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CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 848 OF 2010

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 848 VAN 2010

MEDISYNEBEHEERRAAD

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

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

MRF 15

Registration number:	36/2.7/0223
Name of medicine:	GRAND-PA PARACETAMOL TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 500,0 mg SODIUM BICARBONATE 630,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	GROUP LABORATORIES SA (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE, DUNGARVAN, IRELAND GLAXOSMITHKLINE, EPPING, CAPE TOWN
Packer:	GLAXOSMITHKLINE, DUNGARVAN, IRELAND GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXOSMITHKLINE, DUNGARVAN, IRELAND GLAXOSMITHKLINE, EPPING, CAPE TOWN
FPRR:	GROUP LABORATORIES, EPPING, CAPE TOWN
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF15

Registration number:		A40/16.4/0358
Name of medicine:		STREPSILS STRAWBERRY SUGAR-FREE
Dosage form:		LOZENGES
Active ingredients:		EACH LOZENGE CONTAINS: AMYLMETACRESOL 0,6 mg DICHLOROBENZYL ALCOHOL 1,2 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 8
Applicant:		RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD
Manufacturer:		BOOTS MANUFACTURING, NOTTINGHAM, UK
Packer:		BOOTS MANUFACTURING, NOTTINGHAM, UK NATUR PRODUKT PHARMA LTD, OSTROW, MAZOWIECKA, POLAND PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK
Laboratory:	FPRC:	BOOTS MANUFACTURING, NOTTINGHAM, UK NATUR PRODUKT PHARMA LTD, OSTROW, MAZOWIECKA, POLAND PHARMACEUTICAL CONTRACTORS, ISANDO, KEMPTON PARK PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
	FPRR:	RECKITT BENCKISER PHARMACEUTICALS, ELANDSFONTEIN
Shelf-life:		24 months (Provisional)
Date of registration:		23 JULY 2010

MRF 15

Registration number:	41/20.2.8/0747
Name of medicine:	PREZISTA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DARUNAVIR ETHANOLATE EQUIVALENT TO DARUNAVIR 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO
Packer:	JANSSEN-CILAG SpA, SAN MICHELE, LATINA, ITALY PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	JANSSEN-CILAG SpA, SAN MICHELE, LATINA, ITALY
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	41/26/0933
Name of medicine:	GEMTAZ 1 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: GEMCITABINE HYDROCHLORIDE EQUIVALENT TO GEMCITABINE 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICALS INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF15

Registration number:	41/26/0934
Name of medicine:	GEMTAZ 200 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: GEMCITABINE HYDROCHLORIDE EQUIVALENT TO GEMCITABINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICALS INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/20.2.8/0202
Name of medicine:	NYSIVIR ORAL SOLUTION 2 g
Dosage form:	SOLUTION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: DIDANOSINE 2,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/20.2.8/0203
Name of medicine:	NYSIVIR ORAL SOLUTION 4 g
Dosage form:	SOLUTION
Active ingredients:	EACH 100,0 ml CONTAINS: DIDANOSINE 4,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF15

Registration number:		42/21.5.4/0218
Name of medicine:		SEREFLO 25/50 HFA
Dosage form:		INHALER
Active ingredients:		EACH ACTUATION DELIVERS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 µg FLUTICASONE PROPIONATE 50,0 µg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSEN PARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		23 JULY 2010

MRF 15

Registration number:	42/21.5.4/0219
Name of medicine:	SEREFLO 25/125 HFA
Dosage form:	INHALER
Active ingredients:	EACH ACTUATION DELIVERS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 µg FLUTICASONE PROPIONATE 125,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
FPRR	CIPLA MEDPRO, ROSEN PARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/21.5.4/0220
Name of medicine:	SEREFLO 25/250 HFA
Dosage form:	INHALER
Active ingredients:	EACH ACTUATION DELIVERS: SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 25,0 µg FLUTICASONE PROPIONATE 250,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO(PTY) LTD
Manufacturer:	CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
Laboratory:FPRC:	CIPLA LTD, UNIT II, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	12 months
Date of registration:	23 JULY 2010

MRF15

Registration number:	42/1.2/0423
Name of medicine:	EFEGEN XR 75
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR	RANBAXY (SA), CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/1.2/0424
Name of medicine:	EFEGEN XR 150
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR	RANBAXY (SA), CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/1.2/0425
Name of medicine:	RAN VENLAFAXINE XR 75
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAZINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF15

Registration number:	42/1.2/0426
Name of medicine:	RAN VENLAFAXINE XR 150 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAZINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 150,0 mg
Conditions of registration:	1,2,3,4,5,6,7,8
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/3.1/0467
Name of medicine:	AURO MELOXICAM 7,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:: FPRC	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/3.1/0468
Name of medicine:	AURO MELOXICAM 15 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF15

Registration number:	41/3.1/0469
Name of medicine:	FLAMARYX 7,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	41/3.1/0470
Name of medicine:	FLAMARYX 15 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/20.2.8/0936
Name of medicine:	SONKE LAMIVUDINE + ZIDOVUDINE 150/300 AND SONKE EFAVIRENZ 600 CO-PACK
Dosage form:	TABLETS
Active ingredients:	EACH BLISTER CONTAINS: 2 x SONKE LAMIVUDINE + ZIDOVUDINE TABLETS CONTAINING LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg 1 x SONKE EFAVIRENZ 600 TABLET CONTAINING EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF15

Registration number:	42/20.2.8/0973
Name of medicine:	RENZIR 50 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/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:	23 JULY 2010

MRF 15

Registration number:	42/20.2.8/0974
Name of medicine:	RENZIR 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/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:	23 JULY 2010

MRF 15

Registration number:	42/20.2.8/0976
Name of medicine:	REFAVIN 50 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/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:	23 JULY 2010

MRF15

Registration number:	42/20.2.8/0977
Name of medicine:	REFAVIN 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/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:	23 JULY 2010

MRF 15

Registration number:	42/20.2.8/0979
Name of medicine:	ADCO EFAVIRENZ 50 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/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:	23 JULY 2010

MRF 15

Registration number:	42/20.2.8/0980
Name of medicine:	ADCO EFAVIRENZ 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/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:	23 JULY 2010

MRF15

Registration number:		42/21.2/1033
Name of medicine:		GLIMY 1
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:		DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:		24 months (Provisional)
Date of registration:		23 JULY 2010

MRF 15

Registration number:	42/21.2/1034
Name of medicine:	GLIMY 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	42/21.2/1035
Name of medicine:	GLIMY 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:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF15

Registration number:	43/7.1.3/0032
Name of medicine:	MIGROBEN 80 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN IVERS-LEE AG, BURGDORF, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/7.1.3/0033
Name of medicine:	MIGROBEN 160 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN IVERS-LEE AG, BURGDORF, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/7.1.3/0034
Name of medicine:	RINTEZEX 80 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN IVERS-LEE AG, BURGDORF, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	23 JULY 2010

MRF15

Registration number:	43/7.1.3/0035
Name of medicine:	RINTEZEX 160 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS SA, SPARTAN,
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN IVERS-LEE AG, BURGDORF, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/7.1.3/0036
Name of medicine:	ZOMEVEK 80 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS SA, SPARTAN
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARERA DEL VALLES, BARCELONA, SPAIN IVERS-LEE AG, BURGDORF, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	23 JULY 2010

MRF 15	
Registration number:	43/7.1.3/0037
Name of medicine:	ZOMEVEK 160 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMACEUTICA S.A., BARBERA DEL VALLES, BARCELONA, SPAIN IVERS-LEE AG, BURGDORF, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	36 months
Date of registration:	23 JULY 2010

MRF15	
Registration number:	43/7.1.3/0080
Name of medicine:	CO-ZOMEVEK 80/12,5 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF 15	
Registration number:	43/7.1.3/0081
Name of medicine:	CO-ZOMEVEK 160/12,5 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/7.1.3/0082
Name of medicine:	CO-ZOMEVEK 160/25 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF15

Registration number:	43/7.1.3/0083
Name of medicine:	CO-MIGROBEN 80/12,5 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/7.1.3/0084
Name of medicine:	CO-MIGROBEN 160/12,5 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/7.1.3/0085
Name of medicine:	CO-MIGROBEN 160/25 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF15

Registration number:	43/7.1.3/0087
Name of medicine:	RINTEZEX CO 80/12,5 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/7.1.3/0088
Name of medicine:	RINTEZEX CO 160/12,5 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/7.1.3/0089
Name of medicine:	RINTEZEX CO 160/25 TABLET
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY IVERS-LEE AG, BURGDORF, SWITZERLAND LAMP S. PROSPERO SpA, SAN PROSPERO, MODENA, ITALY MIPHARM SpA, MILAN, ITALY NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS FARMA S.p.A., TORRE ANNUNZIATA, ITALY NOVARTIS PHARMA GmbH, WEHR/BADEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF15

Registration number:	43/21.2/0605
Name of medicine:	DRL GLIMEPIRIDE 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/21.2/0606
Name of medicine:	DRL GLIMEPIRIDE 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC::	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	43/21.2/0607
Name of medicine:	DRL 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:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF15

Registration number:	43/20.2.8/0832
Name of medicine:	ASPEN LAMIVUDINE 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA ASPED OSD, GIBAUD ROAD, PORT ELIZABETH
Packer:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA ASPED OSD, GIBAUD ROAD, PORT ELIZABETH
Laboratory: FPRC:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRC/FPRR:	ASPEN OSD, GIBAUD ROAD, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	23 JULY 2010

MRF 15

Registration number:	44/20.2.8/0294
Name of medicine:	ADCO LAMIVUDINE 300 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HETERO DRUGS, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	HETERO DRUGS, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	HETERO DRUGS, JEEDIMETLA, HYDERABAD, INDIA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months
Date of registration:	23 JULY 2010

MRF 15

Registration number:	44/20.2.8/0295
Name of medicine:	RETLAM 300 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HETERO DRUGS, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	HETERO DRUGS, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	HETERO DRUGS, JEEDIMETLA,

MRF15

Registration number:	44/20.2.8/0296
Name of medicine:	LAVOS 300 mg TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HETERO DRUGS, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	HETERO DRUGS, JEEDIMETLA, HYDERABAD, INDIA ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC:	HETERO DRUGS, JEEDIMETLA,

MRF 15

Registration number:	44/30.1/0897
Name of medicine:	AREPANDRIX H1N1
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: SPLIT INFLUENZA VIRUS A/CALIFORNIA/7/2009(H1N1) V-LIKE VIRUS 3,75 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE S.A. (PTY) LTD
Manufacturer:	GLAXOSMITHKLINE BIOLOGICALS NORTH AMERICA, SAINTE-FOY, QUEBEC, CANADA GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING SA, RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING SA, WAVRE, BELGIUM GLAXOSMITHKLINE BIOLOGICALS, SAINT AMAND LES EAUX, FRANCE GLAXOSMITHKLINE BIOLOGICALS NORTH AMERICA, MARIETTA, PA, USA GLAXO WELCOME OPERATIONS UK, BARNARD CASTLE, DURHAM, UK VETTER PHARMA INTERNATIONAL GmbH, MOOSWIESEN, RAVENSBURG, GERMANY DSM, GREENVILLE, NC, USA BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA HOSPIRA INC, MCPHERSON, KANSAS, USA
Packer:	GLAXOSMITHKLINE BIOLOGICALS NORTH AMERICA, SAINTE-FOY, QUEBEC, CANADA GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING SA, RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING SA, WAVRE, BELGIUM GLAXOSMITHKLINE BIOLOGICALS NORTH AMERICA, MARIETTA, PA, USA GLAXO WELCOME OPERATIONS UK, BARNARD CASTLE, DURHAM, UK VETTER PHAMRA INTERNATIONAL GmbH, MOOSWIESEN, RAVENSBURG, GERMANY HOLLISTER-STIER LABORATORIES, SPOKANE, WA, USA DSM, GREENVILLE, NC, USA PIERRE FABRE MEDICAMENT PRODUCTION, CHATEAURENARD, FRANCE PIERRE FABRE MEDICAMENT PRODUCTION, CHEMIN DE MAZEROLLES, IDRON, FRANCE PIERRE FABRE MEDICAMENT PRODUCTION, IDRON FRANCE BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA HOSPIRA INC, MCPHERSON, KANSAS, USA GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory: FPRC:	GLAXOSMITHKLINE BIOLOGICALS NORTH

	HYDERABAD, INDIA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months
Date of registration:	23 JULY 2010

	HYDERABAD, INDIA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months
Date of registration:	23 JULY 2010

	AMERICA, SAINTE-FOY, QUEBEC, CANADA GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING SA, RIXENSART, BELGIUM GLAXOSMITHKLINE BIOLOGICALS MANUFACTURING SA, WAVRE, BELGIUM GLAXOSMITHKLINE BIOLOGICALS, SAINT AMAND LES EAUX, FRANCE GLAXOSMITHKLINE BIOLOGICALS NORTH AMERICA, MARIETTA, PA, USA GLAXO WELCOME OPERATIONS UK, BARNARD CASTLE, DURHAM, UK VETTER PHARMA INTERNATIONAL GmbH, MOOSWIESEN, RAVENSBURG, GERMANY HOLLISTER-STIER LABORATORIES, SPOKANE, WA, USA DSM, GREENVILLE, NC, USA PIERRE FABRE MEDICAMENT PRODUCTION, CHATEAURENARD, FRANCE PIERRE FABRE MEDICAMENT PRODUCTION, CHEMIN DE MAZEROLLES, IDRON, FRANCE PIERRE FABRE MEDICAMENT PRODUCTION, IDRON FRANCE BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA HOSPIRA INC, MCPHERSON, KANSAS, USA
FPRC/FPRR:	GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Shelf-life:	24 months
Date of registration:	23 JULY 2010