

---

## 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.

MRF 15	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
Shelf-life:	FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE 24 months
Date of registration:	9 OCTOBER 2009
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, PHILADELPHIA, USA PFIZER INC, KALAMAZOO, MICHIGAN, USA
Packer:	PFIZER INC, CONSHOHOCKEN, PHILADELPHIA, USA PFIZER INC, KALAMAZOO, MICHIGAN, USA PFIZER ITALIA S.R.L., SAN MICHELE, LATINA, ITALY
Laboratory:	FPRC: PFIZER INC, KALAMAZOO, MICHIGAN, USA PFIZER ITALIA S.R.L., SAN MICHELE, LATINA, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	FPRR: PFIZER LABORATORIES, SANDTON, JOHANNESBURG 24 months
Date of registration:	9 OCTOBER 2009

MRF 15		MRF 15
Registration number:	07/34/09	37/18.3/0073
Name of medicine:	CONVENIA WATER FOR INJECTIONS	AXIM E-Z-GAS
Dosage form:	INJECTION	GRANULES
Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTIONS 10,0 ml	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, 7	1, 2, 3, 4, 5, 6
Applicant:	PFIZER LABORATORIES (PTY) LTD	AXIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	POTHEON UK LTD, COVINGHAM, SWINDON, WILTSHIRE, UK	TOWER LABORATORIES, CONNECTICUT, USA
Packer:	POTHEON UK LTD, COVINGHAM, SWINDON, WILTSHIRE, UK	TOWER LABORATORIES, CONNECTICUT, USA
Laboratory:	PFIZER INC, KALAMAZOO, MICHIGAN, USA PFIZER ITALIA S.R.L., SAN MICHELE, LATINA, ITALY	TOWER LABORATORIES, CONNECTICUT, USA
FPRC:	CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PFIZER LABORATORIES, SANDTON, JOHANNESBURG	AXIM PHAMACEUTICALS, MIDRAND, RSA
Shelf-life:	24 months	36 months
Date of registration:	9 OCTOBER 2009	9 OCTOBER 2009

MRF 15	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
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 KHULLEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number: 38/5.8/0114	Registration number: 38/21.5.1/0125
Name of medicine: REACTYNE PLUS	Name of medicine: ADCO-PREDNISOLONE SYRUP
Dosage form: TABLET	Dosage form: SYRUP
Active ingredients: EACH TABLET CONTAINS: PSEUDOEPHEDRINE HYDROCHLORIDE 120,0 mg CETIRIZINE DIHYDROCHLORIDE 5,0 mg	Active ingredients: EACH 5,0 ml SYRUP CONTAINS: PREDNISOLONE 15,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PFIZER LABORATORIES (PTY) LTD	Applicant: ADCOCK INGRAM LIMITED
Manufacturer: UCB FARCHIM S.A., CHEMIN DE CROIX, BULLE, SWITZERLAND	Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer: UCB PHARMA S.A., PIANEZZA, TURIN, ITALY	Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC: UCB FARCHIM S.A., CHEMIN DE CROIX, BULLE, SWITZERLAND	Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRC/FPRR: PFIZER LABORATORIES, RETREAT, CAPE TOWN	FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life: 36 months	Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009	Date of registration: 9 OCTOBER 2009

MRF 15	MRF 15
Registration number: 38/20.2.6/0145	Registration number: 38/2.7/0300
Name of medicine: NOVACLOR	Name of medicine: NOVODOL TABLETS
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: CHLOROQUINE PHOSPHATE EQUIVALENT TO CHLOROQUINE 150,0 mg	Active ingredients: EACH TABLET CONTAINS: PARACETAMOL 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration: 1, 2, 3, 4, 5, 6, 8
Applicant: MEDICINE DEVELOPERS INTERNATIONAL CC	Applicant: MEDICINE DEVELOPERS INTERNATIONAL G.C.
Manufacturer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE	Manufacturer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
Packer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE	Packer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
Laboratory: FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE	Laboratory: FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
FPRC: MEDICINE DEVELOPERS INTERNATIONAL, MENLO PARK, PRETORIA	FPRC: MEDICINE DEVELOPERS INTERNATIONAL C.C, MENLO PARK, PRETORIA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009	Date of registration: 9 OCTOBER 2009

MRF 15	MRF 15
Registration number: A38/7.1/0654	Registration number: A38/7.1/0655
Name of medicine: RAMI BLOCK 5/5	Name of medicine: RAMI BLOCK 2.5/2.5
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: RAMIPRIL 5,0 mg FELODIPINE 5,0 mg	Active ingredients: EACH TABLET CONTAINS: RAMIPRIL 2,5 mg FELODIPINE 2,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AVENTIS PHARMA (PTY) LTD	Applicant: AVENTIS PHARMA (PTY) LTD
Manufacturer: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN	Manufacturer: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN
Packer: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY	Packer: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Laboratory: FPRC: AVENTIS PHARMA, WALTLOO, PRETORIA	Laboratory: FPRC: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN
FPRC/FPRR AVENTIS PHARMA, WALTLOO, PRETORIA	FPRC/FPRR AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life: 24 months	Shelf-life: 24 months
Date of registration: 9 OCTOBER 2009	Date of registration: 9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	Registration number:
Name of medicine:	Name of medicine:
Dosage form:	Dosage form:
Active ingredients:	Active ingredients:
Conditions of registration:	Conditions of registration:
Applicant:	Applicant:
Manufacturer:	Manufacturer:
Packer:	Packer:
Laboratory:	Laboratory:
Shelf-life:	Shelf-life:
Date of registration:	Date of registration:
A38/2.9/0701	A39/21.8.1/0076
SABAX PETHIDINE 25	ESTREVA GEL
INJECTION	GEL
EACH 1.0 ml SOLUTION CONTAINS: PETHIDINE HYDROCHLORIDE 25.0 mg	EACH 1.0 g GEL CONTAINS: OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 1.0 mg
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
ADCOCK INGRAM CRITICAL CARE (PTY) LTD	MERCK (PTY) LTD
PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG	LABORATOIRE CHEMINEAU, VOUVRAY, FRANCE LABORATOIRE THERAMEX, CEDEX, MONACO
PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG	LABORATOIRE CHEMINEAU, VOUVRAY, FRANCE LABORATOIRE THERAMEX, CEDEX, MONACO
PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG	LABORATOIRE CHEMINEAU, VOUVRAY, FRANCE LABORATOIRE THERAMEX, CEDEX, MONACO
ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG	MERCK, MODDERFONTEIN, RSA
24 months	36 months
9 OCTOBER 2009	9 OCTOBER 2009



MRF 15	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
FPRC/FPRR:	FPRC: NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
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:	FPRC/FPRR: ABBOTT LABORATORIES SA, CONSTANTIAKLOOF, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number: A39/7.1/0538	Registration number: A39/7.1.3/0547
Name of medicine: VASCULEX 5	Name of medicine: TARKA 240/4
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg	Active ingredients: EACH TABLET CONTAINS: VERAPAMIL HYDROCHLORIDE 240,0 mg TRANSDOLAPRIL 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: HEXAL PHARMA (S.A.) (PTY) LTD	Applicant: ABBOTT LABORATORIES SA (PTY) LTD
Manufacturer: ILSAN ILTAS, GEBZE-KOCAELI, TURKEY HEXAL A/S, HVIDOVRE, DENMARK	Manufacturer: ABBOTT GmbH & CO, LUDWIGSHAFEN, GERMANY
Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA	Packer: ABBOTT GmbH & CO, LUDWIGSHAFEN, GERMANY
Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA	Laboratory: FPRC: ABBOTT GmbH & CO, LUDWIGSHAFEN, GERMANY
FPRC: HEXAL PHARMA, PINETOWN, KZN	FPRC/FPRR: ABBOTT LABORATORIES SA, CONSTANTIAKLOOF, JOHANNESBURG
Shelf-life: 24 months	Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009	Date of registration: 9 OCTOBER 2009

MRF 15	MRF 15
Registration number: A39/3.1/0564	Registration number: A40/7.1.5/0131
Name of medicine: CATAFAST SACHETS	Name of medicine: REVATIO
Dosage form: POWDER	Dosage form: TABLET
Active ingredients: EACH SACHET CONTAINS: DICLOFENAC SODIUM 50,0 mg	Active ingredients: EACH TABLET CONTAINS: SILDENAFIL 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD	Applicant: PFIZER LABORATORIES (PTY) LTD
Manufacturer: MIPHARM S.p.A., MILAN, ITALY	Manufacturer: PFIZER PGM, POCE SUR CISSE, AMBOISE, FRANCE
Packer: MIPHARM S.p.A., MILAN, ITALY NOVARTIS S.A., SPARTAN, KEMPTON PARK	Packer: PFIZER PGM, POCE SUR CISSE, AMBOISE, FRANCE PFIZER Inc, BROOKLYN, NEW YORK, USA
Laboratory: FPRC: MIPHARM S.p.A., MILAN, ITALY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG	Laboratory: FPRC: PFIZER PGM, POCE SUR CISSE, AMBOISE, FRANCE PFIZER Inc, BROOKLYN, NEW YORK, USA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK	FPRC/FPRR: PFIZER LABORATORIES, RETREAT, CAPE TOWN
Shelf-life: 24 months	Shelf-life: 24 months (Provisional)
Date of registration: 9 OCTOBER 2009	Date of registration: 9 OCTOBER 2009

MRF 15	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:	FPRC: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA BAXTER VACCINE AG, ORTH/DONAU, AUSTRIA
FPRC/FPRR:	FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
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:	FPRC: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA BAXTER VACCINE AG, ORTH/DONAU, AUSTRIA
FPRC/FPRR:	FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number: A40/30.3/0217	Registration number: A40/11/0374
Name of medicine: IMMUNATE 1 000 I.U.	Name of medicine: PENTASA 1 g
Dosage form: INJECTION	Dosage form: SUPPOSITORY
Active ingredients: EACH VIAL CONTAINS: HUMAN COAGULATION FACTOR VIII 1 000,0 I.U.	Active ingredients: MESALAZINE 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD	Applicant: FERRING (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	Manufacturer: FERRING A/S, VANLOSE, DENMARK EUROFINS DENMARK A/S, VALLENSBAE STRAND, DENMARK
Packer: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG	Packer: FERRING A/S, VANLOSE, DENMARK
Laboratory: FPRC: BAXTER AG LANGE ALLEE, VIENNA, AUSTRIA BAXTER VACCINE AG, ORTH/DONAU, AUSTRIA	Laboratory: FPRC: FERRING A/S, VANLOSE, DENMARK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG COSI PHARMACEUTICALS, INDUSTRIA-WEST, JOHANNESBURG
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG	FPRR: FERRING, IRENE, CENTURION
Shelf-life: 24 months	Shelf-life: 36 months
Date of registration: 9 OCTOBER 2009	Date of registration: 9 OCTOBER 2009

MRF 15	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
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	MRF 15
Registration number: A40/11.10/0480	Registration number: A40/29/0530
Name of medicine: GAVISCON PLUS LIQUID	Name of medicine: OCTREOSCAN 111
Dosage form: SUSPENSION	Dosage form: INJECTION
Active ingredients: EACH 10,0 ml SUSPENSION CONTAINS: SODIUM ALGINATE 500,0 mg SODIUM BICARBONATE 213,0 mg CALCIUM CARBONATE 325,0 mg	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	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD	Applicant: COVIDIEN (PTY) LTD
Manufacturer: RECKITT BENCKISER HEALTHCARE (UK), HULL, EAST YORKSHIRE, UK	Manufacturer: MALLINCKRODT MEDICAL BV, PETTEN, THE NETHERLANDS
Packer: RECKITT BENCKISER HEALTHCARE (UK), HULL, EAST YORKSHIRE, UK	Packer: MALLINCKRODT MEDICAL BV, PETTEN, THE NETHERLANDS
Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE (UK), HULL, EAST YORKSHIRE, UK CONSULTING CHEMICAL LABORATORY SERVICES, ATLASVILLE, BOKSBURG	Laboratory: FPRC: MALLINCKRODT MEDICAL BV, PETTEN, THE NETHERLANDS
FPRC/FPRR: RECKITT BENCKISER PHARMACEUTICALS, ELANDSFONTEIN	FPRR: COVIDIEN, RANDJESPAK, MIDRAND
Shelf-life: 24 months	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	Date of registration: 9 OCTOBER 2009

MRF 15	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
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
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
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009



MRF 15	MRF 15
Registration number:	Registration number:
Name of medicine:	Name of medicine:
Dosage form:	Dosage form:
Active ingredients:	Active ingredients:
Conditions of registration:	Conditions of registration:
Applicant:	Applicant:
Manufacturer:	Manufacturer:
Packer:	Packer:
Laboratory:	Laboratory:
FPRC:	FPRC:
FPRR:	FPRR:
Shelf-life:	Shelf-life:
Date of registration:	Date of registration:
A40/26/0546	A40/26/0547
EBETAXEL 150 mg	EBETAXEL 300 mg
INFUSION	INFUSION
EACH 25,0 ml SUSPENSION CONTAINS: PACLITAXEL 150,0 mg	EACH 50,0 ml SUSPENSION CONTAINS: PACLITAXEL 300,0 mg
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
PHARMAFRICA (PTY) LTD	PHARMAFRICA (PTY) LTD
EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
EBEWE PHARMA GmbH, UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA
LABOR L+SAG, BAD BOCKLET, GERMANY	LABOR L+SAG, BAD BOCKLET, GERMANY
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
PHARMAFRICA, NEW CENTRE, JOHANNESBURG	PHARMAFRICA, NEW CENTRE, JOHANNESBURG
36 months	36 months
9 OCTOBER 2009	9 OCTOBER 2009

MRF 15	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, PIKERMII, ATTICA, GREECE
Packer:	ELPEN S.A, PIKERMII, ATTICA, GREECE
Laboratory:	ELPEN S.A, PIKERMII, ATTICA, GREECE
FPRC:	FPRC:
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
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
Laboratory:	DR A PHARMACEUTICALS, CORPORATE PARK, IRENE
FPRC:	NEXTPHARMA SAS, LIMAY, FRANCE PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	UCB s.a. PHARMA SECTOR, BRAINE- L'ALLEUD, BELGIUM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	Registration number:
Name of medicine:	Name of medicine:
Dosage form:	Dosage form:
Active ingredients:	Active ingredients:
A40/23/0657 VAMINOLACT SOLUTION 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	A40/2.5/0699 SODIUM VALPROATE IV-WINTHROP INJECTION EACH VIAL CONTAINS: SODIUM VALPROATE 400,0 mg
Conditions of registration:	Conditions of registration:
Applicant:	Applicant:
Manufacturer:	Manufacturer:
Packer:	Packer:
Laboratory:	Laboratory:
FPRC:	FPRC:
Shelf-life:	Shelf-life:
Date of registration:	Date of registration:
1, 2, 3, 4, 5, 6, 8 FRESENIUS KABI S.A. (PTY) LTD FRESENIUS KABIA AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABIA AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABIA AUSTRIA GmbH, GRAZ, AUSTRIA KHULULEKANI LABORATORY SERVICES, RANJESPARK, MIDRAND	1, 2, 3, 4, 5, 6, 7 WINTHROP PHARMACEUTICALS (PTY) LTD GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA WINTHROP PHARMACEUTICALS, MIDRAND, RSA 60 months 9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	Registration number:
A40/34/0781	41/21.5/0016
Name of medicine:	Name of medicine:
SOLVENT FOR SODIUM VALPROATE IV	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:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRC:	FPRC:
FPRR:	FPRR: STRIDES S.A. PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
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:	GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC:	FPRC:
FPRR:	FPRR: WINTHROP PHARMACEUTICALS, MIDRAND, RSA WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Shelf-life:	60 months
Date of registration:	9 OCTOBER 2009

MRF 15	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:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRC:	FPRC:
FPRR:	FPRR: STRIDES S.A. PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
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:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC:	FPRC:
FPRR:	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	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
Shelf-life:	FPRR: SCP PHARMACEUTICALS, MODDERFOTEIN, RSA 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
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
Shelf-life:	FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number: 41/20.1.2/0123	Registration number: 41/24/0137
Name of medicine: AURO AMPICILLIN INJECTION 1 000 mg	Name of medicine: RINGER'S LACTATE B BRAUN
Dosage form: INJECTION	Dosage form: INFUSION
Active ingredients: EACH VIAL CONTAINS: AMPICILLIN 1 000,0 mg AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN 1 000,0 mg	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, 8	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD	Applicant: B BRAUN MEDICAL (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer: B BRAUN MELSUNGEN AG, MESLUNGEN, GERMANY PRODUCTION PHARMA PflIEFFEWIESEN, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., RUBI, BARCELONA, SPAIN
Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Packer: B BRAUN MELSUNGEN AG, MESLUNGEN, GERMANY PRODUCTION PHARMA PflIEFFEWIESEN, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., RUBI, BARCELONA, SPAIN
Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Laboratory: FPRC: B BRAUN MELSUNGEN AG, MESLUNGEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life: 24 months (Provisional)	Shelf-life: 36 months
Date of registration: 9 OCTOBER 2009	Date of registration: 9 OCTOBER 2009

MRF 15	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:	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
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:	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	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:	SANOI-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:	SANOI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
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	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, PIKERM, ATTICA, GREECE
Packer:	ELPEN S.A, PIKERM, ATTICA, GREECE
Laboratory:	ELPEN S.A, PIKERM, ATTICA, GREECE
FPRC:	FPRC:
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
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:	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC:	FPRC:
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	Registration number:
Name of medicine:	Name of medicine:
Dosage form:	Dosage form:
Active ingredients:	Active ingredients:
Conditions of registration:	Conditions of registration:
Applicant:	Applicant:
Manufacturer:	Manufacturer:
Packer:	Packer:
Laboratory:	Laboratory:
Shelf-life:	Shelf-life:
Date of registration:	Date of registration:
41/2.6.5/0453	41/2.6.5/0454
REDDON 1	REDDON 2
TABLET	TABLET
EACH TABLET CONTAINS: RISPERIDONE 1,0 mg	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
DR REDDY'S LABORATORIES (PTY) LTD	DR REDDY'S LABORATORIES (PTY) LTD
DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE, CENTURION	DRA PHARMACEUTICALS, IRENE, CENTURION
DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	DR REDDY'S LABORATORIES LTD, BACHUPALLY VILLAGE, QUTUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM	RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC:	FPRC:
DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
24 months (Provisional)	24 months (Provisional)
9 OCTOBER 2009	9 OCTOBER 2009

MRF 15	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
Shelf-life:	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
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
Shelf-life:	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/29/0486
Name of medicine:	TECHNISCAN 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
FPRC:	MALLINCKRODT MEDICAL B.V., PETTEN, HOLLAND
Shelf-life:	12 months
Date of registration:	9 OCTOBER 2009
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
FPRC:	HEXAL PHARMA, MAHOGANY RIDGE, PINETOWN
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	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
Shelf-life:	FPRC: 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
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
Shelf-life:	FPRC: 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	Registration number:
41/26/0492	41/35/0544
Name of medicine:	Name of medicine:
SANDOZ GEMCITABINE 250 mg IVI	GLUSCAN
Dosage form:	INJECTION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: FLUDEOXYGLUCOSE [ <sub>18</sub> 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:	ITHEMBA LABS, FAURE, CAPE TOWN ATOMIC ENERGY CORPORATION PELINDABA, PRETORIA-WEST
FPRC:	FPRC:
FPRR:	FPRC/FPRR:
HEXAL PHARMA, PINETOWN, KZN	CYCLOTOPE, PELINDABA WEST, PRETORIA WEST
Shelf-life:	12 hours
24 months (Provisional)	9 OCTOBER 2009
Date of registration:	Date of registration:

MRF 15	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
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
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
FRR:	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009



MRF 15	MRF 15		
Registration number:	41/5.3/0565	Registration number:	41/5.3/0566
Name of medicine:	MERCK GALANTAMINE 8	Name of medicine:	MERCK GALANTAMINE 12
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE 8,0 mg	Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE 12,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD	Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA	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	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	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
FPRC:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA	FPRC:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009	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  
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

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  
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

Shelf-life:

24 months (Provisional)

Date of registration:

9 OCTOBER 2009

MRF 15	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 MERCCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
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 MERCCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
Shelf-life:	FPRC: XIXIA PHARMACEUTICALS, MODDERFONTEIN 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	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:	URSAPHARM ARZNEIMITTEL GmbH & Co, SAARBRUCKEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC:	FPRC:
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
MRF 15	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:	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
FPRC:	FPRC:
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	417.1.3/0630
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:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
FPRC:	FPRC:
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	417.1.3/0631
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:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
FPRC:	FPRC:
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15		
Registration number:	41/3.1/0643	Registration number:	41/21.5.1/0664
Name of medicine:	DIPOFAST DROPS	Name of medicine:	TRIAMCINOLONE WINTHROP
Dosage form:	DROPS	Dosage form:	NASAL SPRAY
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: DICLOFENAC POTASSIUM 50,0 mg	Active ingredients:	EACH ACTUATION CONTAINS: TRIAMCINOLONE ACETONIDE 55,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD	Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	LABORATORIO FARMACOLOGICO MILANESE s.r.l., CARONNO PERTUSELLA, ITALY	Manufacturer:	AVENTIS PHARMA, HOLMES CHAPEL, CHESHIRE, UK
Packer:	LABORATORIO FARMACOLOGICO MILANESE s.r.l., CARONNO PERTUSELLA, ITALY	Packer:	AVENTIS PHARMA, HOLMES CHAPEL, CHESHIRE, UK WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC: LABORATORIO FARMACOLOGICO MILANESE s.r.l., CARONNO PERTUSELLA, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	Laboratory:	FPRC: AVENTIS PHARMA, HOLMES CHAPEL, CHESHIRE, UK
FPRC:	PHARMAPLAN, MIDRAND, RSA	FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009	Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15		
Registration number:	41/21.5.1/0665	Registration number:	41/2.6.5/0748
Name of medicine:	TRIAMCINOLONE SANOFI-AVENTIS	Name of medicine:	AUROPIDONE 0,5 mg
Dosage form:	NASAL SPRAY	Dosage form:	TABLET
Active ingredients:	EACH ACTUATION CONTAINS: TRIAMCINOLONE ACETONIDE	Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AVENTIS PHARMA, HOLMES CHAPEL, CHESHIRE, UK	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AVENTIS PHARMA, HOLMES CHAPEL, CHESHIRE, UK	Packer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	AVENTIS PHARMA, HOLMES CHAPEL, CHESHIRE, UK	Laboratory:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA	FPRC:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA	Shelf-life:	24 months
Shelf-life:	24 months	Date of registration:	9 OCTOBER 2009
Date of registration:	9 OCTOBER 2009		

MRF 15	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, ISANDO, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
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
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009