Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 501 Pretoria, 28 March / Maart 2007 No. 29735

CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 351 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 No. 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of 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 No. 101 of 1965).
5. The registration of this medicine shall be subject to regular review regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The registration dossier is subject to review at intervals as determined by Council.
8. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 351 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 No. 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 26 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in die voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies soos goedgedink deur die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die registrasie-aansoek is onderhewig aan hersiening met tussenposes soos deur die Raad bepaal.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslike vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemarking van die produk mag slegs in aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:	02/3.1/15
Name of medicine:	NOROCARP INJECTION FOR DOGS
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CARPROFEN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	NORBROOK LABORATORIES S.A. (PTY) LTD
Manufacturer:	NORBROOK LABORATORIES LTD, NEWRY, NORTHERN IRELAND
Packer:	NORBROOK LABORATORIES LTD, NEWRY, NORTHERN IRELAND
Laboratory: FPRC:	NORBROOK LABORATORIES LTD, NEWRY, NORTHERN IRELAND
FPRR:	NORBROOK LABORATORIES, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	A05/21.1/02
Name of medicine:	DRAXXIN 100 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: TULATHROMYCIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GLOBAL MANUFACTURING, AMBOISE CEDEX, FRANCE
Packer:	PFIZER GLOBAL MANUFACTURING, AMBOISE CEDEX, FRANCE
Laboratory: FPRC:	PFIZER GLOBAL MANUFACTURING, AMBOISE CEDEX, FRANCE SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	PFIZER LABORATORIES, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	38/16.4/0021
Name of medicine:	TEETH AND GUM DEFENCE LISTERINE
Dosage form:	SOLUTION
Active ingredients:	EACH 20,0 ml SOLUTION CONTAINS: SODIUM FLUORIDE 4,420 mg THYMOL 12,780 mg ALCOHOL (95 %) 4,540 ml
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	PFIZER GLOBAL MANUFACTURING, RETREAT CAPE TOWN
Packer:	PFIZER GLOBAL MANUFACTURING, RETREAT CAPE TOWN
Laboratory: FPRC/FPRR:	PFIZER GLOBAL MANUFACTURING, RETREAT CAPE TOWN
Shelf-life:	24 months (provisional)
Date of registration	1 DECEMBER 2006

MRF 15

Registration number:	A39/20.2.8/0343
Name of medicine:	APEX-ACYCLOVIR 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ACYCLOVIR 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA
Packer:	MEDREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA
Laboratory: FPRC:	MEDREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	A39/20.2.8/0344
Name of medicine:	APEX-ACYCLOVIR 400 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ACYCLOVIR 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA
Packer:	MEDREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA
Laboratory: FPRC:	MEDREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)
Date of registration:	1 DECEMBER 2006

MRF 15

Registration number:	A40/20.2.8/0261
Name of medicine:	CIPLA DUOVIR AND NEVIRAPINE CO-PACK
Dosage form:	TABLET
Active ingredients	EACH CARTON CONTAINS: DUOVIR TABLETS CONTAINING: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg NEVIRAPINE TABLETS CONTAINING: NEVIRAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, VIKHROLI, MUMBAI, INDIA
Packer:	CIPLA LTD, VIKHROLI, MUMBAI, INDIA
Laboratory: FPRC:	CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	A40/7.1/0284
Name of medicine:	INDO AMLODIPINE-5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
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, STAR STREET, BOKSBURG, RSA
FPRR:	DEZZO TRADING (392) t/a INDO PHARMA, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	A40/20.1.2/0329
Name of medicine:	INDO AMOXYCILLIN 250
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 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
FPRR:	DEZZO TRADING (392) t/a INDO PHARMA, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:		A40/20.1.2/0330
Name of medicine		INDO AMOXYCILLIN 500
Dosage form		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 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
	FPRR:	DEZZO TRADING (392) t/a INDO PHARMA, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA
Shelf-life:		36 months
Date of registration:		2 FEBRUARY 2007

MRF 15

Registration number:		A40/7.1/0435
Name of medicine:		AMLOBLOC 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SANDOZ (PTY) LTD
Manufacturer:		LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA
Packer:		LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:		24 months (provisional)
Date of registration		2 FEBRUARY 2007

MRF 15

Registration number:	A40/7.1/0436
Name of medicine:	AMLOBLOC 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	A40/20.2.8/0460
Name of medicine:	TRIOMUNE 30
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: STAVUDINE 30,0 mg LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA MEDPRO (PTY)
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA ELI LILLY & CO, BASINGSTOKE, HAMPSHIRE UK
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	A40/21.2/0466
Name of medicine:	INDO METFORMIN-500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration	1, 2, 3, 4, 5, 6
Applicant:	DEZZO TRADING (392) (PTY) LTD t/a INDO PHARMA
Manufacturer	RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
Packer:	RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
Laboratory: FPRC	RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING (392) t/a INDO PHARMA, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	A40/21.2/0467
Name of medicine:	INDO METFORMIN-850
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	DEZZO TRADING (392) (PTY) LTD t/a INDO PHARMA
Manufacturer:	RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
Packer:	RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
Laboratory: FPRC	RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	DEZZO TRADING (392) t/a INDO PHARMA, ANCHORVILLE, LENASIA, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	A40/7.1.3/0722
Name of medicine:	AURO-LISINOPRIL 5 mg
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:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory : FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	A40/7.1.3/0723
Name of medicine:	AURO-LISINOPRIL 10 mg
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:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:		A39/20.1.1/0303
Name of medicine:		APEX-CEFTRIAXONE 1 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:		MJ BIOPHARM, RAIGAD, MAHARASHTRA, INDIA
Packer:		MJ BIOPHARM, RAIGAD, MAHARASHTRA, INDIA
Laboratory:	FPRC:	MJ BIOPHARM, RAIGAD, MAHARASHTRA, INDIA IPCA LABORATORIES, ATHAL, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		1 DECEMBER 2006

MRF 15

Registration number:	41/20.2.8/0235
Name of medicine:	ADCO-NEVIRAPINE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 200,0 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 ADCOCK INGRAM LTD, BRYANSTON,JOHANNESBURG
Laboratory: FPRC/FPRR	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	41/20.2.8/0236
Name of medicine:	ADCO-LAMIVUDINE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 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 ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Laboratory: FPRC/FPRR	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:	41/20.2.8/0237
Name of medicine:	ADCO-ZIDOVUDINE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZIDOVUDINE 300,0 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 ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Laboratory: FPRC/FPRR	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	2 FEBRUARY 2007

MRF 15

Registration number:		A40/7.1.3/0724
Name of medicine:		AURO-LISINOPRIL 20 mg
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:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory:	FPRC	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
	FPRR	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		2 FEBRUARY 2007

MRF 15

Registration number:		41/7.3/0092
Name of medicine:		CIPLA-SUMATRIPTAN 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT III, VERNA, GOA, INDIA
Packer:		CIPLA LTD, UNIT III, VERNA, GOA, INDIA
Laboratory:	FPRC	CIPLA LTD, UNIT III, VERNA, GOA, INDIA
FPRR:		CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		37/34/0528
Name of medicine:		NORBROOK WATER FOR INJECTION
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: WATER FOR INJECTIONS 1,0 ml
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		NORBROOK LABORATORIES S.A. (PTY) LTD
Manufacturer:		NORBROOK LABORATORIES LTD, NEWRY, NORTHERN IRELAND
Packer:		NORBROOK LABORATORIES LTD, NEWRY, NORTHERN IRELAND
Laboratory:	FPRC	NORBROOK LABORATORIES LTD, NEWRY, NORTHERN IRELAND
	FPRR	NORBROOK LABORATORIES, CENTURION, RSA
Shelf-life:		36 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		38/13.1/0195
Name of medicine:		MDI POVIDONE GEL
Dosage form:		GEL
Active ingredients:		EACH 1,0 g GEL CONTAINS: POVIDONE IODINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MEDICINE DEVELOPERS INTERNATIONAL cc
Manufacturer:		IMPILO DRUGS (1966), ISITHEBE, KZN, RSA
Packer:		IMPILO DRUGS (1966), ISITHEBE, KZN, RSA
Laboratory:	FPRC:	IMPILO DRUGS (1966), ISITHEBE, KZN, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG CONSULTING MICROBIOLOGICAL LABORATORIES, MOREHILL, BENONI SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	MDI cc, MENLO PARK, PRETORIA
Shelf-life:		24 months (provisional)
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A38/30.1/0525
Name of medicine:		PENTAXIM
Dosage form:		INJECTION
Active ingredients:		EACH 0,5 ml DOSE CONTAINS: PURIFIED DIPHTHERIA TOXOID 30,0 iu PURIFEID TETANUS TOXOID 40,0 iu PURIFIED PERTUSSIS TOXOID 25,0 ug PURIFIED PERTUSSIS FILAMENTOUS HAEMAGGLUTININ 25,0 ug POLIOVIRUS D ANTIGEN TYPE 1 40,0 D units POLIOVIRUS D ANTIGEN TYPE 2 8,0 D units POLIOVIRUS D ANTIGEN TYPE 3 32,0 D units HAEMOPHILUS INFLUENZA TYPE b POLYSACCHARIDE 10,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AVENTIS PHARMA (PTY) LTD
Manufacturer:		AVENTIS PASTEUR, L'ETOILE, FRANCE
Packer:		AVENTIS PASTEUR, L'ETOILE, FRANCE
Laboratory:	FPRC:	AVENTIS PASTEUR, L'ETOILE, FRANCE
	FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:		36 months
Date of registration		2 MARCH 2007

MRF 15

Registration number:		A38/30.1/0526
Name of medicine:		TETRAXIM
Dosage form:		INJECTION
Active ingredients:		EACH 0,5 ml DOSE CONTAINS: PURIFIED DIPHTHERIA TOXOID 30,0 iu PURIFEID TETANUS TOXOID 40,0 iu PURIFIED PERTUSSIS TOXOID 25,0 ug PURIFIED PERTUSSIS FILAMENTOUS HAEMAGGLUTININ 25,0 ug POLIOVIRUS D ANTIGEN TYPE 1 40,0 D units POLIOVIRUS D ANTIGEN TYPE 2 8,0 D units POLIOVIRUS D ANTIGEN TYPE 3 32,0 D units
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AVENTIS PHARMA (PTY) LTD
Manufacturer:		AVENTIS PASTEUR, L'ETOILE, FRANCE
Packer:		AVENTIS PASTEUR, L'ETOILE, FRANCE
Laboratory:	FPRC:	AVENTIS PASTEUR, L'ETOILE, FRANCE
	FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:		36 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A39/20.1.7/0383
Name of medicine:		MERCK-ITRACONAZOLE 100 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: ITRACONAZOLE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		MARTEC PHARMACEUTICAL INC, TOPPING, KANSAS CITY, USA
Packer:		MARTEC PHARMACEUTICAL INC, TOPPING, KANSAS CITY, USA GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	MARTEC PHARMACEUTICAL INC, TOPPING, KANSAS CITY, USA GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A39/10.2.1/0482
Name of medicine:		ASTHAVENT RESPULES
Dosage form:		SOLUTION
Active ingredients:		EACH 2,5 ml SOLUTION CONTAINS: SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 2,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA-MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT I, VERNA, GOA, INDIA
Packer:		CIPLA LTD, UNIT I, VERNA, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, UNIT I, VERNA, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A39/10.2.1/0483
Name of medicine:		CIPLA-SALBUTAMOL RESPULES
Dosage form:		SOLUTION
Active ingredients:		EACH 2,5 ml SOLUTION CONTAINS: SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 2,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT I, VERNA, GOA, INDIA
Packer:		CIPLA LTD, UNIT I, VERNA, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, UNIT I, VERNA, GOA, INDIA
	FPRR	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A39/8.4/0518
Name of medicine:		VENOFUNDIN
Dosage form:		SOLUTION
Active ingredients:		EACH 1000,0 ml SOLUTION CONTAINS: HETASTARCH 60,0 g SODIUM CHLORIDE 9,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		B BRAUN MEDICAL (PTY) LTD
Manufacturer:		B BRAUN MEDICAL AG, CRISSIER, SWITZERLAND
Packer:		B BRAUN MEDICAL AG, CRISSIER, SWITZERLAND
Laboratory:	FPRC:	B BRAUN MEDICAL AG, CRISSIER, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A39/7.1/0545
Name of medicine:		AUSTELL-AMLODIPINE 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LIMITED, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LIMITED, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LIMITED, SILVASSA, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A39/7.1/0546
Name of medicine:		AUSTELL-AMLODIPINE 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LIMITED, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LIMITED, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LIMITED, SILVASSA, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/21.2/0151
Name of medicine:		ACTAZON 15
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PIOGLITAZONE HYDROCHLORIDE EQUIVALENT TO PIOGLITAZONE 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/21.2/0152
Name of medicine:		ACTAZON 30
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PIOGLITAZONE HYDROCHLORIDE EQUIVALENT TO PIOGLITAZONE 30,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, SALCETTE, GOA, INDIA
	FPRR	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/2.5/0168
Name of medicine:		PHARMA DYNAMICS LAMOTRIGINE 200 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Packer:		MEDOCHEMIE LTD, LIMASSOL, CYPRUS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory:	FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA IMPILO DRUGS, ISITHEBE, KZN
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/2.5/0170
Name of medicine:		PHARMA DYNAMICS LAMOTRIGINE 100 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Packer:		MEDOCHEMIE LTD, LIMASSOL, CYPRUS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory:	FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA IMPILO DRUGS, ISITHEBE, KZN
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/2.5/0171
Name of medicine:		PHARMA DYNAMICS LAMOTRIGINE 25 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Packer:		MEDOCHEMIE LTD, LIMASSOL, CYPRUS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory:	FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA IMPILO DRUGS, ISITHEBE, KZN
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/2.5/0172
Name of medicine:		PHARMA DYNAMICS LAMOTRIGINE 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Packer:		MEDOCHEMIE LTD, LIMASSOL, CYPRUS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory:	FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA IMPILO DRUGS, ISITHEBE, KZN
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:	A40/2.5/0183
Name of medicine:	ADCO-MICTRIN 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	DELTA LIMITED, HAFNARFJORDUR, ICELAND
Packer:	DELTA LIMITED, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	DELTA LIMITED, HAFNARFJORDUR, ICELAND
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months
Date of registration:	2 MARCH 2007

MRF 15

Registration number:	A40/2.5/0185
Name of medicine:	ADCO-MICTRIN 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	DELTA LIMITED, HAFNARFJORDUR, ICELAND
Packer:	DELTA LIMITED, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	DELTA LIMITED, HAFNARFJORDUR, ICELAND
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months
Date of registration:	2 MARCH 2007

MRF 15

Registration number:	A40/2.5/0186
Name of medicine:	ADCO-MICTRIN 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	DELTA LIMITED, HAFNARFJORDUR, ICELAND
Packer:	DELTA LIMITED, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	DELTA LIMITED, HAFNARFJORDUR, ICELAND
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months
Date of registration:	2 MARCH 2007

MRF 15

Registration number:	A40/11.4.3/0247
Name of medicine:	LANCAP 15 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: LANSOPRAZOLE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	KRKA DD, NOVO MESTO, SLOVENIA
Packer:	KRKA DD, NOVO MESTO, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory: FPRC:	KRKA DD, NOVO MESTO, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA IMPILO DRUGS, ISITHEBE, KZN
FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2007

MRF 15

Registration number:		A40/11.4.3/0248
Name of medicine:		LANCAP 30 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: LANSOPRAZOLE 30,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		KRKA DD, NOVO MESTO, SLOVENIA
Packer		KRKA DD, NOVO MESTO, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory:	FPRC:	KRKA DD, NOVO MESTO, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA IMPILO DRUGS, ISITHEBE, KZN
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/27/0266
Name of medicine:		EXJADE 125 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DEFERASIROX 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:		NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:		NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Laboratory:	FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG
	FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK
Shelf-life:		24 months (provisional)
Date of registration:		2 MARCH 2007

MRF 15

Registration number:	A40/27/0267
Name of medicine:	EXJADE 250 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DEFERASIROX 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (provisional)
Date of registration:	2 MARCH 2007

MRF 15

Registration number:	A40/27/0268
Name of medicine:	EXJADE 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DEFERASIROX 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (provisional)
Date of registration:	2 MARCH 2007

MRF 15

Registration number:		A40/2.5/0348
Name of medicine:		TOPLEP 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 25,0 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
	FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/2.5/0349
Name of medicine:		TOPLEP 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 50,0 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
	FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:	A40/2.5/0350
Name of medicine:	TOPLEP 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 100,0 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
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2007

MRF 15

Registration number:	A40/2.5/0351
Name of medicine:	TOPLEP 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 200,0 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
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months
Date of registration:	2 MARCH 2007

MRF 15

Registration number:		A40/5.10/0484
Name of medicine:		ZYDUS-ONDANSETRON 4 mg INJECTION
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
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 AND CHEMICAL SERVICES, SILVERTONDALE, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (provisional)
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/5.10/0485
Name of medicine:		ZYDUS-ONDANSETRON 8 mg INJECTION
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
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 AND CHEMICAL SERVICES, SILVERTONDALE, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (provisional)
Date of registration:		2 MARCH 2007

Registration number:		A40/20.1.2/0500
Name of medicine:		BIO-AMOKSIKLAV 1 000
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:		BIOTECH LABORATORIES (PTY) LTD
Manufacturer:		LEK PHARMACEUTICAL & CHEMICAL CO d.d., PREVALJE, SLOVENIA
Packer:		LEK PHARMACEUTICAL & CHEMICAL CO d.d., PREVALJE, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA
Laboratory:	FPRC:	LEK PHARMACEUTICAL & CHEMICAL CO d.d., PREVALJE, SLOVENIA LEK PHARMACEUTICAL & CHEMICAL CO d.d., LJUBLJANA, SLOVENIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	BIOTECH LABORATORIES, MIDRAND, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

Registration number:		A40/7.1.3/0601
Name of medicine:		QUINAGEN 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory:	FPRC:	MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/7.1.3/0602
Name of medicine		QUINAGEN 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory:	FPRC:	MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/7.1.3/0603
Name of medicine:		QUINAGEN 20 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory:	FPRC:	MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		A40/7.1.3/0604
Name of medicine:		QUINAGEN 40 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory:	FPRC:	MERCK FARMA Y QUIMICA S.A., BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:		41/7.3/0089
Name of medicine:		SUMIG 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT III, VERNA, GOA, INDIA
Packer:		CIPLA LTD, UNIT III, VERNA, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, UNIT III, VERNA, GOA, INDIA
	FPRR	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		2 MARCH 2007

MRF 15

Registration number:	41/7.3/0090
Name of medicine:	SUMIG 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT III, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT III, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT III, VERNA, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	2 MARCH 2007

MRF 15

Registration number:	41/7.3/0091
Name of medicine:	CIPLA-SUMATRIPTAN 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT III, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT III, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT III, VERNA, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	2 MARCH 2007