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

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, PRETIORIA
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 TRANDOLAPRIL 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: 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:	A40/30.3/0216
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:	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, RANDJESPARK, 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, RANJESPARK, 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 SOIDUM 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, MESLUNGEN, GERMANY PRODUCTION PHARMA PFIEFFEWIESEN, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., RUBI, BARCELONA, SPAIN
Packer:		B BRAUN MELSUNGEN AG, MESLUNGEN, GERMANY PRODUCTION PHARMA PFIEFFEWIESEN, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., RUBI, BARCELONA, SPAIN
Laboratory:	FPRC:	B BRAUN MELSUNGEN AG, MESLUNGEN, 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, RANDJESPARK, 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, RANDJESPARK, 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 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:		41/5.3/0565
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 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:		41/1.2/0568
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
	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:		GRANIJECT 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 VINORELBINE 10
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 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 VINORELBINE 50
Dosage form:		INJECTION
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 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, 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:		42/15.4/0127
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, RANDJESPARK, 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:		INJCETION
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:		ZOFER 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, RANDJESPARK, 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

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737
Kaapstad-tak: Tel: (021) 465-7531