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CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 905 OF 2008

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

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
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 905 VAN 2008

MEDISYNEBEHEERRAAD

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

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goekgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleeftyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleeftydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
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 'n 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:		36/7.5/0281
Name of medicine:		BEZACHOLE SR
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: BEZAFIBRATE 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY
Packer:		ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:	VALPHARMA INTERNATIONAL S.p.A., PENNABILLI, PERSARO-URBINO, ITALY SEDEK AGRIKEM, KAMEELDRIFT EAST, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		37/26/0483
Name of medicine:		NEOTALEM
Dosage form:		INJECTION
Active ingredients:		EACH 10,0 ml VIAL CONTAINS: MITOXANTRONE HYDROCHLORIDE EQUIVALENT TO MITOXANTRONE 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		KEY ONCOLOGICS (PTY) LTD
Manufacturer:		LEMERY S.A. de C.V, HUICHAPAN, XOCH, MEXICO
Packer:		LEMERY S.A. de C.V, HUICHAPAN, XOCH, MEXICO
Laboratory:	FPRC:	LEMERY S.A. de C.V, HUICHAPAN, XOCH, MEXICO INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	KEY ONCOLOGICS, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		38/7.1.3/0032
Name of medicine:		AUSTELL-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, 7
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		38/7.1.3/0033
Name of medicine:		AUSTELL-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, 7
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		38/26/0057
Name of medicine:		LITAK 10
Dosage form:		INJECTION
Active ingredients:		EACH 5,0 ml VIAL CONTAINS: CLADRIBINE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		KEY ONCOLOGICS (PTY) LTD
Manufacturer:		HAUPT PHARMA GmbH, WOLFRATSHAUSEN, GERMANY
Packer:		HAUPT PHARMA GmbH, WOLFRATSHAUSEN, GERMANY
Laboratory:	FPRC:	HAUPT PHARMA GmbH, WOLFRATSHAUSEN, GERMANY LIPOMED AG, ARLESHEIM, SWITZERLAND INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	KEY ONCOLOGICS, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		38/20.1.1/0204
Name of medicine:		CEFUROXIME-SAFELINE 1,5 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1,5 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:		DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE
Packer:		DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE
Laboratory:	FPRC:	DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		38/20.1.1/0205
Name of medicine:		CEFUROXIME-SAFELINE 750 mg
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SAFELINE PHARMACEUTICALS (PTY) LTD
Manufacturer:		DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE
Packer:		DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE
Laboratory:	FPRC:	DEMO S.A. PHARMACEUTICAL, KRYONERI, ATHENS, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	SAFELINE PHARMACEUTICALS, FLORIDA, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A04/3.1.5/08
Name of medicine:		TILDREN
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: TILUDRONIC ACID 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CEVA ANCHORPHARM ANIMAL HEALTH S.A (PTY) LTD
Manufacturer:		CEVA SANTE ANIMALE SA, CEDEX, FRANCE CEVA LABORATOIRES STERILYO, SANT AMAND LES EAUX, FRANCE
Packer:		CEVA SANTE ANIMALE SA, CEDEX, FRANCE
Laboratory:	FPRC:	CEVA SANTE ANIMALE SA, CEDEX, FRANCE CEVA LABORATOIRES STERILYO, SANT AMAND LES EAUX, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	CEVA ANCHORPHARM ANIMAL HEALTH, BRAMLEY, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:	A05/22.6.2/10
Name of medicine:	ALIZINE
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: AGLEPRISTONE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	VIRBAC RSA (PTY) LTD
Manufacturer:	VIRBAC SA, CEDEX, FRANCE
Packer:	VIRBAC SA, CEDEX, FRANCE VIRBAC RSA, CENTURION, RSA
Laboratory: FPRC:	VIRBAC SA, CEDEX, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR	VIRBAC RSA, CENTURION, RSA
Shelf-life:	36 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	A38/3.2/0381
Name of medicine:	BONDRONAT 6 mg/6 ml
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: IBANDRONIC ACID 6,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE DIAGNOSTIC GmbH, MANNHEIM, GERMANY
Packer:	ROCHE DIAGNOSTIC GmbH, MANNHEIM, GERMANY ROCHE PRODUCTS, ISANDO, RSA
Laboratory: FPRC:	ROCHE DIAGNOSTIC GmbH, MANNHEIM, GERMANY
FPRC/FPRR:	ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	60 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	A39/21.12/0064
Name of medicine:	CETROTIDE 0,25 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CETRORELIX ACETATE EQUIVALENT TO CETRORELIX 0,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK (PTY) LTD
Manufacturer:	BAXTER ONCOLOGY GmbH, HALLE, GERMANY
Packer:	BAXTER ONCOLOGY GmbH, HALLE, GERMANY SOLVAY PHARMACEUTICALS BV, OLST, THE NETHERLANDS
Laboratory: FPRC:	BAXTER ONCOLOGY GmbH, HALLE, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR	MERCK, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	A39/21.12/0065
Name of medicine:	CETROTIDE 3 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CETRORELIX ACETATE EQUIVALENT TO CETRORELIX 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK (PTY) LTD
Manufacturer:	BAXTER ONCOLOGY GmbH, HALLE, GERMANY
Packer:	BAXTER ONCOLOGY GmbH, HALLE, GERMANY SOLVAY PHARMACEUTICALS BV, OLST, THE NETHERLANDS
Laboratory: FPRC	BAXTER ONCOLOGY GmbH, HALLE, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR	MERCK, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:		A39/2.1/0077
Name of medicine:		B. BRAUN PROPOFOL 1 % (10 mg/ml)
Dosage form:		EMULSION
Active ingredients:		EACH 1,0 ml EMULSION CONTAINS: PROPOFOL 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		B BRAUN MEDICAL (PTY) LTD
Manufacturer:		B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Packer:		B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Laboratory:	FPRC:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	B BRAUN MEDICAL, HONEYDEW, RANDBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A39/30.4/0417
Name of medicine:		CEPROTIN 500 iu
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: PROTEIN C 500,0 iu
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA BAXTER S.p.A., RUFINA, ITALY
Packer:		BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Laboratory:	FPRC:	BAXTER AG, SMOLAGASSE, VIENNA, AUSTRIA
	FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A39/30.4/0418
Name of medicine:		CEPROTIN 1000 iu
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: PROTEIN C 1000,0 iu
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA BAXTER AG, BENATZKYGASSE, VIENNA, AUSTRIA BAXTER S.p.A., RUFINA, ITALY
Packer:		BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Laboratory:	FPRC:	BAXTER AG, SMOLAGASSE, VIENNA, AUSTRIA
	FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A39/1.2/0500
Name of medicine:		TAZERON 15 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MIRTAZAPINE 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN
Packer:		KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN
Laboratory:	FPRC:	COMBINO PHARM S.L., SANT JOAN DESPI, BACELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A39/1.2/0501
Name of medicine:		TAZERON 30 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MIRTAZAPINE 30,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMAPLAN (PTY) LTD
Manufacturer:		KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN
Packer:		KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN
Laboratory:	FPRC:	COMBINO PHARM S.L., SANT JOAN DESPI, BACELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A39/21.5.1/0584
Name of medicine:		SANDOZ BECLOMETHASONE DIPROPIONATE AQ 100
Dosage form:		SUSPENSION
Active ingredients:		EACH METERED NASAL SPRAY DOSE CONTAINS: BECLOMETHASONE DIPROPIONATE 100,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		CHIESI FARMACEUTICI SpA, LEONARDO, PARMA, ITALY
Packer:		CHIESI FARMACEUTICI SpA, LEONARDO, PARMA, ITALY CHIESI FARMACEUTICI SpA, PALERMO, PARMA, ITALY NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	CHIESI FARMACEUTICI SpA, LEONARDO, PARMA, ITALY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/13.4.1/0035
Name of medicine:		CLOBEX SHAMPOO
Dosage form:		SHAMPOO
Active ingredients:		EACH 1,0 g SHAMPOO CONTAINS: CLOBETASOL PROPIONATE 0,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		GALDERMA LABORATORIES S.A. (PTY) LTD
Manufacturer:		LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE
Packer:		LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE
Laboratory:	FPRC:	LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE
	FPRR:	GALDERMA LABORATORIES S.A., BRYANSTON, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/34/0045
Name of medicine:		CIPLA-TAMSULOSIN HYDROCHLORIDE
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 400,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:		CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory:	FPRC:	CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/34/0046
Name of medicine:		UROMAX
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 400,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:		CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory:	FPRC:	CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/20.1.1/0102
Name of medicine:		ZITHROMAX ONE
Dosage form:		GRANULES
Active ingredients:		EACH BOTTLE CONTAINS: AZITHROMYCIN DIHYDRATE EQUIVALENT TO AZITHROMYCIN 2,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PFIZER LABORATORIES (PTY) LTD
Manufacturer:		PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO
Packer:		PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO PFIZER ITALIA s.r.l., LATINA, ITALY PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN
Laboratory:	FPRC:	PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO PFIZER ITALIA s.r.l., LATINA, ITALY
	FPRC/FPRR:	PFIZER GLOBAL MANUFACTURING, RETREAT, CAPE TOWN
	FPRR	PFIZER LABORATORIES, SANDTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/21.2/0132
Name of medicine:		GLIMPID 1
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (SA) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/21.2/0133
Name of medicine:		GLIMPID 2
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (SA) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/21.2/0134
Name of medicine:		GLIMPID 4
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (SA) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/2.5/0166
Name of medicine:		DYNA-LAMOTRIGINE 100 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
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
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/2.5/0167
Name of medicine:		DYNA-LAMOTRIGINE 200 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
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
Laboratory:	FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/2.5/0169
Name of medicine:		DYNA-LAMOTRIGINE 50 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
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
Laboratory:	FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/2.5/0173
Name of medicine:		DYNA-LAMOTRIGINE 25 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
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
Laboratory:	FPRC:	MEDOCHEMIE LTD, LIMASSOL, CYPRUS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/3.1/0240
Name of medicine:		CATAFAST-D TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DICLOFENAC SODIUM 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:		NOVARTIS PHARMA GmbH, WEHR, GERMANY
Packer:		NOVARTIS PHARMA GmbH, WEHR, GERMANY NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS PHARMA GmbH, WEHR, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:	A40/7.1.3/0287
Name of medicine:	COIRBESARTAN WINTHROP 300/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB CO., EVANSVILLE INDIANA, USA SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	A40/7.1.3/0290
Name of medicine:	COIRBESARTAN WINTHROP 150/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB CO., EVANSVILLE INDIANA, USA SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory: FPRC:	SANOFI WINTHROP INDUSTRIE, AMBARES, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:	SANOFI-SYNTHELABO, MIDRAND, RSA
Date of registration:	36 months
	18 APRIL 2008

MRF 15

Registration number:	A40/34/0299
Name of medicine:	CYCLEAN
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: POLYHEXANIDE 0,1 µg
Conditions of registration:	1, 2, 3 ,4, 5, 6, 8
Applicant:	REVISION S.A. (PTY) LTD
Manufacturer:	SAUFLON PHARMACEUTICALS LTD, TWICKENHAM, MIDDLESEX, U.K.
Packer:	SAUFLON PHARMACEUTICALS LTD, TWICKENHAM, MIDDLESEX, U.K
Laboratory: FPRC:	SAUFLON PHARMACEUTICALS LTD, TWICKENHAM, MIDDLESEX, U.K TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
FPRR:	REVISION S.A., BEDFORDVIEW, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	A40/20.1.1/0309
Name of medicine:	LEVOFLOXACIN-WINTHROP 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AVENTIS PHARMA (PTY) LTD
Manufacturer:	AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE
Packer:	AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Laboratory: FPRC:	AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	AVENTIS PHARMA, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:		A40/20.1.1/0310
Name of medicine:		LEVOFLOXACIN-WINTHROP 500
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AVENTIS PHARMA (PTY) LTD
Manufacturer:		AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE
Packer:		AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Laboratory:	FPRC:	AVENTIS PHARMA SPECIALITES, COMPEIGNE, FRANCE AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT, GERMANY
	FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
	FPRR:	AVENTIS PHARMA, MIDRAND, RSA
Shelf-life:		60 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/34/0314
Name of medicine:		OCTREOTIDE HEXAL 0,05 mg
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: OCTREOTIDE 0,05 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY
Manufacturer:		WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY
Packer:		WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY LABOR L+S AG, BAD BOCKLET-GROSSENBACH, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/34/0315
Name of medicine:		OCTREOTIDE HEXAL 0,1 mg
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: OCTREOTIDE 0,1 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (SA) (PTY
Manufacturer:		WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY
Packer:		WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURG AM INN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY LABOR L+S AG, BAD BOCKLET-GROSSENBACH, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	HEXAL PHARMA, PINETOWN, KZN
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/20.1.1/0522
Name of medicine:		TOBI 300 mg/5 ml
Dosage form:		SOLUTION
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: TOBRAMYCIN 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		NOVARTIS SA (PTY) LTD
Manufacturer:		CARDINAL HEALTH INC, WOODSTOCK, ILLINOIS, USA
Packer:		CARDINAL HEALTH INC, WOODSTOCK, ILLINOIS, USA CARDINAL HEALTH LTD, BOLTON, LANCASHIRE, UK
Laboratory:	FPRC:	CARDINAL HEALTH LTD, BOLTON, LANCASHIRE, UK CHIRON CORPORATION, ANNANDALE, NEW JERSEY, USA TEPNEL LIFE SCIENCES, EDINBURGH, UK INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:	A40/21.5.1/0524
Name of medicine:	AP METHYLPRED
Dosage form:	INJECTION
Active ingredients:	EACH 8,0 ml SOLUTION CONTAINS: METHYLPREDNISOLONE SODIUM SUCCINATE EQUIVALENT TO METHYLPREDNISOLONE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB, ANEKAL TALUK, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB, ANEKAL TALUK, BANGALORE, INDIA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	STRIDES ARCOLAB, ANEKAL TALUK, BANGALORE, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months (Provisional)
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	A40/20.2.8/0619
Name of medicine:	SONKE-LASTAD 30
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg STAVUDINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months (provisional)
Date of registration:	18 APRIL 2008

MRF 15

Registration number:		A40/20.2.8/0620
Name of medicine:		SONKE-LASTAD 40
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg STAVUDINE 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOSKBURG
	FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:		24 months (provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/3.1/0664
Name of medicine:		ARROW MELOXICAM 7,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MELOXICAM 7,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM SEDEK AGRIKEM CC, KAMEELDRIFT, PRETORIA
	FPRR:	ARROW PHARMA SA, WOODMEAD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A40/3.1/0665
Name of medicine:		ARROW MELOXICAM 15
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MELOXICAM 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA
Packer:		RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	RX MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM SEDEK AGRIKEM CC, KAMEELDRIFT, PRETORIA
	FPRR:	ARROW PHARMA SA, WOODMEAD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0001
Name of medicine:		ASPEN CARVEDILOL 25 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CARVEDILOL 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMASCIENCE INC, MONTREAL, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Packer:		PHARMASCIENCE INC, MONTREAL, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Laboratory:	FPRC:	PHARMASCIENCE INC, MONTREAL, CANADA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, JOHANNESBURG
	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0002
Name of medicine:		ASPEN CARVEDILOL 6,25 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CARVEDILOL 6,25 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMASCIENCE INC, MONTREAL, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Packer:		PHARMASCIENCE INC, MONTREAL, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Laboratory:	FPRC:	PHARMASCIENCE INC, MONTREAL, CANADA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR	PHARMACARE LTD, WOODMEAD, JOHANNESBURG
	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0003
Name of medicine:		ASPEN CARVEDILOL 12,5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CARVEDILOL 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMASCIENCE INC, MONTREAL, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Packer:		PHARMASCIENCE INC, MONTREAL, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Laboratory:	FPRC:	PHARMASCIENCE INC, MONTREAL, CANADA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, JOHANNESBURG
	FPRC/FPRR	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/30.1/0025
Name of medicine:		VIVAXIM
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml DOSE CONTAINS: SALMONELLA TYPHI Vi POLYSACCHARIDE (Ty2 STRAIN) 25,0 ug HEPATITIS A VIRUS 160,0 antigen units
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AVENTIS PHARMA (PTY) LTD
Manufacturer:		SANOFI PASTEUR, MARCY, L'ETOILE, FRANCE SANOFI PASTEUR, VAL DE REUIL, FRANCE
Packer:		SANOFI PASTEUR, MARCY, L'ETOILE, FRANCE SANOFI PASTEUR, VAL DE REUIL, FRANCE
Laboratory:	FPRC:	SANOFI PASTEUR, MARCY, L'ETOILE, FRANCE SANOFI PASTEUR, VAL DE REUIL, FRANCE
	FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.2.3/0079
Name of medicine:		RIFIZID 150/75
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RIFAMPICIN 150,0 mg ISONIAZID 75,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		DEZZO TRADING (392) (PTY) LTD t/a INDO PHARMA
Manufacturer:		SVIZERA LABS PRIVATE LTD, MUMBAI, INDIA
Packer:		SVIZERA LABS PRIVATE LTD, MUMBAI, INDIA
Laboratory:	FPRC:	SVIZERA LABS PRIVATE LTD, MUMBAI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
	FPRR:	DEZZO TRADING (392) t/a INDO PHARMA, LENASIA, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/5.7.1/0085
Name of medicine:		DYNA-CETIRIZINE SYRUP
Dosage form:		SYRUP
Active ingredients:		EACH 1,0 ml SYRUP CONTAINS: CETIRIZINE DIHYDROCHLORIDE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS hf, KOPAVOGUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Packer:		ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS hf, KOPAVOGUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, PINELANDS, KZN
Laboratory:	FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS hf, KOPAVOGUR, ICELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.5/0093
Name of medicine:		SIMZOR 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.5/0094
Name of medicine:		SIMZOR 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.5/0095
Name of medicine:		SIMZOR 40
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.5/0096
Name of medicine:		SIMZOR 80
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 80,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0110
Name of medicine:		AURO-LISINOPRIL CO 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVLENT TO LISINOPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA 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, RSA
Shelf-life:		24 months (provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0111
Name of medicine:		AURO-LISINOPRIL CO 20 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVLENT TO LISINOPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA 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, RSA
Shelf-life:		24 months (provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0125
Name of medicine:		VEDIBLOK 3,125 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CARVEDILOL 3,125 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE
Packer:		ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA
Laboratory:	FPRC:	ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0126
Name of medicine:		VEDIBLOK 6,25 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CARVEDILOL 6,25 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE
Packer:		ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA
Laboratory:	FPRC:	ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0127
Name of medicine:		VEDIBLOK 12,5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CARVEDILOL 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE
Packer:		ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA
Laboratory:	FPRC:	ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0126
Name of medicine:		VEDIBLOK 6,25 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CARVEDILOL 6,25 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE
Packer:		ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA
Laboratory:	FPRC:	ELPEN PHARMACEUTICAL CO INC, PIKERMI ATTIKIS, GREECE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/16/0190
Name of medicine:		ANDOSEPT-CO
Dosage form:		SOLUTION
Active ingredients:		EACH 15,0 ml SOLUTION CONTAINS: BENZYDAMINE HYDROCHLORIDE 22,5 mg CHLORHEXIDINE GLUCONATE 18,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Packer:		PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Laboratory:	FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:	41/7.3/0245
Name of medicine:	TRIPTAM 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAM 100 ,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA PHRAMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA GERARD LABORATORIES, DUBLIN, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Shelf-life:	24 months
Date of registration:	18 APRIL 2008

Registration number:	41/26/0246
Name of medicine:	FLORACOR 50 mg/ml INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FLUOROURACIL 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	41/20.2.8/0254
Name of medicine:	SEBIVO
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TELBIVUDINE 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMALYTICA S.A., LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	41/21.12/0268
Name of medicine:	FINIDE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FINASTERIDE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	41/20.2.8/0254
Name of medicine:	SEBIVO
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TELBIVUDINE 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMALYTICA S.A., LOCARNO, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	41/21.12/0268
Name of medicine:	FINIDE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FINASTERIDE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:		41/26/0304
Name of medicine:		METHACOR 5 mg/ml
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: METHOTREXATE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ACCORD HEALTHCARE (PTY) LTD
Manufacturer:		INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Packer:		INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:		12 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/26/0305
Name of medicine:		METHACOR 25 mg/ml
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: METHOTREXATE 25 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ACCORD HEALTHCARE (PTY) LTD
Manufacturer:		INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Packer:		INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:		12 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/26/0306
Name of medicine:		METHACOR 100 mg/ml
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: METHOTREXATE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ACCORD HEALTHCARE (PTY) LTD
Manufacturer:		INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Packer:		INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:		12 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.2.8/0330
Name of medicine:		RETLAM 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, 7, 8
Applicant:		ADCOCK INGRAM LIMITED
Manufacturer:		ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:		ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory:	FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
	FPRC/FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:	41/1.2/0394
Name of medicine:	LEXAMIL 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
Laboratory: FPRC/FPRR:	CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:	41/1.2/0395
Name of medicine:	LEXAMIL 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	18 APRIL 2008

MRF 15

Registration number:		41/1.2/0396
Name of medicine:		LEXAMIL 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
Packer:		CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
Laboratory:	FPRC:	CIPLA LTD, KURKUMBH, PUNE, MAHASHTRA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/3.2/0432
Name of medicine:		BONIRAN 70
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SODIUM ALENDRONATE EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (SA) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/3.2/0433
Name of medicine:		RAN-ALENDRONATE 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SODIUM ALENDRONATE EQUIVALENT TO ALENDRONIC ACID 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (SA) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/3.2/0434
Name of medicine:		RAN-ALENDRONATE 70
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SODIUM ALENDRONATE EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (SA) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/26/0435
Name of medicine:		ACCORD-CARBOPLATIN 10 mg/ml INJECTION
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: CARBOPLATIN 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ACCORD HEALTHCARE (PTY) LTD
Manufacturer:		INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD
Packer:		INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	INTAS PHARMACEUTICALS LTD, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.5/0549
Name of medicine:		REDICOR 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.5/0550
Name of medicine:		REDICOR 20
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.5/0551
Name of medicine:		REDICOR 40
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 40,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.5/0552
Name of medicine:		REDICOR 80
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: SIMVASTATIN 80,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/1.2/0584
Name of medicine:		ZOLID 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, 7
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, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/1.2/0585
Name of medicine:		ZOLID 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, 7
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, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0673
Name of medicine:		CIPLA-PERINDOPRIL 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PERINDOPRIL ERBUMINE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT IV), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT IV), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT IV), SALCETTE, GOA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0674
Name of medicine:		CIPLA-PERINDOPRIL 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PERINDOPRIL ERBUMINE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT IV), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT IV), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT IV), SALCETTE, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/0675
Name of medicine:		CIPLA-PERINDOPRIL 8 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PERINDOPRIL ERBUMINE 8,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, (UNIT IV), SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, (UNIT IV), SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, (UNIT IV), SALCETTE, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.2/0687
Name of medicine:		YOMAX 250 mg
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, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT XII, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT XII RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT XII, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA LTD, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.2/0688
Name of medicine:		YOMAX 500 mg
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, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT XII, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT XII, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNITXII, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA LTD, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/2.5/0711
Name of medicine:		EPITOZ 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (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, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE S.A., VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/2.5/0712
Name of medicine:		EPITOZ 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (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, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE S.A., VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/2.5/0713
Name of medicine:		EPITOZ 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (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, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE S.A., VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.2.3/0723
Name of medicine:		RITIB
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RIFAMPICIN 150,0 mg ISONIAZID 75,0 mg ETHAMBUTOL HYDROCHLORIDE 275,0 mg PYRAZINAMIDE 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SVIZERA SA (PTY) LTD
Manufacturer:		SVIZERA LABS PVT LTD, TURBHE, NEW MUMBAI, INDIA
Packer:		SVIZERA LABS PVT LTD, TURBHE, NEW MUMBAI, INDIA
Laboratory:	FPRC:	SVIZERA LABS PVT LTD, TURBHE, NEW MUMBAI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	SVIZERA SA, LENASIA, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/2.5/0724
Name of medicine:		NEUSEIZE 100
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: GABAPENTIN 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY S.A., CENTURION, RSA
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/2.5/0725
Name of medicine:		NEUSEIZE 300
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY S.A., CENTURION, RSA
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/2.5/0726
Name of medicine:		NEUSEIZE 400
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY S.A., CENTURION, RSA
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0751
Name of medicine:		ZINOXIME 125 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 125,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0752
Name of medicine:		ZINOXIME 250 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0753
Name of medicine:		ZINOXIME 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1/0754
Name of medicine:		AURO-AMLODIPINE TABLETS 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1/0755
Name of medicine:		AURO-AMLODIPINE TABLETS 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.3/0788
Name of medicine:		MIGRESS 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, 7, 8
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 SELAMINE LTD t/a ARROW GENERICS LTD, DUBLIN, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.2.8/0806
Name of medicine:		LAZIVIR TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/10.2.1/0849
Name of medicine:		SPIRIVA RESPIMAT
Dosage form:		SOLUTION
Active ingredients:		EACH DOSE CONTAINS: TIOTROPIUM 5,0 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:		BOEHRINGER INGELHEIM PHARMA GmbH & CO, INGELHEIM AM RHEIN, GERMANY
Packer:		BOEHRINGER INGELHEIM PHARMA GmbH & CO, INGELHEIM AM RHEIN, GERMANY
Laboratory:	FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & CO, INGELHEIM AM RHEIN, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
	FPRR:	INGELHEIM PHARMACEUTICALS, RANDBURG, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.3/0861
Name of medicine:		MIGRESS 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, 7, 8
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 SELAMINE LTD t/a ARROW GENERICS LTD, DUBLIN, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA SA, WOODMEAD, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0866
Name of medicine:		SANDOZ CEFTRIAXONE 0,5 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 0,5 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0867
Name of medicine:		SANDOZ CEFTRIAXONE 1,0 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, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0868
Name of medicine:		SANDOZ CEFTRIAXONE 2,0g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 2,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0869
Name of medicine:		ROKEF 0,5 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 0,5 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0870
Name of medicine:		ROKEF 1,0 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, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0871
Name of medicine:		ROKEF 2,0 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 2,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		36 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0872
Name of medicine:		ORZID 1 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME 1,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ORCHID PHARMACEUTICALS SA (PTY) LTD
Manufacturer:		ORCHID HEALTHCARE, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA
Packer:		ORCHID HEALTHCARE, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA
Laboratory:	FPRC:	ORCHID HEALTHCARE, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	ORCHID PHARMACEUTICALS SA, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/0873
Name of medicine:		ORZID 2 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME 2,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ORCHID PHARMACEUTICALS SA (PTY) LTD
Manufacturer:		ORCHID HEALTHCARE, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA
Packer:		ORCHID HEALTHCARE, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA
Laboratory:	FPRC:	ORCHID HEALTHCARE, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
	FPRR:	ORCHID PHARMACEUTICALS SA, POTCHEFSTROOM
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/1050
Name of medicine:		LISINOZIDE 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVLENT TO LISINOPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/7.1.3/1051
Name of medicine:		LISINOZIDE 20 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVLENT TO LISINOPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/21.12/1054
Name of medicine:		AURO-FINASTERIDE TABLETS 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FINASTERIDE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/21.12/1055
Name of medicine:		PROFINA 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: FINASTERIDE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/1063
Name of medicine:		SANDOZ CEFOTAXIME 0,5 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 0,5 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/1064
Name of medicine:		SANDOZ CEFOTAXIME 1,0 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 1,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/1065
Name of medicine:		CLATAX 0,5 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 0,5 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		41/20.1.1/1066
Name of medicine:		CLATAX 1,0 g
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 1,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANDOZ S.A. (PTY) LTD
Manufacturer:		SANDOZ GmbH, KUNDL, AUSTRIA
Packer:		SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA NOVARTIS SA, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		42/7.1.3/0106
Name of medicine:		PERIVAS 4
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		42/7.1.3/0107
Name of medicine:		RAN-PERINDOPRIL 4
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A38/2.6.5/0622
Name of medicine:		MOXOTENS 0,2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MOXONIDINE 0,2 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:		PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:		PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC:	PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
	FPRR:	HEXAL PHARMA, PINETOWN, KZN, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A38/2.6.5/0623
Name of medicine:		MOXOTENS 0,3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MOXONIDINE 0,3 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:		PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:		PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC:	PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
	FPRR:	HEXAL PHARMA, PINETOWN, KZN, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		A38/2.6.5/0624
Name of medicine:		MOXOTENS 0,4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MOXONIDINE 0,4 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:		PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:		PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC:	PERRIGO ISRAEL PHARMACEUTICALS LTD, YERUHAM, ISRAEL CHANELLE PHARMACEUTICALS MANUFACTURING, GALWAY, IRELAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
	FPRR:	HEXAL PHARMA, PINETOWN, KZN, RSA
Shelf-life:		24 months
Date of registration:		18 APRIL 2008

MRF 15

Registration number:		37/28/0521
Name of medicine:		AXIM READICAT 2 %
Dosage form:		SUSPENSION
Active ingredients:		EACH 100,0 ml SUSPENSION CONTAINS: BARIUM SULPHATE 2,0940 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		AXIM PHARMACEUTICALS (PTY) LTD
Manufacturer:		E-Z-EM CANADA INC, ANJOU, QUEBEC, CANADA
Packer:		E-Z-EM CANADA INC, ANJOU, QUEBEC, CANADA
Laboratory:	FPRC:	E-Z-EM CANADA INC, ANJOU, QUEBEC, CANADA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	AXIM PHARMACEUTICALS, MIDRAND, JOHANNESBURG
Shelf-life:		36 months
Date of registration:		13 JUNE 2008

MRF 15

Registration number:		A39/5.4/0212
Name of medicine:		LYRINEL 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: OXYBUTYNIN HYDROCHLORIDE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:		ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA
Packer:		ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA JANSSEN-CILAG SpA, BORGO S. MICHELLE, LATINA, ITALY
Laboratory:	FPRC:	ALZA IRELAND LTD, TIPPERARY, IRELAND JANSSEN-CILAG SpA, BORGO S. MICHELLE, LATINA, ITALY JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
	FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		13 JUNE 2008

MRF 15

Registration number:		A39/5.4/0224
Name of medicine:		LYRINEL 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: OXYBUTYNIN HYDROCHLORIDE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:		ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA13 JUNE 2008
Packer:		ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA JANSSEN-CILAG SpA, BORGO S. MICHELLE, LATINA, ITALY
Laboratory:	FPRC:	ALZA IRELAND LTD, TIPPERARY, IRELAND JANSSEN-CILAG SpA, BORGO S. MICHELLE, LATINA, ITALY JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
	FPRR:	ALZA IRELAND LTD, TIPPERARY, IRELAND JANSSEN-CILAG SpA, BORGO S. MICHELLE, LATINA, ITALY JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
Shelf-life:		18 months
Date of registration:		13 JUNE 2008

MRF 15

Registration number:		A39/5.4/0226
Name of medicine:		LYRINEL 15 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: OXYBUTYNIN HYDROCHLORIDE 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:		ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA
Packer:		ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA JANSSEN-CILAG SpA, BORGO S. MICHELLE, LATINA, ITALY
Laboratory:	FPRC:	ALZA IRELAND LTD, TIPPERARY, IRELAND JANSSEN-CILAG SpA, BORGO S. MICHELLE, LATINA, ITALY JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
	FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, JOHANNESBURG
Shelf-life:		18 months
Date of registration:		13 JUNE 2008

MRF 15

Registration number:		A39/16.2/0544
Name of medicine:		CILODEX EAR DROPS
Dosage form:		SUSPENSION
Active ingredients:		EACH 1,0 ml SUSPENSION CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 3,0 mg DEXAMETHASONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
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, BRYANSTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		13 JUNE 2008

MRF 15

Registration number:	A40/5.10/0213
Name of medicine:	ADCO-NETRIN 2 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE
Packer:	PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE SYNTHON HISPANIA, BARCELONA, SPAIN NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory: FPRC:	PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE SYNTHON HISPANIA, BARCELONA, SPAIN SYNTHON BV, NIJMEGEN, THE NETHERLANDS NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	13 JUNE 2008

MRF 15

Registration number:	A40/21.5.1/0224
Name of medicine:	SPEC-BUDESONIDE 100
Dosage form:	NASAL SPRAY
Active ingredients:	EACH METERED DOSE CONTAINS: BUDESONIDE 100,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	MIPHARM S.p.A, MILAN, ITALY
Packer:	MIPHARM S.p.A, MILAN, ITALY
Laboratory: FPRC:	MIPHARM S.p.A, MILAN, ITALY ANALYTICON, TERENURE, KEMPTON PARK
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	13 JUNE 2008

MRF 15

Registration number:		41/24/0136
Name of medicine:		0,9 % SODIUM CHLORIDE INFUSION B. BRAUN
Dosage form:		INFUSION
Active ingredients:		EACH 1000,0 ml SOLUTION CONTAINS: SODIUM CHLORIDE
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		B BRAUN MEDICAL (PTY) LTD
Manufacturer:		B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN PRODUCTION PHARMA PFIEFFEWIESEN, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A, RUBI, BARCELONA, SPAIN
Packer:		B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN PRODUCTION PHARMA PFIEFFEWIESEN, MELSUNGEN, GERMANY
Laboratory:	FPRC:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG
Shelf-life:		36 months
Date of registration:		13 JUNE 2008

MRF 15

Registration number:		41/7.5/0298
Name of medicine:		CRESTOR 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO: ROSUVASTATIN 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Packer:		IPR PHARMACEUTICALS Inc, CAROLINA, PUERTO RICO IPR PHARMACEUTICALS Inc, CANOVANAS, PUERTO RICO ASTRAZENECA GmbH, PLANKSTADT, GERMANY ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON
Laboratory:	FPRC:	ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK ASTRAZENECA GmbH, PLANKSTADT, GERMANY ANALYTICON, TERENURE, KEMPTON PARK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRC/FPRR:	ASTRAZENECA PHARMACEUTICALS, ALRODE, ALBERTON
Shelf-life:		36 months
Date of registration:		13 JUNE 2008