REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 532 Pretoria, 9 October Oktober 2009 No. 32620

CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1341 OF 2009

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 1341 VAN 2009

MEDISYNEBEHEERRAAD

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

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goekgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleeftyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleeftydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemarking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:		06/1.3/04
Name of medicine:		THIANIL/TREXONIL COMBIPACK
Dosage form:		INJECTION
Active ingredients:		EACH PACK CONTAINS: THIANIL VIAL CONTAINING: THIAFENTANIL OXALATE 10,0 mg/1,0 ml TREXONIL VIAL CONTAINING: NALTREXONE HYDROCHLORIDE 50,0 mg/1,0 ml
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MC PHARMA (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
	FPRR:	MC PHARMA, MNANDI, CENTURION
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		06/1.3/05
Name of medicine:		TREXONIL
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: NALTREXONE HYDROCHLORIDE 50,0 mg/1,0 ml
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MC PHARMA (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
	FPRR:	MC PHARMA, MNANDI, CENTURION
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:	06/1.3/06	
Name of medicine:	THIANIL	
Dosage form:	INJECTION	
Active ingredients:	EACH VIAL CONTAINS: THIAFENTANIL OXALATE	10,0 mg/1,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	
Applicant:	MC PHARMA (PTY) LTD	
Manufacturer:	PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG	
Packer:	PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG	
Laboratory: FPRC:	PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG	
FPRR:	MC PHARMA, MNANDI, CENTURION	
Shelf-life:	24 months	
Date of registration:	14 AUGUST 2009	

MRF 15

Registration number:	34/21.5.1/0343	
Name of medicine:	ASMANEX TWISTHALER 200 ug	
Dosage form:	INHALER	
Active ingredients:	EACH INHALATION CONTAINS: MOMETASONE FUROATE	200,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	
Applicant:	SCHERING-PLOUGH (PTY) LTD	
Manufacturer:	SCHERING-PLOUGH, TUAS STREET, SINGAPORE	
Packer:	SCHERING-PLOUGH, TUAS STREET, SINGAPORE SCHERING-PLOUGH, HEIST-OP-DEN-BERG SCHERING-PLOUGH, WOODMEAD, SANDTON	
Laboratory: FPRC:	SCHERING-PLOUGH, TUAS STREET, SINGAPORE SCHERING-PLOUGH, HEIST-OP-DEN-BERG	
FPRC/FPRR:	SCHERING-PLOUGH, WOODMEAD, SANDTON	
Shelf-life:	18 months	
Date of registration:	14 AUGUST 2009	

MRF 15

Registration number:	34/21.5.1/0344
Name of medicine:	ASMANEX TWISTHALER 400 ug
Dosage form:	INHALER
Active ingredients:	EACH INHALATION CONTAINS: MOMETASONE FUROATE 400,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SCHERING-PLOUGH (PTY) LTD
Manufacturer:	SCHERING-PLOUGH, TUAS STREET, SINGAPORE
Packer:	SCHERING-PLOUGH, TUAS STREET, SINGAPORE SCHERING-PLOUGH, HEIST-OP-DEN-BERG SCHERING-PLOUGH, WOODMEAD, SANDTON
Laboratory: FPRC:	SCHERING-PLOUGH, TUAS STREET, SINGAPORE SCHERING-PLOUGH, HEIST-OP-DEN-BERG
FPRC/FPRR:	SCHERING-PLOUGH, WOODMEAD, SANDTON
Shelf-life:	18 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	37/5.8/0139
Name of medicine:	SINUTAB SINUS PAIN EXTRA STRENGTH
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 500,0 mg PSEUDOEPHEDRINE HYDROCHLORIDE 30,0 mg CHLORPHENIRAMINE MALEATE 2,0 mg CODEINE PHOSPHATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JOHNSON & JOHNSON (PTY) LTD
Manufacturer:	GOEDECKE AG, FREIBURG, GERMANY
Packer:	GOEDECKE AG, FREIBURG, GERMANY JOHNSON & JOHNSON, RETREAT, RSA
Laboratory: FPRC:	GOEDECKE AG, FREIBURG, GERMANY
FPRC/FPRR:	JOHNSON & JOHNSON, RETREAT, RSA
Shelf-life:	24 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:		38/2.7/0261
Name of medicine:		ADVIL LIQUI-GELS 400
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: IBUPROFEN 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		WYETH S.A. (PTY) LTD
Manufacturer:		CARDINAL HEALTH LTD, BLAGROVE, SWINDON, WILTSHIRE, UK
Packer:		WYETH LEDERLE S.p.A., APRILIA, ITALY
Laboratory:	FPRC:	CARDINAL HEALTH LTD, BLAGROVE, SWINDON, WILTSHIRE, UK WYETH LEDERLE S.p.A., APRILIA, ITALY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	WYETH S.A., VORNA VALLEY, MIDRAND
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		38/11.5/0166
Name of medicine:		AGAROL LACTULOSE
Dosage form:		SYRUP
Active ingredients:		EACH 5,0 ml SYRUP CONTAINS: LACTULOSE 3,3 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:		PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC/FPRR:		PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:	A39/3.2/0352
Name of medicine:	SUPLASYN
Dosage form:	INJECTION
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: SODIUM HYALURONATE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACO DISTRIBUTION (PTY) LTD
Manufacturer:	BIONICHE INC, INVERIN, COUNTY GALWAY, IRELAND LIFECORE BIOMEDICAL INC, CHASKA, MINNESOTA, USA
Packer:	BIONICHE INC, INVERIN, COUNTY GALWAY, IRELAND LIFECORE BIOMEDICAL INC, CHASKA, MINNESOTA, USA
Laboratory: FPRC:	BIONICHE INC, INVERIN, COUNTY GALWAY, IRELAND LIFECORE BIOMEDICAL INC, CHASKA, MINNESOTA, USA
FPRR	PHARMACO DISTRIBUTION, SANDTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	A39/30.3/0591
Name of medicine:	RECOMBINATE 250 I.U.
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: FACTOR VIII, OCTOCOG ALFA 250,0 I.U.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	BAXTER HEALTHCARE CORPORATION, THOUSAND OAKS, CALIFORNIA, USA BAXTER S.A., LESSINES, BELGIUM GENETIC INSTITUTE INC, ANDOVER, MASSACHUSETTS, USA
Packer:	BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Laboratory: FPRC:	BAXTER S.A., LESSINES, BELGIUM
FPRC/FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	A39/30.3/0592
Name of medicine:	RECOMBINATE 500 I.U.
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: FACTOR VIII, OCTOCOG ALFA 500,0 I.U.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	BAXTER HEALTHCARE CORPORATION, THOUSAND OAKS, CALIFORNIA, USA BAXTER S.A., LESSINES, BELGIUM GENETIC INSTITUTE INC, ANDOVER, MASSACHUSETTS, USA
Packer:	BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Laboratory: FPRC:	BAXTER S.A., LESSINES, BELGIUM
FPRR	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	A39/30.3/0593
Name of medicine:	RECOMBINATE 1 000 I.U.
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: FACTOR VIII, OCTOCOG ALFA 1 000,0 I.U.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	BAXTER HEALTHCARE CORPORATION, THOUSAND OAKS, CALIFORNIA, USA BAXTER S.A., LESSINES, BELGIUM GENETIC INSTITUTE INC, ANDOVER, MASSACHUSETTS, USA
Packer:	BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Laboratory: FPRC	BAXTER S.A., LESSINES, BELGIUM
FPRR	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:		A39/34/0647
Name of medicine:		PROGRAF 0,5 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: TACROLIMUS 0,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ASTELLAS PHARMA (PTY) LTD
Manufacturer:		FUJISAWA IRELAND LTD, KILLORGLIN, Co. KERRY, IRELAND
Packer:		FUJISAWA IRELAND LTD, KILLORGLIN, Co. KERRY, IRELAND ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	FUJISAWA IRELAND LTD, KILLORGLIN, Co. KERRY, IRELAND
	FPRR:	ASTELLAS PHARMA, BEDFORDVIEW, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/5.10/0323
Name of medicine		SABAX ONDANSETRON 2 mg/ml
Dosage form.		INJECTION
Active ingredients:		EACH 2,0 ml SOLUTION CONTAINS: ONDANSETRON 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ADCOCK INGRAM LIMITED
Manufacturer:		PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE
Packer:		PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE SYNTHON HISPANIA, BARCELONA, SPAIN NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE SYNTHON HISPANIA, BARCELONA, SPAIN SYNTHON BV, NIJMEGEN, THE NETHERLANDS NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA PHARMA-Q, INDUSTRIA, JOHANNESBURG ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
	FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/5.10/0324
Name of medicine:		COVAN ONDANSETRON 2 mg/ml
Dosage form:		INJECTION
Active ingredients:		EACH 2,0 ml SOLUTION CONTAINS: ONDANSETRON 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ADCOCK INGRAM LIMITED
Manufacturer:		PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE
Packer:		PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE SYNTHON HISPANIA, BARCELONA, SPAIN NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE SYNTHON HISPANIA, BARCELONA, SPAIN SYNTHON BV, NIJMEGEN, THE NETHERLANDS NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA PHARMA-Q, INDUSTRIA, JOHANNESBURG ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
	FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/5.10/0325
Name of medicine:		PROPAN ONDANSETRON 2 mg/ml
Dosage form:		INJECTION
Active ingredients:		EACH 2,0 ml SOLUTION CONTAINS: ONDANSETRON 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ADCOCK INGRAM LIMITED
Manufacturer:		PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE
Packer:		PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE SYNTHON HISPANIA, BARCELONA, SPAIN NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA FAMAR S.A., P. FALIRO, GREECE SYNTHON HISPANIA, BARCELONA, SPAIN SYNTHON BV, NIJMEGEN, THE NETHERLANDS NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA PHARMA-Q, INDUSTRIA, JOHANNESBURG ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
	FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/2.6.5/0527
Name of medicine:		RESKIT 0,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 0,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (S.A.) (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 CENTRE FOR QUALITY ASSURANCE, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/2.6.5/0528
Name of medicine:		RESKIT 1
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (S.A.) (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 CENTRE FOR QUALITY ASSURANCE, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/2.6.5/0529
Name of medicine:		RESKIT 2
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		RANBAXY (S.A.) (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 CENTRE FOR QUALITY ASSURANCE, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/26/0609
Name of medicine:		PCH-PACLITAXEL 30
Dosage form:		SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: PACLITAXEL 6,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACHEMIE (PTY) LTD
Manufacturer:		PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS
Packer:		PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	PHARMACHEMIE, RUIMSIG, ROODEPOORT
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/26/0610
Name of medicine:		PCH-PACLITAXEL 100
Dosage form.		SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: PACLITAXEL 6,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACHEMIE (PTY) LTD
Manufacturer:		PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS
Packer:		PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	PHARMACHEMIE, RUIMSIG, ROODEPOORT
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/26/0611
Name of medicine:		PCH-PACLITAXEL 300
Dosage form:		SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: PACLITAXEL 6,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACHEMIE (PTY) LTD
Manufacturer:		PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS
Packer:		PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	PHARMACHEMIE, RUIMSIG, ROODEPOORT
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/2.6.5/0674
Name of medicine:		SANDOZ RISPERIDONE 1
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ SA (PTY) LTD
Manufacturer:		NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA
Packer:		NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA NOVARTIS SA, SPARTAN, KEMPTON PARK
	FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/2.6.5/0675
Name of medicine:		SANDOZ RISPERIDONE 2
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: RISPERIDONE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ SA (PTY) LTD
Manufacturer:		NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA
Packer:		NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory:	FPRC:	NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA NOVARTIS SA, SPARTAN, KEMPTON PARK
	FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:	A40/2.6.5/0676
Name of medicine:	SANDOZ RISPERIDONE 3
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA
Packer:	NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	A40/2.6.5/0677
Name of medicine:	SANDOZ RISPERIDONE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA
Packer:	NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS (BANGLADESH) LTD, TONGI, GAZIPUR, BANGLADESH, INDIA NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:		A40/2.5/0768
Name of medicine:		ZYDUS LAMOTRIGINE 50 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE S.A., VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/2.5/0769
Name of medicine:		ZYDUS LAMOTRIGINE 100 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE S.A., VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		A40/2.5/0770
Name of medicine:		ZYDUS LAMOTRIGINE 200 mg TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE S.A., VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/0041
Name of medicine:		ZYDUS-LISINOPRIL/HYDROCHLOROTHIAZIDE 20/12,5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:		ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/5.7.1/0119
Name of medicine:		LORMEG 10
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LORATADINE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		GULF DRUG COMPANY (PTY) LTD
Manufacturer:		ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:		ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory:	FPRC:	ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES ATLASVILLE, BOKSBURG PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG CONSULTING MICROBIOLOGICAL LABORATORY, MOREWILL, BEYERSPARK
	FPRR:	GULF DRUG COMPANY, MOUNT EDGECOMBE, KZN
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/26/0160
Name of medicine:		CIPLA-CISPLATIN 10
Dosage form:		INJECTION
Active ingredients:		EACH 20,0 ml VIAL CONTAINS: CISPLATIN 10,0 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:		14 AUGUST 2009

MRF 15

Registration number:		41/26/0161
Name of medicine:		CIPLA-CISPLATIN 50
Dosage form:		INJECTION
Active ingredients:		EACH 50,0 ml VIAL CONTAINS: CISPLATIN 50,0 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:		14 AUGUST 2009

MRF 15

Registration number:		41/21.5.1/0243
Name of medicine:		REDIPRED
Dosage form:		LIQUID
Active ingredients:		EACH 5,0 ml LIQUID CONTAINS: PREDNISOLONE SODIUM PHOSPHATE EQUIVALENT TO PREDNISOLONE 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND GLAXOSMITHKLINE, EPPING, CAPE TOWN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:		SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND GLAXOSMITHKLINE, EPPING, CAPE TOWN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:	SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND GLAXOSMITHKLINE, EPPING, CAPE TOWN M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/0499
Name of medicine:		AUSTOZAAR-25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/0500
Name of medicine:		AUSTOZAAR-50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/0501
Name of medicine:		AUSTOZAAR-100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/0502
Name of medicine:		LORTELL-25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/0503
Name of medicine:		LORTELL-50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/0517
Name of medicine:		LORTELL-100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.5/0644
Name of medicine:		CIALIS 5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TADALAFIL 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ELI LILLY (S.A.) (PTY) LTD
Manufacturer:		ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK LILLY DEL CARIBE INC, CAROLINA, PUERTO RICO
Packer:		ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK BRECON PHARMACEUTICALS LTD, HAY-ON-WYE, HEREFORD, UK CARDINAL HEALTH UK, CORBY, NORTH HAMPTONSHIRE, UK LILLY S.A., ALCOBENDAS, MADRID, SPAIN
Laboratory:	FPRC:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK LILLY S.A., ALCOBENDAS, MADRID, SPAIN
	FPRR:	ELI LILLY (S.A.), BRYANSTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.5/0645
Name of medicine:		CIALIS 2,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: TADALAFIL 2,5mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ELI LILLY (S.A.) (PTY) LTD
Manufacturer:		ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK LILLY DEL CARIBE INC, CAROLINA, PUERTO RICO
Packer:		ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK BRECON PHARMACEUTICALS LTD, HAY-ON-WYE, HEREFORD, UK CARDINAL HEALTH UK, CORBY, NORTH HAMPTONSHIRE, UK LILLY S.A., ALCOBENDAS, MADRID, SPAIN
Laboratory:	FPRC:	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK LILLY S.A., ALCOBENDAS, MADRID, SPAIN
	FPRR:	ELI LILLY (S.A.), BRYANSTON, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1/0659
Name of medicine:		AMTAS 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
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, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1/0660
Name of medicine:		AMTAS 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
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
	FPRC/FPRR:	ACCORD HEALTHCARE, RIVONIA, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/20.2.8/0808
Name of medicine:		AURO-STAVUDINE CAPSULES 15 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: STAVUDINE 15,0 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 DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/20.2.8/0809
Name of medicine:		AURO-STAVUDINE CAPSULES 20 mg
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: STAVUDINE 20,0 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 DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/30.2/0883
Name of medicine:		ERBITUX 5 mg/ml
Dosage form:		INFUSION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: CETUXIMAB 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		MERCK (PTY) LTD
Manufacturer:		BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY
Packer:		MERCK KgaA, DARMSTADT, GERMANY
Laboratory:	FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH, BIBERACH AN DER RISS, GERMANY MERCK KgaA, DARMSTADT, GERMANY
	FPRR:	MERCK, MODDERFONTEIN, RSA
Shelf-life:		24 months (provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/26/1002
Name of medicine:		ACCORD VINCRISTINE 1 mg/ml INJECTION
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: VINCRISTINE SULPHATE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
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, JOHANNESBURG
Shelf-life:		24 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/20.1.1/1018
Name of medicine:		AUSTELL LEVOFLOXACIN 250 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/20.1.1/1019
Name of medicine:		AUSTELL LEVOFLOXACIN 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUSTELL LABORATORIES (PTY) LTD
Manufacturer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:		IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/1074
Name of medicine:		SPEC LOSARTAN 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:		SPECPHARM (PTY) LTD
Manufacturer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
	FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/1075
Name of medicine:		SPEC LOSARTAN 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:		SPECPHARM (PTY) LTD
Manufacturer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
	FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/1076
Name of medicine:		SPEC LOSARTAN 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:		SPECPHARM (PTY) LTD
Manufacturer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
	FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/7.1.3/1077
Name of medicine:		SPEC LOSARTAN 12,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
	FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:	41/26/1095	
Name of medicine:	LOXAT 30	
Dosage form:	INFUSION	
Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL mg	30,0
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	
Applicant:	SANDOZ S.A.(PTY) LTD	
Manufacturer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY	
Packer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY	
Laboratory: FPRC:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY	
FPRC/FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK	
Shelf-life:	24 months (Provisional)	
Date of registration:	14 AUGUST 2009	

MRF 15

Registration number:	41/26/1096	
Name of medicine:	LOXAT 100	
Dosage form:	INFUSION	
Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL	100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	
Applicant:	SANDOZ S.A.(PTY) LTD	
Manufacturer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY	
Packer:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY	
Laboratory: FPRC:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY	
FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK	
Shelf-life:	24 months (Provisional)	
Date of registration:	14 AUGUST 2009	

MRF 15

Registration number:		41/26/1097
Name of medicine:		LOXAT 300
Dosage form:		INFUSION
Active ingredients:		EACH VIAL CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SANDOZ S.A.(PTY) LTD
Manufacturer:		HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
Packer:		HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
Laboratory:	FPRC:	HAUPT PHARMA WOLFRATSHAUSEN GmbH, WOLFRATSHAUSEN, GERMANY
	FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:		24 months (Provisional)
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/2.9/1103
Name of medicine:		OXYNORM 5 mg CAPSULES
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: OXYCODONE HYDROCHLORIDE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MEDWICH PHARMA (PTY) LTD
Manufacturer:		BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:		BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVULLE, BOKSBURG
	FPRR:	MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
Shelf-life:		36 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/2.9/1103
Name of medicine:		OXYNORM 5 mg CAPSULES
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: OXYCODONE HYDROCHLORIDE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MEDWICH PHARMA (PTY) LTD
Manufacturer:		BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:		BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
Shelf-life:		36 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		41/2.9/1104
Name of medicine:		OXYNORM 10 mg CAPSULES
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: OXYCODONE HYDROCHLORIDE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		MEDWICH PHARMA (PTY) LTD
Manufacturer:		BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:		BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRC/FPRR:	MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
Shelf-life:		36 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:	41/2.9/1105
Name of medicine:	OXYNORM 20 mg CAPSULES
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: OXYCODONE HYDROCHLORIDE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory: FPRC:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	MEDWICH PHARMA, LYNNWOOD GLEN, PRETORIA
Shelf-life:	36 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	42/30.1/0118
Name of medicine:	ADACEL QUADRA
Dosage form:	SUSPENSION
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: DIPHTHERIA TOXOID 2,0 Lf PERTUSSIS TOXOID 2,5 ug FILAMENTOUS HAEMAGGLUTININ 5,0 ug FIMBRIAE TYPE 2+3 5,0 ug PERTACTIN 3,0 ug TETANUS TOXOID 5,0 Lf POLIOMYELITIS VIRUS TYPE 1 40 D-antigen units POLIOMYELITIS VIRUS TYPE 2 8 D-antigen units POLIOMYELITIS VIRUS TYPE 3 32 D-antigen units
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA AVENTIS PASTEUR SA, MARCY L'ETOILE, FRANCE AVENTIS PASTEUR SA, VAL DE REUIL, FRANCE
Packer:	AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA AVENTIS PASTEUR SA, MARCY L'ETOILE, FRANCE AVENTIS PASTEUR SA, VAL DE REUIL, FRANCE
Laboratory: FPRC:	AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA AVENTIS PASTEUR SA, MARCY L'ETOILE, FRANCE AVENTIS PASTEUR SA, VAL DE REUIL, FRANCE
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	42/26/0132
Name of medicine:	SANDOZ VINORELBINE 10 mg/1 ml
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer:	SANDOZ S.A., BUENOS AIRES, ARGENTINA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SANDOZ S.A., BUENOS AIRES, ARGENTINA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	42/26/0133
Name of medicine:	SANDOZ VINORELBINE 50 mg/5 ml
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer:	SANDOZ S.A., BUENOS AIRES, ARGENTINA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SANDOZ S.A., BUENOS AIRES, ARGENTINA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	42/26/0134
Name of medicine:	NEUVEL 10 mg/1 ml
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer:	SANDOZ S.A., BUENOS AIRES, ARGENTINA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SANDOZ S.A., BUENOS AIRES, ARGENTINA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	42/26/0135
Name of medicine:	SANDOZ VINORELBINE 50 mg/5 ml
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer:	SANDOZ S.A., BUENOS AIRES, ARGENTINA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG SANDOZ SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SANDOZ S.A., BUENOS AIRES, ARGENTINA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	42/5.7.1/0143
Name of medicine:	ASPEN CETIRIZINE 1 mg/ml
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, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL 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:	14 AUGUST 2009

MRF 15

Registration number:	42/20.2.2/0446
Name of medicine:	GLENMARK TERBINAFINE 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GLENMARK PHARMACEUTICALS SOUTH AFRICA (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:	GLENMARK PHARMACEUTICALS, VORNA VALLEY, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	42/20.1.1/0592
Name of medicine:	MOXIBAY IV
Dosage form:	INFUSION
Active ingredients:	EACH 250,0 ml SOLUTION CONTAINS: MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY
Packer:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY BAYER, WILLOWTON, PIETERMARITZBURG
Laboratory: FPRC:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	BAYER, ISANDO, KEMPTON PARK
Shelf-life:	60 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:	42/20.1.1/0593
Name of medicine:	MOXIBAY TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY
Packer:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY BAYER, WILLOWTON, PIETERMARITZBURG
Laboratory: FPRC:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	BAYER, ISANDO, KEMPTON PARK
Shelf-life:	60 months
Date of registration:	14 AUGUST 2009

MRF 15

Registration number:		42/20.1.1/0594
Name of medicine:		BAYQUIN TABLETS
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BAYER (PTY) LTD
Manufacturer:		BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY
Packer:		BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY BAYER, WILLOWTON, PIETERMARITZBURG
Laboratory:	FPRC:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	BAYER, ISANDO, KEMPTON PARK
Shelf-life:		60 months
Date of registration:		14 AUGUST 2009

MRF 15

Registration number:		42/20.1.1/0595
Name of medicine:		BAYQUIN IV
Dosage form:		INFUSION
Active ingredients:		EACH 250,0 ml SOLUTION CONTAINS: MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 400,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BAYER (PTY) LTD
Manufacturer:		BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY
Packer:		BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY BAYER, WILLOWTON, PIETERMARITZBURG
Laboratory:	FPRC:	BAYER HEALTHCARE AG, LEVERKUSEN, GERMANY RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	BAYER, ISANDO, KEMPTON PARK
Shelf-life:		60 months
Date of registration:		14 AUGUST 2009