MRF 15

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

MRF 15

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

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

MRF 15

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

MRF15

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

RF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

RF 15

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

MRF 15

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

MRF15

Registration number:	43/34/0613
Name of medicine:	ZOMEDRON
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: ZOLEDRONIC ACID 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA
FPRR:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/5.7.1/0643
Name of medicine:	AURO CETIRIZINE TABLETS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	43/5.7.1/0644
Name of medicine:	AURO CETIRIZINE TABLETS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF15

Registration number:	43/5.7.1/0645
Name of medicine:	TRANTRIN TABLETS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

3F 15

Registration number:	43/5.7.1/0646
Name of medicine:	TRANTRIN TABLETS 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

RF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

RF 15

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

MRF 15

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

MRF15

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

RF 15

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

MRF 15

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

MRF15

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

RF 15

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

MRF 15

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

MRF15

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

RF 15

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

MRF 15

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

MRF15

Registration number:	44/20.2.8/0780
Name of medicine:	*CIPLA EFAVIRENZ 600 mg/TENOFOVIR 300 mg/EMTRICITABINE 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1,2,3,4,5,6,7,8,9,10**
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	09 February 2012

MMRF 15

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

MRF 15

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

MRF15

Registration number:	45/20.2.8/0078
Name of medicine:	RAOLIN 100/25 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 100,0 mg RITONAVIR 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

Registration number:	45/20.2.8/0079
Name of medicine:	RAOLIN 200/50 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 200,0 mg RITONAVIR 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

45/20.2.8/0080

MECOTRIL 100/25 mg TABLETS

TABLET

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

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

AUROBINDO PHARMA (PTY) LTD

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

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

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

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

24 months (Provisional)

2 MARCH 2012

MRF 15

Registration number:	45/20.2.8/0081
Name of medicine:	MECOTRIL 200/50 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOPINAVIR 200,0 mg RITONAVIR 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	2 MARCH 2012

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

:F 15

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

MRF 15

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

MRF15 :F 15

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

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

MRF 15

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

MRF15

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

F 15

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

MRF 15

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

MRF15 F 15

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

Registration number:	42/7.1.3/0947
Name of medicine:	IRBELO 75
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory::FPRC	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, *MIDRAND, RSA* CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/7.1.3/0948
Name of medicine:	IRBELO 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	42/7.1.3/0949
Name of medicine:	IRBELO 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/7.1.3/0950
Name of medicine:	RAN IRBESARTAN 75
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	42/7.1.3/0951
Name of medicine:	RAN IRBESARTAN 150
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	42/7.1.3/0952
Name of medicine:	RAN IRBESARTAN 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, SIRMOUR,HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA BE-TABS PHARMACEUTICALS (PTY) LTD, STORMHILL, ROODEPOORT, RSA
FPRR:	RANBAXY SA (PTY) LTD, LENCHEN AVENUE NORTH, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

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

MRF 15

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

MRF15 F 15

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

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF 15

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

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

RF 15

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

MRF 15

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

MRF15

Registration number:	43/7.1.3/1044
Name of medicine:	BIQURETIC 10/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quinapril Hydrochloride equivalent to Quinapril 10,0 mg Hydrochlorothiazide 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/7.1.3/1045
Name of medicine:	BIQURETIC 20/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quinapril Hydrochloride equivalent to Quinapril 20,0 mg Hydrochlorothiazide 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

Registration number:	43/7.1.3/1046
Name of medicine:	AURO QUINAPRIL CO 10/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quinapril Hydrochloride equivalent to Quinapril 10,0 mg Hydrochlorothiazide 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF15

Registration number:	43/7.1.3/1047
Name of medicine:	AURO QUINAPRIL CO 20/12,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quinapril Hydrochloride equivalent to Quinapril 20,0 mg Hydrochlorothiazide 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH INDIA M &L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

RF 15

Registration number:	44/20.1.1/0316
Name of medicine:	KANAMYCIN 1 g BIOTECH
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: KANAMYCIN SULPHATE EQUIVALENT TO KANAMYCIN 1000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF JB CHEMICALS & PHARMACEUTICALS LIMITED), PANOLI, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF JB CHEMICALS & PHARMACEUTICALS LIMITED), PANOLI, INDIA PHARMA-Q (PTY) LTD TRADING AS COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA
Laboratory: FPRC	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF JB CHEMICALS & PHARMACEUTICALS LIMITED), PANOLI, INDIA PHARMA-Q (PTY) LTD TRADING AS COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	20 APRIL 2012

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

*ADDITIONAL CONDITIONS OF REGISTRATION

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

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

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

Provide periodic progress reports on the method development and data.

**ADDITIONAL CONDITIONS OF REGISTRATION

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

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

Provide periodic progress reports on the method development and data.

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