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IMPORTANT NOTICE

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CONTENTS**INHOUD**

No.	Page No.	Gazette No.	No.	Bladsy No.	Koerant No.
GENERAL NOTICE			ALGEMENE KENNISGEWING		
Health, Department of			Gesondheid, Departement van		
<i>General Notice</i>			<i>Algemene Kennisgewing</i>		
194			194		
Medicines and Related Substances Act (101/1965): Medicines Control Council: Conditions of registration of a medicine in terms of the provision of section 15 (7)			Wet op Beheer van Medisyne en Verwante Stowwe (101/1965): Medisynebeheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalings van artikel 15 (7)		
	3	34184		4	34184

GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 194 OF 2011

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 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 194 VAN 2011**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 goedgekeur 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 goedgekeurde 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 rakleef tyd 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 rakleef tydperiode 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. Bemaking 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 vrystellingssertifikaat 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:	42/8.2/0150
Name of medicine:	INNOHEP 2 500 IU anti-Xa
Dosage form:	INJECTION
Active ingredients:	EACH 0,25 ml SOLUTION CONTAINS: TINZAPARIN SODIUM 2 500,0 IU anti-Xa
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Packer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Laboratory: FPRC:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF15	
Registration number:	42/8.2/0151
Name of medicine:	INNOHEP 10 000 IU anti-Xa
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: TINZAPARIN SODIUM 10 000,0 IU anti-Xa
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Packer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Laboratory: FPRC:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15	
Registration number:	42/8.2/1109
Name of medicine:	INNOHEP 3 500 IU anti-Xa
Dosage form:	INJECTION
Active ingredients:	EACH 0,35 ml SOLUTION CONTAINS: TINZAPARIN SODIUM 3 500,0 IU anti-Xa
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Packer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Laboratory: FPRC:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	41/7.1.3/0506
Name of medicine:	VERSYLON 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT- BUTYLAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	LUPIN LTD, VERNA, SALTETTE GOA, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	LUPIN LTD, VERNA, SALTETTE GOA, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH

MRF15

Registration number:	41/25/0756
Name of medicine:	NUTRIFLEX LIPID PLUS
Dosage form:	INFUSION
Active ingredients:	EACH 1000,0 ml MIXTURE CONTAINS: L-isoleucine 2,26 g L-leucine 3,01 g L-methionine 1,88 g L-lysine 2,18 g L-phenylalanine 3,37 g L-threonine 1,74 g L-tryptophan 0,54 g L-valine 2,50 g L-arginine 2,59 g L-histidine 1,20 g L-alanine 4,66 g Glycine 1,58 g L-proline 3,26 g L-serine 2,88 g Sodium Chloride 0,402 g Calcium Chloride 0,47 g Magnesium Acetate 0,686 g Potassium Acetate 2,747 g Sodium dihydrogen phosphate 1,872 g Glucose 120,0 g Aspartic Acid 1,44 g Glutamic Acid 3,37 g Sodium Hydroxide 0,781 g Sodium Acetate 0,222 g Zinc Acetate 5,264 g Medium chain triglycerides 20,0 g Soya oil 20,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Packer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY

MRF 15

Registration number:	41/25/0757
Name of medicine:	NUTRIFLEX LIPID PERI
Dosage form:	INFUSION
Active ingredients:	EACH 1000,0 ml MIXTURE CONTAINS: L-isoleucine 1,87 g L-leucine 2,50 g L-methionine 1,57 g L-lysine 1,81 g L-phenylalanine 2,81 g L-threonine 1,46 g L-tryptophan 0,46 g L-valine 2,08 g L-arginine 2,16 g L-histidine 1,00 g L-alanine 3,88 g Glycine 1,32 g L-proline 2,72 g L-serine 2,40 g Sodium Chloride 0,865 g Calcium Chloride 0,353 g Magnesium Acetate 0,515 g Potassium Acetate 2,354 g Sodium dihydrogen phosphate 0,936 g Glucose 64,0 g Aspartic Acid 1,20 g Glutamic Acid 2,80 g Sodium Hydroxide 0,64 g Sodium Acetate 0,435 g Zinc Acetate 5,30 g Medium chain triglycerides 20,0 g Soya oil 20,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Packer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY

Laboratory: FPRC:

LUPIN LTD, VERNA, SALCETTE
GOA, INDIA
PHARMACARE LTD, KORSTEN,
PORT ELIZABETH
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG

FPRC/FPRR:

PHARMACARE LTD, KORTEN,
PORT ELIZABETH

FPRR:

PHARMACARE LTD,
WOODMEAD, SANDTON

Shelf-life:

24 months

Date of registration:

11 FEBRUARY 2011

Laboratory:

FPRC:

B BRAUN MELSUNGEN
AG, PFIEFFEWIESEN,
MELSUNGEN, GERMANY

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:

24 months

Date of registration:

11 FEBRUARY 2011

Laboratory: FPRC:

B BRAUN MELSUNGEN
AG, PFIEFFEWIESEN,
MELSUNGEN, GERMANY

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:

24 months

Date of registration:

11 FEBRUARY 2011

MRF 15

Registration number: 41/25/0758

Name of medicine: NUTRIFLEX LIPID PLUS
WITHOUT
ELECTROLYRES

Dosage form: INFUSION

Active ingredients: EACH 1000,0 ml
MIXTURE CONTAINS:
L-isoleucine 2,26 g
L-leucine 3,01 g
L-methionine 1,88 g
L-lysine 2,18 g
L-phenylalanine 3,37 g
L-threonine 1,74 g
L-tryptophan 0,54 g
L-valine 2,50 g
L-arginine 2,59 g
L-histidine 1,20 g
L-alanine 4,66 g
Glycine 1,58 g
L-proline 3,26 g
L-serine 2,88 g
Glucose 120,0 g
Aspartic Acid 1,44 g
Glutamic Acid 3,37 g
Medium chain triglycerides
20,0 g
Soya oil 20,0 g

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

Applicant: B BRAUN MEDICAL (PTY)
LTD

Manufacturer: B BRAUN MELSUNGEN
AG, MELSUNGEN,
GERMANY
B BRAUN MELSUNGEN
AG, PFIEFFEWIESEN,
MELSUNGEN, GERMANY

MRF15

Registration number: 41/25/0759

Name of medicine: NUTRIFLEX LIPID
SPECIAL

Dosage form: INFUSION

Active ingredients: EACH 1000,0 ml
MIXTURE CONTAINS:
L-isoleucine 3,28 g
L-leucine 4,38 g
L-methionine 2,74 g
L-lysine 3,18 g
L-phenylalanine 4,92 g
L-threonine 2,54 g
L-tryptophan 0,80 g
L-valine 3,60 g
L-arginine 3,78 g
L-histidine 1,75 g
L-alanine 6,79 g
Glycine 2,31 g
L-proline 4,76 g
L-serine 4,20g
Sodium Chloride 0,378 g
Calcium Chloride 0,623 g
Magnesium Acetate
0,91g
Potassium Acetate 3,689
g
Sodium dihydrogen
phosphate 2,496 g
Glucose 144,0 g
Aspartic Acid 2,10 g
Glutamic Acid 4,91 g
Sodium Hydroxide 1,171 g
Sodium Acetate 0,25 g
Zinc Acetate 7,02 g
Medium chain
triglycerides 20,0 g
Soya oil 20,0 g

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

Applicant: B BRAUN MEDICAL
(PTY) LTD

Manufacturer: B BRAUN MELSUNGEN
AG, MELSUNGEN,
GERMANY
B BRAUN MELSUNGEN
AG, PFIEFFEWIESEN,
MELSUNGEN,
GERMANY

MRF 15

Registration number: 42/5.7.1/0339

Name of medicine: TELFAST SUSPENSION

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
FEXOFENADINE HYDROCHLORIDE
30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SANOFI-AVENTIS SOUTH AFRICA
(PTY) LTD

Manufacturer: SANOFI-AVENTIS U.S. LLC, KANSAS
CITY, MISSOURI, USA

Packer: B BRAUN MELSUNGEN
AG, MELSUNGEN,
GERMANY
B BRAUN MELSUNGEN
AG, 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: 24 months

Date of registration: 11 FEBRUARY 2011

Packer: B BRAUN MELSUNGEN
AG, MELSUNGEN,
GERMANY
B BRAUN MELSUNGEN
AG, 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: 24 months

Date of registration: 11 FEBRUARY 2011

Packer: SANOFI-AVENTIS U.S. LLC, KANSAS
CITY, MISSOURI, USA
WINTHROP PHARMACEUTICALS,
WALTLOO, PRETORIA

Laboratory: FPRC: SANOFI-AVENTIS U.S. LLC, KANSAS
CITY, MISSOURI, USA

FPRC/FPRR WINTHROP PHARMACEUTICALS,
WALTLOO, PRETORIA

FPRR: SANOFI-AVENTIS S.A., MIDRAND, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 11 FEBRUARY 2011

MRF 15

Registration number: 43/20.2.8/0581

Name of medicine: ARROW EFAVIRENZ

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EFAVIRENZ 600,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD

Manufacturer: EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA

Packer: EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA

Laboratory: FPRC : EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
SEDEK AGRIKEM, KAMEELDRIFT-EAST, PRETORIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA

FPRR: ARROW PHARMA SA, WOODMEAD

Shelf-life: 24 months (Provisional)

Date of registration: 11 FEBRUARY 2011

MRF15

Registration number: 44/20.2.8/0106

Name of medicine: ADCO LAMIVUDINE AND ZIDOVUDINE 150/300

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, 8

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 11 FEBRUARY 2011

MRF 15

Registration number: 44/20.2.8/0107

Name of medicine: ZILAM 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, 8

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 11 FEBRUARY 2011

MRF 15

Registration number:	41/21.2/0658
Name of medicine:	ACCORD GLIMEPIRIDE 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:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 FEBRUARY 2011

MRF15

Registration number:	41/11.4.3/0663
Name of medicine:	ACCORD OMEPRAZOLE 40 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OMEPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	SOFARIMEX INDUSTRIES QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	SOFARIMEX INDUSTRIES QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG BE-TABS PHARMACEUTICALS, ROODEPOORT
Laboratory:	FPRC: SOFARIMEX INDUSTRIES QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG BE-TABS PHARMACEUTICALS, ROODEPOORT CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA
Shelf-life:	24 months (Provisional)
Date of registration:	18 FEBRUARY 2011

MRF 15

Registration number:	42/7.1.3/0325
Name of medicine:	LOSAAR PLUS 50/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	SOFARIMEX INDUSTRIA QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	SOFARIMEX INDUSTRIA QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA BE-TABS PHARMACEUTICALS, ROODEPOORT COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
Laboratory:	FPRC INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA BE-TABS PHARMACEUTICALS, ROODEPOORT COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 FEBRUARY 2011

MRF 15

Registration number: 42/7.1.3/0326

Name of medicine: LOSAAR PLUS 100/25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
100,0 mg
HYDROCHLOROTHIAZIDE
25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ACCORD HEALTHCARE (PTY) LTD

Manufacturer: SOFARIMEX INDUSTRIA QUIMICA e FARMACEUTICA, CACEM, PORTUGAL
INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA

Packer: SOFARIMEX INDUSTRIA QUIMICA e FARMACEUTICA, CACEM, PORTUGAL
INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT
COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG

Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT
COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG

FPRR: ACCORD HEALTHCARE, RIVONIA, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 18 FEBRUARY 2011

MRF15

Registration number: A40/3/0326

Name of medicine: MICROVISC

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
SODIUM HYALURONATE 10,0 mg

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

Applicant: ECO PHARMACEUTICALS (PTY) LTD

Manufacturer: BOHUS BIOTECH AB, STROMSTAD, SWEDEN

Packer: BOHUS BIOTECH AB, STROMSTAD, SWEDEN
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA

Laboratory: FPRC: BOHUS BIOTECH AB, STROMSTAD, SWEDEN
PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
ANALYCEN NORDIC AB, LIDKOPING, SWEDEN
MIKROBIOLOGISKA LABORATORIET, GOTEBOG, SWEDEN

FPRR: ECO PHARMACEUTICALS, NORTHWOLD, RANDBURG

Shelf-life: 36 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: A40/3/0327

Name of medicine: MICROVISC PLUS

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
SODIUM HYALURONATE 14,0 mg

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

Applicant: ECO PHARMACEUTICALS (PTY) LTD

Manufacturer: BOHUS BIOTECH AB, STROMSTAD, SWEDEN

Packer: BOHUS BIOTECH AB, STROMSTAD, SWEDEN
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA

Laboratory: FPRC: BOHUS BIOTECH AB, STROMSTAD, SWEDEN
PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
ANALYCEN NORDIC AB, LIDKOPING, SWEDEN
MIKROBIOLOGISKA LABORATORIET, GOTEBOG, SWEDEN
ECO PHARMACEUTICALS, NORTHWOLD, RANDBURG

FPRR: ECO PHARMACEUTICALS, NORTHWOLD, RANDBURG

Shelf-life: 36 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/26/0162

Name of medicine: CIPLA DOCETAXEL 20

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
DOCETAXEL 20,0 mg

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA

Packer: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA

Laboratory: FPRC: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA

FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: 24 months

Date of registration: 4 MARCH 2011

MRF15

Registration number: 41/26/0163

Name of medicine: CIPLA DOCETAXEL 80

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
DOCETAXEL 80,0 mg

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA

Packer: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA

Laboratory: FPRC: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA

FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: 24 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/1.2/0297

Name of medicine: GLENMARK CITALOPRAM 20 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE
EQUIVALENT TO CITALOPRAM 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: BOUWER BARTLETT (PTY) LTD

Manufacturer: GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA

Packer: GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA

Laboratory: FPRC: GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA

FPRR: BOUWER BARTLETT, VORNA VALLEY, MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15	
Registration number:	41/26/0423
Name of medicine:	CIPLA PACLITAXEL 30 mg/5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 5,0 ml VIAL CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15	
Registration number:	41/26/0424
Name of medicine:	CIPLA PACLITAXEL 100 mg/16,7 ml
Dosage form:	INJECTION
Active ingredients:	EACH 20,0 ml VIAL CONTAINS: PACLITAXEL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15	
Registration number:	41/26/0425
Name of medicine:	CIPLA PACLITAXEL 300 mg/50 ml
Dosage form:	INJECTION
Active ingredients:	EACH 50,0 ml VIAL CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number: 41/25/0760

Name of medicine: NUTRIFLEX LIPID SPECIAL WITHOUT ELECTROLYTES

Dosage form: INFUSION

Active ingredients: EACH 1 000,0 ml MIXTURE CONTAINS:
 L-isoleucine 3,28 g
 L-leucine 4,38 g
 L-methionine 2,74 g
 L-lysine 3,18 g
 L-phenylalanine 4,92 g
 L-threonine 2,54 g
 L-tryptophan 0,80 g
 L-valine 3,60 g
 L-arginine 3,78 g
 L-histidine 1,75 g
 L-alanine 6,79 g
 Glycine 2,31 g
 L-proline 4,76 g
 L-serine 4,20g
 Glucose 144,0 g
 Aspartic Acid 2,10 g
 Glutamic Acid 4,91 g
 Medium chain triglycerides 20,0 g
 Soya oil 20,0 g

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY
 B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY

Packer: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY
 B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY

MRF15

Registration number: 41/3.1/0762

Name of medicine: ENBREL 25 mg PS

Dosage form: INJECTION

Active ingredients: EACH PRE-FILLED SYRINGE CONTAINS:
 ETANERCEPT 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: PFIZER LABORATORIES (PTY) LTD

Manufacturer: VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY
 AMGEN INC RHODE ISLAND, WEST GREENWICH, RHODE ISLAND
 WYETH BIOPHARMA, CLONDALKIN, DUBLIN

Packer: VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY
 WYETH PHARMACEUTICALS, HAVANT, HAMPSHIRE, UK
 PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG

MRF 15

Registration number: 41/3.1/0763

Name of medicine: ENBREL 50 mg PS

Dosage form: INJECTION

Active ingredients: EACH PRE-FILLED SYRINGE CONTAINS:
 ETANERCEPT 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: PFIZER LABORATORIES (PTY) LTD

Manufacturer: VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY
 AMGEN INC RHODE ISLAND, WEST GREENWICH, RHODE ISLAND
 WYETH BIOPHARMA, CLONDALKIN, DUBLIN

Packer: VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY
 WYETH PHARMACEUTICALS, HAVANT, HAMPSHIRE, UK
 PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG

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: 24 months

Date of
registration: 4 MARCH 2011

Laboratory:
FPRC: VETTER PHARMA-
FERTIGUNG GmbH & Co,
RAVENSBURG, GERMANY
AMGEN INC RHODE
ISLAND, WEST
GREENWICH, RHODE
ISLAND
WYETH BIOPHARMA,
CLONDALKIN, DUBLIN
WYETH
PHARMACEUTICALS,
HAVANT, HAMPSHIRE, UK
PHARMA-Q, INDUSTRIA-
WEST, JOHANNESBURG

FPRR: PFIZER LABORATORIES,
SANDTON,
JOHANNESBURG

Shelf-life: 24 months
(Provisional)

Date of registration: 4 MARCH 2011

Laboratory: FPRC: VETTER PHARMA-FERTIGUNG GmbH
& Co, RAVENSBURG, GERMANY
AMGEN INC RHODE ISLAND, WEST
GREENWICH, RHODE ISLAND
WYETH BIOPHARMA, CLONDALKIN,
DUBLIN
WYETH PHARMACEUTICALS,
HAVANT, HAMPSHIRE, UK
PHARMA-Q, INDUSTRIA-WEST,
JOHANNESBURG

FPRR: PFIZER LABORATORIES, SANDTON,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/11.5/0764

Name of medicine: ANLAC SYRUP

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP
CONTAINS:
LACTULOSE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ARROW PHARMA SOUTH
AFRICA (PTY) LTD

Manufacturer: LACSA, MERBANK, DURBAN

Packer: DIVPHARM MANUFACTURING
& PACKAGING, LONGDALE,
JOHANNESBURG

Laboratory: FPRC: TECHNIKON LABORATORIES,
ROBERTVILLE, FLORIDA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG

FPRR: ARROW PHARMA S.A.,
SANDOWN, JOHANNESBURG

Shelf-life: 24 months
(Provisional)

Date of registration: 4 MARCH 2011

MRF15

Registration number: 41/7.1/0782

Name of medicine: MERCK AMLODIPINE 5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE BESYLATE
EQUIVALENT TO
AMLODIPINE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: MERCK GENERICS RSA (PTY)
LTD

Manufacturer: GENPHARM
PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO, CANADA
MERCK PHARMACEUTICAL
MANUFACTURING, WADEVILLE,
GERMISTON

Packer: GENPHARM
PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO, CANADA
MERCK PHARMACEUTICAL
MANUFACTURING, WADEVILLE,
GERMISTON
GENERICS UK, POTTERS BAR,
HERTFORDSHIRE, UK

Laboratory: FPRC: GENPHARM
PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO, CANADA
MERCK PHARMACEUTICAL
MANUFACTURING, WADEVILLE,
GERMISTON
GENERICS UK, POTTERS BAR,
HERTFORDSHIRE, UK
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: MERCK GENERICS,
MODDERFONTEIN

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/7.1/0783

Name of medicine: MERCK AMLODIPINE 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE BESYLATE
EQUIVALENT TO
AMLODIPINE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS
INC, ETOBICOKE, ONTARIO,
CANADA
MERCK PHARMACEUTICAL
MANUFACTURING, WADEVILLE,
GERMISTON

Packer: GENPHARM PHARMACEUTICALS
INC, ETOBICOKE, ONTARIO,
CANADA
MERCK PHARMACEUTICAL
MANUFACTURING, WADEVILLE,
GERMISTON
GENERICS UK, POTTERS BAR,
HERTFORDSHIRE, UK

Laboratory: FPRC: GENPHARM PHARMACEUTICALS
INC, ETOBICOKE, ONTARIO,
CANADA
MERCK PHARMACEUTICAL
MANUFACTURING, WADEVILLE,
GERMISTON
GENERICS UK, POTTERS BAR,
HERTFORDSHIRE, UK
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY, NORTH-
WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: MERCK GENERICS,
MODDERFONTEIN

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/5.2/0990

Name of medicine: ASPEN GALANTAMINE 12 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GALANTAMINE 12,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: PHARMACARE LIMITED

Manufacturer: ALPHAPHARM PTY LTD,
CAROLE PARK, QUEENSLAND,
AUSTRALIA

Packer: ALPHAPHARM PTY LTD,
CAROLE PARK, QUEENSLAND,
AUSTRALIA
GENERICS UK, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES,
DUBLIN, IRELAND

Laboratory: FPRC: ALPHAPHARM PTY LTD,
CAROLE PARK, QUEENSLAND,
AUSTRALIA
GENERICS UK, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES,
DUBLIN, IRELAND
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
MERCK FARMA y QUIMICA S.A.,
MOLLET DEL VALLES,
BARCELONA, SPAIN
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

FPRR: PHARMACARE LTD,
WOODMEAD, SANDTON

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF15

Registration number: 41/5.2/0991

Name of medicine: ASPEN GALANTAMINE 8 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GALANTAMINE 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: PHARMACARE LIMITED

Manufacturer: ALPHAPHARM PTY LTD,
CAROLE PARK,
QUEENSLAND, AUSTRALIA

Packer: ALPHAPHARM PTY LTD,
CAROLE PARK,
QUEENSLAND, AUSTRALIA
GENERICS UK, POTTERS
BAR, HERTFORDSHIRE, UK
GERARD LABORATORIES,
DUBLIN, IRELAND

Laboratory: FPRC: ALPHAPHARM PTY LTD,
CAROLE PARK,
QUEENSLAND, AUSTRALIA
GENERICS UK, POTTERS
BAR, HERTFORDSHIRE, UK
GERARD LABORATORIES,
DUBLIN, IRELAND
M&L LABORATORY
SERVICES, ORMONDE,
JOHANNESBURG
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
MERCK FARMA y QUIMICA
S.A., MOLLET DEL VALLES,
BARCELONA, SPAIN
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

FPRR: PHARMACARE LTD,
WOODMEAD, SANDTON

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/7.1.3/1000

Name of medicine: NETRASOL CO 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
50,0 mg
HYDROCHLOROTHIAZIDE
12,5 mg

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

Applicant: SPECIPHARM (PTY) LTD

Manufacturer: SPECIFAR S.A.,
VARVARA, ATHENS,
GREECE

Packer: SPECIFAR S.A.,
VARVARA, ATHENS,
GREECE
JANSSEN
PHARMACEUTICA,
WOODMEAD, SANDTON
DIVPHARM
MANUFACTURING &
PACKAGING, LONGDALE,
JOHANNESBURG

Laboratory: FPRC: SPECIFAR S.A.,
VARVARA, ATHENS,
GREECE

FPRR: SPECIPHARM, HALFWAY
HOUSE, MIDRAND

Shelf-life: 24 months

Date of registration: 04 MARCH 2011

MRF 15

Registration number: 41/7.1.3/1001

Name of medicine: NETRASOL CO 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
100,0 mg
HYDROCHLOROTHIAZIDE
25,0 mg

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

Applicant: SPECPHARM (PTY) LTD

Manufacturer: SPECIFAR S.A.,
VARVARA, ATHENS,
GREECE

Packer: SPECIFAR S.A.,
VARVARA, ATHENS,
GREECE
JANSSEN
PHARMACEUTICA,
WOODMEAD, SANDTON
DIVPHARM
MANUFACTURING &
PACKAGING, LONGDALE,
JOHANNESBURG

Laboratory: FPRC: SPECIFAR S.A.,
VARVARA, ATHENS,
GREECE

FPRR: SPECPHARM, HALFWAY
HOUSE, MIDRAND

Shelf-life: 24 months

Date of registration: 04 MARCH 2011

MRF15

Registration number: 41/5.3/1015

Name of medicine: GALANTIC 4

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GALANTAMINE
HYDROBROMIDE EQUIVALENT
TO GALANTAMINE 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SANDOZ S.A. (PTY) LTD

Manufacturer: SANDOZ PVT LTD, VILLAGE
DIGHE, NAVI MUMBAI, INDIA

Packer: SANDOZ PVT LTD, VILLAGE
DIGHE, NAVI MUMBAI, INDIA
NOVARTIS S.A., SPARTAN,
KEMPTON PARK

Laboratory: FPRC: SANDOZ PVT LTD, VILLAGE
DIGHE, NAVI MUMBAI, INDIA
NOVARTIS S.A., SPARTAN,
KEMPTON PARK

FPRR: SANDOZ S.A., SPARTAN,
KEMPTON PARK

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/5.3/1016

Name of medicine: GALANTIC 8

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GALANTAMINE HYDROBROMIDE
EQUIVALENT TO GALANTAMINE
8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SANDOZ S.A. (PTY) LTD

Manufacturer: SANDOZ PVT LTD, VILLAGE DIGHE,
NAVI MUMBAI, INDIA

Packer: SANDOZ PVT LTD, VILLAGE DIGHE,
NAVI MUMBAI, INDIA
NOVARTIS S.A., SPARTAN,
KEMPTON PARK

Laboratory: FPRC: SANDOZ PVT LTD, VILLAGE DIGHE,
NAVI MUMBAI, INDIA
NOVARTIS S.A., SPARTAN,
KEMPTON PARK

FPRR: SANDOZ S.A., SPARTAN, KEMPTON
PARK

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/5.3/1017

Name of medicine: GALANTIC 12

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GALANTAMINE
HYDROBROMIDE EQUIVALENT
TO GALANTAMINE 12,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SANDOZ S.A. (PTY) LTD

Manufacturer: SANDOZ PVT LTD, VILLAGE
DIGHE, NAVI MUMBAI, INDIA

Packer: SANDOZ PVT LTD, VILLAGE
DIGHE, NAVI MUMBAI, INDIA
NOVARTIS S.A., SPARTAN,
KEMPTON PARK

Laboratory: FPRC: SANDOZ PVT LTD, VILLAGE
DIGHE, NAVI MUMBAI, INDIA
NOVARTIS S.A., SPARTAN,
KEMPTON PARK

FPRR: SANDOZ S.A., SPARTAN,
KEMPTON PARK

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF15

Registration number: 41/7.1.3/1031

Name of medicine: RAN LOSARTAN PLUS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
50,0 mg
HYDROCHLOROTHIAZIDE
12,5 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES
LTD, DEWAS, MADHYA
PRADESH, INDIA

Packer: RANBAXY LABORATORIES
LTD, DEWAS, MADHYA
PRADESH, INDIA

Laboratory: FPRC: RANBAXY LABORATORIES
LTD, DEWAS, MADHYA
PRADESH, INDIA
KHULULEKANI
LABORATORY SERVICES,
COVENTRY PARK,
MIDRAND
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: RANBAXY (SA), CENTURION

Shelf-life: 24 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/7.1.3/1034

Name of medicine: RAN LOSARTAN FORTE
PLUS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
100,0 mg
HYDROCHLOROTHIAZIDE
25,0 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES
LTD, DEWAS, MADHYA
PRADESH, INDIA

Packer: RANBAXY LABORATORIES
LTD, DEWAS, MADHYA
PRADESH, INDIA

Laboratory: FPRC: RANBAXY LABORATORIES
LTD, DEWAS, MADHYA
PRADESH, INDIA
KHULULEKANI
LABORATORY SERVICES,
COVENTRY PARK, MIDRAND
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: RANBAXY (SA), CENTURION

Shelf-life: 24 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 41/7.1.3/1035

Name of medicine: LOHYPE PLUS 50/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
50,0 mg
HYDROCHLOROTHIAZIDE
12,5 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA

Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: RANBAXY (SA), CENTURION

Shelf-life: 24 months

Date of registration: 4 MARCH 2011

MRF15

Registration number: 41/7.1.3/1036

Name of medicine: LOHYPE FORTE PLUS 100/25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
100,0 mg
HYDROCHLOROTHIAZIDE
25,0 mg

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

Applicant: RANBAXY (SA) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA

Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: RANBAXY (SA), CENTURION

Shelf-life: 24 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 42/26/0020

Name of medicine: ASPEN VINOELBIN 10 mg/1 ml

Dosage form: INFUSION

Active ingredients: EACH 1,0 ml VIAL CONTAINS:
VINOELBIN TARTRATE EQUIVALENT TO
VINOELBIN 10,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA

Packer: S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA

FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

FPRR: PHARMACARE LTD, WOODMEAD, SANDTON

Shelf-life: 24 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number:	42/26/0021
Name of medicine:	ASPEN VINORELBIN 50 mg/5 ml
Dosage form:	INFUSION
Active ingredients:	EACH 5,0 ml VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
FPRC:	RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	42/20.1.1/0079
Name of medicine:	MYLAN CEFTAZIDIME 500 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Packer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Laboratory:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
FPRC:	G.E.T. SRL, SANREMO, ITALY GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/20.1.1/0080
Name of medicine:	MYLAN CEFTAZIDIME 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:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Packer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Laboratory:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
FPRC:	G.E.T. SRL, SANREMO, ITALY GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/20.1.1/0081
Name of medicine:	MYLAN CEFTAZIDIME 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:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Packer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Laboratory: FPRC:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY G.E.T. SRL, SANREMO, ITALY GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	42/5.7.1/0344
Name of medicine:	FEXOFENADINE-WINTHROP SUSPENSION 6mg/ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: FEXOFENADINE HYDROCHLORIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA
Packer:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	WINTHROP PHARMACEUTICALS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/3.2/0452
Name of medicine:	ACTONEL 75 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS RISEDRONATE SODIUM 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI AVENTIS SA (PTY) LTD
Manufacturer:	OSG NORWICH PHARMACEUTICALS, NORTH NORWICH, NEW YORK, USA PROCTER & GAMBLE PHARMACEUTICALS, MANATI, PUERTO RICO
Packer:	PROCTER & GAMBLE PHARMACEUTICALS, WEITERSTADT, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC:	PROCTER & GAMBLE PHARMACEUTICALS, WEITERSTADT, GERMANY
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/34/0664
Name of medicine:	ZOBONE
Dosage form:	POWDER
Active ingredients:	EACH VIAL CONTAINS: ZOLEDRONIC ACID 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	42/20.2.8/0838
Name of medicine:	ASPEN ATAZANAVIR 150 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/20.2.8/0839
Name of medicine:	ASPEN ATAZANAVIR 200 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number: 42/1.2/1001
 Name of medicine: NEXITO 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, 8
 Applicant: PHARMAPLAN (PTY) LTD
 Manufacturer: SUN PHARMACEUTICAL
 INDUSTRIES LTD,
 SILVASSA, DADRA &
 NAGAR HAVELI, INDIA
 Packer: SUN PHARMACEUTICAL
 INDUSTRIES LTD,
 SILVASSA, DADRA &
 NAGAR HAVELI, INDIA
 Laboratory:
 FPRC: SUN PHARMACEUTICAL
 INDUSTRIES LTD,
 SILVASSA, DADRA &
 NAGAR HAVELI, INDIA
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: PHARMAPLAN, MIDRAND,
 RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 MARCH 2011

MRF15

Registration number: 42/11.4.3/1003
 Name of medicine: NEXIAM 10 mg SACHETS
 Dosage form: GRANULES
 Active ingredients: EACH SACHET CONTAINS:
 ESOMEPRAZOLE 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ASTRAZENECA
 PHARMACEUTICALS (PTY)
 LTD
 Manufacturer: ASTRAZENECA AB,
 SODERTALJE, SWEDEN
 Packer: ASTRAZENECA AB,
 SODERTALJE, SWEDEN
 Laboratory:
 FPRC: ASTRAZENECA AB,
 SODERTALJE, SWEDEN
 CONSULTING CHEMICAL
 LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: ASTRAZENECA
 PHARMACEUTICALS,
 SUNNINGHILL,
 JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/20.2.8/0230
 Name of medicine: NEVIVIR
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 NEVIRAPINE 200,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: BLISS PHARMACEUTICALS
 cc
 Manufacturer: HETERO DRUG LTD,
 JEEDIMETLA,
 HYDERABAD, INDIA
 Packer: HETERO DRUG LTD,
 JEEDIMETLA,
 HYDERABAD, INDIA
 Laboratory: FPRC: HETERO DRUG LTD,
 JEEDIMETLA,
 HYDERABAD, INDIA
 FPRR: BLISS
 PHARMACEUTICALS,
 WOODMEAD, SANDTON
 Shelf-life: 24 months
 Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/20.2.8/0234

Name of medicine: ATAZOR 100

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE
EQUIVALENT TO
ATAZANAVIR 100,0 mg

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

Applicant: DEZZO TRADING 392 (PTY)
LTD t/a INDO PHARMA

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,
ATLASVILLE, BOKSBURG

FPRR: DEZZO TRADING 392, t/a
INDO PHARMA,
ANCHORVILLE, LENASIA

Shelf-life: 36 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/20.2.8/0235

Name of medicine: ATAZOR 150

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE
EQUIVALENT TO
ATAZANAVIR 150,0 mg

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

Applicant: DEZZO TRADING 392 (PTY) LTD
t/a INDO PHARMA

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, ATLASVILLE,
BOKSBURG

FPRR: DEZZO TRADING 392, t/a INDO
PHARMA, ANCHORVILLE,
LENASIA

Shelf-life: 36 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/20.2.8/0236

Name of medicine: ATAZOR 200

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE
EQUIVALENT TO
ATAZANAVIR 200,0 mg

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

Applicant: DEZZO TRADING 392 (PTY) LTD
t/a INDO PHARMA

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, ATLASVILLE,
BOKSBURG

FPRR: DEZZO TRADING 392, t/a INDO
PHARMA, ANCHORVILLE,
LENASIA

Shelf-life: 36 months

Date of registration: 4 MARCH 2011

MRF 15	
Registration number:	43/2.2/0247
Name of medicine:	MEDPLOZ 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOLPIDEM TARTRATE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15	
Registration number:	43/2.2/0257
Name of medicine:	MEDPLOZ 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOLPIDEM TARTRATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15	
Registration number:	43/7.1.3/0493
Name of medicine:	AURO LOSARTAN TABLETS 25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number: 43/7.1.3/0494

Name of medicine: AURO LOSARTAN TABLETS 50 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND

FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF15

Registration number: 43/7.1.3/0495

Name of medicine: AURO LOSARTAN TABLETS 100 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND

FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/7.1.3/0496

Name of medicine: RASOL 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND

FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/7.1.3/0497

Name of medicine: RASOL 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
M&L LABORATORY
SERVICES, ORMONDE,
JOHANNESBURG
KHULULEKANI LABORATORY
SERVICES, COVENTRY PARK,
MIDRAND

FPRR: AUROBINDO PHARMA,
MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF15

Registration number: 43/7.1.3/0498

Name of medicine: RASOL 100

Dosage form: TABLET

Active ingredients: EACH TABLET
CONTAINS:
LOSARTAN POTASSIUM
100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA
(PTY) LTD

Manufacturer: AUROBINDO PHARMA
LTD, QUTHUBULLAPUR
MANDAL, RANGA
REDDY, ANDHRA
PRADESH, INDIA

Packer: AUROBINDO PHARMA
LTD, QUTHUBULLAPUR
MANDAL, RANGA
REDDY, ANDHRA
PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA
LTD, QUTHUBULLAPUR
MANDAL, RANGA
REDDY, ANDHRA
PRADESH, INDIA
M&L LABORATORY
SERVICES, ORMONDE,
JOHANNESBURG
KHULULEKANI
LABORATORY
SERVICES, COVENTRY
PARK, MIDRAND

FPRR: AUROBINDO PHARMA,
MEYERSDAL,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/20.2.8/0580

Name of medicine: VIREF

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EFAVIRENZ 600,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ARROW PHARMA SOUTH
AFRICA (PTY) LTD

Manufacturer: EMCURE
PHARMACEUTICALS LTD,
HINJWADI, PUNE, INDIA

Packer: EMCURE
PHARMACEUTICALS LTD,
HINJWADI, PUNE, INDIA
DIVPHARM
MANUFACTURING &
PACKAGING, LONGDALE,
JOHANNESBURG
TECHNIKON
LABORATORIES,
ROBERTVILLE, FLORIDA

Laboratory: FPRC: EMCURE
PHARMACEUTICALS LTD,
HINJWADI, PUNE, INDIA
SEDEK AGRKEM,
KAMEELDRIFT-EAST,
PRETORIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG
TECHNIKON
LABORATORIES,
ROBERTVILLE, FLORIDA

FPRR: ARROW PHARMA SA,
WOODMEAD

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/20.1.1/0647

Name of medicine: DORIBAX 500 mg

Dosage form: INFUSION

Active ingredients: EACH VIAL CONTAINS:
DORIPENEM
MONOHYDRATE
EQUIVALENT TO
DORIPENEM 500,0 mg

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

Applicant: JANSSEN PHARMACEUTICA
(PTY) LTD

Manufacturer: SHIONOGI & CO LTD,
IWATE, JAPAN

Packer: SHIONOGI & CO LTD,
IWATE, JAPAN
ORTHO-MCNEIL
PHARMACEUTICAL INC,
SOUTH RARITAN, NEW
JERSEY, USA

Laboratory: FPRC: SHIONOGI & CO LTD,
IWATE, JAPAN
ORTHO-MCNEIL
PHARMACEUTICAL INC,
SOUTH RARITAN, NEW
JERSEY, USA

FPRR: JANSSEN
PHARMACEUTICA,
WOODMEAD, SANDTON

Shelf-life: 36 months

Date of registration: 4 MARCH 2011

MRF15

Registration number: 43/18.8/0648

Name of medicine: RUBY

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DROSPIRENONE 3,0
mg
ETHINYLESTRADIOL 0,03
mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: PHARMA DYNAMICS (PTY)
LTD

Manufacturer: LABORATORIOS LEON
FARMA S.A.,
VILLAQUILAMBRE, LEON,
SPAIN

Packer: LABORATORIOS LEON
FARMA S.A.,
VILLAQUILAMBRE, LEON,
SPAIN

Laboratory: FPRC: LABORATORIOS LEON
FARMA S.A.,
VILLAQUILAMBRE, LEON,
SPAIN
CONSULTING CHEMICAL
LABORATORY,
ATLASVILLE, BOKSBURG

FPRR: PHARMA DYNAMICS,
SILVERWOOD, WESTLAKE

Shelf-life: 24 months (Provisional)

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/20.1.6/0680

Name of medicine: SUPIROBAN

Dosage form: OINTMENT

Active ingredients: EACH 1,0 g OINTMENT
CONTAINS:
MUPIROCIN 2,0 mg

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

Applicant: GLENMARK
PHARMACEUTICALS SOUTH
AFRICA (PTY) LTD

Manufacturer: GLENMARK
PHARMACEUTICALS, BARDEZ,
GOA, INDIA

Packer: GLENMARK
PHARMACEUTICALS, BARDEZ,
GOA, INDIA

Laboratory: FPRC: GLENMARK
PHARMACEUTICALS, BARDEZ,
GOA, INDIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

FPRR: GLENMARK
PHARMACEUTICALS S.A.,
VORNA VALLEY, MIDRAND

Shelf-life: 24 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/30.2/0944

Name of medicine: ACTEMRA 80

Dosage form: INFUSION

Active ingredients: EACH 4,0 ml SOLUTION
CONTAINS:
TOCILIZUMAB 80,0 mg

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

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: CHUGAI PHARMA
MANUFACTURING CO,
UTSUNOMIYA-CITY,
TOCHIGI, JAPAN

Packer: CHUGAI PHARMA
MANUFACTURING CO,
UTSUNOMIYA-CITY,
TOCHIGI, JAPAN
F HOFFMANN-LA ROCHE
LTD, WURMISWEG,
KAISERAUGST,
SWITZERLAND

Laboratory: CHUGAI PHARMA
FPRC: MANUFACTURING CO,
UTSUNOMIYA-CITY,
TOCHIGI, JAPAN
ROCHE PHARMA AG,
GRENZACH-WYHLEN,
GERMANY

FPRR: ROCHE PRODUCTS,
ISANDO, RSA

Shelf-life: 30 months

Date of registration: 4 MARCH 2011

MRF15

Registration number: 43/30.2/0945

Name of medicine: ACTEMRA 200

Dosage form: INFUSION

Active ingredients: EACH 10,0 ml SOLUTION
CONTAINS:
TOCILIZUMAB 200,0 mg

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

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: CHUGAI PHARMA
MANUFACTURING CO,
UTSUNOMIYA-CITY,
TOCHIGI, JAPAN

Packer: CHUGAI PHARMA
MANUFACTURING CO,
UTSUNOMIYA-CITY,
TOCHIGI, JAPAN
F HOFFMANN-LA ROCHE
LTD, WURMISWEG,
KAISERAUGST,
SWITZERLAND

Laboratory: FPRC: CHUGAI PHARMA
MANUFACTURING CO,
UTSUNOMIYA-CITY,
TOCHIGI, JAPAN
ROCHE PHARMA AG,
GRENZACH-WYHLEN,
GERMANY

FPRR: ROCHE PRODUCTS,

Shelf-life: 30 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number: 43/30.2/0946

Name of medicine: ACTEMRA 400

Dosage form: INFUSION

Active ingredients: EACH 20,0 ml SOLUTION
CONTAINS:
TOCILIZUMAB 400,0 mg

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

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: CHUGAI PHARMA
MANUFACTURING CO,
UTSUNOMIYA-CITY, TOCHIGI,
JAPAN

Packer: CHUGAI PHARMA
MANUFACTURING CO,
UTSUNOMIYA-CITY, TOCHIGI,
JAPAN
F HOFFMANN-LA ROCHE LTD,
WURMISWEG, KAISERAUGST,
SWITZERLAND

Laboratory: FPRC: CHUGAI PHARMA
MANUFACTURING CO,
UTSUNOMIYA-CITY, TOCHIGI,
JAPAN
ROCHE PHARMA AG,
GRENZACH-WYHLEN,
GERMANY

FPRR: ROCHE PRODUCTS, ISANDO,
RSA

Shelf-life: 30 months

Date of registration: 4 MARCH 2011

MRF 15

Registration number:	44/20.2.8/0108
Name of medicine:	PROPAN LAMIVUDINE AND ZIDOVUDINE 150/300
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, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

Registration number:	42/20.2.8/0687
Name of medicine:	ISENTRESS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RALTEGRAVIR POTASSIUM EQUIVALENT TO RALTEGRAVIR 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK & CO INC, ELKTON, VIRGINIA, USA
Packer:	MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, MIDRAND
Laboratory: FPRC:	MERCK & CO INC, ELKTON, VIRGINIA, USA MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS
FPRC/FPRR:	MSD, HALFWAY HOUSE, MIDRAND
Shelf-life:	36 months
Date of registration:	4 MARCH 2011