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ACCEPTABLE PAYMENT FOR SERVICES AND GOODS IN GOVERNMENT PRINTING WORKS

**WITH IMMEDIATE EFFECT ALL
PAYMENTS FOR SERVICES RENDERED
AND GOODS DISPATCHED SHOULD BE
BY MEANS OF BANK GUARANTEED
CHEQUES ONLY**

**IMPLEMENTATION OF THIS
CIRCULAR IS WITHOUT EXCEPTION**

**S. MBHELE
EXECUTIVE DIRECTOR: MARKETING**

**Tel.: (012) 334-4764
Cell: 082 889 5059**

GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 1321 OF 2006

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by Council.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to regular review regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The registration dossier is subject to review at intervals as determined by Council.
8. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 1321 VAN 2006**MEDISYNEBEHEERRAAD****VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET NO. 101 VAN 1965)**

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 26 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in die voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies soos goedgevind deur die Raad.
6. Die eerste twee produksielote moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die registrasie-aansoek is onderhewig aan hersiening met tussenposes soos deur die Raad bepaal.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslike vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemaking van die produk mag slegs in aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vulot 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: G/10.1/0640

Name of medicine: DIMETAPP COUGH EXPECTORANT

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIFENESIN 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: WYETH SOUTH AFRICA (PTY) LTD

Manufacturer: WHITEHALL-ROBINS, RICHMOND, VIRGINIA,
USA

Packer: WHITEHALL-ROBINS, RICHMOND, VIRGINIA,
USA

Laboratory:FPRC: WHITEHALL-ROBINS, RICHMOND, VIRGINIA,
USA
ASPEN PHARMACARE, WILSONIA,
EAST LONDON, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: WYETH S.A., MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/30.1/0047

Name of medicine: OKAVAX

Dosage form: INJECTION

Active ingredients: EACH 0,5 ml DOSE CONTAINS:
ATTENUATED LIVE VARICELLA-ZOSTER
VIRUS (OKA STRAIN) 1 000,0 PFU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: AVENTIS PHARMA (PTY) LTD

Manufacturer: KAN-ONJI INSTITUTE, KAN-ONJI CITY,
KAGAWA, JAPAN

Packer: KAN-ONJI INSTITUTE, KAN-ONJI CITY,
KAGAWA, JAPAN

Laboratory:FPRC: KAN-ONJI INSTITUTE, KAN-ONJI CITY,
KAGAWA, JAPAN
FPRR/FPRC: AVENTIS PHARMA, WALTLOO, PRETORIA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/34/0140

Name of medicine: AIR PRODUCTS MEDICAL OXYGEN (GASEOUS)

Dosage form: GAS

Active ingredients: EACH CYLINDER CONTAINS:
OXYGEN 99,5 % v/v

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: AIR PRODUCTS SOUTH AFRICA (PTY) LTD

Manufacturer: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK

Packer: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC/FPRR: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 37/34/0141

Name of medicine: AIR PRODUCTS MEDICAL OXYGEN (LIQUID)

Dosage form: LIQUID

Active ingredients: EACH CYLINDER CONTAINS:
OXYGEN 99,5 % v/v

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: AIR PRODUCTS SOUTH AFRICA (PTY) LTD

Manufacturer: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK
AIR PRODUCTS S.A., VANDERBIJLPARK, RSA
AIR PRODUCTS S.A., ISCOR WORKS,
NEW CASTLE, RSA
AIR PRODUCTS S.A., STIKLAND TRIANGLE,
BELLVILLE

Packer: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK
AIR PRODUCTS S.A., VANDERBIJLPARK, RSA
AIR PRODUCTS S.A., ISCOR WORKS,
NEW CASTLE, RSA
AIR PRODUCTS S.A., STIKLAND TRIANGLE,
BELLVILLE

Laboratory:FPRC: AIR PRODUCTS S.A., VANDERBIJLPARK, RSA
AIR PRODUCTS S.A., ISCOR WORKS,
NEW CASTLE, RSA
AIR PRODUCTS S.A., STIKLAND TRIANGLE,
BELLVILLE

FPRC/FPRR: AIR PRODUCTS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	37/2.6.5/0319
Name of medicine:	RISPERDAL QUICKLET 0,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO
Packer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO JANSSEN-CILAG FARMACEUTICA Lda, BACARENA, PORTUGAL JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Laboratory:FPRC:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO JANSSEN-CILAG FARMACEUTICA Lda, BACARENA, PORTUGAL JANSSEN PHARMACEUTICA N.V., BEERSE, BELGIUM
FPRC/FPRR:	JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	37/2.6.5/0320
Name of medicine:	RISPERDAL QUICKLET 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO
Packer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO JANSSEN-CILAG FARMACEUTICA Lda, BACARENA, PORTUGAL JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Laboratory:FPRC:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO JANSSEN-CILAG FARMACEUTICA Lda, BACARENA, PORTUGAL JANSSEN PHARMACEUTICA N.V., BEERSE, BELGIUM
FPRC/FPRR:	JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: 37/2.6.5/0321

Name of medicine: RISPERDAL QUICKLET 2 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: JANSSEN ORTHO LLC, GURABO, PUERTO RICO

Packer: JANSSEN ORTHO LLC, GURABO, PUERTO RICO
JANSSEN-CILAG FARMACEUTICA Lda, BACARENA,
PORTUGAL
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory:FPRC: JANSSEN ORTHO LLC, GURABO, PUERTO RICO
JANSSEN-CILAG FARMACEUTICA Lda, BACARENA,
PORTUGAL
JANSSEN PHARMACEUTICA N.V., BEERSE,
BELGIUM

FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	37/20.1.1/0382
Name of medicine:	GENERIX-CEFAZOLIN 0,5 g INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFAZOLIN SODIUM EQUIVALENT TO CEFAZOLIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENERIX INTERNATIONAL S.A. (PTY) LTD
Manufacturer:	HARBIN GENERAL PHARMACEUTICAL FACTORY, HARBIN, PEOPLE'S REPUBLIC OF CHINA
Packer:	HARBIN GENERAL PHARMACEUTICAL FACTORY, HARBIN, PEOPLE'S REPUBLIC OF CHINA
Laboratory:FPRC:	HARBIN GENERAL PHARMACEUTICAL FACTORY, HARBIN, PEOPLE'S REPUBLIC OF CHINA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG
FPRR:	GENERIX INTERNATIONAL S.A., ATHLONE, CAPE TOWN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	37/20.1.1/0383
Name of medicine:	GENERIX-CEFAZOLIN 1,0 g INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFAZOLIN SODIUM EQUIVALENT TO CEFAZOLIN 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENERIX INTERNATIONAL S.A. (PTY) LTD
Manufacturer:	HARBIN GENERAL PHARMACEUTICAL FACTORY, HARBIN, PEOPLE'S REPUBLIC OF CHINA
Packer:	HARBIN GENERAL PHARMACEUTICAL FACTORY, HARBIN, PEOPLE'S REPUBLIC OF CHINA
Laboratory:FPRC:	HARBIN GENERAL PHARMACEUTICAL FACTORY, HARBIN, PEOPLE'S REPUBLIC OF CHINA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG
FPRR:	GENERIX INTERNATIONAL S.A., ATHLONE, CAPE TOWN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	37/2.5/0482
Name of medicine:	PARTID-200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARBAMAZEPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MDI CC
Manufacturer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Laboratory:FPRC:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRR:	MDI CC, MENLO PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15 (MBR 15)

Registration number:	37/25.2/0505
Name of medicine:	OLICLINOMEL N4-550
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS: a) 5,5 % AMINO ACIDS SOLUTION compartment b) 20 % GLUCOSE SOLUTION compartment c) 10 % LIPID EMULSION compartment SEE ADDENDUM
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
Packer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory:FPRC:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

ADDENDUM

- a) 5,5 % AMINO ACIDS SOLUTION compartment
containing per 1,0 litre:

L-alanine	11,39 g
L-arginine	6,33 g
Glycine	5,67 g
L-histidine	2,64 g
L-isoleucine	3,30 g
L-leucine	4,02 g
L-lysine	3,19 g
L-methionine	2,20 g
L-phenylalanine	3,08 g
L-proline	3,74 g
L-serine	2,75 g
L-threonine	2,31 g
L-tryptophan	0,99 g
L-tyrosine	0,22 g
L-valine	3,19 g

- b) 20 % GLUCOSE SOLUTION compartment
containing per 1,0 litre:

Glucose monohydrate equivalent to Glucose	200,00 g
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- c) 10 % LIPID EMULSION compartment containing per 1,0 litre:

Refined soya-bean oil + Refined olive oil	100,00 g
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MRF 15 (MBR 15)

Registration number:	37/25.2/0506
Name of medicine:	OLICLINOMEL N6-900
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS: a) 8,5 % AMINO ACIDS SOLUTION compartment b) 30 % GLUCOSE SOLUTION compartment c) 20 % LIPID EMULSION compartment SEE ADDENDUM
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
Packer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory:FPRC:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

ADDENDUM

- a) 8,5 % AMINO ACIDS SOLUTION compartment
containing per 1,0 litre:

L-alanine	17,60 g
L-arginine	9,78 g
Glycine	8,76 g
L-histidine	4,08 g
L-isoleucine	5,10 g
L-leucine	6,21 g
L-lysine	4,93 g
L-methionine	3,40 g
L-phenylalanine	4,76 g
L-proline	5,78 g
L-serine	4,25 g
L-threonine	3,57 g
L-tryptophan	1,53 g
L-tyrosine	0,34 g
L-valine	4,93 g

- b) 30 % GLUCOSE SOLUTION compartment
containing per 1,0 litre:

Glucose monohydrate equivalent to Glucose	300,00 g
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- c) 20 % LIPID EMULSION compartment containing per 1,0 litre:

Refined soya-bean oil + Refined olive oil	200,00 g
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MRF 15 (MBR 15)

Registration number:	37/25.2/0507
Name of medicine:	OLICLINOMEL N7-1000
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS: a) 10 % AMINO ACIDS SOLUTION compartment b) 40 % GLUCOSE SOLUTION compartment c) 20 % LIPID EMULSION compartment SEE ADDENDUM
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
Packer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory:FPRC:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

ADDENDUM

- a) 10 % AMINO ACIDS SOLUTION compartment
containing per 1,0 litre:

L-alanine	20,70 g
L-arginine	11,50 g
Glycine	10,30 g
L-histidine	4,80 g
L-isoleucine	6,00 g
L-leucine	7,30 g
L-lysine	5,80 g
L-methionine	4,00 g
L-phenylalanine	5,60 g
L-proline	6,80 g
L-serine	5,00 g
L-threonine	4,20 g
L-tryptophan	1,80 g
L-tyrosine	0,40 g
L-valine	5,80 g

- b) 40 % GLUCOSE SOLUTION compartment
containing per 1,0 litre:

Glucose monohydrate equivalent to	
Glucose	400,00 g

- c) 20 % LIPID EMULSION compartment containing per 1,0 litre:

Refined soya-bean oil +	
Refined olive oil	200,00 g

MRF 15

Registration number:	37/21.10/0560
Name of medicine:	LUVERIS 75 I.U.
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: RECOMBINANT HUMAN LUTEINISING HORMONE 75,0 I.U.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERONO S.A. (PTY) LTD
Manufacturer:	LABORATOIRES SERONO S.A., AUBONNE, SWITZERLAND
Packer:	LABORATOIRES SERONO S.A., AUBONNE, SWITZERLAND
Laboratory:FPRC:	LABORATOIRES SERONO S.A., AUBONNE, SWITZERLAND
FPRR:	RBM, COLLERETO GIACOSA, ITALY SERONO S.A., FOURWAYS, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	37/20.1.1/0624
Name of medicine:	BMS-CEFEPIME 500 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME HYDROCHLORIDE EQUIVALENT TO CEFEPIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY
Packer:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY
Laboratory:FPRC:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	37/20.1.1/0625
Name of medicine:	BMS-CEFEPIME 1 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME HYDROCHLORIDE EQUIVALENT TO CEFEPIME 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY
Packer:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY
Laboratory:FPRC:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	37/20.1.1/0626
Name of medicine:	BMS-CEFEPIME 2 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME HYDROCHLORIDE EQUIVALENT TO CEFEPIME 2,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY
Packer:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY
Laboratory:FPRC:	BRISTOL-MYERS SQUIBB S.p.A., SERMONETA, LATINA, ITALY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	37/34/0643
Name of medicine:	NICORETTE MICROTAB 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NICOTINE β -CYCLODEXTRIN EQUIVALENT TO NICOTINE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WARNER-LAMBERT SOUTH AFRICA (PTY) LTD
Manufacturer:	PFIZER HEALTH AB, HELSINGBORG, SWEDEN
Packer:	PFIZER HEALTH AB, HELSINGBORG, SWEDEN
Laboratory:FPRC:	PFIZER HEALTH AB, HELSINGBORG, SWEDEN KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	WARNER-LAMBERT S.A., TOKAI, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	37/20.1.2/0674
Name of medicine:	CLAVICIN
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 1000,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	STRIDES SA PHARMACEUTICALS (PTY) LTD
Manufacturer:	STRIDES ARCOLAB LTD, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LTD, BANGALORE, INDIA
Laboratory:FPRC:	STRIDES ARCOLAB LTD, BANGALORE, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA
FPRR:	NOVARTIS, SPARTAN, KEMPTON PARK, RSA STRIDES S.A., ARCADIA, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	38/34/0085
Name of medicine:	MAXIDRONATE 90 mg/10 ml
Dosage form:	INFUSION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: MONOSODIUM PAMIDRONATE MONOHYDRATE EQUIVALENT TO DISODIUM PAMIDRONATE ANHYDRATE 90,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	PHARMA-SKAN, SKANDERBORG, DENMARK
Packer:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK FPRR: HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	38/20.1.1/0149
Name of medicine:	CEFIXAL 100 mg/5 ml
Dosage form:	POWDER
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: CEFIXIME TRIHYDRATE EQUIVALENT TO CEFIXIME 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	CIMEX AG, LIESBERG, SWITZERLAND
Packer:	CIMEX AG, LIESBERG, SWITZERLAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	CIMEX AG, LIESBERG, SWITZERLAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	38/20.1.1/0150
Name of medicine:	CEFIXAL 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFIXIME TRIHYDRATE EQUIVALENT TO CEFIXIME 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	CIMEX AG, LIESBERG, SWITZERLAND
Packer:	CIMEX AG, LIESBERG, SWITZERLAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	CIMEX AG, LIESBERG, SWITZERLAND SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	38/34/0158
Name of medicine:	MAXIDRONATE 15 mg/5 ml
Dosage form:	INFUSION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: MONOSODIUM PAMIDRONATE MONOHYDRATE EQUIVALENT TO DISODIUM PAMIDRONATE ANHYDRATE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	PHARMA-SKAN, SKANDERBORG, DENMARK
Packer:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK FPRR: HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	38/34/0159
Name of medicine:	MAXIDRONATE 60 mg/10 ml
Dosage form:	INFUSION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: MONOSODIUM PAMIDRONATE MONOHYDRATE EQUIVALENT TO DISODIUM PAMIDRONATE ANHYDRATE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	PHARMA-SKAN, SKANDERBORG, DENMARK
Packer:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	PHARMA-SKAN, SKANDERBORG, DENMARK GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK FPRR: HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	38/20.1.1/0163
Name of medicine:	RAN-CLARITHROMYCIN SUSPENSION 250 mg/5 ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: CLARITHROMYCIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	RANBAXY (S.A.), CENTURION, PRETORIA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	38/20.1.1/0176
Name of medicine:	RAN-CLARITHROMYCIN SUSPENSION 125 mg/5 ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: CLARITHROMYCIN 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, INDIA
Laboratory:FPRC:	RANBAXY LABORATORIES LTD, DEWAS, INDIA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	RANBAXY (S.A.), CENTURION, PRETORIA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: 38/15.2/0203

Name of medicine: ALREX

Dosage form: SUSPENSION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:
LOTEPREDNOL ETABONATE 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SOFLENS (PTY) LTD

Manufacturer: BAUSCH & LOMB INC, TAMPA, FLORIDA, USA

Packer: BAUSCH & LOMB INC, TAMPA, FLORIDA, USA
COLUMBIA PHARMACEUTICALS, BARDENE,
BOKSBURG

Laboratory:FPRC: BAUSCH & LOMB INC, TAMPA, FLORIDA, USA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: SOFLENS, RIVONIA, SANDTON, RSA

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/21.2/0224

Name of medicine: GLUCTAM MR 30 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLICLAZIDE 30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: EGIS PHARMACEUTICALS S.A. (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES, WICKLOW,
IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES, WICKLOW,
IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA, RSA

Laboratory:FPRC: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER (IRELAND) INDUSTRIES, WICKLOW,
IRELAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA

FPRR: EGIS PHARMACEUTICALS, RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/5.1/0278

Name of medicine: EPIPEN JUNIOR AUTO-INJECTOR

Dosage form: AUTO-INJECTOR

Active ingredients: EACH 0,3 ml SOLUTION CONTAINS:
ADRENALINE 0,15 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK (PTY) LTD

Manufacturer: MERIDIAN MEDICAL TECHNOLOGIES,
ST LOUIS, MO, USA

Packer: MERIDIAN MEDICAL TECHNOLOGIES,
ST LOUIS, MO, USA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
MERCK PHARMACEUTICALS
MANUFACTURING, WADEVILLE, GERMISTON

Laboratory:FPRC: MERIDIAN MEDICAL TECHNOLOGIES,
ST LOUIS, MO, USA
SCIENTIFIC ASSOCIATES, ST LOUIS, MISSOURI,
USA
SKYLAND SCIENTIFIC SERVICES, BELGRADE,
MONTANA, USA
O'NEAL SCIENTIFIC SERVICES, ST LOUIS,
MISSOURI, USA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
MERCK PHARMACEUTICALS
MANUFACTURING, WADEVILLE, GERMISTON

FPRR: MERCK, MODDERFONTEIN, RSA

Shelf-life: 20 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: 38/20.2.2/0304

Name of medicine: CLODERMA TOPICAL CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g CREAM CONTAINS:
CLOTRIMAZOLE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MDI CC

Manufacturer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Packer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Laboratory:FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
FPRR: MDI CC, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	38/20.2.2/0305
Name of medicine:	CLOFEM VAGINAL CREAM
Dosage form:	CREAM
Active ingredients:	EACH 1,0 g CREAM CONTAINS: CLOTRIMAZOLE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MDI CC
Manufacturer:	PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
Packer:	PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
Laboratory:FPRC: FPRR:	PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE MDI CC, MENLO PARK, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0358
Name of medicine:	FLUTEX COUGH MIXTURE HONEY
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0359
Name of medicine:	FLUTEX COUGH MIXTURE ORANGE
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0360
Name of medicine:	FLUTEX COUGH MIXTURE BLACKCURRANT
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0361
Name of medicine:	LENNON COUGH MIXTURE HONEY
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0362
Name of medicine:	LENNON COUGH MIXTURE ORANGE
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0363
Name of medicine:	LENNON COUGH MIXTURE BLACKCURRANT
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0364
Name of medicine:	MUCOSPECT EXPECTORANT HONEY
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0365
Name of medicine:	MUCOSPECT EXPECTORANT ORANGE
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0366
Name of medicine:	MUCOSPECT EXPECTORANT BLACKCURRANT
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/10.1/0367
Name of medicine:	WOODWARDS COUGH MIXTURE HONEY
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: GUAIPHENESIN . 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number: A38/10.1/0368

Name of medicine: WOODWARDS COUGH MIXTURE ORANGE

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM

FPRC/FPRR: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/10.1/0369

Name of medicine: WOODWARDS COUGH MIXTURE BLACKCURRANT

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
GUAIPHENESIN 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Packer: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM

FPRC/FPRR: PHARMACARE LIMITED, KORSTEN,
PORT ELIZABETH

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/20.1.2/0385

Name of medicine: AMPOXIN 250

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
AMPICILLIN SODIUM EQUIVALENT TO
AMPICILLIN 125,0 mg
CLOXACILLIN SODIUM EQUIVALENT TO
CLOXACILLIN 125,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: UNICHEM SA (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, SOLAN, INDIA

Packer: UNICHEM LABORATORIES LTD, SOLAN, INDIA

Laboratory:FPRC: UNICHEM LABORATORIES LTD, SOLAN, INDIA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG
FPRR: UNICHEM, NOORDBRUG, POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A38/20.1.2/0386
Name of medicine:	AMPOXIN 500
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN 250,0 mg CLOXACILLIN SODIUM EQUIVALENT TO CLOXACILLIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM SA (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LTD, SOLAN, INDIA
Packer:	UNICHEM LABORATORIES LTD, SOLAN, INDIA
Laboratory:FPRC:	UNICHEM LABORATORIES LTD, SOLAN, INDIA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG
FPRR:	UNICHEM, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/20.1.2/0388
Name of medicine:	AMPOXIN 1000
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN 500,0 mg CLOXACILLIN SODIUM EQUIVALENT TO CLOXACILLIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM SA (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LTD, SOLAN, INDIA
Packer:	UNICHEM LABORATORIES LTD, SOLAN, INDIA
Laboratory:FPRC:	UNICHEM LABORATORIES LTD, SOLAN, INDIA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG
FPRR:	UNICHEM, NOORDBRUG, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/11.5/0389
Name of medicine:	PICOPREP
Dosage form:	POWDER
Active ingredients:	EACH SACHET CONTAINS: SODIUM PICOSULPHATE 10,0 mg MAGNESIUM OXIDE 3,0 g CITRIC ACID 12,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BETA PHARMACEUTICALS cc
Manufacturer:	DFC THOMPSON AUSTRALIA THORNLEIGH, NEW SOUTH WALES, AUSTRALIA
Packer:	A.C.E. PACKWELL, BELROSE, NEW SOUTH WALES, AUSTRALIA BETA PHARMACEUTICALS, KINI BAY, PORT ELIZABETH
Laboratory:FPRC:	AMDEL LABORATORIES, ASQUITH, SYDNEY, AUSTRALIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG
FPRR:	BETA PHARMACEUTICALS, KINI BAY, PORT ELIZABETH
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number: A38/5.7.1/0400

Name of medicine: FEXADIN 120

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 120,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.1/0401

Name of medicine: FEXADIN 180

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 180,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULTY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM

FPRR: RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.1/0407

Name of medicine: FENOFEX 120

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 120,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM

FPRR: RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A38/5.7.1/0408

Name of medicine: FENOFEX 180

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 180,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A38/12/0425
Name of medicine:	NUBEND-400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALBENDAZOLE 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Packer:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
Laboratory:FPRC: FPRC/FPRR:	KOPRAN LTD, KHALAPUR, RAIGAD, INDIA BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A38/12/0426

Name of medicine: WORMADOLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ALBENDAZOLE 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Packer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Laboratory:FPRC: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A38/8.4/0439
Name of medicine:	GELPLEX
Dosage form:	INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: SUCCINYLATED GELATIN 4,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	IVEX PHARMACEUTICALS LTD, LARNE, NORTHERN IRELAND
Packer:	IVEX PHARMACEUTICALS LTD, LARNE, NORTHERN IRELAND
Laboratory:FPRC:	IVEX PHARMACEUTICALS LTD, LARNE, NORTHERN IRELAND BODYCOTE MATERIALS TESTING LTD, MIDLOTHIAN, SCOTLAND BIOLOGICAL LABORATORIES LTD, COUNTY MAYO, IRELAND
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/7.3/0507
Name of medicine:	MIGREX 50 TABLETS
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
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL AG, HOLZKIRCHEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL AG, HOLZKIRCHEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	36 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/7.3/0508
Name of medicine:	MIGREX 100 TABLETS
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
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL AG, HOLZKIRCHEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY HEXAL AG, HOLZKIRCHEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	36 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/3.2/0562
Name of medicine:	BONDRONAT 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBANDRONIC ACID 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND
Packer:	F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND F. HOFFMANN-LA ROCHE LTD, KAISERAUGST, SWITZERLAND ROCHE PRODUCTS, ISANDO, RSA
Laboratory:FPRC:	F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND
FPRC/FPRR:	ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/1.2/0616
Name of medicine:	APEX-SERTRALINE 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG FPRR: CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/1.2/0617
Name of medicine:	APEX-SERTRALINE 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/5.7.2/0620
Name of medicine:	APEX-DOMPERIDONE 10 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOMPERIDONE MALEATE EQUIVALENT TO DOMPERIDONE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory:FPRC:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A38/5.7.2/0636
Name of medicine:	VOMI-GUARD 10 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOMPERIDONE MALEATE EQUIVALENT TO DOMPERIDONE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Packer:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA
Laboratory:FPRC:	MEDREICH STERILAB LTD, VIRGONAGAR, BANGALORE, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/21.8.1/0035

Name of medicine: MENOSTAR

Dosage form: TRANSDERMAL DELIVERY SYSTEM

Active ingredients: EACH CM₂ CONTAINS:
ESTRADIOL HEMIHYDRATE 0,30 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SCHERING (PTY) LTD

Manufacturer: 3M PHARMACEUTICALS, NORTHRIDGE,
CALIFORNIA, USA

Packer: 3M PHARMACEUTICALS, NORTHRIDGE,
CALIFORNIA, USA
SCHERING GmbH & CO, WEIMAR, GERMANY

Laboratory:FPRC: 3M SANTE, CEDEX, FRANCE
SCHERING GmbH & CO, WEIMAR, GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: SCHERING, MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/2.6/0072
Name of medicine:	STRESAM
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ETIFOXINE HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATOIRES BIOCOTEX, BEAUVAIS, FRANCE
Packer:	LABORATOIRES BIOCOTEX, BEAUVAIS, FRANCE
Laboratory:FPRC: FPRC/FPRR:	LABORATOIRES BIOCOTEX, BEAUVAIS, FRANCE ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15 (MBR 15)

Registration number:	A39/5.7.1/0103
Name of medicine:	CETIRIZINE-HEXAL 1,0 mg/ml ORAL SOLUTION
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: CETIRIZINE DIHYDROCHLORIDE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	SALUTAS PHARMA, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/11.4.3/0116

Name of medicine: ADCO-ROZNAL 15

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
LANSOPRAZOLE 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: LICONSA S.A., GUADALAJARA, SPAIN

Packer: LICONSA S.A., GUADALAJARA, SPAIN

Laboratory:FPRC: LICONSA S.A., GUADALAJARA, SPAIN
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/20.1.1/0149
Name of medicine:	APEX-OFLOXACIN 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OFLOXACIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	INSPECTORATE M&L, ORMONDE, JOHANNESBURG CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/20.1.1/0150
Name of medicine:	APEX-OFLOXACIN 400 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG FPRR: CAMOX PHARMACEUTICALS, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/6.2/0155
Name of medicine:	HEXARONE 150 mg/3 ml
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: AMIODARONE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA
Packer:	EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/6.2/0156
Name of medicine:	AMIODARONE HCL – HEXAL 150 mg/3 ml
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: AMIODARONE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA
Packer:	EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	EBEWE ARZNEIMITTEL, UNTERACH, AUSTRIA SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/26/0170

Name of medicine: CARBOSIN 600

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

Applicant: PHARMACHEMIE (PTY) LTD

Manufacturer: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS

Packer: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMACHEMIE, CENTURION, RSA

Shelf-life: 24 months provisional

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/18.1/0189
Name of medicine:	TORAHXAL 2,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TORASEMIDE 2,5 mg
Conditions of registration:	I, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENCE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/18.1/0190
Name of medicine:	TORAHExAL 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TORASEMIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/18.1/0191
Name of medicine:	TORAHExAL 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TORASEMIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/18.1/0192
Name of medicine:	TORASEMIDE-HEXAL 2,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TORASEMIDE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/18.1/0193
Name of medicine:	TORASEMIDE-HEXAL 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TORASEMIDE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/18.1/0194
Name of medicine:	TORASEMIDE-HEXAL 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TORASEMIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, KZN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/16.1/0198
Name of medicine:	SINUSTOP PAEDIATRIC NASAL DROPS
Dosage form:	DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: OXYMETAZOLINE HYDROCHLORIDE 0,250 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/16.1/0200
Name of medicine:	NAZENE PAEDIATRIC NASAL METERED SPRAY
Dosage form:	SPRAY
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: OXYMETAZOLINE HYDROCHLORIDE 0,250 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/16.1/0201
Name of medicine:	NAZENE PAEDIATRIC NASAL DROPS
Dosage form:	DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: OXYMETAZOLINE HYDROCHLORIDE 0,250 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/2.1/0210
Name of medicine:	ABBOTT-SEVOFLURANE
Dosage form:	LIQUID
Active ingredients:	EACH BOTTLE CONTAINS: SEVOFLURANE
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ABBOTT-LABORATORIES S.A. (PTY) LTD
Manufacturer:	CENTRAL GLASS CO. LTD, YAMAMGUCHI PREFECTURE, JAPAN ABBOTT S.p.A., LATINA, ITALY
Packer:	ABBOTT LABORATORIES LTD, QUEENSBOROUGH, KENT, UK ABBOTT S.p.A., LATINA, ITALY
Laboratory:FPRC:	ABBOTT LABORATORIES LTD, QUEENSBOROUGH, KENT, UK ABBOTT S.p.A., LATINA, ITALY
FPRC/FPRR:	ABBOTT LABORATORIES S.A., CONSTANTIA KLOOF, JOHANNESBURG, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/20.1.2/0213
Name of medicine:	MERCK-CO-AMOXICLAV 1000 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	SANDOZ GmbH, KUNDL, AUSTRIA
Packer:	SANDOZ GmbH, KUNDL, AUSTRIA
Laboratory:FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA GERARD LABORATORIES, DUBLIN, IRELAND GENERICS LTD, STATION CLOSE, HERTFORDSHIRE, U.K. GENERICS LTD, LETCHWORTH, HERTFORDSHIRE, U.K. RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, RSA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/1.2/0217
Name of medicine:	ADCO-MIRTERON 15
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MIRTAZEPINE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	DELTA LTD, HAFNARFJORDUR, ICELAND
Packer:	DELTA LTD, HAFNARFJORDUR, ICELAND
Laboratory:FPRC: FPRC/FPRR:	DELTA LTD, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/1.2/0218
Name of medicine:	ADCO-MIRTERON 30
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MIRTAZEPINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	DELTA LTD, HAFNARFJORDUR, ICELAND
Packer:	DELTA LTD, HAFNARFJORDUR, ICELAND
Laboratory:FPRC: FPRC/FPRR:	DELTA LTD, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/1.2/0219
Name of medicine:	ADCO-MIRTERON 45
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MIRTAZEPINE 45,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	DELTA LTD, HAFNARFJORDUR, ICELAND
Packer:	DELTA LTD, HAFNARFJORDUR, ICELAND
Laboratory:FPRC: FPRC/FPRR:	DELTA LTD, HAFNARFJORDUR, ICELAND ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/16.1/0225
Name of medicine:	NAZENE ADULT NASAL DROPS
Dosage form:	DROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: OXYMETAZOLINE HYDROCHLORIDE 0,50 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/34/0230
Name of medicine:	CELLCEPT 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	ROCHE S.p.A., SEGRATE, ITALY
Packer:	ROCHE S.p.A., SEGRATE, ITALY F. HOFFMANN-LA ROCHE, KAISERAUGST, SWITZERLAND ROCHE PRODUCTS, ISANDO, RSA
Laboratory:FPRC:	ROCHE S.p.A., SEGRATE, ITALY F. HOFFMAN-LA ROCHE, BASEL, SWITZERLAND
FPRC/FPRR:	ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/11.5/0285
Name of medicine:	LENNON SENNA 7,5 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CALCIUM SENNOSIDES EQUIVALENT TO SENNOSIDES 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFTSROOM
FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/2.9/0318
Name of medicine:	TRAMAZAC INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml AMPOULE CONTAINS: TRAMADOL HYDROCHLORIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA
Laboratory:FPRC:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL AND CHEMICAL SERVICES, SILVERTONDALE, LTD INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/5.7.1/0384
Name of medicine:	BETEK
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/11.4.3/0468

Name of medicine: ACIPHEX 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RABEPRAZOLE SODIUM 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: EISAI CO LTD, KODAMA-GUN, SAITAMA-KEN,
JAPAN

Packer: UNIPACK LTD, SHOTGATE, ESSEX, UK
CILAG AG, SCHAFFHAUSEN, SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory:FPRC: EISAI CO LTD, KODAMA-GUN, SAITAMA-KEN,
JAPAN
CILAG AG, SCHAFFHAUSEN, SWITZERLAND
THE BOOTS CO PLC. NOTTINGHAM UK
FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months provisional packed in PVC/PVdC/PE
Laminate/Al Blisters
24 months packed in Al/Al foil Blisters

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/11.4.3/0469

Name of medicine: ACIPHEX 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RABEPRAZOLE SODIUM 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: EISAI CO LTD, KODAMA-GUN, SAITAMA-KEN,
JAPAN

Packer: UNIPACK LTD, SHOTGATE, ESSEX, UK
CILAG AG, SCHAFFHAUSEN, SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory:FPRC: EISAI CO LTD, KODAMA-GUN, SAITAMA-KEN,
JAPAN
CILAG AG, SCHAFFHAUSEN, SWITZERLAND
THE BOOTS CO PLC. NOTTINGHAM UK

FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months provisional packed in PVC/PVdC/PE
Laminate/AlBlisters
24 months packed in Al/Al foil Blisters

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/7.1/0532
Name of medicine:	AMLODAC 5 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA
Laboratory:FPRC:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/7.1/0533
Name of medicine:	AMLODAC 10 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA
Laboratory:FPRC:	ZYDUS CADILA HEALTHCARE LTD, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number: A39/5.10/0557

Name of medicine: ONDANTOR 4

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number: A39/5.10/0558

Name of medicine: ONDANTOR 8

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: ANALYTICON, TERENURE, KEMPTON PARK
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 JULY 2006

MRF 15

Registration number:	A39/5.10/0568
Name of medicine:	MERCK-ONDANSETRON 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	36 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/5.10/0569
Name of medicine:	MERCK-ONDANSETRON 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	36 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/5.10/0570
Name of medicine:	MERGENSIC 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	36 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/5.10/0571
Name of medicine:	MERGENSIC 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE
Packer:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC:	PHARMATHEN PHARMACEUTICAL INDUSTRY, ATHENS, GREECE GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (U.K.) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	36 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/30.1/0585
Name of medicine:	ROTARIX
Dosage form:	POWDER
Active ingredients:	EACH 1,0 ml DOSE CONTAINS: LIVE ATTENUATED HUMAN ROTAVIRUS, RIX4414 STRAIN not less than 10 ⁶ CCID ₅₀
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM PARC DE LA NOIRE EPINE, WAVRE, BELGIUM
Packer:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM CRNA, FLEURUS, BELGIUM GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory:FPRC:	GLAXOSMITHKLINE BIOLOGICALS S.A., RIXENSART, BELGIUM
FPRC/FPRR:	GLAXOSMITHKLINE, EPPING, CAPE TOWN
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/21.12/0629
Name of medicine:	ANDROFEM 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CYPROTERONE ACETATE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory:FPRC: FPRR:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A39/21.12/0630
Name of medicine:	CIPLA-CYPROTERONE ACETATE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CYPROTERONE ACETATE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory:FPRC: FPRR:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15 (MBR 15)

Registration number:	A39/21.10/0631
Name of medicine:	GONAL-f PEN 300 I.U./0,5 ml (22 MICROGRAMS/0,5 ml)
Dosage form:	INJECTION
Active ingredients:	EACH CARTRIDGE CONTAINS: FOLLITROPIN ALFA 300,0 I.U.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERONO SOUTH AFRICA (PTY) LTD
Manufacturer:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY
Packer:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY LABORATOIRES SERONO SA, COINSINS, SWITZERLAND
Laboratory:FPRC:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY
FPRR:	SERONO SA, KINGFISHER, FOURWAYS, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15 (MBR 15)

Registration number:	A39/21.10/0632
Name of medicine:	GONAL-f PEN 450 I.U./0,75 ml (33 MICROGRAMS/0,75 ml)
Dosage form:	INJECTION
Active ingredients:	EACH CARTRIDGE CONTAINS: FOLLITROPIN ALFA 450,0 I.U.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERONO SOUTH AFRICA (PTY) LTD
Manufacturer:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY
Packer:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY LABORATOIRES SERONO SA, COINSINS, SWITZERLAND
Laboratory:FPRC:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY
FPRR:	SERONO SA, KINGFISHER, FOURWAYS, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15 (MBR 15)

Registration number:	A39/21.10/0633
Name of medicine:	GONAL-f PEN 900 I.U./1,5 ml (66 MICROGRAMS/1,5 ml)
Dosage form:	INJECTION
Active ingredients:	EACH CARTRIDGE CONTAINS: FOLLITROPIN ALFA 900,0 I.U.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERONO SOUTH AFRICA (PTY) LTD
Manufacturer:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY
Packer:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY LABORATOIRES SERONO SA, COINSINS, SWITZERLAND
Laboratory:FPRC:	INDUSTRIA FARMACEUTICA SERONO, BARI, ITALY
FPRR:	SERONO SA, KINGFISHER, FOURWAYS, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A40/26/0005
Name of medicine:	VELCADE
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: BORTEZOMIB 3,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA
Packer:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA JANSSEN PHARMACEUTICA N.V, BEERSE, BELGIUM JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Laboratory:FPRC:	JANSSEN PHARMACEUTICA N.V, BEERSE, BELGIUM
FPRC/FPRR:	JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A40/11.5/0079
Name of medicine:	ADCOSENNA TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SENNA DRY EXTRACT EQUIVALENT TO SENNOSIDES A & B 13,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A40/11.5/0080
Name of medicine:	FRESHEN SENNA TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SENNA DRY EXTRACT EQUIVALENT TO SENNOSIDES A & B 13,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A40/11.5/0081
Name of medicine:	PROPAN SENNA TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SENNA DRY EXTRACT EQUIVALENT TO SENNOSIDES A & B 13,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A40/11.5/0082
Name of medicine:	PURITONE SENNA TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SENNA DRY EXTRACT EQUIVALENT TO SENNOSIDES A & B 13,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Packer:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Laboratory:FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA
Shelf-life:	24 months provisional
Date of registration:	7 JULY 2006

MRF 15

Registration number:	A40/2.7/0147
Name of medicine:	BEDORAL 30
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml AMPOULE CONTAINS: KETOROLAC TROMETHAMINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life:	24 months
Date of registration:	7 JULY 2006
