CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 826 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 826 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 5005 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 aile 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 kopiee van die protokolle vir die toets van die massalot en die vullot sowel as ses kopiee 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:		35/25.2/0332
Name of medicine:		CLINOLEIC 20 %
Dosage form:		INFUSION
Active ingredients:		EACH 100,0 ml EMULSION CONTAINS: ESSENTIAL FATTY ACIDS 4,0 g
Conditions of registration:		1,2,3,4,5,6
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		CLINTEC PARENTERAL, MONTARGIS, CEDEX, FRANCE
Packer:		CLINTEC PARENTERAL, MONTARGIS, CEDEX, FRANCE
Laboratory:	FPRC:	CLINTEC PARENTERAL, MONTARGIS, CEDEX, FRANCE
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		18 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		37/13.9.1/0241
Name of medicine:		DOVOBET
Dosage form:		OINTMENT
Active ingredients:		EACH 1,0 g OINTMENT CONTAINS: BETAMETHASONE DIPROPIONATE EQUIVALENT TO BETAMETHASONE 0,5 mg CALCIPOTRIOL 50,0 ug
Conditions of registration:		1,2,3,4,5,6
Applicant:		ADCOCK INGRAM LIMITED
Manufacturer:		LEO LABORATORIES, DUBLIN, IRELAND
Packer:		LEO LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC:	LEO LABORATORIES, DUBLIN, IRELAND LEO PHARMACEUTICAL PRODUCTS, BALLERUP, DENMARK PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		37/21.2/0572
Name of medicine:		ARROW-GLICLAZIDE 80 mg
Dosage form:		TABLETS
Active ingredients:		EACH TABLET CONTAINS: GLiCLAZIDE 80,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		SIGMA PHARMACEUTICALS, DANDENONG, CROYDON, AUSTRALIA
Packer:		SIGMA PHARMACEUTICALS, DANDENONG, CROYDON, AUSTRALIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	SIGMA PHARMACEUTICALS, MERRINDALE, CROYDON, AUSTRALIA SEDEK AGRIKEM, KAMEELDRIFT RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		24 months
Date of registration		8 JUNE 2007

MRF 15

Registration number:		37/20.1.1/0690
Name of medicine:		APEX-AZITHROMYCIN 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AZITHROMYCIN DIHYDRATE EQUIVALENT TO AZITHROMYCIN 500,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:		INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:		INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:	FPRC	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE M&L LABORATORIES, ORMONDE, JOHANNESBURG
	FPRR	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG
Shelf-life:		24 months
Date of registration		8 JUNE 2007

MRF 15

Registration number:		38/7.1.3/0042
Name of medicine:		APEX-L1SINOPRIL 5 mg
Dosage form:		TABLETS
Active ingredients:		EACH TABLET CONTAINS: L1SINOPRIL 5,Omg
Conditions of registration:		1,2,3,4,5,6
Applicant:		CAMOX PHARMACEUTICALS (PTY) LTO
Manufacturer:		MEDOCHEMIE, L1MASSOL, CYPRUS
Packer:		MEDOCHEMIE, L1MASSOL, CYPRUS
Laboratory:	FPRC:	MEDOCHEMIE, L1MASSOL, CYPRUS INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG
Shelf-life:		48 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		38/7.1.3/0043
Name of medicine:		APEX-L1SINOPRIL 10 mg
Dosage form:		TABLETS
Active ingredients:		EACH TABLET CONTAINS: L1SINOPRIL 10,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		CAMOX PHARMACEUTICALS (PTY) LTO
Manufacturer:		MEDOCHEMIE, L1MASSOL, CYPRUS
Packer:		MEDOCHEMIE, L1MASSOL, CYPRUS
Laboratory:	FPRC:	MEDOCHEMIE, L1MASSOL, CYPRUS INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG
Shelf-life:		48 months
Date of registration:		8 JUNE 2007

MRF15

Registration number:		*38/34/0086*
Name of medicine:		ZOMETA4mg
Dosage form:		SOLUTION
Active ingredients:		EACH 5,0 ml VIAL CONTAINS: ZOLEDRONIC ACID 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:		NOVARTIS PHARMA AG, STEIN, SWITZERLAND
Packer:		NOVARTIS PHARMA AG, STEIN, SWITZERLAND NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS PHARMA AG, STEIN, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		*38/7.1.3/0104*
Name of medicine:		APEX-L1SINOPRIL 20 mg
Dosage form:		TABLETS
Active ingredients:		EACH TABLET CONTAINS: L1SINOPRIL 20,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		CAMOX PHARMACEUTICALS (PTY) LTO
Manufacturer:		MEDOCHEMIE, L1MASSOL, CYPRUS
Packer:		MEDOCHEMIE, L1MASSOL, CYPRUS
Laboratory:	FPRC:	MEDOCHEMIE, L1MASSOL, CYPRUS INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG
Shelf-life:		48 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A38/20.2.8/0382
Name of medicine:		ASPEN ZIDOLAM
Dosage form:		TABLETS
Active ingredients:		EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Packer:		PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Laboratory:	FPRC:	ASPEN PHARMACARE, WILSONIA, EAST LONDON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A39/7.5/0131
Name of medicine:		PHARMA DYNAMICS SIMVASTATIN 40 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 40,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		KRKA, NOVO MESTO, SLOVENIA
Packer:		KRKA, NOVO MESTO, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA IMPILO DRUGS ISITHEBE, KZN
Laboratory:	FPRC:	KRKA, NOVO MESTO, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA IMPILO DRUGS ISITHEBE, KZN
	FPRR:	PHARMA DYNAMICS, SILVERWOORD, WESTLAKE
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:	A39/7.5/0132
Name of medicine:	SIMVACOR 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 40,0 mg
Conditions of registration	1,2,3,4,5,6
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer	KRKA, NOVO MESTO, SLOVENIA
Packer:	KRKA, NOVO MESTO, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA IMPILO DRUGS ISITHEBE, KZN
Laboratory: FPRC	KRKA, NOVO MESTO, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
FPRR:	PHARMA DYNAMICS, SILVERWOORD, WESTLAKE
Shelf-life:	24 months
Date of registration:	8 JUNE 2007

MRF 15

Registration number:	*A39/11A.* 3/0391
Name of medicine:	AUSTAC-75
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 75,0 mg
Conditions of registration:	1,2,3,4,5,6
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	8 JUNE 2007

MRF 15

Registration number:		A39/11.4.3/0392
Name of medicine:		AUSTELL-RANITIDINE 75 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A39/11.4.3/0393
Name of medicine:		AUSTAC-150
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 150,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A39/11.4.3/0394
Name of medicine:		AUSTAC-300
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 300,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/7.5/0093
Name of medicine:		AUSTELL-PRAVASTATIN 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PRAVASTATIN SODIUM 10,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/7.5/0094
Name of medicine:		AUSTELL-PRAVASTATIN 20 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PRAVASTATIN SODIUM 20,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUSTELL LABORATORIES (PTY) LTO
Manufacturer:		IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVE LI, INDIA
Packer:		IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/7.5/0095
Name of medicine:		AUSTELL-PRAVASTATIN 40 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PRAVASTATIN SODIUM 40,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LIMITED, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, GROENKLOOF. PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		*A40/6,2/0096*
Name of medicine:		ARYCOR IV
Dosage form:		INJECTION
Active ingredients:		EACH 3,0 ml SOLUTION CONTAINS: AMIODARONE HYDROCHLORIDE 150,0 mg
Conditions of registration:		1,2, 3, 4, 5, 6
Applicant:		SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:		SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:		SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE UPON TYNE, U.K. PHARMACEUTICAL CONTRACTORS, ISANDO, JOHANNESBURG
Laboratory:	FPRC	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG AVENTIS PHARMA, WALTLOO, PRETORIA
	FPRR	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf Life:		24 months
Date of reqlstration:		8 JUNE 2007

MRF 15

Registration number:		*A40/2,510139*
Name of medicine:		AR LAMOTRIGINE 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA
Packer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA SEDEK AGRIKEM, KAMEELDRIFT TECNIKON LABORATORIES, ROBERTVILLE, FLORIDA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		*M0/2.5/0140*
Name of medicine:		AR LAMOTRIGINE 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA
Packer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA SEDEK AGRIKEM, KAMEELDRIFT TECNIKON LABORATORIES, ROBERTVILLE, FLORIDA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		*MO/2. 510 141*
Name of medicine:		AR LAMOTRIGINE 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA
Packer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA SEDEK AGRIKEM, KAMEELDRIFT TECNIKON LABORATORIES, ROBERTVILLE, FLORIDA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/2.5/0142
Name of medicine:		AR LAMOTRIGINE 200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA
Packer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA SEDEK AGRIKEM, KAMEELDRIFT TECNIKON LABORATORIES, ROBERTVILLE, FLORIDA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/2.5/0143
Name of medicine:		ARROW LAMOTRIGINE 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA
Packer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA SEDEK AGRIKEM, KAMEELDRIFT TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:	*A40/2.5/0144*	
Name of medicine:	ARROW LAMOTRIGINE 50	
Dosage form:	TABLET	
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE	50,0 mg
Conditions of registration:	1,2,3,4,5,6	
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTO	
Manufacturer:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA	
Packer:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA	
Laboratory: FPRC:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA SEDEK AGRIKEM, KAMEELDRIFT TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM	
FPRR	ARROW PHARMA SA, WOODMEAD, RSA	
Shelf-life:	36 months	
Date of registration:	8 JUNE 2007	

MRF 15

Registration number:	*A40/2.510145*	
Name of medicine:	ARROW LAMOTRIGINE 100	
Dosage form:	TABLET	
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE	100,0 mg
Conditions of registration:	1,2,3,4,5,6	
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	
Manufacturer:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA	
Packer:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA	
Laboratory: FPRC:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA SEDEK AGRIKEM, KAMEELDRIFT TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM	
FPRR:	ARROW PHARMA SA, WOODMEAD, RSA	
Shelf life:	36 months	
Date of registration:	8 JUNE 2007	

MRF 15

Registration number:		A40/2.5/0146
Name of medicine:		ARROW LAMOTRIGINE 200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTO
Manufacturer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA
Packer:		TORRENT PHARMACEUTICALS, MEHSANA, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS, MEHSANA, INDIA SEDEK AGRIKEM, KAMEELDRIFT TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/2.9/0220
Name of medicine:		TRAMASPEN 100 mg/2 ml
Dosage form:		INJECTION
Active ingredients:		EACH 2,0 ml AMPOULE CONTAINS: TRAMADOL HYDROCHLORIDE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMACARE LIMITED
Manufacturer:		PIERREL FARMACEUTICI S.p.A, CAPUA, ITALY
Packer:		PIERREL FARMACEUTICI S.p.A, CAPUA, ITALY
Laboratory:	FPRC:	PIERREL FARMACEUTICI S.p.A, CAPUA, ITALY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORIES, ORMONDE, JOHANNESBURG ASPEN PHARMACARE, WILSONIA, EAST LONDON
	FPRR:	PHARMACARELTD,KORSTEN,PORT ELIZABETH
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		MO/20.1.1/0230
Name of medicine:		TYGACIL
Dosage form:		INFUSION
Active ingredients:		EACH 5,0 ml VIAL CONTAINS: TIGECYCLINE 50,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		WYETH SOUTH AFRICA (PTY) LTD
Manufacturer:		WYETH PARENTERALS, CAROLINA, PUERTO RICO
Packer:		WYETH PARENTERALS, CAROLINA, PUERTO RICO WYETH PHARMACEUTICALS, HAVANT, HAMPSHIRE, UK
Laboratory:	FPRC:	WYETH PARENTERALS, CAROLINA, PUERTO RICO WYETH PHARMACEUTICALS, HAVANT, HAMPSHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	WYETH SA, MIDRAND, RSA
Shelf-life:		12 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		MO/11.4.3/0249
Name of medicine:		GASTRID 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:		8 JUNE 2007

MRF 15

Registration number:		*MO/11.4.3/0250*
Name of medicine:		GASTRID 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 DO, NOVO MESTO, SLOVENIA
Packer:		KRKA DO, NOVO MESTO, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN IMPILO DRUGS, ISITHEBE, KZN
Laboratory:	FPRC	KRKA DO, 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:		8 JUNE 2007

MRF 15

Registration number:		*MO/7.1.3/0288*
Name of medicine:		SARBEN 150
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: IRBESARTAN 150,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		SANOFI-SYNTHELABO (PTY) LTO
Manufacturer:		BRISTOL-MYERS SQUIBB CO, EVANSVILLE, INDIANA, USA SANOFI-WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:		SANOFI-WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, ISANDO, RSA AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:	FPRC	SANOFI-WINTHROP INDUSTRIE, AMBARES, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/7.1.3/0289
Name of medicine:		SARBEN 300
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: IRBESARTAN 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		SANOFI-SYNTHELABO (PTY) LTO
Manufacturer:		BRISTOL-MYERS SQUIBB CO, EVANSVILLE, INDIANA, USA SANOFI-WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:		SANOFI-WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, ISANDO, RSA AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:	FPRC:	SANOFI-WINTHROP INDUSTRIE, AMBARES, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/7.1.3/0291
Name of medicine:		SARBEN 75
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: IRBESARTAN 75,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:		BRISTOL-MYERS SQUIBB CO, EVANSVILLE, INDIANA, USA SANOFI-WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:		SANOFI-WINTHROP INDUSTRIE, AMBARES, FRANCE PHARMACEUTICAL CONTRACTORS, (SANDO, RSA AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:	FPRC:	SANOFI·WINTHROP INDUSTRIE, AMBARES, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:		36 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/20.2.8/0562
Name of medicine:		AURO-ZIDOVUDINE ORAL SOLUTION 50 mg/5 ml
Dosage form:		SOLUTION
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: ZIDOVUDINE 50,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTO, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTO, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTO, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/21 .*1210567*
Name of medicine:		FINPRO
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FINASTERIDE 5,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, QUTUBULLAPUR, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, QUTUBULLAPUR, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, QUTUBULLAPUR, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICALS 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:		8 JUNE 2007

MRF 15

Registration number:		*M0/7.3/0612*
Name of medicine:		ARROW 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:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA ARROW GENERICS LTO, DUBLIN, IRELAND M&L LABORATORIES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		*M0/7.3/0613*
Name of medicine:		ARROW 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:		ARROW PHARMA SOUTH AFRICA (PTY) LTO
Manufacturer:		ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA ARROW GENERICS LTD, DUBLIN, IRELAND M&L LABORATORIES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/1.2/0712
Name of medicine:		ZYDUS-PAROXETINE 20 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 20,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant		ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SIVERTONDALE, RSA
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/1.210740
Name of medicine:		CITALOPRAM-WINTHROP 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:	TROPON GmbH, KOLN, GERMANY 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:		8 JUNE 2007

MRF 15

Registration number:		*A40/1.210741*
Name of medicine:		CITALOPRAM-WINTHROP 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:	TROPON GmbH, KOLN, GERMANY 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:		8 JUNE 2007

MRF 15

Registration number:		*A40/2.5/0763*
Name of medicine:		LAMIDUS TABLETS 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ZYDUS HEALTHCARE SA (PTY) LTO
Manufacturer:		ZYDUS CADILA HEALTHCARE LTO, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		*M0/2.5/0764*
Name of medicine:		LAMIDUS TABLETS 100 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ZYDUS HEALTHCARE SA (PTY) LTO
Manufacturer:		ZYDUS CADILA HEALTHCARE LTO, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTO, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTO, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK,POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		*M0/2.5/0765*
Name of medicine:		LAMIDUS TABLETS 200 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK,POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		A40/26/0776
Name of medicine:		NEXAVAR200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SORAFENIB TOSYLATE EQUIVALENT TO SORAFENIB 200,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		BAYER (PTY) LTO T/A BAYER SCHERING
Manufacturer:		BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY
Packer:		BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL CONTRACTORS, ISANDO SPECPHARM HOLDINGS, MIDRAND
Laboratory:	FPRC:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	BAYER, ISANDO, RSA
Shelf-life:		24 months (provisional)
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		*41/20.1.210055*
Name of medicine:		AURO-AMOXYCILLIN CAPSULES 250 mg
Dosage form:		CAPSULES
Active ingredients:		EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUROBINDO PHARMA (PTY) LTO
Manufacturer:		AUROBINDO PHARMA LTD, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		41/20.1.2/0056
Name of medicine:		AURO-AMOXYCILLIN CAPSULES 500 mg
Dosage form:		CAPSULES
Active ingredients:		EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA (PTY) LTO
Packer:		AUROBINDO PHARMA LTD, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTO, HYDERABAD, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF15

Registration number:		41/20.2.8/0140
Name of medicine:		CIPLA-LAMIVUDINE 300
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMIVUDINE 300,0 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 LTO, UNIT III, VERNA, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		41/21.2/0193
Name of medicine:		BIGSENS 1 000
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 1 000,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		8 JUNE 2007

MRF 15

Registration number:		41/5.7.1/0214
Name of medicine:		NEOLORIDIN 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DESLORATADINE 5,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE SA , VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		8 JUNE 2007

MRF 15

Registration number:	41/10.2.1/0228
Name of medicine:	MERCK-SALBUTAMOL INHALER
Dosage form:	INHALANT
Active ingredients:	EACH METERED DOSE CONTAINS: SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 100,0 ug
Conditions of registration:	1,2,3,4,5,6
Applicant:	MERCK GENERICS RSA (PTY) LTO
Manufacturer:	INYX PHARMA LTD, RUNCORN, CHESHIRE, UK
Packer:	INYX PHARMA LTD, RUNCORN, CHESHIRE, UK GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON
Laboratory: FPRC:	INYX PHARMA LTO, RUNCORN, CHESHIRE, UK MERCK PHARMACEUTICAL MANUFACTURERS, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	8 JUNE 2007

MRF 15

Registration number:	41/20.2.8/0230
Name of medicine:	NEVAID 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, AEROTON, JOHANNESBURG
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	8 JUNE 2007

MRF 15

Registration number:	41/20.2.8/0331
Name of medicine:	ADCO-LAMIVUDINE SOLUTION
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LAMIVUDINE 10,0 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
Laboratory FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (Provisional)
Date of registration:	8 JUNE 2007

MRF 15

Registration number:	41/20.2.8/0510
Name of medicine:	ADCO-ZIDOVUDINE SYRUP ALCOHOL AND SUGAR FREE
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: ZIDOVUDINE 50,0 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
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (Provisional)
Date of registration:	8 JUNE 2007

MRF 15

Registration number:	*41/20.2.8/0511*
Name of medicine:	ADCO-ZIDOVUDINE SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: ZIDOVUDINE 50,0 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
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (Provisional)
Date of registration:	8 JUNE 2007

MRF 15

Registration number:	*41/20.2.8/0514*
Name of medicine:	ADCO-LAMIVUDINE SOLUTION ALCOHOL AND SUGAR FREE
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LAMIVUDINE 10,0 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
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	24 months (Provisional)
Date of registration:	8 JUNE 2007

MRF 15

Registration number:		A39/5.8/0451
Name of medicine:		EFFERFLU-C
Dosage form:		TABLET
Active ingredients:		EACH EFFERVESCENT TABLET CONTAINS: PARACETAMOL 500,0 mg SODIUM ASCORBATE EQUIVALENT TO VITAMIN C 250,0 mg CHLORPHENAMINE MALEATE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		E-PHARMA TRENTO S.p.A., TRENTO, ITALY
Packer:		E-PHARMA TRENTO S.p.A., TRENTO, ITALY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMACEUTICAL ENTERPRISES, N'DABENI,RSA
Laboratory:	FPRC:	E-PHARMA TRENTO S.p.A., TRENTO, ITALY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months (provisional)
Date of registration:		14 MAY 2007