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## GENERAL NOTICE ALGEMENE KENNISGEWING

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### NOTICE 963 OF 2013

#### 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.

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 36/7.1.5/0385                      Name of medicine: LILLY TADALAFIL 20 mg                      Dosage form: TABLET                      Active ingredients: EACH TABLET CONTAINS: TADALAFIL 20,0 mg</p>	<p>Registration number: A39/32.11/0158                      Name of medicine: REN-ACID SK-F 209                      Dosage form: DIALYSATE                      Active ingredients: EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 7,718 g SODIUM CHLORIDE 214,8 g ACETIC ACID 4,207 g</p>	<p>Registration number: A39/32.11/0159                      Name of medicine: REN-ACID SK-F 207 LOW Ca**                      Dosage form: DIALYSATE                      Active ingredients: EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 6,431 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g</p>	<p>Registration number: A39/32.11/0159                      Name of medicine: REN-ACID SK-F 207 LOW Ca**                      Dosage form: DIALYSATE                      Active ingredients: EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 6,431 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g</p>
<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7                      Applicant: ELI LILLY (S.A.) (PTY) LTD                      Manufacturer: ELI LILLY &amp; Co, LILLY TECHNOLOGY CENTER, INDIANAPOLIS, INDIANA, USA                      Packer: LILLY SA, ALCOBENDAS, MADRID, SPAIN                      ELI LILLY &amp; Co LTD, BASINGSTOKE, HAMPSHIRE, UK</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7                      Applicant: FRESENIUS KABI SA (PTY) LTD                      Manufacturer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA                      Packer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7                      Applicant: FRESENIUS KABI SA (PTY) LTD                      Manufacturer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA                      Packer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7                      Applicant: FRESENIUS KABI SA (PTY) LTD                      Manufacturer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA                      Packer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p>
<p>Laboratory: FPRC:                      ELI LILLY &amp; Co, LILLY TECHNOLOGY CENTER, INDIANAPOLIS, INDIANA, USA                      ELI LILLY &amp; Co, LILLY CORPORATE CENTER, INDIANAPOLIS, INDIANA, USA                      ELI LILLY &amp; CO LTD, BASINGSTOKE, HAMPSHIRE, UK                      CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA                      SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p>	<p>Laboratory: FPRC:                      FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p>	<p>Laboratory: FPRC:                      FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p>	<p>Laboratory: FPRC:                      FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p>
<p>Shelf-life: 36 months                      Date of registration: 15 AUGUST 2013</p>	<p>Shelf-life: 24 months                      Date of registration: 15 AUGUST 2013</p>	<p>Shelf-life: 24 months                      Date of registration: 15 AUGUST 2013</p>	<p>Shelf-life: 24 months                      Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: A39/32.11/0160</p> <p>Name of medicine: REN-ACID SK-F 203</p> <p>Dosage form: DIALYSATE</p> <p>Active ingredients: EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 9,004 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: FRESENIUS KABI SA (PTY) LTD</p> <p>Manufacturer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>Packer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>Laboratory: FPRC: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>FPRR: FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, RSA</p> <p>FPRR: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: A39/32.11/0404</p> <p>Name of medicine: REN-ACID SK-F 213</p> <p>Dosage form: DIALYSATE</p> <p>Active ingredients: EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 9,004 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g DEXTROSE MONOHYDRATE EQUIVALENT TO DEXTROSE ANHYDROUS 38,5 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: FRESENIUS KABI SA (PTY) LTD</p> <p>Manufacturer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>Packer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>Laboratory: FPRC: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>FPRR: FRESENIUS KABI SOUTH AFRICA (PTY) LTD, INDUSTRIAL PARK, MIDRAND, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: A39/32.11/0405</p> <p>Name of medicine: REN-ACID SK-F 219 LOW Ca**/GLUCOSE</p> <p>Dosage form: DIALYSATE</p> <p>Active ingredients: EACH 1 000,0 ml SOLUTION CONTAINS: MAGNESIUM CHLORIDE 3,558 g POTASSIUM CHLORIDE 5,222 g CALCIUM CHLORIDE 6,431 g SODIUM CHLORIDE 210,7 g ACETIC ACID 6,311 g DEXTROSE MONOHYDRATE EQUIVALENT TO DEXTROSE ANHYDROUS 38,5 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: FRESENIUS KABI SA (PTY) LTD</p> <p>Manufacturer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>Packer: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>Laboratory: FPRC: FRESENIUS KABI MANUFACTURING (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>FPRR: FRESENIUS KABI SOUTH AFRICA (PTY) LTD, INDUSTRIAL PARK, MIDRAND, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 41/11.4.3/0099</p> <p>Name of medicine: PEPTAZOL 40</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMACO DISTRIBUTION (PTY) LTD</p> <p>Manufacturer: QUIMICA MONTEPELLIER S.A., BUENOS AIRES, ARGENTINA</p> <p>Packer: QUIMICA MONTEPELLIER S.A., BUENOS AIRES, ARGENTINA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: QUIMICA MONTEPELLIER S.A., BUENOS AIRES, ARGENTINA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>FPRR: PHARMACO DISTRIBUTION (PTY) LTD, SANDTON, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/7.1.3/0115</p> <p>Name of medicine: COIRBESARTAN WINTHROP 300/25 (TABLET)</p> <p>Dosage form: TABLET</p> <p>Active ingredients: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 25,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE</p> <p>Packer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE &amp; WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA</p> <p>Laboratory: FPRC: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE &amp; WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Shelf-life: 24 Months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/7.1.3/0116</p> <p>Name of medicine: SARBEN HCTZ 300/25 (TABLET)</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 25,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE</p> <p>Packer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE &amp; WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA</p> <p>Laboratory: FPRC: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE &amp; WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Shelf-life: 24 Months</p> <p>Date of registration: 15 AUGUST 2013</p>

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<p>Registration number: 42/7.1.3/0117</p> <p>Name of medicine: COAPROVEL 300/25 (TABLET)</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: IRBESARTAN 300.0 mg, HYDROCHLOROTHIAZIDE 25.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE</p> <p>Packer: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE &amp; WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA</p> <p>Laboratory: FPRC: SANOFI WINTHROP INDUSTRIE, CARBON BLANC CEDEX, FRANCE SANOFI-SYNTHELABO LIMITED, NEWCASTLE-UPON-TYNE, TYNE &amp; WEAR, UK CHINOIN Co. LTD, VERESEGYHAZ, HUNGARY WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRC: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Shelf-life: 24 Months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/3.2/0222</p> <p>Name of medicine: ARROW ALENDRONATE 70</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ALENDRONATE SODIUM TRIHYDRATE EQUIVALENT TO ALENDRONIC ACID 70.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SA (PTY) LTD</p> <p>Manufacturer: ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA ARROW LABORATORIES LTD, CROYDEN SOUTH, VICTORIA, AUSTRALIA</p> <p>Packer: ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA ARROW LABORATORIES LTD, CROYDEN SOUTH, VICTORIA, AUSTRALIA DIVPHARM MANUFACTURING &amp; PACKAGING, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA</p> <p>Laboratory: FPRC: ARROW PHARMA (MALTA) LTD, BIRZEBBUGIA, MALTA ARROW LABORATORIES LTD, CROYDEN SOUTH, VICTORIA, AUSTRALIA SELAMINE LTD t/a ARROW GENERICS LTD, CLONSHAUGH, DUBLIN, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA</p> <p>FPRC: ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/34/0377</p> <p>Name of medicine: IMMUNOLATE 250 CAPSULE</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ZYDUS HEALTHCARE SA (PTY) LTD</p> <p>Manufacturer: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA</p> <p>Packer: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA</p> <p>Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRC: ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>

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<p>Registration number: 42/5.10/0577</p> <p>Name of medicine: VOMIZ D 4 mg</p> <p>Dosage form: DISPERSIBLE TABLET</p> <p>Active ingredients: EACH DISPERSIBLE TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 4,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ZYDUS HEALTHCARE SA (PTY) LTD</p> <p>Manufacturer: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA</p> <p>Packer: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA</p> <p>Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA</p> <p>FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRR: ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/5.10/0578</p> <p>Name of medicine: VOMIZ D 8 mg</p> <p>Dosage form: DISPERSIBLE TABLET</p> <p>Active ingredients: EACH DISPERSIBLE TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 8,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ZYDUS HEALTHCARE SA (PTY) LTD</p> <p>Manufacturer: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA</p> <p>Packer: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA</p> <p>Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA</p> <p>FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRR: ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/1.2/0850</p> <p>Name of medicine: AURO CITALOPRAM 10 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AUROBINDO PHARMA (PTY) LTD</p> <p>Manufacturer: AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 42/1.2/0851</p> <p>Name of medicine: AURO CITALOPRAM 40 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 40,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AUROBINDO PHARMA (PTY) LTD</p> <p>Manufacturer: AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/20.1.1/0999</p> <p>Name of medicine: DEPUY CMW 2 GENTAMICIN BONE CEMENT</p> <p>Dosage form: POWDER/LIQUID MIX</p> <p>Active ingredients: EACH 40 g UNIT CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 1,0 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ORTHOMEDICS PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: DEPUY INTERNATIONAL LTD, BLACKPOOL, LANCASHIRE, UK</p> <p>Packer: DEPUY INTERNATIONAL LTD, BLACKPOOL, LANCASHIRE, UK</p> <p>Laboratory: FPRC: DEPUY INTERNATIONAL LTD, BLACKPOOL, LANCASHIRE, UK, JOHNSON &amp; JOHNSON MEDICAL LTD, SKIPTON, NORTH YORKSHIRE, UK, ISOTRON Plc, EUROWAY TRADING ESTATE, BRADFORD, UK, STERIGENICS UK LTD, SOMERCOTES, DERBYSHIRE, UK</p> <p>FPRR: ORTHOMEDICS PHARMACEUTICALS (PTY) LTD, SYBRAND PARK, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/2.5/1017</p> <p>Name of medicine: TORCETAM 250</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 250,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: TRINITY PHARMA (PTY) LTD</p> <p>Manufacturer: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA</p> <p>Packer: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA</p> <p>Laboratory: FPRC: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA, INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA, RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRR: TRINITY PHARMA (PTY) LTD, CNR SLOANE &amp; MEADOWBROOK CLOSE, BRYANSTON, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 42/2.5/1018</p> <p>Name of medicine: TORCETAM 500</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: TRINITY PHARMA (PTY) LTD</p> <p>Manufacturer: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA</p> <p>Packer: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA</p> <p>Laboratory: FPRC: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRC: TRINITY PHARMA (PTY) LTD, CNR SLOANE &amp; MEADOWBROOK CLOSE, BRYANSTON, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 42/2.5/1019</p> <p>Name of medicine: TORCETAM 750</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: TRINITY PHARMA (PTY) LTD</p> <p>Manufacturer: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA</p> <p>Packer: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA</p> <p>Laboratory: FPRC: TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRC: TRINITY PHARMA (PTY) LTD, CNR SLOANE &amp; MEADOWBROOK CLOSE, BRYANSTON, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/11.4.3/0090</p> <p>Name of medicine: PEPTAZOL 20</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMACO DISTRIBUTION (PTY) LTD</p> <p>Manufacturer: QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA</p> <p>Packer: QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA PHARMA-Q, INDUSTIRA WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: QUIMICA MONTPELLIER S.A., BUENOS AIRES, ARGENTINA PHARMA-Q, INDUSTIRA WEST, JOHANNESBURG, RSA</p> <p>FPRC: PHARMACO DISTRIBUTION (PTY) LTD, SANDTON, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>



MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	43/26/0237	43/26/0239	43/26/0244
Name of medicine:	PACLITAXEL FRESENIUS 6 mg/ml (30 mg/5 ml)	PACLITAXEL FRESENIUS 6 mg/ml (300 mg/50 ml)	PACLITAXEL FRESENIUS 6 mg/ml (100 mg/16,7 ml)
Dosage form:	CONCENTRATE FOR SOLUTION	CONCENTRATE FOR SOLUTION FOR INFUSION	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 5,0 ml CONTAINS: PACLITAXEL 30,0 mg	EACH 50,0 ml CONTAINS: PACLITAXEL 300,0 mg	EACH 16,7 ml CONTAINS: PACLITAXEL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Applicant:	FRESENIUS KABI SA (PTY) LTD	FRESENIUS KABI SA (PTY) LTD	FRESENIUS KABI SA (PTY) LTD
Manufacturer:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Packer:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Laboratory: FPRC:	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA	LABORATORIOS FILAXIS S.A., MARTINEZ, BUENOS AIRES, ARGENTINA
Shelf-life:	24 months stored at or below 25 °C 28 days in-use stored at 2-8 °C for undiluted but opened product	24 months stored at or below 25 °C 28 days in-use stored at 2-8 °C for undiluted but opened product	24 months stored at or below 25 °C 28 days in-use stored at 2-8 °C for undiluted but opened product
Date of registration:	15 AUGUST 2013	15 AUGUST 2013	15 AUGUST 2013

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 43/32.16/0352</p>	<p>Registration number: 43/5.7.1/0358</p>	<p>Registration number: 43/5.7.1/0359</p>	
<p>Name of medicine: PROMUS ELEMENT MONORAIL EVEROLIMUS ELUTING CORONARY STENT SYSTEM</p>	<p>Name of medicine: DEZZO CETIRIZINE 10 mg</p>	<p>Name of medicine: ZINALLERG</p>	
<p>Dosage form: STENT</p>	<p>Dosage form: TABLET</p>	<p>Dosage form: TABLET</p>	
<p>Active ingredients: EACH STENT CONTAINS: EVEROLIMUS 100,0 µg per cm<sup>2</sup></p>	<p>Active ingredients: EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg</p>	<p>Active ingredients: EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg</p>	
<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p>	
<p>Applicant: BOSTON SCIENTIFIC SOUTH AFRICA (PTY) LTD</p>	<p>Applicant: DEZZO TRADING 392 (PTY) LTD</p>	<p>Applicant: DEZZO TRADING 392 (PTY) LTD</p>	
<p>Manufacturer: BOSTON SCIENTIFIC IRELAND LTD, GALWAY, IRELAND BOSTON SCIENTIFIC SCIMED, INC., MAPLE GROVE, MINNESOTA, USA ISOTRON IRELAND LTD, TULLAMORE, OFFALY, IRELAND BOSTON SCIENTIFIC CORPORATION COVENTRY, COVENTRY, USA</p>	<p>Manufacturer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p>	<p>Manufacturer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p>	
<p>Packer: BOSTON SCIENTIFIC IRELAND LTD, GALWAY, IRELAND BOSTON SCIENTIFIC SCIMED, INC., MAPLE GROVE, MINNESOTA, USA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA</p>	<p>Packer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p>	<p>Packer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p>	
<p>Laboratory: FPRC BOSTON SCIENTIFIC SOUTH AFRICA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA</p>	<p>Laboratory: FPRC: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p>	<p>Laboratory: FPRC: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p>	
<p>FPRR: BOSTON SCIENTIFIC SOUTH AFRICA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA</p>	<p>FPRR: DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA</p>	<p>FPRR: DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA</p>	
<p>Shelf-life: 24 months</p>	<p>Shelf-life: 24 months</p>	<p>Shelf-life: 24 months</p>	
<p>Date of registration: 15 AUGUST 2013</p>	<p>Date of registration: 15 AUGUST 2013</p>	<p>Date of registration: 15 AUGUST 2013</p>	

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 43/20 1.1/0389</p> <p>Name of medicine: PIPERACILLIN AND TAZOBACTAM 4,0/0,5 g ADCO</p> <p>Dosage form: LYOPHILIZED POWDER FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: PIPERACILLIN 4,0 g PIPERACILLIN SODIUM EQUIVALENT TO TAZOBACTAM 0,5 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA</p> <p>Packer: ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA</p> <p>Laboratory: FPRC: ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA</p> <p>FPRC: ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIAL WEST, JOHANNESBURG, RSA</p> <p>FPRC: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA</p> <p>FPRC: ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/20 1.1/0553</p> <p>Name of medicine: FRESENIUS CEFTAZIDIME 500 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFTAZIDIME 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: FRESENIUS KABI SA (PTY) LTD</p> <p>Manufacturer: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL</p> <p>Packer: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL</p> <p>Laboratory: FPRC: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>FPRC: FRESENIUS KABI SA (PTY) LTD, INDUSTRIAL PARK, MIDRAND, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/20 1.1/0554</p> <p>Name of medicine: FRESENIUS CEFTAZIDIME 1 000 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFTAZIDIME 1 000,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: FRESENIUS KABI SA (PTY) LTD</p> <p>Manufacturer: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL</p> <p>Packer: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL</p> <p>Laboratory: FPRC: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>FPRC: FRESENIUS KABI SA (PTY) LTD, INDUSTRIAL PARK, MIDRAND, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/20 1.1/0553</p> <p>Name of medicine: FRESENIUS CEFTAZIDIME 500 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFTAZIDIME 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: FRESENIUS KABI SA (PTY) LTD</p> <p>Manufacturer: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL</p> <p>Packer: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL</p> <p>Laboratory: FPRC: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>FPRC: FRESENIUS KABI SA (PTY) LTD, INDUSTRIAL PARK, MIDRAND, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	Registration number: 43/20.1.1/0555	Registration number: 43/2.5/0597	Registration number: 43/2.5/0598
Name of medicine: FRESENIUS CEFTAZIDIME 2 000 mg	Name of medicine: EPILEPTIN 600	Name of medicine: EPILEPTIN 800	Name of medicine: EPILEPTIN 800
Dosage form: POWDER FOR SOLUTION FOR INJECTION	Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH VIAL CONTAINS: CEFTAZIDIME 2 000,0 mg	Active ingredients: EACH TABLET CONTAINS: GABAPENTIN 600,0 mg	Active ingredients: EACH TABLET CONTAINS: GABAPENTIN 800,0 mg	Active ingredients: EACH TABLET CONTAINS: GABAPENTIN 800,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: FRESENIUS KABI SA (PTY) LTD	Applicant: PHARMAPLAN (PTY) LTD	Applicant: PHARMAPLAN (PTY) LTD	Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL	Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Packer: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL	Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC: LABESFAL LABORATORIOS ALMIRO SA LAGEDO, SANTIAGO DE BESTEIROS, PORTUGAL	Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA
FPRR: SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	FPRR: CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	FPRR: CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	FPRR: CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR: FRESENIUS KABI SA (PTY) LTD, INDUSTRIA PARK, MIDRAND, RSA	FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, RSA	FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, RSA	FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months	Shelf-life: 24 months	Shelf-life: 24 months
Date of registration: 15 AUGUST 2013	Date of registration: 15 AUGUST 2013	Date of registration: 15 AUGUST 2013	Date of registration: 15 AUGUST 2013

MRF 15	MRF 15	MRF 15
<p>Registration number: 43/26/0793</p> <p>Name of medicine: DOCEFREZ 20</p> <p>Dosage form: POWDER FOR SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: DOCETAXEL ANHYDROUS 20,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMAPLAN (PTY) LTD</p> <p>Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA</p> <p>Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA</p> <p>Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/26/0794</p> <p>Name of medicine: DOCEFREZ 80</p> <p>Dosage form: POWDER FOR SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: DOCETAXEL ANHYDROUS 80,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMAPLAN (PTY) LTD</p> <p>Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA</p> <p>Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA</p> <p>Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/26/0795</p> <p>Name of medicine: DOCEFREZ DILUENT</p> <p>Dosage form: SOLVENT FOR SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: ETHANOL IN POLYSORBATE 80 26,76 % <i>m/m</i></p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMAPLAN (PTY) LTD</p> <p>Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA</p> <p>Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA</p> <p>Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>

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<p>Registration number: 43/30.1/0808</p> <p>Name of medicine: SIMPONI</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 0,5 ml SOLUTION CONTAINS: GOLIMUMAB 50,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: JANSSEN PHARMACEUTICA (PTY) LTD</p> <p>Manufacturer: BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA</p> <p>Packer: BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA CILAG AG, SCHAFFHAUSEN, SWITZERLAND</p> <p>Laboratory: FPRC: BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA CENTOCOR B.V., LEIDEN, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA CILAG AG, SCHAFFHAUSEN, SWITZERLAND</p> <p>FPRR: JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/2.6.5/0870</p> <p>Name of medicine: ZYPOGEN 2.5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 2,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (S.A.) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULILEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/2.6.5/0871</p> <p>Name of medicine: ZYPOGEN 5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (S.A.) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULILEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 43/2.6.5/0872</p> <p>Name of medicine: ZYPOGEN 10</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (S.A.) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/2.6.5/0873</p> <p>Name of medicine: RAN OLANZAPINE 2,5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 2,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (S.A.) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/2.6.5/0874</p> <p>Name of medicine: RAN OLANZAPINE 5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (S.A.) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 43/2.6.5/0875</p> <p>Name of medicine: RAN OLANZAPINE 10</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (S.A.) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 43/2.6.5/1016</p> <p>Name of medicine: CLOMENT ORAL SUSPENSION 50 mg/ml</p> <p>Dosage form: SUSPENSION</p> <p>Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS: CLOZAPINE 50,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMAPLAN (PTY) LTD</p> <p>Manufacturer: DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND</p> <p>Packer: DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND</p> <p>Laboratory: FPRC: DOUGLAS MANUFACTURING LTD, LINCOLN, AUCKLAND, NEW ZEALAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 19 APRIL 2013</p>	<p>Registration number: 44/2.6.5/0003</p> <p>Name of medicine: PERIDA 0,5 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 0,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>



MRF 15	MRF 15	MRF 15
<p>Registration number: 44/2.6.5/0004</p> <p>Name of medicine: PERIDA 1 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 1,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Laboratory: FPRC: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRC: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/2.6.5/0005</p> <p>Name of medicine: PERIDA 2 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 2,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Laboratory: FPRC: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRC/FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/2.6.5/0006</p> <p>Name of medicine: PERIDA 3 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 3,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Laboratory: FPRC: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 44/2.6.5/0007</p> <p>Name of medicine: PERIDA 4 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 4,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/2.6.5/0008</p> <p>Name of medicine: PERIDA 6 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RISPERIDONE 6,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA</p> <p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/5.2/0047</p> <p>Name of medicine: ALFUZOSIN SANOFI-AVENTIS 10 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ALFUZOSIN HYDROCHLORIDE 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: SANOFI WINTHROP INDUSTRIE, GUSTAV EIFFEL, TOURS, FRANCE</p> <p>Packer: SANOFI WINTHROP INDUSTRIE, GUSTAV EIFFEL, TOURS, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Laboratory: FPRC: SANOFI WINTHROP INDUSTRIE, GUSTAV EIFFEL, TOURS, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>

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<p>Registration number: 447.1.3/0443</p> <p>Name of medicine: ASPEN IRBESARTAN 150 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: IRBESARTAN 150,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMACARE LIMITED</p> <p>Manufacturer: ACTAVIS HF, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA</p> <p>Packer: ACTAVIS HF, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA</p> <p>Laboratory: FPRC: ACTAVIS HF, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA, RSA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRC: PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 447.1.3/0444</p> <p>Name of medicine: ASPEN IRBESARTAN 300 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: IRBESARTAN 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMACARE LIMITED</p> <p>Manufacturer: ACTAVIS HF, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA</p> <p>Packer: ACTAVIS HF, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA</p> <p>Laboratory: FPRC: ACTAVIS HF, HAFNAFJORDUR, ICELAND PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA, RSA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRC: PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, SANDTON, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/32.11/0489</p> <p>Name of medicine: ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 192A</p> <p>Dosage form: SOLUTION</p> <p>Active ingredients: EACH 1 000,0 ml OF SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE DIHYDRATE 7,72 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g ACETIC ACID, GLACIAL 6,31 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: B BRAUN MEDICAL (PTY) LTD</p> <p>Manufacturer: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIAL WEST, JOHANNESBURG, RSA</p> <p>Packer: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIAL WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIAL WEST, JOHANNESBURG, RSA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRC: B BRAUN MEDICAL (PTY) LTD, NORTHRIDING, RANDBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/32.11/0489</p> <p>Name of medicine: ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 192A</p> <p>Dosage form: SOLUTION</p> <p>Active ingredients: EACH 1 000,0 ml OF SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE DIHYDRATE 7,72 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g ACETIC ACID, GLACIAL 6,31 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: B BRAUN MEDICAL (PTY) LTD</p> <p>Manufacturer: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIAL WEST, JOHANNESBURG, RSA</p> <p>Packer: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIAL WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIAL WEST, JOHANNESBURG, RSA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRC: B BRAUN MEDICAL (PTY) LTD, NORTHRIDING, RANDBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>

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<p>Registration number: 44/32.11/0490</p> <p>Name of medicine: ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 196A</p> <p>Dosage form: SOLUTION</p> <p>Active ingredients: EACH 1 000,0 ml OF SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE DIHYDRATE 6,43 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g ACETIC ACID, GLACIAL 6,31 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: B BRAUN MEDICAL (PTY) LTD</p> <p>Manufacturer: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>Packer: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: B BRAUN MEDICAL (PTY) LTD, NORTHRIDING, RANDBURG, RSA</p> <p>FPRR:</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/32.11/0491</p> <p>Name of medicine: ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 380A</p> <p>Dosage form: SOLUTION</p> <p>Active ingredients: EACH 1 000,0 ml OF SOLUTION CONTAINS: SODIUM CHLORIDE 210,68 g POTASSIUM CHLORIDE 5,22 g CALCIUM CHLORIDE DIHYDRATE 7,72 g MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g ACETIC ACID, GLACIAL 6,31 g GLUCOSE MONOHYDRATE 30,50 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: B BRAUN MEDICAL (PTY) LTD</p> <p>Manufacturer: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>Packer: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: B BRAUN AVITUM AG, GLANDORF, GERMANY PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: B BRAUN MEDICAL (PTY) LTD, NORTHRIDING, RANDBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/7.1.3/0508</p> <p>Name of medicine: ADCOTAN 40</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 40,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Packer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Laboratory: FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF15	MMRF 15
<p>Registration number: 44/7.1.3/0509</p> <p>Name of medicine: ADCOTAN 80</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 80,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Packer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Laboratory: FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>FPRC: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/7.1.3/0510</p> <p>Name of medicine: ADCOTAN 160</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 160,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Packer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Laboratory: FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>FPRC: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/7.1.3/0514</p> <p>Name of medicine: PROPAN VALSARTAN 40</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 40,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Packer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Laboratory: FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>FPRC: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF-15	MRF-15	MRF-15
<p><b>Registration number:</b> 44/7.1.3/0515</p> <p><b>Name of medicine:</b> PROPAN VALSARTAN 80</p> <p><b>Dosage form:</b> TABLET</p> <p><b>Active ingredients:</b> EACH TABLET CONTAINS: VALSARTAN 80,0 mg</p> <p><b>Conditions of registration:</b> 1, 2, 3, 4, 5, 6, 7</p> <p><b>Applicant:</b> ADCOCK INGRAM LIMITED</p> <p><b>Manufacturer:</b> LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p><b>Packer:</b> LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p><b>Laboratory:</b> FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p><b>FPRR:</b> ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p><b>Shelf-life:</b> 24 months</p> <p><b>Date of registration:</b> 15 AUGUST 2013</p>	<p><b>Registration number:</b> 44/7.1.3/0516</p> <p><b>Name of medicine:</b> PROPAN VALSARTAN 160</p> <p><b>Dosage form:</b> TABLET</p> <p><b>Active ingredients:</b> EACH TABLET CONTAINS: VALSARTAN 160,0 mg</p> <p><b>Conditions of registration:</b> 1, 2, 3, 4, 5, 6, 7</p> <p><b>Applicant:</b> ADCOCK INGRAM LIMITED</p> <p><b>Manufacturer:</b> LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p><b>Packer:</b> LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p><b>Laboratory:</b> FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p><b>FPRR:</b> ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p><b>Shelf-life:</b> 24 months</p> <p><b>Date of registration:</b> 15 AUGUST 2013</p>	<p><b>Registration number:</b> 44/7.1.3/0517</p> <p><b>Name of medicine:</b> COVAN VALSARTAN 40</p> <p><b>Dosage form:</b> TABLET</p> <p><b>Active ingredients:</b> EACH TABLET CONTAINS: VALSARTAN 40,0 mg</p> <p><b>Conditions of registration:</b> 1, 2, 3, 4, 5, 6, 7</p> <p><b>Applicant:</b> ADCOCK INGRAM LIMITED</p> <p><b>Manufacturer:</b> LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p><b>Packer:</b> LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p><b>Laboratory:</b> FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p><b>FPRR:</b> ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p><b>Shelf-life:</b> 24 months</p> <p><b>Date of registration:</b> 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 44/7.1.3/0518</p> <p>Name of medicine: COVAN VALSARTAN 80</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 80,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Packer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Laboratory: FPRC: LABORATORIOS LICONSA, AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/7.1.3/0519</p> <p>Name of medicine: COVAN VALSARTAN 160</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 160,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Packer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Laboratory: FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/7.1.3/0520</p> <p>Name of medicine: ADCO VALSARTAN 40</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 40,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Packer: LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN</p> <p>Laboratory: FPRC: LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED – RESEARCH &amp; DEVELOPMENT, AEROTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF15	MRF 15
Registration number:	Registration number:	Registration number:
Name of medicine:	Name of medicine:	Name of medicine:
Dosage form:	Dosage form:	Dosage form:
Active ingredients:	Active ingredients:	Active ingredients:
Conditions of registration:	Conditions of registration:	Conditions of registration:
Applicant:	Applicant:	Applicant:
Manufacturer:	Manufacturer:	Manufacturer:
Packer:	Packer:	Packer:
Laboratory:	Laboratory:	Laboratory:
FPRR:	FPRR:	FPRR:
Shelf-life:	Shelf-life:	Shelf-life:
Date of registration:	Date of registration:	Date of registration:
44/7.1.3/0523	44/7.1.3/0522	44/7.1.3/0521
RESTAN VALSARTAN 40	ADCO VALSARTAN 160	ADCO VALSARTAN 80
TABLET	TABLET	TABLET
EACH TABLET CONTAINS: VALSARTAN 40,0 mg	EACH TABLET CONTAINS: VALSARTAN 160,0 mg	EACH TABLET CONTAINS: VALSARTAN 80,0 mg
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED
LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN
LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN	LABORATORIOS LICONSA, S.A., AZUQUECA DE HENARES (GUADALAJARA), SPAIN
ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD.	ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD.	ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD.
WADEVILLE, GERMISTON, RSA	WADEVILLE, GERMISTON, RSA	WADEVILLE, GERMISTON, RSA
ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD.	ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD.	ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD.
ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
24 months	24 months	24 months
15 AUGUST 2013	15 AUGUST 2013	15 AUGUST 2013



MRF 15		MRF 15		MRF 15	
Registration number:	44/7.1.3/0524	Registration number:	44/7.1.3/0525	Registration number:	44/7.1.3/0609
Name of medicine:	RESTAN VALSARTAN 80	Name of medicine:	RESTAN VALSARTAN 160	Name of medicine:	LEPITRIN CO 100/25
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg	Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN	Manufacturer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN	Manufacturer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND
Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN	Packer:	LABORATORIOS CINFA, S.A., HUARTE (PAMPLONA), SPAIN	Packer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC:
	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA		ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA		ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
	ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA		ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA		ADCOCK INGRAM HEALTHCARE (WADEVILLE) (PTY) LTD, WADEVILLE, GERMISTON, RSA
	ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA		ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA		ADCOCK INGRAM LIMITED – RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (Provisional) manufactured with hydrochlorothiazide sourced from Cambrex and losartan potassium sourced from Dr Reddy's
Date of registration:	15 AUGUST 2013	Date of registration:	15 AUGUST 2013	Date of registration:	15 AUGUST 2013

MRF 15	MRF 15	MRF 15
<p>Registration number: 44/2.9/0931</p> <p>Name of medicine: ULTRACET</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 37,5 mg PARACETAMOL 325,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: JANSSEN PHARMACEUTICA (PTY) LTD</p> <p>Manufacturer: JANSSEN-CILAG SpA, BORGO S MICHELE, LATINA, ITALY</p> <p>Packer: JANSSEN-CILAG SpA, BORGO S MICHELE, LATINA, ITALY</p> <p>Laboratory: FPRC: JANSSEN-CILAG SpA, BORGO S MICHELE, LATINA, ITALY SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/20.2.8/0941</p> <p>Name of medicine: SEBIVO ORAL SOLUTION</p> <p>Dosage form: SOLUTION</p> <p>Active ingredients: EACH 1,0 ml OF SOLUTION CONTAINS: TELBIVUDINE 20,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: NOVARTIS PHARMA SAS, HUNINGUE, FRANCE</p> <p>Packer: NOVARTIS PHARMA SAS, HUNINGUE, FRANCE DIVPHARM MANUFACTURING &amp; PACKAGING (PTY) LTD LONGDALE, JOHANNESBURG, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Laboratory: FPRC: NOVARTIS PHARMA SAS, HUNINGUE, FRANCE SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA PHARMANALYTICA S.A., LOCARNO, SWITZERLAND M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 36 months manufactured by Novartis, France, stored at or below 30 °C</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/5.3/0944</p> <p>Name of medicine: ZEPANALZ 5 mg TABLETS</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AUROBINDO PHARMA (PTY) LTD</p> <p>Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 44/5.3/0945</p> <p>Name of medicine: ZEPANALZ 10 mg TABLETS</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AUROBINDO PHARMA (PTY) LTD</p> <p>Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULLEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/7.1.3/1010</p> <p>Name of medicine: BILOCOR CO 2,5/6,25</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: BISOPROLOL FUMARATE 2,5 mg HYDROCHLOROTHIAZIDE 6,25 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA</p> <p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA</p> <p>Laboratory: FPRC: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA</p> <p>Shelf-life: 24 months manufactured by Lupin, Aurangabad, India with Bisoprolol fumarate sourced from Uricem and Hydrochlorothiazide sourced from IPCA</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/7.1.3/1011</p> <p>Name of medicine: BILOCOR CO 5/6,25</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: BISOPROLOL FUMARATE 5,0 mg HYDROCHLOROTHIAZIDE 6,25 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA</p> <p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA</p> <p>Laboratory: FPRC: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA</p> <p>Shelf-life: 24 months manufactured by Lupin, Aurangabad, India with Bisoprolol fumarate sourced from Uricem and Hydrochlorothiazide sourced from IPCA</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 44/34/1046 Name of medicine: WATER FOR INJECTION FOR SANDOZ TEICOPLANIN 200</p>	<p>Registration number: 44/20.1.1/1045 Name of medicine: SANDOZ TEICOPLANIN 200</p>	<p>Registration number: 44/7.1.3/1012 Name of medicine: BILOCOR CO 10/6,25</p>	<p>Registration number: 44/34/1046 Name of medicine: WATER FOR INJECTION FOR SANDOZ TEICOPLANIN 200</p>
<p>Dosage form: SOLVENT FOR SOLUTION FOR INJECTION</p>	<p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p>	<p>Dosage form: TABLET</p>	<p>Dosage form: SOLVENT FOR SOLUTION FOR INJECTION</p>
<p>Active ingredients: EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml</p>	<p>Active ingredients: EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg</p>	<p>Active ingredients: EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg HYDROCHLOROTHIAZIDE 6,25 mg</p>	<p>Active ingredients: EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml</p>
<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p>
<p>Applicant: SANDOZ SA (PTY) LTD</p>	<p>Applicant: SANDOZ SA (PTY) LTD</p>	<p>Applicant: PHARMA DYNAMICS (PTY) LTD</p>	<p>Applicant: SANDOZ SA (PTY) LTD</p>
<p>Manufacturer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p>	<p>Manufacturer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p>	<p>Manufacturer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA</p>	<p>Manufacturer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p>
<p>Packer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p>	<p>Packer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p>	<p>Packer: LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA LUPIN LIMITED, CHIKAL THANA, AURANGABAD, MAHARASHTRA, INDIA</p>	<p>Packer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p>
<p>Laboratory: FPRC</p>	<p>Laboratory: FPRC</p>	<p>Laboratory: FPRC</p>	<p>Laboratory: FPRC</p>
<p>Laboratory: FPRC LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p>	<p>Laboratory: FPRC LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p>	<p>Laboratory: FPRC PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA</p>	<p>Laboratory: FPRC LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p>
<p>FPRC</p>	<p>FPRC</p>	<p>FPRC</p>	<p>FPRC</p>
<p>Shelf-life: 24 months (Provisional) manufactured by Lek, Slovenia.</p>	<p>Shelf-life: 24 months manufactured by Lek, Slovenia with Teicoplanin sourced from Dong Kook</p>	<p>Shelf-life: 24 months manufactured by Lupin, Aurangabad, India with Bisoprolol fumarate sourced from Unidern and Hydrochlorothiazide sourced from IFCA</p>	<p>Shelf-life: 24 months (Provisional) manufactured by Lek, Slovenia.</p>
<p>Date of registration: 15 AUGUST 2013</p>	<p>Date of registration: 15 AUGUST 2013</p>	<p>Date of registration: 15 AUGUST 2013</p>	<p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 44/20.1.1/1082</p> <p>Name of medicine: PLANITEC 200</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p> <p>Packer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p> <p>Laboratory: FPRC: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p> <p>FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months manufactured by Lek, Slovenia.</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 44/34/1083</p> <p>Name of medicine: PLANITEC WATER FOR INJECTION</p> <p>Dosage form: SOLVENT FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,0 ml</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p> <p>Packer: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p> <p>Laboratory: FPRC: LEK PHARMACEUTICALS, d.d., LJUBLJANA, SLOVENIA</p> <p>FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (Provisional) manufactured by Lek, Slovenia.</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/21.2/0173</p> <p>Name of medicine: DIAGLUMED 80</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: GLICLAZIDE 80,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD</p> <p>Manufacturer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p> <p>Packer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p> <p>Laboratory: FPRC: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p> <p>FPRC: DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF-15	MRF-15
<p>Registration number: 45/21.2/0174</p> <p>Name of medicine: GLICLAZIDE DEZZO 80</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: GLICLAZIDE 80,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD</p> <p>Manufacturer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p> <p>Packer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA</p> <p>Laboratory: FPRC: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/21.12/0180</p> <p>Name of medicine: FEMONC 2,5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LETROZOLE 2,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (S.A.) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Packer: RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Laboratory: FPRC: RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA</p> <p>FPRR: RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/21.12/0181</p> <p>Name of medicine: FEMOLET 2,5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LETROZOLE 2,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (S.A.) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Packer: RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA</p> <p>Laboratory: FPRC: RANBAXY LABORATORIES LIMITED, PAONTA SAHIB, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA</p> <p>FPRR: RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/7.1.3/0301</p> <p>Name of medicine: MYLACAND 8 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 8,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: MYLAN (PTY) LTD</p> <p>Manufacturer: MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>Packer: MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>Laboratory: FPRC: MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN</p> <p>ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA</p> <p>PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: MYLAN (PTY) LTD, MODDERFONTEIN, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/7.1.3/0302</p> <p>Name of medicine: MYLACAND 16 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: MYLAN (PTY) LTD</p> <p>Manufacturer: MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>Packer: MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN</p> <p>MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>Laboratory: FPRC: MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN</p> <p>ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA</p> <p>PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: MYLAN (PTY) LTD, MODDERFONTEIN, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/11/0463</p> <p>Name of medicine: MEZAVANT</p> <p>Dosage form: PROLONGED RELEASE TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: MESALAZINE 1 200,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: COSMO SpA, COLOMBO, LAINATE-MILAN, ITALY</p> <p>Packer: COSMO SpA, COLOMBO, LAINATE-MILAN, ITALY</p> <p>Laboratory: FPRC: COSMO SpA, COLOMBO, LAINATE-MILAN, ITALY</p> <p>ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA</p> <p>ADCOCK INGRAM LTD – RESEARCH &amp; DEVELOPMENT, AEROTON, RSA</p> <p>FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA</p> <p>ADCOCK INGRAM LTD – RESEARCH &amp; DEVELOPMENT, AEROTON RSA</p> <p>ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/7.5/0502</p> <p>Name of medicine: STORWIN 10 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: WINTHROP PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>Packer: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>Laboratory: FPRC: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>FPRC: WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Shelf-life: 24 months manufactured with Rosuvastatin sourced from MSN.</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/7.5/0503</p> <p>Name of medicine: STORWIN 20 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: WINTHROP PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>Packer: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>Laboratory: FPRC: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>FPRC: WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Shelf-life: 24 months manufactured with Rosuvastatin sourced from MSN.</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/7.5/0504</p> <p>Name of medicine: STORWIN 40 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: WINTHROP PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>Packer: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>Laboratory: FPRC: ZENTIVA K.S., DOLNI MECHOLOPY, PRAHA, CZECH REPUBLIC</p> <p>FPRC: WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Shelf-life: 24 months manufactured with Rosuvastatin sourced from MSN.</p> <p>Date of registration: 15 AUGUST 2013</p>



MRF 15	MRF 15	MRF 15
<p>Registration number: 45/21.2/0557</p> <p>Name of medicine: TRAJENTA</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LINAGLIPTIN 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: INGELHEIM PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, OAK STREET, COLUMBUS, OHIO, USA</p> <p>Packer: BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, OAK STREET, COLUMBUS, OHIO, USA SIXARP, LLC-PRAXIS PACKAGING SOLUTIONS, CATERPILLAR DRIVE, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC-PRAXIS PACKAGING SOLUTIONS, WILSON ROAD, COLUMBUS, OHIO, USA</p> <p>Laboratory: FPRC: BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>FPRR: INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDSBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/20.2.9/0586</p> <p>Name of medicine: VOLIRET 500 mg TABLETS</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO VALACICLOVIR 500,0,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AUROBINDO PHARMA (PTY) LTD</p> <p>Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/20.2.9/0587</p> <p>Name of medicine: VOLIRET 1 g TABLETS</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO VALACICLOVIR 1,0 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AUROBINDO PHARMA (PTY) LTD</p> <p>Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/20.2.8/0590</p> <p>Name of medicine: SHILOVA 500 mg TABLETS</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO VALACICLOVIR 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AUROBINDO PHARMA (PTY) LTD</p> <p>Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/20.2.8/0591</p> <p>Name of medicine: SHILOVA 1 g TABLETS</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO VALACICLOVIR 1,0 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AUROBINDO PHARMA (PTY) LTD</p> <p>Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/15.4/0710</p> <p>Name of medicine: SAFLUTAN</p> <p>Dosage form: OPHTHALMIC SOLUTION</p> <p>Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: TAFLUPROST 15,0 µg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MSD (PTY) LTD</p> <p>Manufacturer: SANTEN OY, TAMPERE, FINLAND LABORATOIRE UNITHER, COUTANCES CEDEX, FRANCE</p> <p>Packer: SANTEN OY, TAMPERE, FINLAND LABORATOIRE UNITHER, COUTANCES CEDEX, FRANCE MERCK SHARP &amp; DOHME BV, HAARLEM, THE NETHERLANDS</p> <p>Laboratory: FPRC: SANTEN OY, TAMPERE, FINLAND LABORATOIRE UNITHER, COUTANCES CEDEX, FRANCE MERCK SHARP &amp; DOHME BV, HAARLEM, THE NETHERLANDS MERCK SHARP &amp; DOHME LTD, CRAWLINGTON NORTHUMBERLAND, UK MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/20.2.8/0723</p> <p>Name of medicine: ACTIPREZ 1 000</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALACYCLOVIR HYDROCHLORIDE EQUIVALENT TO VALACYCLOVIR 1 000,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ARROW PHARMA SA (PTY) LTD</p> <p>Manufacturer: ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA</p> <p>Packer: ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING &amp; PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA</p> <p>Laboratory: FPRC: ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 45/20.2.8/0924</p> <p>Name of medicine: RINAVO</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RITONAVIR 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: MYLAN (PTY) LTD</p> <p>Manufacturer: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>Packer: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA</p> <p>Laboratory: FPRC: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: MYLAN (PTY) LTD, MODDERFONTEIN, RSA</p> <p>Shelf-life: 24 months (Provisional)</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 46/20.2.6/0025</p> <p>Name of medicine: FALCIRONE</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ATOVAQUONE 250,0 mg PROGUANIL HYDROCHLORIDE 100,0mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: CIPLA LIFE SCIENCES (PTY) LTD</p> <p>Manufacturer: CIPLA LTD, UNIT 1, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA</p> <p>Packer: CIPLA LTD, UNIT 1, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA</p> <p>Laboratory: FPRC: CIPLA LTD, UNIT 1, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA</p> <p>FPRR: CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 46/20.2.6/0027</p> <p>Name of medicine: NUMAL</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ATOVAQUONE 250,0 mg PROGUANIL HYDROCHLORIDE 100,0mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: CIPLA LIFE SCIENCES (PTY) LTD</p> <p>Manufacturer: CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA</p> <p>Packer: CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA</p> <p>Laboratory: FPRC: CIPLA LTD, UNIT I, PATALGANGA, DIST. RAIGAD, MAHARASHTRA, INDIA</p> <p>FPRR: CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 47/20.2.8/0118</p> <p>Name of medicine: EFTENEM</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg EMTRICITABINE 200,0 mg TENOFIVIR DISOPROXIL FUMARATE 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SPECPHARM (PTY) LTD</p> <p>Manufacturer: HETERO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA</p> <p>Packer: HETERO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA SPECPHARM HOLDING (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: HETERO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA SPECPHARM HOLDING (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months (Provisional) manufactured by Hetero Laboratories Ltd, India.</p> <p>Date of registration: 15 AUGUST 2013</p>	<p>Registration number: 47/20.2.8/0304</p> <p>Name of medicine: EMTEWIN TABLET</p> <p>Dosage form: EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENOFIVIR DISOPROXIL FUMARATE 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: WINTHROP PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: HETERO DRUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Packer: HETERO DRUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>Laboratory: FPRC: HETERO DRUGS LTD, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA</p> <p>FPRR: WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 15 AUGUST 2013</p>