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GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1148 OF 2007

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
8. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
9. A post-registration inspection must be conducted on the first production batch of the imported product.
10. Marketing of the product may only commence following a satisfactory post-registration inspection report.
11. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
12. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
13. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 1148 VAN 2007

MEDISYNEBEHEERRAAD

VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET 101 VAN 1965)

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goekgekeur is.
4. Die applicant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslik vervaardigde produk uitgevoer word.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
10. Bemarking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
11. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
12. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
13. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:		35/30.1/0024
Name of medicine:		EUVAX B INJ
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: PURIFIED HBs ANTIGEN 20,0 ug ALUMINIUM HYDROXIDE GEL 0,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		LG CHEMICAL LTD, CHUNBUK-DO, KOREA
Packer:		LG CHEMICAL LTD, CHUNBUK-DO, KOREA
Laboratory:	FPRC:	LG CHEMICAL LTD, CHUNBUK-DO, KOREA NATIONAL CONTROL LABORATORY, UNIVERSITY OF THE FREE STATE, BLOEMFONTEIN
	FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		37/10.2.1/0351
Name of medicine:		VENTEZE-ECO
Dosage form:		INHALATION
Active ingredients:		EACH ACTUATION DELIVERS: SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 100,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMACARE LIMITED
Manufacturer:		INYX PHARMA, RUNCORN, CHESHIRE, U.K. PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:		INYX PHARMA, RUNCORN, CHESHIRE, U.K. PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:	INYX PHARMA, RUNCORN, CHESHIRE, U.K.
	FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:	37/3.1/0399
Name of medicine:	ARCOXIA 60 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ETORICOXIB 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK & CO INC, ELKTON, VIRGINIA, USA
Packer:	MMD – HOLLAND, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, RSA
Laboratory: FPRC:	MERCK & CO INC, ELKTON, VIRGINIA, USA
FPRC/FPRR:	MSD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	37/3.1/0400
Name of medicine:	ARCOXIA 90 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ETORICOXIB 90,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK & CO INC, ELKTON, VIRGINIA, USA
Packer:	MMD – HOLLAND, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, RSA
Laboratory: FPRC:	MERCK & CO INC, ELKTON, VIRGINIA, USA
FPRC/FPRR:	MSD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	37/3.1/0401
Name of medicine:	ARCOXIA 120 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ETORICOXIB 120,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK & CO INC, ELKTON, VIRGINIA, USA
Packer:	MMD – HOLLAND, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, RSA
Laboratory: FPRC:	MERCK & CO INC, ELKTON, VIRGINIA, USA
FPRC/FPRR:	MSD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	A39/11.9/0075
Name of medicine:	LOPERIM
Dosage form:	DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LOPERAMIDE HYDROCHLORIDE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory: FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR:	EQUITY PHARMACEUTICALS, HAZELWOOD, PRETORIA
Shelf-life:	24 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:		A39/I0.1/0390
Name of medicine:		DURO-TUSS LINCTUS
Dosage form:		LIQUID
Active ingredients:		EACH 5,0 ml LIQUID CONTAINS: BROMHEXINE HYDROCHLORIDE 4,0 mg SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		3M PHARMACEUTICALS S.A (PTY) LTD
Manufacturer:		3M PHARMACEUTICALS, CHILVERS ROAD, THORNLEY, AUSTRALIA PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:		3M PHARMACEUTICALS, CHILVERS ROAD, THORNLEY, AUSTRALIA PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	3M PHARMACEUTICALS, CHILVERS ROAD, THORNLEY, AUSTRALIA PHARMA-Q, INDUSTRIA, JOHANNESBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	3M PHARMACEUTICALS, WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A39/3/0622
Name of medicine:		HEALON 5
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: SODIUM HYALURONATE 23,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		GENOP HEALTHCARE (PTY) LTD
Manufacturer:		ADVANCED MEDICAL OPTICS UPPSALA AB, UPPSALA, SWEDEN OCTAPHARMA AB, STOCKHOLM, SWEDEN
Packer:		ADVANCED MEDICAL OPTICS UPPSALA AB, UPPSALA, SWEDEN
Laboratory:	FPRC:	ADVANCED MEDICAL OPTICS UPPSALA AB, UPPSALA, SWEDEN INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	GENOP HEALTHCARE, HALFWAY HOUSE, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:	A39/16.4/0623
Name of medicine:	CEPACOL PLUS MOUTHWASH
Dosage form:	SOLUTION
Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: BENZYDAMINE HYDROCHLORIDE 22,50 mg CHLORHEXIDINE GLUCONATE 18,00 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (provisional)
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	A39/16.4/0624
Name of medicine:	CEPACOL PLUS THROAT SPRAY
Dosage form:	SOLUTION
Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: BENZYDAMINE HYDROCHLORIDE 22,50 mg CHLORHEXIDINE GLUCONATE 18,00 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (provisional)
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	A39/16.4/0626
Name of medicine:	MEDI-KEEL C ANTISEPTIC AND ANTI-INFLAMMATORY MOUTHWASH
Dosage form:	SOLUTION
Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: BENZYDAMINE HYDROCHLORIDE 22,50 mg CHLORHEXIDINE GLUCONATE 18,00 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (provisional)
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	A39/16.4/0628
Name of medicine:	MEDI-KEEL C ANTISEPTIC AND ANTI-INFLAMMATORY THROAT SPRAY
Dosage form:	SOLUTION
Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: BENZYDAMINE HYDROCHLORIDE 22,50 mg CHLORHEXIDINE GLUCONATE 18,00 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (provisional)
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:		A40/28/0245
Name of medicine:		OPTIRAY 320 – 75 ml
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: IOVERSOL EQUIVALENT TO ORGANICALLY BOUND IODINE 320,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		TYCO HEALTHCARE (PTY) LTD
Manufacturer:		TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Packer:		TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Laboratory:	FPRC:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA BIOCHEMICAL AND SCIENTIFIC cc, HILTON,KWA-ZULU NATAL
	FPRR:	TYCO HEALTHCARE, MIDRAND, RSA
Shelf-life:		36 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A40/28/0246
Name of medicine:		OPTIRAY 350 – 75 ml
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: IOVERSOL EQUIVALENT TO ORGANICALLY BOUND IODINE 350,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		TYCO HEALTHCARE (PTY) LTD
Manufacturer:		TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Packer:		TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA
Laboratory:	FPRC:	TYCO HEALTHCARE INC, RALEIGH, NORTH CAROLINA, USA BIOCHEMICAL AND SCIENTIFIC cc, HILTON, KWA-ZULU NATAL
	FPRR:	TYCO HEALTHCARE, MIDRAND, RSA
Shelf-life:		36 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A40/20.2.8/0303
Name of medicine:		SONKE-ZIDOVUDINE 300
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ZIDOVUDINE 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A40/20.2.8/0341
Name of medicine:		SONKE-NEVIRAPINE TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		RANBAXY (SA) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:		24 months (provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A40/20.2.8/0421
Name of medicine:		SONKE-STAVUDINE 30
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: STAVUDINE 30,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY S.A., CENTURION, RSA
Shelf-life:		24 months (provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A40/20.2.8/0422
Name of medicine:		SONKE-STAVUDINE 40
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: STAVUDINE 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY S.A., CENTURION, RSA
Shelf-life:		24 months (provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:	A40/20.1.1/0454
Name of medicine:	ORPIC 2 mg/ml IV
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN SA, ATTIKIS, GREECE
Packer:	PHARMATHEN SA, ATTIKIS, GREECE PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Laboratory: FPRC:	PHARMATHEN SA, ATTIKIS, GREECE SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	ASPEN PHARMACARE, WILSONIA, EAST LONDON PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	36 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	A40/2.5/0471
Name of medicine:	PIRAMAX 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:		A40/2.5/0472
Name of medicine:		PIRAMAX 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
Packer:		CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
Laboratory:	FPRC:	CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A40/2.5/0473
Name of medicine:		PIRAMAX 200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
Packer:		CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
Laboratory:	FPRC:	CIPLA LTD, KURKUMBH, PUNE DISTRICT, MAHARASHTRA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A40/20.1.2/0568
Name of medicine:		RANCLAV 1 g
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:		RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		A40/2.1/0671
Name of medicine:		PLOFED 1 % 20 ml
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml EMULSION CONTAINS: PROPOFOL 10,0 mg
Conditions of registration		I, 2, 3, 4, 5, 6
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND
Packer:		WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND
Laboratory:	FPRC:	WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		36 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:	A40/2.1/0672
Name of medicine:	CIPLA-PROPOFOL 1 %
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml EMULSION CONTAINS: PROPOFOL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND
Packer:	WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND
Laboratory: FPRC:	WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	36 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	A40/30.1/0730
Name of medicine:	ROTATEQ
Dosage form:	SOLUTION
Active ingredients:	EACH 2,0 ml DOSE CONTAINS: HUMAN-BOVINE ROTAVIRUS REASSORTANTS: G1 3,01 x 10 IU G2 4,39 x 10 IU G3 5,98 x 10 IU G4 3,51 x 10 IU P1 4,13 x 10 IU
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK & CO INC, WEST POINT, PENNSYLVANIA, USA
Packer:	MERCK & CO INC, WEST POINT, PENNSYLVANIA, USA
Laboratory: FPRC:	MERCK & CO INC, WEST POINT, PENNSYLVANIA, USA
FPRR:	MSD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:		41/21.2/0013
Name of medicine:		MERCK-GLIMEPIRIDE 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/21.2/0014
Name of medicine:		MERCK-GLIMEPIRIDE 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/21.2/0015
Name of medicine:		MERCK-GLIMEPIRIDE 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	MERCK FARMA y QUIMICA, MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/7.1.3/0116
Name of medicine:		LYSIN 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:	41/7.1.3/0117
Name of medicine:	LYSIN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	41/7.1.3/0118
Name of medicine:	LYSIN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:		41/8.2/0120
Name of medicine:		CIPLA-WARFARIN 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: WARFARIN SODIUM CLATHRATE EQUIVALENT TO WARFARIN SODIUM 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, DISTRICT RAIGAD, MAHARASHTRA, INDIA
Packer:		CIPLA LTD, DISTRICT RAIGAD, MAHARASHTRA, INDIA
Laboratory:	FPRC:	CIPLA LTD, DISTRICT RAIGAD, MAHARASHTRA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/8.2/0121
Name of medicine:		CIPLA-WARFARIN 3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: WARFARIN SODIUM CLATHRATE EQUIVALENT TO WARFARIN SODIUM 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, DISTRICT RAIGAD, MAHARASHTRA, INDIA
Packer:		CIPLA LTD, DISTRICT RAIGAD, MAHARASHTRA, INDIA
Laboratory:	FPRC:	CIPLA LTD, DISTRICT RAIGAD, MAHARASHTRA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/5.7.1/0133
Name of medicine:		FEXAWAY 120
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 120,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/5.7.1/0134
Name of medicine:		FEXAWAY 180
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 180,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/2.5/0149
Name of medicine:		GLENMARK-TOPIRAMATE TABLETS 25 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		BOUWER BARTLETT (PTY) LTD
Manufacturer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory:	FPRC:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
	FPRR:	BOUWER BARTLETT, VORNA VALLEY, MIDRAND
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/2.5/0150
Name of medicine:		GLENMARK-TOPIRAMATE TABLETS 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		BOUWER BARTLETT (PTY) LTD
Manufacturer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory:	FPRC:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
	FPRR:	BOUWER BARTLETT, VORNA VALLEY, MIDRAND
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/2.5/0151
Name of medicine:		GLENMARK-TOPIRAMATE TABLETS 100 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		BOUWER BARTLETT (PTY) LTD
Manufacturer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory:	FPRC:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
	FPRR:	BOUWER BARTLETT, VORNA VALLEY, MIDRAND
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/2.5/0152
Name of medicine:		GLENMARK-TOPIRAMATE TABLETS 200 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		BOUWER BARTLETT (PTY) LTD
Manufacturer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory:	FPRC:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
	FPRR:	BOUWER BARTLETT, VORNA VALLEY, MIDRAND
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/5.10/0185
Name of medicine:		OSETRON ODT-4
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ONDANSETRON 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/5.10/0186
Name of medicine:		OSETRON ODT-8
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ONDANSETRON 8,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:	41/11.5/0259
Name of medicine:	FRESHEN LACTULOSE SYRUP - CARAMEL
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: LACTULOSE 3,3 g
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (Provisional)
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:		41/20.1.2/0261
Name of medicine:		AMYN S 125
Dosage form:		SUSPENSION
Active ingredients:		EACH 5,0 ml SUSPENSION CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		DEZZO TRADING 392 (PTY) LTD t/a INDO PHARMA
Manufacturer:		KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Packer:		KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Laboratory:	FPRC:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
	FPRR:	DEZZO TRADING, LENASIA, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/19/0303
Name of medicine:		SPEC-OXYTOCIN 5 IU
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: OXYTOCIN 8,33 IU
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		ROTEX-MEDICA, TRITTAN, GERMANY
Packer:		ROTEX-MEDICA, TRITTAN, GERMANY
Laboratory:	FPRC:	ROTEX-MEDICA, TRITTAN, GERMANY ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SPECPHARM, MIDRAND, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/5.7.1/0319
Name of medicine:		FASTWAY 120
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 120,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/5.7.1/0320
Name of medicine:		FASTWAY 180
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 180,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/1.2/0367
Name of medicine:		MERCK-MIRTAZAPINE 15
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MIRTAZAPINE 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/1.2/0368
Name of medicine:		MERCK-MIRTAZAPINE 30
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MIRTAZAPINE 30,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC:	ALPHAPHARM, CAROLE PARK, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:		24 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:		41/1.2/0378
Name of medicine:		CITALOPRAM SANOFI-AVENTIS 20 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:		TROPON GmbH, KOLN, GERMANY
Packer:		ARTESAN PHARMA GmbH & Co, LUCHOW, GERMANY AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:	FPRC:	ARTESAN PHARMA GmbH & Co, LUCHOW, GERMANY RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:		48 months
Date of registration:		10 AUGUST 2007

MRF 15

Registration number:	41/1.2/0379
Name of medicine:	CITALOPRAM SANOFI-AVENTIS 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	TROPON GmbH, KOLN, GERMANY
Packer:	ARTESAN PHARMA GmbH & Co, LUCHOW, GERMANY AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory: FPRC:	ARTESAN PHARMA GmbH & Co, LUCHOW, GERMANY RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	48 months
Date of registration:	10 AUGUST 2007

MRF 15

Registration number:	41/21.12/0421
Name of medicine:	CIPLA-FINASTERIDE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FINASTERIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:	CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory: FPRC:	CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELVILLE
Shelf-life:	24 months
Date of registration:	10 AUGUST 2007