CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 559 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 559 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 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 gebruikgedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF15

Registration number:		36/30.3/0057
Name of medicine:		ALBUMIN HUMAN 20 % OCTAPHARMA
Dosage form:		SOLUTION
Active ingredients:		EACH 1 000,0 ml SOLUTION CONTAINS: HUMAN ALBUMIN 200,0 g
Conditions of registration:		1,2,3,4,5,6
Applicant:		JE ECKARD
Manufacturer:		OCTAPHARMA PHARMAZEUTIKA, VIENNA, AUSTRIA
Packer:		OCTAPHARMA PHARMAZEUTIKA, VIENNA, AUSTRIA
Laboratory:	FPRC:	OCTAPHARMA PHARMAZEUTIKA, VIENNA, AUSTRIA
	FPRR:	JE ECKARD, MONUMENT PARK, PRETORIA
Shelf-life:		36 months
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		37/21.10/0374
Name of medicine:		OVIDREL 250 ug
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CHORIOGONADOTROPIN ALFA 250,0 ug
Conditions of registration:		1,2,3,4,5,6
Applicant:		SERONO SOUTH AFRICA (PTY) LTD
Manufacturer:		INDUSTRIA FARMACEUTICA SERONO S.p.A., BARI, ITALY
Packer:		INDUSTRIA FARMACEUTICA SERONO S.p.A., BARI, ITALY
Laboratory:	FPRC:	INDUSTRIA FARMACEUTICA SERONO S.p.A., BARI, ITALY RBM, COLLERETIO GIACOSA, ITALY
	FPRR:	SERONO S.A., FOURWAYS, SANDTON
Shelf-life:		24 months
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		38/2.7/0299
Name of medicine:		NOVODOLSYRUP
Dosage form:		SYRUP
Active ingredients:		EACH 5,0 ml SYRUP CONTAINS: PARACETAMOL 120,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		MEDICINE DEVELOPERS INTERNATIONAL c.c.
Manufacturer:		PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
Packer:		PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
Laboratory:	FPRC:	PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
	FPRR:	MEDICINE DEVELOPERS INTERNATIONAL C.c, MENLO PARK, PRETORIA
Shelf-life:		24 months
Date of registration		13 APRIL 2007

MRF 15

Registration number:		*A38/1.210618*
Name of medicine:		CAMOX-SERTRALINE 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:		INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:		INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:	FPRC:	INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA M&L LABORATORIES, ORMONDE, JOHANNESBURG
	FPRR	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG,RSA
Shelf-life:		24 months
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		A38/1.2/0619
Name of medicine:		CAMOX-SERTRALINE 100 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:		INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:		INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:	FPRC:	INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA M&L LABORATORIES, ORMONDE, JOHANNESBURG
	FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG,RSA
Shelf-life:		24 months
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		A39n.1.3/0066
Name of medicine:		ZESTOZIDE 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: L1SINOPRIL DIHYDRATE EQUIVALENT TO L1SINOPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:		LABORATORIOS LESVI SL, BARCELONA, SPAIN
Packer:		LABORATORIOS LESVI SL, BARCELONA, SPAIN MERCK FARMA YQUIMICA S.A., BARCELONA, SPAIN GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC:	LABORATORIOS LESVI SL, BARCELONA, SPAIN MERCK FARMA YQUIMICA S.A., BARCELONA, SPAIN GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTUE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	XIXIA PHARMACEUTICALS, MODDERFORTEIN
Shelf-life:		36 months
Date of registration:		13 APRIL 2007

MRF15

Registration number:	A39/7.1.3/0067
Name of medicine:	ZESTOZIDE 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: L1SINOPRILDIHYDRATE EQUIVALENT TO L1SINOPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIOS LESVI SL, BARCELONA, SPAIN
Packer:	LABORATORIOS LESVI SL, BARCELONA, SPAIN MERCK FARMA YQUIMICA S.A., BARCELONA, SPAIN GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory: FPRC:	LABORATORIOS LESVI SL, BARCELONA, SPAIN MERCK FARMA YQUIMICA S.A., BARCELONA, SPAIN GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTUE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	XIXIA PHARMACEUTICALS, MODDERFORTEIN
Shelf-life:	36 months
Date of registration:	13 April 2007

MRF 15

Registration number:	*A39/11 .5/0261*
Name of medicine:	LAXADOR SENNA 7,5 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CALCIUM SENNOSIDES EQUIVALENT TO SENNOSIDES 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN,PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Packer:	PHARMACARE LIMITED, KORSTEN,PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Laboratory: FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFTSROOM
FPRC/FPRR	PHARMACARE LIMITED, KORSTEN,PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Shelf-life:	24 months (provisional)
Date of registration:	13 APRIL 2007

MRF 15

Registration number:		A39/20.2.3/0325
Name of medicine		ANTIB-4
Dosage form		TABLET
Active ingredients:		EACH TABLET CONTAINS: RIFAMPICIN 150,Omg ISONIAZID 75,0 mg PYRAZINAMIDE 400,0 mg ETHAMBUTOL HYDROCHLORIDE 275,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		MEDICINE DEVELOPERS INTERNATIONAL cc
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,STAR STREET,BOKSBURG,RSA
	FPRR:	MOl cc, MENLOPARK, PRETORIA, RSA
Shelf-life:		24 months
Date of registration:		2 FEBRUARY 2007

MRF 15

Registration number:		A39/20.2.8/0345
Name of medicine:		IMMUNAC 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:		MEOREICH 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, SILVERTONOALE, RSA M&L LABORATORIES, ORMONDE, JOHANNESBURG
	FPRR:	. CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG,RSA
Shelf-life:		24 months (provisional)
Date of registration		13 APRIL 2007

MRF 15

Registration number:	A39/20.2.8/0346
Name of medicine:	IMMUNAC 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:	MEOREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA
Packer:	MEOREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA
Laboratory: FPRC:	MEOREICH STERILAB LTD, VIRGONAR BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA M&L LABORATORIES, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG,RSA
Shelf-life:	24 months (provisional)
Date of registration:	13 APRIL 2007

MRF 15

Registration number:	A39/5.8/0450
Name of medicine:	EFFERCO-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:	13 APRIL 2007

MRF 15

Registration number:	A39/1.2/0596
Name of medicine:	ZYLIN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 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 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:	13 APRIL 2007

MRF 15

Registration number:	A39/20.2.8/0610
Name of medicine:	VARI-LAMIVUDINE 150 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg
Conditions of registration:	1,2,3,4,5,6
Applicant:	LEBASI PHARMACEUTICALS CC
Manufacturer:	VARICHEM PHARMACEUTICALS (PVT) LTD, HARARE, ZIMBABWE
Packer:	VARICHEM PHARMACEUTICALS (PVT) LTD, HARARE, ZIMBABWE
Laboratory: FPRC:	VARICHEM PHARMACEUTICALS (PVT) LTD, HARARE, ZIMBABWE RERSEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR	LEBASI PHARMACEUTICALS, POTCHEFSTROOM
Shelf-life:	24 months
Date of registration:	13 APRIL 2007

MRF 15

Registration number:		A40/7.1/0077
Name of medicine:		STAMLATE 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 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, 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
	FPRR:	DR. REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		13 APRIL 2007

MRF 15

Registration number:	A40/7.1/0078
Name of medicine:	STAMLATE 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE MALEATE EQUIVALENT TO AMLODIPINE 10,0 rng
Conditions of registration:	1,2,3,4,5,6
Applicant:	DR. REDDY'S LASORATORIES (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
FPRR:	DR. REDDY'S LASORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	13 APRIL 2007

MRF 15

Registration number:		*A40/26/0352*
Name of medicine:		DOXORUBICIN "EBEWE" 10 mg
Dosage form:		SOLUTION
Active ingredients:		EACH VIAL CONTAINS: DOXORUBICIN HYDROCHLORIDE *2,0 mg/ml*
Conditions of registration:		1,2,3,4,5,6
Applicant:		PHARMAFRICA (PTY) LTD
Manufacturer:		EBEWE PHARMA Ges.m.b.H., UNTERACH, AUSTRIA
Packer:		EBEWE PHARMA Ges.m.b.H., UNTERACH, AUSTRIA
Laboratory:	FPRC:	EBEWE PHARMA Ges.m.b.H., UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+SAG, BAD BOCKLET, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAFRICA, NEW CENTRE, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		*A40/26/0353*
Name of medicine:		DOXORUBICIN "EBEWE" 50 mg
Dosage form:		SOLUTION
Active ingredients:		EACH VIAL CONTAINS: DOXORUBICIN HYDROCHLORIDE *2,0 mg/ml*
Conditions of registration:		1,2,3,4,5,6
Applicant:		PHARMAFRICA (PTY) LTD
Manufacturer:		EBEWE PHARMA Ges.m.b.H., UNTERACH, AUSTRIA
Packer:		EBEWE PHARMA Gas.m.b.H., UNTERACH, AUSTRIA
Laboratory:	FPRC:	EBEWE PHARMA Ges.m.b.H., UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+SAG, BAD BOCKLET, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAFRICA, NEW CENTRE, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		A40/7.5/0399
Name of medicine:		MEDPRO SIMVASTATIN 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		CIPLA MEOPRO (PTY) LTO
Manufacturer:		CIPLA LTO, KURKUMBH, PUNE, INOlA
Packer:		CIPLA LTO, KURKUMBH, PUNE, INDIA
Laboratory:	FPRC:	CIPLA LTO, KURKUMBH, PUNE, INDIA
	FPRR:	CIPLA MEOPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		*A40n.5/0400*
Name of medicine:		MEDPRO SIMVASTATIN 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS SIMVASTATIN 20,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		CIPLA MEDPRO (PTY) LTO
Manufacturer:		CIPLA LTO, KURKUMBH, PUNE, INDIA
Packer:		CIPLALTO, KURKUMBH, PUNE, INDIA
Laboratory:	FPRC:	CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR:		CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		A40/15.4/0511
Name of medicine:		TRAVOPROSTITIMOLOL ALCON
Dosage form:		DROPS
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: TRAVOPROST 40,0 ug TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		ALCON LABORATORIES (S.A.) (PTY) LTD
Manufacturer:		S.A. ALCON-COUVREUR N.V., PUURS, BELGIUM
Packer:		S.A. ALCON-COUVREUR N.V., PUURS, BELGIUM
Laboratory:	FPRC:	S.A. ALCON-COUVREUR N.V., PUURS, BELGIUM RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ALCON LABORATORIES (S.A.), BRYANSTON, RSA
Shelf-life:		36 months
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		A40/20.2.3/0535
Name of medicine:		RIFINAH 300 FC
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RIFAMPICIN 300,0 mg ISONIAZID 150,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AVENTIS PHARMA (PTY) LTD
Manufacturer:		AVENTIS PHARMA, WALTLOO, PRETORIA
Packer:		AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:	FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		*A40/1.210564*
Name of medicine:		CILORAM
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIOE EQUIVALENT TO CITALOPRAM 20,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUROBINDO PHARMA (PTY) LTO
Manufacturer:		AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTO, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		*A40/5.*7.1/0588
Name of medicine:		FEXO-FAST 120
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 120,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		SANDOZ (PTY) LTD
Manufacturer:		SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA
Packer:		SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA
Laboratory:	FPRC:	SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA ANALYTICON, TERENURE, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRC/FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		A40/5.7.1*10589*
Name of medicine:		FEXO-FAST 180
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FEXOFENADINE HYDROCHLORIDE 180,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		SANDOZ (PTY) LTD
Manufacturer:		SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA
Packer:		SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA
Laboratory:	FPRC:	SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA ANALYTICON, TERENURE, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRC/FPRR	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		A40/21.*210638*
Name of medicine:		AURO-METFORMIN 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUROBINOO PHARMA (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
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF15

Registration number:		A40/21.2/0639
Name of medicine:		AURO-METFORMIN 850 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROSINDD PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROSINDD PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROSINDO PHARMA, ROSESANK, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF 15

Registration number:		A40/21 *.210640*
Name of medicine:		AURO-METFORMIN 1 000 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 1000,0 mg
Conditions of registration:		1,2,3,4,5,6
Applicant:		AUROBINDO PHARMA (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
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (provisional)
Date of registration:		13 APRIL 2007

MRF 15

Registration number:	A40/20.2.8/0681
Name of medicine:	VIREAD
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1,2,3,4,5,6
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA PHARMACARE LTO, KORSTEN, PORT ELIZABETH CARDINAL HEALTH GERMANY GmbH, SCHORNDORF, GERMANY GILEAD SCIENCES INC, SAN DIMAS, CALIFORNIA, USA GILEAD SCIENCES LTD, DUBLIN, IRELAND
Laboratory: FPRC:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA PATHEON INC, BURLINGTON, ONTARIO, CANADA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM GILEAD SCIENCES INC, SAN DIMAS, CALIFORNIA, USA GILEAD SCIENCES LTD, DUBLIN, IRELAND
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	36 months (packed in HOPE containers) 24 months (packed in Alu/Alu blisters) 24 weeks (bulk product transported in HOPE containers)
Date of registration:	13 APRIL 2007

MRF 15

Registration number:	41/20.2.8/0171
Name of medicine:	TRUVADA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg
Conditions of registration:	1,2,3,4,5,6
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA PHARMACARE LTO, KORSTEN, PORT ELIZABETH
Packer:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH CARDINAL HEALTH GERMANY GmbH, SCHORNDORF, GERMANY GILEAD SCIENCES INC, SAN DIMAS, CALIFORNIA, USA GILEAD SCIENCES LTD, DUBLIN, IRELAND
Laboratory: FPRC:	ALTANA PHARMA ORANIENBURG GmbH, ORANIENBURG, GERMANY PATHEON INC, MISSISSAUGA, ONTARIO, CANADA PATHEON INC, BURLINGTON, ONTARIO, CANADA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM GILEAD SCIENCES INC, SAN DIMAS, CALIFORNIA, USA GILEAD SCIENCES LTD, DUBLIN, IRELAND
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months(provisional)
Date of registration:	13 APRIL 2007

MRF 15

Registration number:	41/20.2.8/0229
Name of medicine:	LAVaS 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, WAOEVILLE, GERMISTON ADCOCK INGRAM LTO, AEROTON, JOHANNESBURG
Laboratory: FPRC,FPRR:	ADCOCK INGRAM HEALTHCARE, WAOEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	13 April 2007