, BERLIN, GERMANY QUALIPHAR NV/SA, BORNEM, BELGIUM
Laboratory:	FPRC: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY BERLIN-CHEMIE, GLIENICKER, BERLIN, GERMANY QUALIPHAR NV/SA, BORNEM, BELGIUM
	FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
	FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	A40/7.1.3/0404
Name of medicine:	OLMETEC 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY
Packer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY BERLIN-CHEMIE, GLIENICKER, BERLIN, GERMANY QUALIPHAR NV/SA, BORNEM, BELGIUM
Laboratory:	FPRC: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY BERLIN-CHEMIE, GLIENICKER, BERLIN, GERMANY QUALIPHAR NV/SA, BORNEM, BELGIUM
	FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
	FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: A40/11.10/0480
 Name of medicine: GAVISCON PLUS LIQUID
 Dosage form: SUSPENSION
 Active ingredients: EACH 10,0 ml SUSPENSION CONTAINS:
 SODIUM ALGinate 500,0 mg
 SODIUM BICARBONATE 213,0 mg
 CALCIUM CARBONATE 325,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: RECKITT BENCKISER
 PHARMACEUTICALS (PTY) LTD
 Manufacturer: RECKITT BENCKISER HEALTHCARE (UK),
 HULL, EAST YORKSHIRE, UK
 Packer: RECKITT BENCKISER HEALTHCARE (UK),
 HULL, EAST YORKSHIRE, UK
 Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE (UK),
 HULL, EAST YORKSHIRE, UK
 CONSULTING CHEMICAL LABORATORY
 SERVICES, ATLASVILLE, BOKSBURG
 FPRC/FPRR: RECKITT BENCKISER
 PHARMACEUTICALS, ELANDSFONTEIN
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A40/29/0530
 Name of medicine: OCTREOSCAN 111
 Dosage form: INJECTION
 Active ingredients: EACH PACK CONTAINS:
 VIAL A CONTAINING:
 INDIUM (III) CHLORIDE 122,0 MBq
 VIAL B CONTAINING:
 PENTETREOTIDE 10,0 ug
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: COVIDIEN (PTY) LTD
 Manufacturer: MALLINCKRODT MEDICAL BV, PETTEN, THE
 NETHERLANDS
 Packer: MALLINCKRODT MEDICAL BV, PETTEN, THE
 NETHERLANDS
 Laboratory: FPRC: MALLINCKRODT MEDICAL BV, PETTEN, THE
 NETHERLANDS
 FPRR: COVIDIEN, RANDJES PARK, MIDRAND
 Shelf-life: 8 days for vial A stored at or below 25 °C
 24 months for vial B stored at 2 – 8 °C
 8 days for the kit (vials A & B) stored at or below
 25 °C
 6 hours for the labelled product stored at or
 below 25 °C
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	A40/26/0544
Name of medicine:	EBETAXEL 30 mg
Dosage form:	INFUSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAFRICA (PTY) LTD
Manufacturer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Packer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Laboratory:	FPRC: EBEWE PHARMA GmbH, UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+SAG, BAD BOCKLET, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PHARMAFRICA, NEW CENTRE, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	A40/26/0545
Name of medicine:	EBETAXEL 100 mg
Dosage form:	INFUSION
Active ingredients:	EACH 16,6 ml SUSPENSION CONTAINS: PACLITAXEL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAFRICA (PTY) LTD
Manufacturer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Packer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Laboratory:	FPRC: EBEWE PHARMA GmbH, UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+SAG, BAD BOCKLET, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PHARMAFRICA, NEW CENTRE, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	A40/26/0546
Name of medicine:	EBETAXEL 150 mg
Dosage form:	INFUSION
Active ingredients:	EACH 25,0 ml SUSPENSION CONTAINS: PACLITAXEL 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAFRICA (PTY) LTD
Manufacturer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Packer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Laboratory:	FPRC: EBEWE PHARMA GmbH, UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+SAG, BAD BOCKLET, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PHARMAFRICA, NEW CENTRE, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	A40/26/0547
Name of medicine:	EBETAXEL 300 mg
Dosage form:	INFUSION
Active ingredients:	EACH 50,0 ml SUSPENSION CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAFRICA (PTY) LTD
Manufacturer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Packer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
Laboratory:	FPRC: EBEWE PHARMA GmbH, UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+SAG, BAD BOCKLET, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PHARMAFRICA, NEW CENTRE, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	A40/20.1.1/0555
Name of medicine:	CLAREN 500 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	ELPEN S.A, PIKERMI, ATTICA, GREECE
Packer:	ELPEN S.A, PIKERMI, ATTICA, GREECE
Laboratory:	FPRC: ELPEN S.A, PIKERMI, ATTICA, GREECE
	FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	A40/2.5/0587
Name of medicine:	KEPPRA 100 mg
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LEVETIRACETAM 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AHN PHARMA (PTY) LTD
Manufacturer:	NEXTPHARMA SAS, LIMAY, FRANCE PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	NEXTPHARMA SAS, LIMAY, FRANCE PHARMACARE LTD, KORSTEN, PORT ELIZABETH DRA PHARMACEUTICALS, CORPORATE PARK, IRENE
Laboratory:	FPRC: NEXTPHARMA SAS, LIMAY, FRANCE PHARMACARE LTD, KORSTEN, PORT ELIZABETH UCB s.a. PHARMA SECTOR, BRAINE- L'ALLEUD, BELGIUM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: AHN PHARMA, WOODMEAD, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: A40/23/0657

Name of medicine: VAMINOLACT

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:

ALANINE	6,3 g	LYSINE	5,6 g
ARGININE	4,1 g	METHIONINE	1,3 g
ASPARTIC ACID	4,1 g	PHENYLALANINE	2,7 g
CYSTEINE	1,0 g	PROLINE	5,6 g
GLUTAMIC ACID	7,1 g	SERINE	3,8 g
GLYCINE	2,1 g	TAURINE	0,3 g
HISTIDINE	2,1 g	THREONINE	3,6 g
ISOLEUCINE	3,1 g	TRYPTOPHAN	1,4 g
LEUCINE	7,0 g	TYROSINE	0,5 g
VALINE	3,6 g		

Conditions of registration: 1, 2, 3, 4, 5, 6, 8

Applicant: FRESENIUS KABI S.A. (PTY) LTD

Manufacturer: FRESENIUS KABIA AUSTRIA GmbH, GRAZ, AUSTRIA

Packer: FRESENIUS KABIA AUSTRIA GmbH, GRAZ, AUSTRIA

Laboratory: FPRC: FRESENIUS KABIA AUSTRIA GmbH, GRAZ, AUSTRIA
KHULULEKANI LABORATORY SERVICES, RANJES PARK, MIDRAND

FPRR: FRESENIUS KABI, HALFWAY HOUSE, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A40/2.5/0699

Name of medicine: SODIUM VALPROATE IV-WINTHROP

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
SODIUM VALPROATE 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: WINTHROP PHARMACEUTICALS (PTY) LTD

Manufacturer: GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE

Packer: GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA

Laboratory: FPRC: GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE
WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG

FPRR: WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
WINTHROP PHARMACEUTICALS, MIDRAND, RSA

Shelf-life: 60 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: A40/34/0781
 Name of medicine: SOLVENT FOR SODIUM VALPROATE IV
 Dosage form: INJECTION
 Active ingredients: EACH AMPOULE CONTAINS:
 WATER FOR INJECTIONS 4,0 ml

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: WINTHROP PHARMACEUTICALS (PTY) LTD
 Manufacturer: SANOFI WINTHROP INDUSTRIE, AMBARES,
 FRANCE
 CHINOIN-CSANYIKVOLGY INJECTION PLANT,
 MISKOLC, HUNGARY
 Packer: SANOFI WINTHROP INDUSTRIE, AMBARES,
 FRANCE
 CHINOIN-CSANYIKVOLGY INJECTION PLANT,
 MISKOLC, HUNGARY
 GLAXO WELLCOME PRODUCTION CO, NOTRE
 DAME DE BONDEVILLE, FRANCE
 WINTHROP PHARMACEUTICALS, WALTLOO,
 PRETORIA
 Laboratory: FPRC: GLAXO WELLCOME PRODUCTION CO, NOTRE
 DAME DE BONDEVILLE, FRANCE
 WINTHROP PHARMACEUTICALS, WALTLOO,
 PRETORIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 FPRR: WINTHROP PHARMACEUTICALS, MIDRAND,
 RSA
 WINTHROP PHARMACEUTICALS, WALTLOO,
 PRETORIA
 Shelf-life: 60 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/21.5/0016
 Name of medicine: CORTAJECT 100 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 HYDROCORTISONE SODIUM SUCCINATE
 EQUIVALENT TO
 HYDROCORTISONE 100,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 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
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 FPRR: STRIDES S.A. PHARMACEUTICALS, ARCADIA,
 PRETORIA
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/21.5/0017
 Name of medicine: CORTAJECT 500 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 HYDROCORTISONE SODIUM SUCCINATE
 EQUIVALENT TO HYDROCORTISONE
 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 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
 NOVARTIS S.A., SPARTAN, KEMPTON
 PARK
 FPRR: STRIDES S.A. PHARMACEUTICALS,
 ARCADIA, PRETORIA
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/21.12/0020
 Name of medicine: DRL-FINASTERIDE 5
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 FINASTERIDE 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: DR REDDY'S LABORATORIES LTD, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE, CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD
 PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/5.7.2/0048

Name of medicine: MYLAN GRANISETRON 3 mg/3 ml

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml SOLUTION CONTAINS:
GRANISETRON HYDROCHLORIDE
EQUIVALENT TO GRANISETRON 3,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SCP PHARMACEUTICALS (PTY) LTD

Manufacturer: ECZACIBASI ILAC SANAYI, LULEBURGAZ,
TURKEY

Packer: ECZACIBASI ILAC SANAYI, LULEBURGAZ,
TURKEY

Laboratory: FPRC: ECZACIBASI ILAC SANAYI, LULEBURGAZ,
TURKEY
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
MERCK PHARMACEUTICAL
MANUFACTURING, WADEVILLE,
GERMISTON

FPRR: SCP PHARMACEUTICALS,
MODDERFOTEIN, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/20.1.2/0122

Name of medicine: AURO AMPICILLIN INJECTION 500 mg

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
AMPICILLIN SODIUM EQUIVALENT TO
AMPICILLIN 500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, HYDERABAD,
ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, HYDERABAD,
ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, HYDERABAD,
ANDHRA PRADESH, INDIA

FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/20.1.2/0123
 Name of medicine: AURO AMPICILLIN INJECTION 1 000 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 AMPICILLIN SODIUM EQUIVALENT TO
 AMPICILLIN 1 000,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
 MANDAL, HYDERABAD, ANDHRA PRADESH,
 INDIA

 Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
 MANDAL, HYDERABAD, ANDHRA PRADESH,
 INDIA

 Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
 MANDAL, HYDERABAD, ANDHRA PRADESH,
 INDIA

 FPRR: AUROBINDO PHARMA, MEYERSDAL,
 JOHANNESBURG

 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/24/0137
 Name of medicine: RINGER'S LACTATE B BRAUN
 Dosage form: INFUSION
 Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
 SODIUM CHLORIDE 6,000 g
 POTASSIUM CHLORIDE 0,400 g
 CALCIUM CHLORIDE DIHYDRATE 0,270 g
 SODIUM LACTATE 3,120 g

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: B BRAUN MEDICAL (PTY) LTD
 Manufacturer: B BRAUN MELSUNGEN AG, MELSUNGEN,
 GERMANY
 PRODUCTION PHARMA PFIEFFEWIESEN,
 MELSUNGEN, GERMANY
 B BRAUN MEDICAL S.A., RUBI, BARCELONA,
 SPAIN

 Packer: B BRAUN MELSUNGEN AG, MELSUNGEN,
 GERMANY
 PRODUCTION PHARMA PFIEFFEWIESEN,
 MELSUNGEN, GERMANY
 B BRAUN MEDICAL S.A., RUBI, BARCELONA,
 SPAIN

 Laboratory: FPRC: B BRAUN MELSUNGEN AG, MELSUNGEN,
 GERMANY
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 COSI PHARMACEUTICALS, INDUSTRIA WEST,
 JOHANNESBURG
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG

 FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG.

 Shelf-life: 36 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/21.5.1/0225
Name of medicine: DEXONA INJECTION
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
DEXAMETHASONE SODIUM PHOSPHATE
EQUIVALENT TO
DEXAMETHASONE PHOSPHATE 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ZYDUS HEALTHCARE (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
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/21.1/0348
Name of medicine: INSULIN GLULISINE-WINTHROP
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
INSULIN GLULISINE EQUIVALENT TO
HUMAN INSULIN 100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer: AVENTIS PHARMA DEUTSCHLAND GmbH,
FRANKFURT, GERMANY
Packer: AVENTIS PHARMA DEUTSCHLAND GmbH,
FRANKFURT, GERMANY
WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA

Laboratory: FPRC: AVENTIS PHARMA DEUTSCHLAND GmbH,
FRANKFURT, GERMANY

FPRC/FPRR: WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA

FPRR SANOFI-AVENTIS S.A., MIDRAND, RSA

Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	41/21.1/0349
Name of medicine:	INSULIN GLULISINE SANOFI-AVENTIS
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: INSULIN GLULISINE EQUIVALENT TO HUMAN INSULIN 100,0 IU
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Packer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/20.1.1/0376
Name of medicine:	CEFEPIME SAFELINE 1 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME HYDROCHLORIDE EQUIVALENT TO CEFEPIME 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEMO S.A., LAMIA, ATHENS, GREECE
Packer:	DEMO S.A., LAMIA, ATHENS, GREECE
Laboratory:	FPRC: DEMO S.A., LAMIA, ATHENS, GREECE
FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/20.1.1/0405
Name of medicine:	CLAREN 250 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	ELPEN S.A, PIKERMI, ATTICA, GREECE
Packer:	ELPEN S.A, PIKERMI, ATTICA, GREECE
Laboratory:	FPRC: ELPEN S.A, PIKERMI, ATTICA, GREECE
	FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/2.6.5/0452
Name of medicine:	REDDON 0,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/2.6.5/0453
Name of medicine:	REDDON 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:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/2.6.5/0454
Name of medicine:	REDDON 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:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 41/2.6.5/0455
Name of medicine: REDDON 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: DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE,
CENTURION
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/2.6.5/0456
Name of medicine: REDDON 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: DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE,
CENTURION
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
BACHUPALLY VILLAGE, QUTUBULLAPUR
MANDAL, RANGA REDDY DISTRICT,
ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/29/0486
 Name of medicine: TECHNESCAN DMSA
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 DIMERCAPTOSUCCINIC ACID 1,2 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: COVIDIEN (PTY) LTD
 Manufacturer: MALLINCKRODT MEDICAL B.V., PETTEN,
 HOLLAND
 Packer: MALLINCKRODT MEDICAL B.V., PETTEN,
 HOLLAND

 Laboratory: FPRC: MALLINCKRODT MEDICAL B.V., PETTEN,
 HOLLAND
 PET LABS PHARMACEUTICAL,
 GROENKLOOF, PRETORIA
 BIOCHEMICAL & SCIENTIFIC CONSULTANTS,
 HILTON, KZN

 FPRR: COVIDIEN, RANDJES PARK, MIDRAND

 Shelf-life: 12 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/26/0489
 Name of medicine: HEXAL GEMCITABINE 1 g IVI
 Dosage form: INFUSION
 Active ingredients: EACH VIAL CONTAINS:
 GEMCITABINE HYDROCHLORIDE
 EQUIVALENT TO GEMCITABINE 1,0 g

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: HEXAL PHARMA (SA) (PTY) LTD
 Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA

 Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 TECHNIKON LABORATORIES, ROBERTVILLE,
 FLORIDA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK

 Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 NOVARTIS S.A., SPARTAN, KEMPTON PARK

 FPRR: HEXAL PHARMA, MAHOGANY RIDGE,
 PINETOWN

 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/26/0490

Name of medicine: HEXAL GEMCITABINE 200 mg IVI

Dosage form: INFUSION

Active ingredients: EACH VIAL CONTAINS:
GEMCITABINE HYDROCHLORIDE
EQUIVALENT TO GEMCITABINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA

Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE, JOHANNESBURG
TECHNIKON LABORATORIES,
ROBERTVILLE, FLORIDA
NOVARTIS S.A., SPARTAN, KEMPTON
PARK

Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
NOVARTIS S.A., SPARTAN, KEMPTON
PARK

FPRR: HEXAL PHARMA, MAHOGANY RIDGE,
PINETOWN

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/26/0491

Name of medicine: SANDOZ GEMCITABINE 1 g IVI

Dosage form: INFUSION

Active ingredients: EACH VIAL CONTAINS:
GEMCITABINE HYDROCHLORIDE
EQUIVALENT TO GEMCITABINE 1,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA

Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
DIVPHARM MANUFACTURING &
PACKAGING; LONGDALE, JOHANNESBURG
TECHNIKON LABORATORIES,
ROBERTVILLE, FLORIDA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
NOVARTIS S.A., SPARTAN, KEMPTON PARK

FPRR: HEXAL PHARMA, PINETOWN, KZN

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/26/0492
 Name of medicine: SANDOZ GEMCITABINE 250 mg IVI
 Dosage form: INFUSION
 Active ingredients: EACH VIAL CONTAINS:
 GEMCITABINE HYDROCHLORIDE EQUIVALENT
 TO GEMCITABINE 250,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: HEXAL PHARMA (S.A.) (PTY) LTD
 Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 DIVPHARM MANUFACTURING & PACKAGING;
 LONGDALE, JOHANNESBURG
 TECHNIKON LABORATORIES, ROBERTVILLE,
 FLORIDA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 FPRR: HEXAL PHARMA, PINETOWN, KZN
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/35/0544
 Name of medicine: GLUSCAN
 Dosage form: INJECTION
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 FLUDEOXYGLUCOSE [^{18}F] 600,0 MBq
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: CYCLOTOPE (PTY) LTD
 Manufacturer: CYCLOTOPE, PELINDABA WEST,
 PRETORIA WEST
 ITHEMBA LABS, FAURE, CAPE TOWN
 Packer: CYCLOTOPE, PELINDABA WEST,
 PRETORIA WEST
 ITHEMBA LABS, FAURE, CAPE TOWN
 Laboratory: FPRC: ITHEMBA LABS, FAURE, CAPE TOWN
 ATOMIC ENERGY CORPORATION
 PELINDABA, PRETORIA-WEST
 FPRC/FPRR: CYCLOTOPE, PELINDABA WEST,
 PRETORIA WEST
 Shelf-life: 12 hours
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/7.5/0556
Name of medicine: LIPANTHYL 160 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
FENOFIBRATE 160,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SOLVAY PHARMA (PTY) LTD
Manufacturer: LABORATORIES FOURNIER SA,
FONTAINE-LES-DIJON, FRANCE
Packer: LABORATORIES FOURNIER SA,
FONTAINE-LES-DIJON, FRANCE

Laboratory: FPRC: LABORATORIES FOURNIER SA,
FONTAINE-LES-DIJON, FRANCE

FPRR: SOLVAY PHARMA, RANDJESPAK,
MIDRAND
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/5.3/0564
Name of medicine: MERCK GALANTAMINE 4
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
GALANTAMINE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer: ALPHAPHARM, BRISBANE, QUEENSLAND,
AUSTRALIA
Packer: ALPHAPHARM, BRISBANE, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERIC UK LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERIC UK LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/5.3/0565
 Name of medicine: MERCK GALANTAMINE 8
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 GALANTAMINE 8,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: XIXIA PHARMACEUTICALS (PTY) LTD
 Manufacturer: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 Packer: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON
 GENERICS UK LTD, POTTERS BAR,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 Laboratory: FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON
 GENERICS UK LTD, POTTERS BAR,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
 RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/5.3/0566
 Name of medicine: MERCK GALANTAMINE 12
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 GALANTAMINE 12,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: XIXIA PHARMACEUTICALS (PTY) LTD
 Manufacturer: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 Packer: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON
 GENERICS UK LTD, POTTERS BAR,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 Laboratory: FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON
 GENERICS UK LTD, POTTERS BAR,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
 RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	41/1.2/0567
Name of medicine:	MYLAN ESCITALOPRAM 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICIS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/1.2/0568
Name of medicine:	MYLAN ESCITALOPRAM 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICIS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/1.2/0569
Name of medicine:	MYLAN ESCITALOPRAM 15
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/1.2/0570
Name of medicine:	MYLAN ESCITALOPRAM 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/8.2/0611
Name of medicine:	ARROW CLOPIDOGREL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL BISULPHITE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory: FPRC:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA
FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/15.4/0629
Name of medicine:	OCULET
Dosage form:	EYE DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: POVIDONE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMAFRICA (PTY) LTD
Manufacturer:	URSAPHARM ARZNEIMITTEL GmbH & Co, SAARBRUCKEN, GERMANY
Packer:	URSAPHARM ARZNEIMITTEL GmbH & Co, SAARBRUCKEN, GERMANY
Laboratory: FPRC:	URSAPHARM ARZNEIMITTEL GmbH & Co, SAARBRUCKEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAFRICA, NEW CENTRE, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 41/7.1.3/0630
Name of medicine: SPEC PERINDOPRIL PLUS 2
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL TERT-BUTYLAMINE 2,0 mg
INDAPAMIDE 0,625 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE
FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/7.1.3/0631
Name of medicine: SPEC PERINDOPRIL PLUS 4
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL TERT-BUTYLAMINE 2,0 mg
INDAPAMIDE 0,625 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS,
GREECE
Packer: SPECIFAR S.A., VARVARA, ATHENS,
GREECE
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS,
GREECE
FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/3.1/0643
Name of medicine: DIPOFAST DROPS
Dosage form: DROPS
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
DICLOFENAC POTASSIUM 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: LABORATORIO FARMACOLOGICO MILANESE
s.r.l., CARONNO PERTUSELLA, ITALY
Packer: LABORATORIO FARMACOLOGICO MILANESE
s.r.l., CARONNO PERTUSELLA, ITALY
Laboratory: FPRC: LABORATORIO FARMACOLOGICO MILANESE
s.r.l., CARONNO PERTUSELLA, ITALY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 36 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/21.5.1/0664
Name of medicine: TRIAMCINOLONE WINTHROP
Dosage form: NASAL SPRAY
Active ingredients: EACH ACTUATION CONTAINS:
TRIAMCINOLONE ACETONIDE 55,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer: AVENTIS PHARMA, HOLMES CHAPEL,
CHESHIRE, UK
Packer: AVENTIS PHARMA, HOLMES CHAPEL,
CHESHIRE, UK
WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA
Laboratory: FPRC: AVENTIS PHARMA, HOLMES CHAPEL,
CHESHIRE, UK
FPRC/FPRR: WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA
FPRR: SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/21.5.1/0665
 Name of medicine: TRIAMCINOLONE SANOFI-AVENTIS
 Dosage form: NASAL SPRAY
 Active ingredients: EACH ACTUATION CONTAINS:
 TRIAMCINOLONE ACETONIDE 55,0 ug
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
 Manufacturer: AVENTIS PHARMA, HOLMES CHAPEL,
 CHESHIRE, UK
 Packer: AVENTIS PHARMA, HOLMES CHAPEL,
 CHESHIRE, UK
 WINTHROP PHARMACEUTICALS, WALTLOO,
 PRETORIA
 Laboratory: FPRC: AVENTIS PHARMA, HOLMES CHAPEL,
 CHESHIRE, UK
 FPRC/FPRR: WINTHROP PHARMACEUTICALS, WALTLOO,
 PRETORIA
 FPRR: SANOFI-AVENTIS S.A., MIDRAND, RSA
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/2.6.5/0748
 Name of medicine: AUROPIDONE 0,5 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 0,5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 FPRR: AUROBINDO PHARMA, MEYERSDAL,
 JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/11.4.1/0772
Name of medicine: DIGESTIF RENNIE ORANGE TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CALCIUM CARBONATE 680,0 mg
MAGNESIUM CARBONATE 80,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: BAYER (PTY) LTD
Manufacturer: BAYER SANTE FAMILIALE, GAILLARD, FRANCE
Packer: BAYER SANTE FAMILIALE, GAILLARD, FRANCE
ROCHE PRODUCTS, ISANDO, RSA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
Laboratory: FPRC: BAYER SANTE FAMILIALE, GAILLARD, FRANCE
ROCHE PRODUCTS, ISANDO, RSA
FPRR: BAYER, ISANDO, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0884
Name of medicine: ARANESP 10 ug
Dosage form: INJECTION
Active ingredients: EACH 0,4 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 10,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer: AMGEN INC, THOUSAND OAKS,
CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA
Packer: AMGEN EUROPE B.V., BREDA, THE
NETHERLANDS
Laboratory: FPRC: CHARLES RIVERS LABORATORIES,
TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE
NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE,
UK
FPRR: BATSWADI PHARMACEUTICALS,
BRYANSTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0885

Name of medicine: ARANESP 15 ug

Dosage form: INJECTION

Active ingredients: EACH 0,375 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 15,0 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD

Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA

Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS

Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK

FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG

Shelf-life: 24 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0886

Name of medicine: ARANESP 20 ug

Dosage form: INJECTION

Active ingredients: EACH 0,5 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 20,0 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD

Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA

Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS

Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK

FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG

Shelf-life: 24 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0887
Name of medicine: ARANESP 30 ug
Dosage form: INJECTION
Active ingredients: EACH 0,3 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 30,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA
Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0888
Name of medicine: ARANESP 40 ug
Dosage form: INJECTION
Active ingredients: EACH 0,4 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 40,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA
Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0889
Name of medicine: ARANESP 50 ug
Dosage form: INJECTION
Active ingredients: EACH 0,5 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 50,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA
Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0890
Name of medicine: ARANESP 60 ug
Dosage form: INJECTION
Active ingredients: EACH 0,3 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 60,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA
Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0891

Name of medicine: ARANESP 80 ug

Dosage form: INJECTION

Active ingredients: EACH 0,4 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 80,0 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD

Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA

Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS

Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK

FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG

Shelf-life: 24 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0892

Name of medicine: ARANESP 100 ug

Dosage form: INJECTION

Active ingredients: EACH 0,5 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 100,0 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD

Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA

Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS

Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK

FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG

Shelf-life: 24 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0893
 Name of medicine: ARANESP 150 ug
 Dosage form: INJECTION
 Active ingredients: EACH 0,3 ml SOLUTION CONTAINS:
 DARBEPOETIN ALFA 150,0 ug
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD
 Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
 AMGEN INC, LONGMONT, COLORADO, USA
 Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
 Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
 OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
 NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
 FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0894
 Name of medicine: ARANESP 300 ug
 Dosage form: INJECTION
 Active ingredients: EACH 0,6 ml SOLUTION CONTAINS:
 DARBEPOETIN ALFA 300,0 ug
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD
 Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
 AMGEN INC, LONGMONT, COLORADO, USA
 Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
 Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
 OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
 NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
 FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/8.3/0895
Name of medicine: ARANESP 500 ug
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
DARBEPOETIN ALFA 500,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer: AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
AMGEN INC, LONGMONT, COLORADO, USA
Packer: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory: FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/7.1.3/0941
Name of medicine: ACECYL 2 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL TERT-BUTYLAMINE 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: THEBE MEDICARE (PTY) LTD
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
FPRR: THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	41/7.1.3/0942
Name of medicine:	ACECYL 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Laboratory:	FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
	FPRR: THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/7.1.3/0943
Name of medicine:	ACECYL 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Laboratory:	FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
	FPRR: THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 41/1.2/0944
Name of medicine: ILLOVEX SR 37,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VENLAFAXINE HYDROCHLORIDE EQUIVALENT
TO VENLAFAXINE 37,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
Packer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI,
KZN
Laboratory: FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/1.2/0945
Name of medicine: ILLOVEX SR 75 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
VENLAFAXINE HYDROCHLORIDE
EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
Packer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES,
N'DABENI, KZN
Laboratory: FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND
ACTAVIS LTD, ZEJTUN, MALTA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/1.2/0946
 Name of medicine: ILLOVEX SR 150 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 VENLAFAXINE HYDROCHLORIDE EQUIVALENT
 TO VENLAFAXINE 150,0mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 Packer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 PHARMACEUTICAL ENTERPRISES, N'DABENI,
 KZN
 Laboratory: FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/21.5.1/0967
 Name of medicine: GENEMIST
 Dosage form: SUSPENSION
 Active ingredients: EACH SPRAY CONTAINS:
 FLUTICASONE FUROATE 27,5 ug
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY)
 LTD
 Manufacturer: GLAXO OPERATIONS UK LTD, BARNARD
 CASTLE, COUNTY DURHAM, UK
 Packer: GLAXO OPERATIONS UK LTD, BARNARD
 CASTLE, COUNTY DURHAM, UK
 GLAXOSMITHKLINE S.A., EPPING, CAPE
 TOWN
 Laboratory: FPRC: GLAXO OPERATIONS UK LTD, BARNARD
 CASTLE, COUNTY DURHAM, UK
 FPRC/FPRR: GLAXOSMITHKLINE S.A., EPPING, CAPE
 TOWN
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	41/20.2.8/0988
Name of medicine:	ASPEN ABACAVIR 20 mg/ml
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN PORT ELIZABETH GLAXOSMITHKLINE, EPPING, CAPE TOWN
Packer:	PHARMACARE LTD, KORSTEN PORT ELIZABETH GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory:	FPRC: M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM GLAXOSMITHKLINE, EPPING, CAPE TOWN
	FPRC/FPRR: PHARMACARE LTD, KORSTEN PORT ELIZABETH
	FPRR PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/5.3/1012
Name of medicine:	SANDOZ GALANTAMINE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
	FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 41/5.3/1013
 Name of medicine: SANDOZ GALANTAMINE 8
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 GALANTAMINE HYDROBROMIDE EQUIVALENT
 TO GALANTAMINE 8,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: SANDOZ S.A. (PTY) LTD
 Manufacturer: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI
 MUMBAI, INDIA
 Packer: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI
 MUMBAI, INDIA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 Laboratory: FPRC: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI
 MUMBAI, INDIA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/5.3/1014
 Name of medicine: SANDOZ GALANTAMINE 12
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 GALANTAMINE HYDROBROMIDE
 EQUIVALENT TO GALANTAMINE 12,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: SANDOZ S.A. (PTY) LTD
 Manufacturer: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI
 MUMBAI, INDIA
 Packer: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI
 MUMBAI, INDIA
 NOVARTIS S.A., SPARTAN, KEMPTON
 PARK
 Laboratory: FPRC: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI
 MUMBAI, INDIA
 NOVARTIS S.A., SPARTAN, KEMPTON
 PARK
 FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/20.1.1/1083

Name of medicine: STRIDES TOBRAMYCIN 1,2 g/30 ml

Dosage form: INJECTION

Active ingredients: EACH 30,0 ml SOLUTION CONTAINS:
TOBRAMYCIN SULPHATE EQUIVALENT TO
TOBRAMYCIN 1,2 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

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
NOVARTIS S.A., SPARTAN, KEMPTON PARK

FPRR: STRIDES SA PHARMACEUTICALS, ARCADIA,
PRETORIA

Shelf-life: 24 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/20.1.1/1084

Name of medicine: STRIDES TOBRAMYCIN 80 mg/2 ml

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
TOBRAMYCIN SULPHATE EQUIVALENT TO
TOBRAMYCIN 80,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

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
NOVARTIS S.A., SPARTAN, KEMPTON PARK

FPRR: STRIDES SA PHARMACEUTICALS,
ARCADIA, PRETORIA

Shelf-life: 24 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	41/2.9/1098
Name of medicine:	OXYCONTIN 5 mg PROLONGED RELEASE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXYCODONE HYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	41/2.9/1099
Name of medicine:	OXYCONTIN 10 mg PROLONGED RELEASE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXYCODONE HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 41/2.9/1100

Name of medicine: OXYCONTIN 20 mg PROLONGED RELEASE TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
OXYCODONE HYDROCHLORIDE 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MEDWICH PHARMA (PTY) LTD

Manufacturer: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK

Packer: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK

Laboratory: FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: MEDWICH PHARMA, LYNNWOOD GLEN,
PRETORIA

Shelf-life: 36 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/2.9/1101

Name of medicine: OXYCONTIN 40 mg PROLONGED RELEASE TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
OXYCODONE HYDROCHLORIDE 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MEDWICH PHARMA (PTY) LTD

Manufacturer: BARD PHARMACEUTICALS LTD,
CAMBRIDGE, UK

Packer: BARD PHARMACEUTICALS LTD,
CAMBRIDGE, UK

Laboratory: FPRC: BARD PHARMACEUTICALS LTD,
CAMBRIDGE, UK
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: MEDWICH PHARMA, LYNNWOOD GLEN,
PRETORIA

Shelf-life: 36 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/2.9/1102
 Name of medicine: OXYCONTIN 80 mg PROLONGED RELEASE TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 OXYCODONE HYDROCHLORIDE 80,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MEDWICH PHARMA (PTY) LTD
 Manufacturer: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
 Packer: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
 Laboratory: FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
 Shelf-life: 36 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/2.5/1106
 Name of medicine: MYLAN OXCARBAZEPINE 600
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 OXCARBAZEPINE 600,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: XIXIA PHARMACEUTICALS (PTY) LTD
 Manufacturer: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMACEUTICALS MANUFACTURING,
 WADEVILLE, GERMISTON
 Packer: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMACEUTICALS MANUFACTURING,
 WADEVILLE, GERMISTON
 GENERICS UK, POTTERS BAR,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 Laboratory: FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND,
 AUSTRALIA
 MERCK PHARMACEUTICALS MANUFACTURING,
 WADEVILLE, GERMISTON
 GENERICS UK, POTTERS BAR,
 HERTFORDSHIRE, UK
 GERARD LABORATORIES, DUBLIN, IRELAND
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
 RSA
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/5.7.2/0010

Name of medicine: SANDOZ GRANISETRON 1 mg/1 ml IVI

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
GRANISETRON HYDROCHLORIDE EQUIVALENT TO
GRANISETRON 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SANDOZ S.A. (PTY) LTD

Manufacturer: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA
HAMELN PHARMACEUTICALS GmbH, HAMELN,
GERMANY

Packer: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA
HAMELN PHARMACEUTICALS GmbH, HAMELN,
GERMANY
TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA

Laboratory: FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA
HAMELN PHARMACEUTICALS GmbH, HAMELN,
GERMANY
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
LEK PHARMACEUTICALS d.d., VEROVSKOVA,
LJUBLJANA, SLOVENIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/5.7.2/0011

Name of medicine: GRANIJECT 3 mg/3 ml IVI

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml SOLUTION CONTAINS:
GRANISETRON HYDROCHLORIDE EQUIVALENT
TO GRANISETRON 3,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SANDOZ S.A. (PTY) LTD

Manufacturer: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA
HAMELN PHARMACEUTICALS GmbH, HAMELN,
GERMANY

Packer: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA
HAMELN PHARMACEUTICALS GmbH, HAMELN,
GERMANY
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA

Laboratory: FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA
HAMELN PHARMACEUTICALS GmbH, HAMELN,
GERMANY
SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
LEK PHARMACEUTICALS d.d., VEROVSKOVA,
LJUBLJANA, SLOVENIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	42/5.7.2/0012
Name of medicine:	SANDOZ GRANISETRON 3 mg/3 ml IVI
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY
Packer:	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/5.7.2/0013
Name of medicine:	GRANJECT 1 mg/1 ml IVI
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY
Packer:	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 42/21.5.1/0042
Name of medicine: ADROJECT 120 mg/30 ml
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
DEXAMETHASONE PHOSPHATE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
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
NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR: STRIDES SA PHARMACEUTICALS, ARCADIA,
PRETORIA
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/10.2.1/0043
Name of medicine: MERCK-SALBUTAMOL K HALER
Dosage form: INHALER
Active ingredients: EACH DOSE CONTAINS:
SALBUTAMOL SULPHATE EQUIVALENT TO
SALBUTAMOL 0,1 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer: INYX PHARMA, RANCORN, CHESHIRE, UK
Packer: INYX PHARMA, RANCORN, CHESHIRE, UK
Laboratory: FPRC: INYX PHARMA, RANCORN, CHESHIRE, UK
MERCK PHARMACEUTICAL
MANUFACTURING, WADEVILLE,
GERMISTON
GENERICS (UK) LTD, STATION CLOSE,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN,
IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: XIXIA PHARMACEUTICALS,
MODDERFONTEIN, RSA
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/32/0055
 Name of medicine: HELICAP
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 UREA 37,0 kBq
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: LEBASI PHARMACEUTICALS CC
 Manufacturer: INSTITUTE OF ISOTOPES CO LTD, BUDAPEST,
 HUNGARY
 Packer: INSTITUTE OF ISOTOPES CO LTD, BUDAPEST,
 HUNGARY
 Laboratory: FPRC: INSTITUTE OF ISOTOPES CO LTD, BUDAPEST,
 HUNGARY
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: LEBASI PHARMACEUTICALS, POTCHEFSTROOM
 Shelf-life: 12 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/3.1/0058
 Name of medicine: AUSTIFEN – 200 TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 IBUPROFEN 200,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUSTELL LABORATORIES (PTY) LTD
 Manufacturer: IPCA LABORATORIES, SILVASSA, DADRA &
 NAGAR HAVELI, INDIA
 Packer: IPCA LABORATORIES, SILVASSA, DADRA &
 NAGAR HAVELI, INDIA
 Laboratory: FPRC: IPCA LABORATORIES, SILVASSA, DADRA &
 NAGAR HAVELI, INDIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 FPRR: AUSTELL LABORATORIES, SPRINGFIELD,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/3.1/0059
Name of medicine: AUSTIFEN – 400 TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
IBUPROFEN 400,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUSTELL LABORATORIES (PTY) LTD
Manufacturer: IPCA LABORATORIES, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
Packer: IPCA LABORATORIES, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
Laboratory: FPRC: IPCA LABORATORIES, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/3.1/0060
Name of medicine: AUSTIFEN – 600 TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
IBUPROFEN 600,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUSTELL LABORATORIES (PTY) LTD
Manufacturer: IPCA LABORATORIES, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
Packer: IPCA LABORATORIES, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
Laboratory: FPRC: IPCA LABORATORIES, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/3.1/0061
 Name of medicine: IBUCARE-200
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 IBUPROFEN 200,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUSTELL LABORATORIES (PTY) LTD
 Manufacturer: IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
 Packer: IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
 Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
 M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
 FPRR: AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/3.1/0062
 Name of medicine: IBUCARE-400
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 IBUPROFEN 400,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUSTELL LABORATORIES (PTY) LTD
 Manufacturer: IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
 Packer: IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
 Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
 M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
 FPRR: AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/3.1/0063
Name of medicine: IBUCARE-600
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
IBUPROFEN 600,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUSTELL LABORATORIES (PTY) LTD
Manufacturer: IPCA LABORATORIES LTD, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
Packer: IPCA LABORATORIES LTD, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA &
NAGAR HAVELI, INDIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/2.6.5/0075
Name of medicine: HALOJECT 5 mg/ml
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
HALOPERIDOL 5,0 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
NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: STRIDES SA PHARMACEUTICALS,
ARCADIA, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/26/0083
Name of medicine: CIPLA VINOELBINE 10
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
VINOELBINE TARTRATE EQUIVALENT TO
VINOELBINE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer: CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, UNIT V, VERNA, GOA, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE

Shelf-life: 24 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/26/0084
Name of medicine: CIPLA VINOELBINE 50
Dosage form: INJECTION
Active ingredients: EACH 5,0 ml SOLUTION CONTAINS:
VINOELBINE TARTRATE EQUIVALENT TO
VINOELBINE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer: CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, UNIT V, VERNA, GOA, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE

Shelf-life: 24 months

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	42/26/0088
Name of medicine:	ACCORD GEMCITABINE 200 mg
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml VIAL CONTAINS: GEMCITABINE HYDROCHLORIDE EQUIVALENT TO GEMCITABINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/26/0089
Name of medicine:	WINTHROP GEMCITABINE 200 mg
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml VIAL CONTAINS: GEMCITABINE HYDROCHLORIDE EQUIVALENT TO GEMCITABINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/21.12/0121
Name of medicine:	SENSIPAR 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CINACALCET HYDROCHLORIDE RQUIVALENT TO CINACALCET 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA BUDELPACK HAMONT N.V., HAMONT, BELGIUM BRECON PHARMACEUTICALS LTD, HAY ON WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, WYE VALLEY, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BUILTH WELLS, POWYS, WALES CARDINAL HEALTH UK, GREAT OAKLY, CORBY, NORTHHAMPTONSHIRE, UK CARDINAL HEALTH UK, WESTHOUGHTON, BOLTON, LANCASHIRE, UK CARDINAL HEALTH UK, SWINDON, WILTSHIRE, UK AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory:	FPRC: PATHEON INC, BURLINGTON, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
	FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/21.12/0122
Name of medicine:	SENSIPAR 60 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CINACALCET HYDROCHLORIDE RQUIVALENT TO CINACALCET 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA BUDELPACK HAMONT N.V., HAMONT, BELGIUM BRECON PHARMACEUTICALS LTD, HAY ON WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, WYE VALLEY, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BUILTH WELLS, POWYS, WALES CARDINAL HEALTH UK, GREAT OAKLY, CORBY, NORTHHAMPTONSHIRE, UK CARDINAL HEALTH UK, WESTHOUGHTON, BOLTON, LANCASHIRE, UK CARDINAL HEALTH UK, SWINDON, WILTSHIRE, UK AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory:	FPRC: PATHEON INC, BURLINGTON, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
	FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/21.12/0123
Name of medicine:	SENSIPAR 90 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CINACALCET HYDROCHLORIDE RQUIVALENT TO CINACALCET 90,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA BUDELPACK HAMONT N.V., HAMONT, BELGIUM BRECON PHARMACEUTICALS LTD, HAY ON WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, WYE VALLEY, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BUILTH WELLS, POWYS, WALES CARDINAL HEALTH UK, GREAT OAKLY, CORBY, NORTHAMPTONSHIRE, UK CARDINAL HEALTH UK, WESTHOUGHTON, BOLTON, LANCASHIRE, UK CARDINAL HEALTH UK, SWINDON, WILTSHIRE, UK AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory:	FPRC: PATHEON INC, BURLINGTON, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
	FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/15.4/0127
Name of medicine:	GANFORT
Dosage form:	EYE DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: BIMATOPROST 0,3 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALLERGAN PHARMACEUTICALS, WESTPORT, COUNTY MAYO, IRELAND
Packer:	ALLERGAN PHARMACEUTICALS, WESTPORT, COUNTY MAYO, IRELAND
Laboratory:	FPRC: ALLERGAN PHARMACEUTICALS, WESTPORT, COUNTY MAYO, IRELAND
	FPRR: ALLERGAN PHARMACEUTICALS, RANDJESPAK, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/1.2/0137
Name of medicine:	XIXIA ESCITALOPRAM 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/1.2/0138
Name of medicine:	XIXIA ESCITALOPRAM 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 42/1.2/0139

Name of medicine: XIXIA ESCITALOPRAM 15

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ESCITALOPRAM OXALATE EQUIVALENT TO
ESCITALOPRAM 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA
MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES,
BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE,
GERMISTON

Packer: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA
MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES,
BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE,
GERMISTON
GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA
MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES,
BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE,
GERMISTON
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-
WEST UNIVERSITY, POTCHEFSTROOM

FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/1.2/0140

Name of medicine: XIXIA ESCITALOPRAM 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ESCITALOPRAM OXALATE EQUIVALENT TO
ESCITALOPRAM 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA
MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES,
BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON

Packer: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA
MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES,
BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA
MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES,
BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY, POTCHEFSTROOM

FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN

Shelf-life: 24 months (Provisional)

Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0156
Name of medicine:	RISPACOR 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0157
Name of medicine:	RISPACOR 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0158
Name of medicine:	RISPACOR 3
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0159
Name of medicine:	RISPACOR 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0161
Name of medicine:	ACCORD RISPERIDONE 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0162
Name of medicine:	ACCORD RISPERIDONE 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0163
Name of medicine:	ACCORD RISPERIDONE 3
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0164
Name of medicine:	ACCORD RISPERIDONE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/21.10/0184
Name of medicine:	FOSTIMON 75 IU POWDER FOR SOLUTION FOR INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: UROFOLLITROPIN 75,0 IU
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DELFRAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND
Packer:	IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND
Laboratory:	FPRC: IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: DELFRAN PHARMACEUTICALS, ELDORAIGNE, CENTURION
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/34/0185
Name of medicine:	FOSTIMON 75 IU SOLVENT FOR SOLUTION FOR INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: SODIUM CHLORIDE 0,9 % 1,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	DELFRAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND GELFIPHARMA INTERNATIONAL Srl, LODI, SAN GRATO, ITALY
Packer:	IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND
Laboratory:	FPRC: IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: DELFRAN PHARMACEUTICALS, ELDORAIGNE, CENTURION
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/26/0227
Name of medicine:	TORISEL 25 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: TEMSIROLIMUS 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WYETH SOUTH AFRICA (PTY) LTD
Manufacturer:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Packer:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE WYETH LEDERLE S.p.A, CATANIA, ITALY PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Laboratory:	FPRC: PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE WYETH LEDERLE S.p.A, CATANIA, ITALY PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG WYETH RESEARCH, GOSPORT, UK WYETH LEDERLE RESEARCH, PEARL RIVER, NEW YORK, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: WYETH S.A., VORNA VALLEY, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/34/0228
Name of medicine:	DILUENT FOR TORISEL 25 mg/ml CONCENTRATE FOR INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,8 ml VIAL CONTAINS: DEHYDRATED ALCOHOL 438,0 mg POLYETHYLENE GLYCOL 400 941,0 mg POLYSORBATE 80 880,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	WYETH SOUTH AFRICA (PTY) LTD
Manufacturer:	BEN VENUE LABORATORIES, BEDFORD, OHIO, USA
Packer:	BEN VENUE LABORATORIES, BEDFORD, OHIO, USA WYETH LEDERLE S.p.A., CATANIA, ITALY PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Laboratory:	FPRC: BEN VENUE LABORATORIES, BEDFORD, OHIO, USA WYETH LEDERLE S.p.A., CATANIA, ITALY PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
	FPRR: WYETH S.A., VORNA VALLEY, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/20.2.8/0565
Name of medicine:	PHARMA-Q LAMIVUDINE SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 1,0 ml SYRUP CONTAINS: LAMIVUDINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA-Q (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Laboratory:	FPRC: CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRC/FPRR: PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0573
Name of medicine:	SEROQUEL XR 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Packer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Laboratory:	FPRC: ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0574
Name of medicine:	SEROQUEL XR 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:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Packer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Laboratory:	FPRC: ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/2.6.5/0575
Name of medicine:	SEROQUEL XR 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:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Packer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Laboratory:	FPRC: ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 42/2.6.5/0576
 Name of medicine: SEROQUEL XR 400
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 QUETIAPINE FUMARATE EQUIVALENT TO
 QUETIAPINE 400,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD
 Manufacturer: ASTRAZENECA PHARMACEUTICALS, NEWARK,
 DELAWARE, USA
 ASTRAZENECA UK LTD, MACCLESFIELD,
 CHESHIRE, UK
 Packer: ASTRAZENECA PHARMACEUTICALS, NEWARK,
 DELAWARE, USA
 ASTRAZENECA UK LTD, MACCLESFIELD,
 CHESHIRE, UK
 Laboratory: FPRC: ASTRAZENECA PHARMACEUTICALS, NEWARK,
 DELAWARE, USA
 ASTRAZENECA UK LTD, MACCLESFIELD,
 CHESHIRE, UK
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: ASTRAZENECA PHARMACEUTICALS,
 SUNNINGHILL, JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/11.3/0630
 Name of medicine: RANBUTE 10
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 SIBUTRAMINE HYDROCHLORIDE
 MONOHYDRATE 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: RANBAXY (S.A.) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES LTD, PAONTA
 SAHIB, HIMACHAL PRADESH, INDIA
 Packer: RANBAXY LABORATORIES LTD, PAONTA
 SAHIB, HIMACHAL PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA
 SAHIB, HIMACHAL PRADESH, INDIA
 KHULULEKANI LABORATORY SERVICES,
 COVENTRY PARK, MIDRAND
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: RANBAXY (S.A.), CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/11.3/0631
Name of medicine: RANBUTE 15
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
SIBUTRAMINE HYDROCHLORIDE
MONOHYDRATE 15,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB,
HIMACHAL PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB,
HIMACHAL PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB,
HIMACHAL PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES,
COVENTRY PARK, MIDRAND
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: RANBAXY (S.A.), CENTURION, RSA
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/21.5.1/0638
Name of medicine: ADROJECT 4 mg/ml
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
DEXAMETHASONE PHOSPHATE 4,0 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
NOVARTIS S.A., SPARTAN, KEMPTON
PARK
FPRR: STRIDES SA PHARMACEUTICALS,
ARCADIA, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number:	42/21.5.1/0639
Name of medicine:	ADROJECT 20 mg/5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DEXAMETHASONE PHOSPHATE 4,0 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 NOVARTIS S.A., SPARTAN, KEMPTON PARK
	FPRR: STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/5.10/0662
Name of medicine:	ZOFER RAPITAB 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA
Laboratory:	FPRC: SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 42/5.10/0663
Name of medicine: ZOGER RAPITAB 8
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 8,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL INDUSTRIES, HALOL,
PAMCHMAHAL, GUJARAT, INDIA
Packer: SUN PHARMACEUTICAL INDUSTRIES, HALOL,
PAMCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES, HALOL,
PAMCHMAHAL, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/20.2.2/0683
Name of medicine: BIO-FLUCONAZOLE IV
Dosage form: INFUSION
Active ingredients: EACH 100,0 ml SOLUTION CONTAINS:
FLUCONAZOLE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BIOTECH LABORATORIES (PTY) LTD
Manufacturer: UNIQUE PHARMACEUTICAL
LABORATORIES, PANOLI, GUJARAT, INDIA
Packer: UNIQUE PHARMACEUTICAL
LABORATORIES, PANOLI, GUJARAT, INDIA
Laboratory: FPRC: UNIQUE PHARMACEUTICAL
LABORATORIES, PANOLI, GUJARAT, INDIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
RESEARCH INSTITUTE FOR INDUSTRIAL
SERVICES, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: BIOTECH LABORATORIES, RANDJESPAK,
MIDRAND
Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/26/0902
 Name of medicine: WINTHROP GEMCITABINE 1 g
 Dosage form: INJECTION
 Active ingredients: EACH 50,0 ml VIAL CONTAINS:
 GEMCITABINE HYDROCHLORIDE EQUIVALENT
 TO GENCITABINE 1,0 g
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 42/26/0903
 Name of medicine: ACCORD GEMCITABINE 1 g
 Dosage form: INJECTION
 Active ingredients: EACH 50,0 ml VIAL CONTAINS:
 GEMCITABINE HYDROCHLORIDE
 EQUIVALENT TO GENCITABINE 1,0 g
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA,
 SANAND, AHMEDABAD, INDIA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 9 OCTOBER 2009

MRF 15	
Registration number:	42/20.2.8/0978
Name of medicine:	REFAVIN 200 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
	FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	
Registration number:	42/5.7.2/1007
Name of medicine:	ASPEN GRANISETRON 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15

Registration number:	42/5.7.2/1008
Name of medicine:	ASPEN GRANISETRON 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
