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**AIDS HELPLINE: 0800-0123-22 Prevention is the cure**



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## GOVERNMENT NOTICES • GOEWERMENSKENNISGEWINGS

## DEPARTMENT OF HEALTH

NO. 916

12 AUGUST 2016

## 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 (101/1965)

MRF1 M

MRF 15	MRF 15	MRF 15
<p>Registration number: 09/1,3/18</p> <p>Name of medicine: DOLOREX</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: BUTORPHANOL TATRATE EQUIVALENT TO BUTORPHANOL 10.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: INTERVET SA (PTY) LTD</p> <p>Manufacturer: INTERVET INTERNATIONAL GmbH, UNTERSCHLEISSHEIM, GERMANY INTERVET INTERNATIONAL B.V., BOXMEER, THE NETHERLANDS</p> <p>Packer: INTERVET INTERNATIONAL GmbH, UNTERSCHLEISSHEIM, GERMANY INTERVET INTERNATIONAL B.V., BOXMEER, THE NETHERLANDS</p> <p>Laboratory: FPRR: INTERVET INTERNATIONAL GmbH, UNTERSCHLEISSHEIM, GERMANY INTERVET INTERNATIONAL B.V., BOXMEER, THE NETHERLANDS BIOINDUSTRIAL SERVICES CC, KEMPTON PARK, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 11/12,2/11</p> <p>Name of medicine: LEVENTA 1mg/ml ORAL SOLUTION FOR DOGS</p> <p>Dosage form: ORAL SOLUTION</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: LEVOTHYROXINE SODIUM 1.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: INTERVET SA (PTY) LTD</p> <p>Manufacturer: INTERVET PRODUCTIONS S.A., IGOVILLE, FRANCE</p> <p>Packer: INTERVET PRODUCTIONS S.A., IGOVILLE, FRANCE</p> <p>Laboratory: FPRR: INTERVET PRODUCTIONS S.A., IGOVILLE, FRANCE BIOINDUSTRIAL SERVICES CC, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 37/1,3/0330</p> <p>Name of medicine: ENALAPRIL 5 BIOTECH</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ENALAPRIL MALEATE 5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BIOTECH LABORATORIES (PTY) LTD</p> <p>Manufacturer: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA</p> <p>Packer: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE INDUSTRIAL JOHANNESBURG, RSA WRAPSA MANUFACTURING AND PACKAGING (PTY) LTD, HENNOESPARK, CENTURION, RSA</p> <p>Laboratory: FPRR: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 3777.1.30331</p> <p>Name of medicine: ENALAPRIL 10 BIOTECH</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ENALAPRIL MALEATE 10.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BIOTECH LABORATORIES (PTY) LTD</p> <p>Manufacturer: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA</p> <p>Packer: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA MANUFACTURING AND PACKAGING (PTY) LTD, HENNOPSPARK, CENTURION, RSA</p> <p>Laboratory: FPRC : LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SLVERTONDALE, PRETORIA, RSA</p> <p>FPRR: BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 3777.1.30332</p> <p>Name of medicine: ENALAPRIL 20 BIOTECH</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ENALAPRIL MALEATE 20.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BIOTECH LABORATORIES (PTY) LTD</p> <p>Manufacturer: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA</p> <p>Packer: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA MANUFACTURING AND PACKAGING (PTY) LTD, HENNOPSPARK, CENTURION, RSA</p> <p>Laboratory: FPRC: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SLVERTONDALE, PRETORIA, RSA</p> <p>FPRR: BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 417.1.30337</p> <p>Name of medicine: OLMETEC PLUS 20/12.5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20.0 mg HYDROCHLOROTHIAZIDE 12.5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Packer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Laboratory: FPRC SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA</p> <p>FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 3777.1.30333</p> <p>Name of medicine: ENALAPRIL 10 BIOTECH</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ENALAPRIL MALEATE 10.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BIOTECH LABORATORIES (PTY) LTD</p> <p>Manufacturer: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA</p> <p>Packer: LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA MANUFACTURING AND PACKAGING (PTY) LTD, HENNOPSPARK, CENTURION, RSA</p> <p>Laboratory: FPRC : LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SLVERTONDALE, PRETORIA, RSA</p> <p>FPRR: BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 417.1.30338</p> <p>Name of medicine: OLMETEC PLUS 20/25</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20,0 mg HYDROCHLOROTHIAZIDE 25,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Packer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Laboratory: FPRC: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA</p> <p>FPRC: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 42/17.1/0180</p> <p>Name of medicine: SPEC ATRACURIUM 25</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH AMPOULE CONTAINS: ATRACURIUM BESYLATE 25,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SPECPHARM (PTY) LTD</p> <p>Manufacturer: HAMELN PHARMACEUTICALS, GERMANY</p> <p>Packer: HAMELN PHARMACEUTICALS, GERMANY</p> <p>Laboratory: FPRC: HAMELN PHARMACEUTICALS, GERMANY SPECPHARMA HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: SPECPHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 42/17.1/0181</p> <p>Name of medicine: SPEC ATRACURIUM 50</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH AMPOULE CONTAINS: ATRACURIUM BESYLATE 50,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SPECPHARM (PTY) LTD</p> <p>Manufacturer: HAMELN PHARMACEUTICALS, GERMANY</p> <p>Packer: HAMELN PHARMACEUTICALS, GERMANY</p> <p>Laboratory: FPRC: HAMELN PHARMACEUTICALS, GERMANY SPECPHARMA HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: SPECPHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 427.1.3/0789</p> <p>Name of medicine: OMESAR PLUS 20/12.5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Packer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Laboratory: FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 42/26/0745</p> <p>Name of medicine: MERCK EPIRUBICIN 50 mg</p> <p>Dosage form: INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: EPIRUBICIN HYDROCHLORIDE 50.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: XIXIA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM</p> <p>Packer: THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRR: THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 42/26/0744</p> <p>Name of medicine: MERCK EPIRUBICIN 10 mg</p> <p>Dosage form: INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: EPIRUBICIN HYDROCHLORIDE 10.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: XIXIA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM</p> <p>Packer: THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRR: THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 427.1.3/0789</p> <p>Name of medicine: OMESAR PLUS 20/12.5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Packer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Laboratory: FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	MRF15	15
<p>Registration number: 427.1.3/0770</p> <p>Name of medicine: OMESAR PLUS 20/25.0</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20,0 mg HYDROCHLOROTHIAZIDE 25,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Packer: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY</p> <p>Laboratory: FPRC: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA</p> <p>FPRC: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 427.1.1/0859</p> <p>Name of medicine: ACAQUIN 250</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LEVOPLOZACIN 250,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AKACIA HEALTHCARE (PTY) LTD</p> <p>Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE FAMAR SA, ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE</p> <p>Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>FPRC: AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 427.1.1/0860</p> <p>Name of medicine: ACAQUIN 500</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LEVOPLOZACIN 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AKACIA HEALTHCARE (PTY) LTD</p> <p>Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE FAMAR SA, ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE</p> <p>Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE INSTITUTE FOR PHARMACEUTICAL AND CHEMISTRY SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRC: AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>



<p>Registration number: Name of medicine: Dosage form: Active ingredients: Conditions of registration: Applicant: Manufacturer: Packer: Laboratory: FPRC: Shelf-life: Date of registration:</p>	<p>43/2.5/0267 VANAPRO SYRUP SYRUP EACH 5.0 ml SYRUP CONTAINS: SODIUM VALPROATE 200.0 mg 1, 2, 3, 4, 5, 6, 7 ADCOCK INGRAM LIMITED ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA 24 months 18 FEBRUARY 2016</p>
<p>Registration number: Name of medicine: Dosage form: Active ingredients: Conditions of registration: Applicant: Manufacturer: Packer: Laboratory: FPRC: Shelf-life: Date of registration:</p>	<p>43/20.1./1/0640 AURO CEFAZOLIN 250 mg POWDER FOR INJECTION EACH VIAL CONTAINS: CEFAZOLIN SODIUM EQUIVALENT TO CEFAZOLIN 250.0 mg 1, 2, 3, 4, 5, 6, 7, 8 AUROBINDO PHARMA (PTY) LTD AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RS KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA 24 months (provisional) 18 FEBRUARY 2016</p>
<p>Registration number: Name of medicine: Dosage form: Active ingredients: Conditions of registration: Applicant: Manufacturer: Packer: Laboratory: FPRC: Shelf-life: Date of registration:</p>	<p>43/20.1./1/0641 AURO CEFAZOLIN 500 mg POWDER FOR INJECTION EACH VIAL CONTAINS: CEFAZOLIN SODIUM EQUIVALENT TO CEFAZOLIN 500.0 mg 1, 2, 3, 4, 5, 6, 7, 8 AUROBINDO PHARMA (PTY) LTD AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RS KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA 24 months (provisional) 18 FEBRUARY 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 43/20.1.1/0642</p> <p>Name of medicine: AURO CEFAZOLIN 1 g</p> <p>Dosage form: POWDER FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFAZOLIN SODIUM EQUIVALENT TO CEFAZOLIN 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 VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RS KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 43/8/0830</p> <p>Name of medicine: SOLUSPIRIN VC</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ASPIRIN 100 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: RESMED HEALTHCARE</p> <p>Manufacturer: RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA</p> <p>Packer: RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA</p> <p>Laboratory: FPRC: RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA</p> <p>FPRR: RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 44/20.2.8/0009</p> <p>Name of medicine: COMOZEN</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg NEVIRAPINE 200,0 mg ZIDOVUDINE 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: BLISS PHARMACEUTICALS cc</p> <p>Manufacturer: HETERO DRUGS LIMITED, JEEDIMETLA, HYDRABAD, INDIA</p> <p>Packer: HETERO DRUGS LIMITED, JEEDIMETLA, HYDRABAD, INDIA</p> <p>Laboratory: FPRC: HETERO DRUGS LIMITED, JEEDIMETLA, HYDRABAD, INDIA</p> <p>FPRR: BLISS PHARMACEUTICALS cc, ORMONDE, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 44/28/0236</p> <p>Name of medicine: MAGNEGITA 5 ml</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 5.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUIMINE EQUIVALENT TO GADOLINIUM 393.15 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MEDICINES DEVELOPERS INTERNATIONAL cc</p> <p>Manufacturer: JSC FARMMAK, KIEV, UKRAINE</p> <p>Packer: JSC FARMMAK, KIEV, UKRAINE</p> <p>Laboratory: FPRC: JSC FARMMAK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 44/28/0237</p> <p>Name of medicine: MAGNEGITA 10 ml</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 10.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUIMINE EQUIVALENT TO GADOLINIUM 786.30 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MEDICINES DEVELOPERS INTERNATIONAL cc</p> <p>Manufacturer: JSC FARMMAK, KIEV, UKRAINE</p> <p>Packer: JSC FARMMAK, KIEV, UKRAINE</p> <p>Laboratory: FPRC: JSC FARMMAK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 44/28/0238</p> <p>Name of medicine: MAGNEGITA 15 ml</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 15.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUIMINE EQUIVALENT TO GADOLINIUM 1179.45 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MEDICINES DEVELOPERS INTERNATIONAL cc</p> <p>Manufacturer: JSC FARMMAK, KIEV, UKRAINE</p> <p>Packer: JSC FARMMAK, KIEV, UKRAINE</p> <p>Laboratory: FPRC: JSC FARMMAK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	44/28/0239	44/28/0240	44/28/0241
Name of medicine:	MAGNEGITA 20 ml	MAGNEGITA 30 ml	MAGNEGITA 100 ml
Dosage form:	SOLUTION FOR INJECTION	SOLUTION FOR INJECTION	SOLUTION FOR INJECTION
Active ingredients:	EACH 20,0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUMINE EQUIVALENT TO GADOLINIUM 1572,60 mg	EACH 30,0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUMINE EQUIVALENT TO GADOLINIUM 2358,90 mg	EACH 100,0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUMINE EQUIVALENT TO GADOLINIUM 7863,0 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:	MEDICINES DEVELOPERS INTERNATIONAL cc	MEDICINES DEVELOPERS INTERNATIONAL cc	MEDICINES DEVELOPERS INTERNATIONAL cc
Manufacturer:	JSC FARMMAK, KIEV, UKRAINE	JSC FARMMAK, KIEV, UKRAINE	JSC FARMMAK, KIEV, UKRAINE
Packer:	JSC FARMMAK, KIEV, UKRAINE	JSC FARMMAK, KIEV, UKRAINE	JSC FARMMAK, KIEV, UKRAINE
Laboratory:	FPRC: JSC FARMMAK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	FPRC: JSC FARMMAK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	FPRC: JSC FARMMAK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSA	MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSA	MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSA
Shelf-life:	36 months	36 months	36 months
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016	18 FEBRUARY 2016

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 44/5.7.1/0843</p> <p>Name of medicine: GLENCET 5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LEVOCETIRIZINE DIHYDROCHLORIDE 5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: GLENMARK PHARMACEUTICALS SA (PTY) LTD</p> <p>Manufacturer: GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA</p> <p>Packer: GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA</p> <p>Laboratory: FPRC: GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>FPRR: GLENMARK PHARMACEUTICALS SA (PTY) LTD, VORNA VALLEY, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 44/24/0896</p> <p>Name of medicine: HYDRASSIST ORS</p> <p>Dosage form: POWDER</p> <p>Active ingredients: EACH SACHET CONTAINS: GLUCOSE ANHYDROUS 2 700.0 mg TRISODIUM CITRATE DIHYDRATE 580.0 mg SODIUM CHLORIDE 520.0 mg POTASSIUM CHLORIDE 300.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: TRINITY PHARMA (PTY) LTD</p> <p>Manufacturer: PT. NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA</p> <p>Packer: PT. NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA</p> <p>Laboratory: FPRC: PT. NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRR: TRINITY PHARMA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 44/5.3/0833</p> <p>Name of medicine: CURLOVON 5</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</p> <p>Applicant: DR REDDY'S LABORATORIES (PTY) LTD</p> <p>Manufacturer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Packer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS (PTY) LTD, IRENE, CENTURION, RSA TEHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRR: DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 44/5.3/0833</p> <p>Name of medicine: CURLOVON 5</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</p> <p>Applicant: DR REDDY'S LABORATORIES (PTY) LTD</p> <p>Manufacturer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Packer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS (PTY) LTD, IRENE, CENTURION, RSA TEHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRR: DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

<p>Registration number: 44/5.3/0934</p> <p>Name of medicine: CURLOVON 10</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</p> <p>Applicant: DR REDDY'S LABORATORIES (PTY) LTD</p> <p>Manufacturer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Packer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS (PTY) LTD, IRENE, CENTURION, RSA TEHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRC: DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 457/1/0150</p> <p>Name of medicine: URODOXA 1 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 10 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, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 457/1/0151</p> <p>Name of medicine: URODOXA 2 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 2,0 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, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>
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MRF 15

Registration number:	457.1/0152	Registration number:	457.1/0154	Registration number:	457.1/0153
Name of medicine:	URODOXA 4 mg	Name of medicine:	FLOCARD 1 mg	Name of medicine:	URODOXA 8 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 4.0 mg	Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 1.0 mg	Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 8.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	Laboratory:	FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	Laboratory:	FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA
FPRC:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRC:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRC:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/7.1/0155</p> <p>Name of medicine: FLOCARD 2 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 2,0 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, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 45/7.1/0156</p> <p>Name of medicine: FLOCARD 4 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 4,0 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, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC/FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 45/7.1/0157</p> <p>Name of medicine: FLOCARD 8 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 8,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Manufacturer: AUROBINDO PHARMA (PTY) LTD</p> <p>Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>



MRF-15	MRF-15	MRF-15
<p>Registration number: 457/1/0158</p> <p>Name of medicine: DUROCARD 1 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 1,0 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, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRR: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 457/1/0159</p> <p>Name of medicine: DUROCARD 2 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 1,0 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, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRR: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 457/1/0160</p> <p>Name of medicine: DUROCARD 4 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 4,0 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, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRR: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>

Rf-15

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.1/0161	Registration number:	45/6.2/0288	Registration number:	45/7.1.5/0470
Name of medicine:	DUROCARD 8 mg	Name of medicine:	OGRAVIA 75 mg	Name of medicine:	ROVETA 25
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 8.0 mg	Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75.0 mg	Active ingredients:	EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 25.0 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
Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	PHARMACARE LIMITED	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, TALUKA-KADDI, DISTRICT MEHSANA, INDRAD, GUJARAT, INDIA	Manufacturer:	ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA
Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	TORRENT PHARMACEUTICALS LIMITED, TALUKA-KADDI, DISTRICT MEHSANA, INDRAD, GUJARAT, INDIA	Packer:	ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE INDUSTRIA, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA
Laboratory: FPRC:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULILEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LIMITED, TALUKA-KADDI, DISTRICT MEHSANA, INDRAD, GUJARAT, INDIA ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SEDEK AGRIKEM CC, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRC:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRC:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA	FPRC:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF-15	MRF-15	MRF-15
<p>Registration number: 457.1.5/0471</p> <p>Name of medicine: ROVETA 100</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA</p> <p>Packer: ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SEDEK AGRICHEM CC, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 45/5.8/0480</p> <p>Name of medicine: FLUSIN DAY TIME</p> <p>Dosage form: SOFT GEL CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: PARACETAMOL 325.0 mg DEXTROMETHORPHAN HYDROCHLORIDE 10.0 mg PHENYLPHRINE HYDROCHLORIDE 0.5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: PHARMACARE LIMITED</p> <p>Manufacturer: STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALOR, INDIA</p> <p>Packer: STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALOR, INDIA</p> <p>Laboratory: FPRC: STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALOR, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, RORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA ASPEN, PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA</p> <p>FPRR: PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 45/34/0517</p> <p>Name of medicine: TAMAX 0.4</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 0.4 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SUN PHARMACEUTICALS SA (PTY) LTD</p> <p>Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LIMITED, SILVASSA, DADRA &amp; NAGAR HAVELI, INDIA</p> <p>Packer: SUN PHARMACEUTICAL INDUSTRIES LIMITED, SILVASSA, DADRA &amp; NAGAR HAVELI, INDIA</p> <p>Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LIMITED, SILVASSA, DADRA &amp; NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRR: SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>

RF 15

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 4518.210594</p> <p>Name of medicine: MYLAN CLOPIDOGREL 75 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CLOPIDOGREL 75,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</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 (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 4512.910658</p> <p>Name of medicine: MYLAN REMIFENTANIL 1 mg</p> <p>Dosage form: POWDER CONCENTRATE FOR INJECTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE EQUIVALENT TO REMIFENTANIL 1,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MYLAN (PTY) LTD</p> <p>Manufacturer: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Packer: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Shelf-life: 18 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 4512.910659</p> <p>Name of medicine: MYLAN REMIFENTANIL 2 mg</p> <p>Dosage form: POWDER CONCENTRATE FOR SOLUTION FOR INJECTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE EQUIVALENT TO REMIFENTANIL 2,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MYLAN (PTY) LTD</p> <p>Manufacturer: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Packer: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 4512.910658</p> <p>Name of medicine: MYLAN REMIFENTANIL 1 mg</p> <p>Dosage form: POWDER CONCENTRATE FOR INJECTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE EQUIVALENT TO REMIFENTANIL 1,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MYLAN (PTY) LTD</p> <p>Manufacturer: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Packer: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: LABORATORIO REIG-JOFFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Shelf-life: 18 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF-15	<p>Registration number: 45/20.1./0798</p> <p>Name of medicine: CIPROFLOXACIN FRESENIUS 2 mg/ml 100 ml</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH 50.0 ml SOLUTION CONTAINS: CIPROFLOXACIN HYDROGEN SULPHATE EQUIVALENT TO CIPROFLOXACIN 200.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: FRESENIUS KABI (PTY) LTD</p> <p>Manufacturer: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND</p> <p>Packer: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND</p> <p>Laboratory: FPRC: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>Shelf-life: FPRC: FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA 24 months (Poland/kabipack bottles) 36 months (Norway/free flex bags)</p> <p>Date of registration: 18 FEBRUARY 2016</p>
MRF-15	<p>Registration number: 45/20.1./10797</p> <p>Name of medicine: CIPROFLOXACIN FRESENIUS 2 mg/ml 50 ml</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH 50.0 ml SOLUTION CONTAINS: CIPROFLOXACIN HYDROGEN SULPHATE EQUIVALENT TO CIPROFLOXACIN 100.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: FRESENIUS KABI (PTY) LTD</p> <p>Manufacturer: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND</p> <p>Packer: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND</p> <p>Laboratory: FPRC: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>Shelf-life: FPRC: FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA 24 months (Poland/kabipack bottles) 36 months (Norway/free flex bags)</p> <p>Date of registration: 18 FEBRUARY 2016</p>
MRF-15	<p>Registration number: 45/2,9/0660</p> <p>Name of medicine: MYLAN REMIFENTANIL 5 mg</p> <p>Dosage form: POWDER CONCENTRATE FOR SOLUTION FOR INJECTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE EQUIVALENT TO REMIFENTANIL 5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MYLAN (PTY) LTD</p> <p>Manufacturer: LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Packer: LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN MYLAN S.A.S., SAINT-PIERRE, FRANCE ACORN LABORATORIES (PTY) LTD, NORT-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>Shelf-life: FPRC: MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	<p>Registration number: 45/20.1.1/0799</p> <p>Name of medicine: CIPROFLOXACIN FRESENIUS 2 mg/ml 250 ml SOLUTION FOR INFUSION</p> <p>Dosage form: EACH 50.0 ml SOLUTION CONTAINS: CIPROFLOXACIN HYDROGEN SULPHATE EQUIVALENT TO CIPROFLOXACIN 500.0 mg</p> <p>Active ingredients: 1, 2, 3, 4, 5, 6, 7</p> <p>Conditions of registration: FRESENIUS KABI (PTY) LTD</p> <p>Applicant: FRESENIUS KABI NORGE AS, HALDEN, NORWAY</p> <p>Manufacturer: FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND</p> <p>Packer: FRESENIUS KABI NORGE AS, HALDEN, NORWAY</p> <p>Laboratory: FPRC: FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND</p> <p>FPRC: BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN; FORT ELIZABETH, RSA KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>Shelf-life: 24 months (Poland/kabipack bottles) 36 months (Norway/free flex bags)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	MRF 15	<p>Registration number: 457.1.3/0800</p> <p>Name of medicine: RAPHEX 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</p> <p>Applicant: ASTRA ZENECA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>Packer: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>Laboratory: FPRC: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>FPRC: AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTOND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	MRF 15	<p>Registration number: 4577.1.3/0801</p> <p>Name of medicine: RAPHEX 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</p> <p>Applicant: ASTRA ZENECA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>Packer: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>Laboratory: FPRC: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>FPRC: AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTOND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>
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MRF 15	MRF 15	MRF 15
<p>Registration number: 4577.1.3/0802</p> <p>Name of medicine: RAPHEX 32 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 32,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ASTRA-ZENECA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>Packer: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>Laboratory: FPRC: AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTOND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 4577.1.3/0803</p> <p>Name of medicine: RAPHEX PLUS 16/12,5 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg HYDROCHLOROTHIAZIDE 12,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ASTRA-ZENECA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>Packer: ASTRAZENECA AB, SODERTALJE, SWEDEN</p> <p>Laboratory: FPRC: ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTOND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 45/20.2.2/0904</p> <p>Name of medicine: ARICON 50</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: FLUCONAZOLE 50,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE FAWAR SA, ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA</p> <p>Shelf-life: 48 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	<p>Registration number: 45/20.2.2/0905</p> <p>Name of medicine: ARICON 150</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: FLUCONAZOLE 150,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>Packer: PHARMATHEN S.A., ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SEDEK AGRICHEM CC, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 48 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	MRF 15	<p>Registration number: 45/20.2.2/0906</p> <p>Name of medicine: ARICON 200</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: FLUCONAZOLE 200,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE FAMAR SA, ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SEDEK AGRICHEM CC, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 48 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	MRF 15	<p>Registration number: 45/2,9/1111</p> <p>Name of medicine: FERTINAC 2 mg</p> <p>Dosage form: INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE 2,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY SA (PTY) LTD</p> <p>Manufacturer: LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Packer: LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN</p> <p>Laboratory: FPRC: LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN KHULULEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: RANBAXY SA (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>
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MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	45/2.9/1111	45/3.1/1150	45/20.1/1200
Name of medicine:	FERTINAC 2 mg	MOTIFINE	DYNAFLOC IV 100 ml
Dosage form:	INJECTION	CAPSULE	SOLUTION FOR INFUSION
Active ingredients:	EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE 2,0 mg	EACH CAPSULE CONTAINS: DICLOFENAC SODIUM 75,0 mg	EACH 100,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE MONOHYDRATE EQUIVALENT TO CIPROFLOXACIN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY SA (PTY) LTD	BIOTECH LABORATORIES (PTY) LTD	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN	TEMLER IRELAND LTD, KERRY, BANSHAGH, IRELAND	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA
Packer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN	TEMLER WERKE GmbH, MUNCHEN, GERMANY	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA
Laboratory:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN	TEMLER WERKE GmbH, MUNCHEN, GERMANY	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA
FPRR:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN KHULILEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	FPRR: BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA	FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (provisional)	48 months	24 months
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016	18 FEBRUARY 2016

MRF 15	Registration number: 45/20.1.1/1201 DYNAFLOC IV 200 ml SOLUTION FOR INFUSION EACH 100.0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE MONOHYDRATE EQUIVALENT TO CIPROFLOXACIN 400.0 mg 1, 2, 3, 4, 5, 6, 7 PHARMA DYNAMICS (PTY) LTD CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	Registration number: 46/18.1/0015 FUROSIX TABLET EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg 1, 2, 3, 4, 5, 6, 7, 8 PHARMADYNE HEALTHCARE (PTY) LTD INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA/SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Registration number: 46/18.1/0016 RENOSIX 40 TABLET EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg 1, 2, 3, 4, 5, 6, 7, 8 PHARMADYNE HEALTHCARE (PTY) LTD INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA/SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
MRF 15	Registration number: 45/20.1.1/1201 DYNAFLOC IV 200 ml SOLUTION FOR INFUSION EACH 100.0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE MONOHYDRATE EQUIVALENT TO CIPROFLOXACIN 400.0 mg 1, 2, 3, 4, 5, 6, 7 PHARMA DYNAMICS (PTY) LTD CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	Registration number: 46/18.1/0015 FUROSIX TABLET EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg 1, 2, 3, 4, 5, 6, 7, 8 PHARMADYNE HEALTHCARE (PTY) LTD INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA/SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Registration number: 46/18.1/0016 RENOSIX 40 TABLET EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg 1, 2, 3, 4, 5, 6, 7, 8 PHARMADYNE HEALTHCARE (PTY) LTD INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA/SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
MRF 15	Registration number: 45/20.1.1/1201 DYNAFLOC IV 200 ml SOLUTION FOR INFUSION EACH 100.0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE MONOHYDRATE EQUIVALENT TO CIPROFLOXACIN 400.0 mg 1, 2, 3, 4, 5, 6, 7 PHARMA DYNAMICS (PTY) LTD CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	Registration number: 46/18.1/0015 FUROSIX TABLET EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg 1, 2, 3, 4, 5, 6, 7, 8 PHARMADYNE HEALTHCARE (PTY) LTD INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA/SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Registration number: 46/18.1/0016 RENOSIX 40 TABLET EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg 1, 2, 3, 4, 5, 6, 7, 8 PHARMADYNE HEALTHCARE (PTY) LTD INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA/SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA

MRF 15	<p>Registration number: 46/18.1/0017</p> <p>Name of medicine: FRUSEMIDE PHARMADYNE 40</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: PHARMADYNE HEALTHCARE (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 (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: ACTAVIS PHARMA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	MRF15
	<p>Registration number: 46/26/0210</p> <p>Name of medicine: INTAPLAT 50 mg</p> <p>Dosage form: CONCENTRATE FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: OXALIPLATIN 50,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	
	<p>Registration number: 46/26/0211</p> <p>Name of medicine: INTAPLAT 100 mg</p> <p>Dosage form: CONCENTRATE FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: OXALIPLATIN 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	

MRF 15	Registration number: 46/2.5/0338	Registration number: 46/2.5/0339	MRF 15
Name of medicine: LEVETIRACETAM UNICORN 250	Name of medicine: LEVETIRACETAM UNICORN 750	Name of medicine: BISOLPROLOL UNICHEM 5 mg	Name of medicine: BISOLPROLOL UNICHEM 5 mg
Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 250,0 mg	Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg	Active ingredients: EACH TABLET CONTAINS: BISOLPROLOL FUMARATE 5,0 mg	Active ingredients: EACH TABLET CONTAINS: BISOLPROLOL FUMARATE 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	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
Applicant: UNICORN PHARMACEUTICALS (PTY) LTD	Applicant: UNICORN PHARMACEUTICALS (PTY) LTD	Applicant: UNICHEM SA (PTY) LTD	Applicant: UNICHEM SA (PTY) LTD
Manufacturer: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA	Manufacturer: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA	Manufacturer: UNICHEM LABORATORIES LIMITED, BARDEZ, GOA, INDIA	Manufacturer: UNICHEM LABORATORIES LIMITED, BARDEZ, GOA, INDIA
Packer: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA	Packer: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA	Packer: UNICHEM LABORATORIES LIMITED, BARDEZ, GOA, INDIA	Packer: UNICHEM LABORATORIES LIMITED, BARDEZ, GOA, INDIA
Laboratory: FPRR: UNICORN PHARMACEUTICALS (PTY) LTD, WOODSTOCK, CAPE TOWN, RSA	Laboratory: FPRR: UNICORN PHARMACEUTICALS (PTY) LTD, WOODSTOCK, CAPE TOWN, RSA	Laboratory: FPRR: UNICHEM LABORATORIES LIMITED, BARDEZ, GOA, INDIA	Laboratory: FPRR: UNICHEM LABORATORIES LIMITED, BARDEZ, GOA, INDIA
Shelf-life: 24 months (provisional)	Shelf-life: 24 months (provisional)	Shelf-life: 24 months	Shelf-life: 24 months
Date of registration: 18 FEBRUARY 2016	Date of registration: 18 FEBRUARY 2016	Date of registration: 18 FEBRUARY 2016	Date of registration: 18 FEBRUARY 2016

MRF-15	MRF-15	MRF-15
Registration number:	46/5.11/0427	46/5.11/0416
Name of medicine:	MEMINIST 10	MEMANTINE UNICHEM 10
Dosage form:	TABLET	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM SA (PTY) LTD	UNICHEM SA (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA
Laboratory: FPRC:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
Laboratory: FPRR:	UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	36 months	36 months
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016
Registration number:	46/5.2/0391	46/5.2/0391
Name of medicine:	BISOPROLOL UNICHEM 10 mg	BISOPROLOL UNICHEM 10 mg
Dosage form:	TABLET	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM SA (PTY) LTD	UNICHEM SA (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA
Laboratory: FPRC:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
Laboratory: FPRR:	UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months	24 months
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 46/20.1.2/0492</p> <p>Name of medicine: APEX-DESLORATADINE 5 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DESLORATADINE 5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: CAMOX PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE</p> <p>Packer: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE</p> <p>Laboratory: FPRC: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 46/20.1.2/0493</p> <p>Name of medicine: AERZIT 5 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DESLORATADINE 5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: CAMOX PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE</p> <p>Packer: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE</p> <p>Laboratory: FPRC: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 46/15.4/0918</p> <p>Name of medicine: SPERSATAN</p> <p>Dosage form: EYE DROPS</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: LATANOPROST 50.0 µg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ADCOCK INGRAM LIMITED</p> <p>Manufacturer: VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE</p> <p>Packer: VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE</p> <p>Laboratory: FPRC: VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA</p> <p>Shelf-life: 36 months (stored at 2-8°C) 28 days (in-use stored at 25°C)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 46/20.1.2/0492</p> <p>Name of medicine: APEX-DESLORATADINE 5 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DESLORATADINE 5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: CAMOX PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE</p> <p>Packer: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE</p> <p>Laboratory: FPRC: GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF-15	MRF-15	MRF-15	MRF-15
<p>Registration number: 47/21/10165</p> <p>Name of medicine: RYZODEG</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: INSULIN DEGLUDEC 70.0 units INSULIN ASPART 30.0 units</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: NOVO NORDISK (PTY) LTD</p> <p>Manufacturer: NOVO NORDISK A/S, BAGSVAERD, DENMARK</p> <p>Packer: NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, HILLEROD, DENMARK NOVO NORDISK A/S, HILLEROD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK PRODUCTION SAS, CHERTRES, FRANCE</p> <p>Laboratory: FPRC: NOVO NORDISK A/S, HILLEROD, DENMARK</p> <p>FPRC: NOVO NORDISK (PTY) LTD, SANDTON, RSA</p> <p>Shelf-life: 30 months (stored at 2-8°C) 28 days (in-use, stored at or below 30°C)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 47/32/0508</p> <p>Name of medicine: REVLIMID 10 mg</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE ONTAINS: LENALIDOMIDE 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7.</p> <p>Applicant: KEY ONCOLOGICS (PTY) LTD</p> <p>Manufacturer: PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM/ CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND</p> <p>Packer: PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND ACINO PHARM AG, LIESBERG, SWITZERLAND ACINO PHARM AG, AESCH, SWITZERLAND</p> <p>Laboratory: FPRC: PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM/ CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND SOLVIAS AG, KAISERAUGST, SWITZERLAND CELGENE CORPORATION, SUMMIT, NEW JERSEY, USA CELSIS LABORATORIES, EDISON, NEW JERSEY, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRC: KEY ONCOLOGICS (PTY) LTD, HOUGHTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 47/32/0507</p> <p>Name of medicine: REVLIMID 5 mg</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE ONTAINS: LENALIDOMIDE 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7.</p> <p>Applicant: KEY ONCOLOGICS (PTY) LTD</p> <p>Manufacturer: PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM/ CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND</p> <p>Packer: PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND ACINO PHARM AG, LIESBERG, SWITZERLAND ACINO PHARM AG, AESCH, SWITZERLAND</p> <p>Laboratory: FPRC: PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM/ CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND SOLVIAS AG, KAISERAUGST, SWITZERLAND CELGENE CORPORATION, SUMMIT, NEW JERSEY, USA CELSIS LABORATORIES, EDISON, NEW JERSEY, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRC: KEY ONCOLOGICS (PTY) LTD, HOUGHTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 47/21/10165</p> <p>Name of medicine: RYZODEG</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: INSULIN DEGLUDEC 70.0 units INSULIN ASPART 30.0 units</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: NOVO NORDISK (PTY) LTD</p> <p>Manufacturer: NOVO NORDISK A/S, BAGSVAERD, DENMARK</p> <p>Packer: NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, HILLEROD, DENMARK NOVO NORDISK A/S, HILLEROD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK PRODUCTION SAS, CHERTRES, FRANCE</p> <p>Laboratory: FPRC: NOVO NORDISK A/S, HILLEROD, DENMARK</p> <p>FPRC: NOVO NORDISK (PTY) LTD, SANDTON, RSA</p> <p>Shelf-life: 30 months (stored at 2-8°C) 28 days (in-use, stored at or below 30°C)</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 47/15-4/0526</p> <p>Name of medicine: LOXOPTIC</p> <p>Dosage form: OPHTHALMIC SOLUTION</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: BETAXOLOL HYDROCHLORIDE EQUIVALENT TO BETAZOLOL 5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7.</p> <p>Applicant: ACTOR PHARMA (PTY) LTD</p> <p>Manufacturer: FDC LIMITED, WALUJ, AURANGABAD, MAHARASHTRA, INDIA</p> <p>Packer: FDC LIMITED, WALUJ, AURANGABAD, MAHARASHTRA, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: FDC LIMITED, WALUJ, AURANGABAD, MAHARASHTRA, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE INDUSTRIAL, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPRR: ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 47/32/0510</p> <p>Name of medicine: REVLIMID 25 mg</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE OBTAINS: LENALIDOMIDE 25.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7.</p> <p>Applicant: KEY ONCOLOGICS (PTY) LTD</p> <p>Manufacturer: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND</p> <p>Packer: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND ACINO PHARM AG, LIESBERG, SWITZERLAND ACINO PHARM AG, AESCH, SWITZERLAND</p> <p>Laboratory: FPRC: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND SOLVIA AG, KAISERAUGST, SWITZERLAND CELGENE CORPORATION, SUMMIT, NEW JERSEY, USA CELSIS LABORATORIES, EDISON, NEW JERSEY, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: KEY ONCOLOGICS (PTY) LTD, HOUGHTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 47/32/0509</p> <p>Name of medicine: REVLIMID 15 mg</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE OBTAINS: LENALIDOMIDE 15.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7.</p> <p>Applicant: KEY ONCOLOGICS (PTY) LTD</p> <p>Manufacturer: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND</p> <p>Packer: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND ACINO PHARM AG, LIESBERG, SWITZERLAND ACINO PHARM AG, AESCH, SWITZERLAND</p> <p>Laboratory: FPRC: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND SOLVIA AG, KAISERAUGST, SWITZERLAND CELGENE CORPORATION, SUMMIT, NEW JERSEY, USA CELSIS LABORATORIES, EDISON, NEW JERSEY, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: KEY ONCOLOGICS (PTY) LTD, HOUGHTON, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>



MRF-15	<p>Registration number: 47/18.1/0948</p> <p>Name of medicine: LIXETIC 10 mg/ml</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: FRUSEMIDE 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: CLARIS LIFESCIENCES LIMITED, SANAND, AHMEDABAD, INDIA</p> <p>Packer: CLARIS LIFESCIENCES LIMITED, SANAND, AHMEDABAD, INDIA</p> <p>Laboratory: FPRC: CLARIS LIFESCIENCES LIMITED, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	
MRF-15	<p>Registration number: 48/20.2.8/0028</p> <p>Name of medicine: NEVIRAPINE LITHA</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: LITHA PHARMA (PTY) LTD</p> <p>Manufacturer: MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA</p> <p>Packer: MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA</p> <p>Laboratory: FPRC: MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRIKEM CC, SILVERTONDALE, PRETORIA, RSA</p> <p>FPRR: LITHA PHARMA (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	
MRF-15	<p>Registration number: 48/20.2.8/0029</p> <p>Name of medicine: NEPRAZ</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: LITHA PHARMA (PTY) LTD</p> <p>Manufacturer: MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA</p> <p>Packer: MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA</p> <p>Laboratory: FPRC: MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRIKEM CC, SILVERTONDALE, PRETORIA, RSA</p> <p>FPRR: LITHA PHARMA (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	

MRF 15	Registration number: 4877 :10037	Registration number: 4877 :10039
Name of medicine: AMLODIPINE DEZZO 5	Name of medicine: VASCOLOK 5 mg	Name of medicine: VASCOLOK 5 mg
Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg	Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg	Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 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
Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA
Manufacturer: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA
Packer: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	Packer: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	Packer: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA
Shelf-life: 24 months	Shelf-life: 24 months	Shelf-life: 24 months
Date of registration: 18 FEBRUARY 2016	Date of registration: 18 FEBRUARY 2016	Date of registration: 18 FEBRUARY 2016

MRF-15	<p>Registration number: 4877.1/0584</p> <p>Name of medicine: AMLODIPINE HETERO 5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: HETERO DRUGS SA</p> <p>Manufacturer: HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOONAGAR DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Packer: HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOONAGAR DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOONAGAR DISTRICT, ANDHRA PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AGORN PHARMACEUTICAL (PTY) LTD, NORTH-RIDING, RANDBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	MRF-15
MRF-15	<p>Registration number: 48/20.2.8/0403</p> <p>Name of medicine: TIVICAY 50 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOLUTEGRAVIR 50,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: GLAXO OPERATIONS UK LTD T/A GLAXO WELLCOME OPERATIONS, WARE, HERTFORDSHIRE, UNITED KINGDOM</p> <p>Packer: GLAXO OPERATIONS UK LTD T/A GLAXO WELLCOME OPERATIONS, WARE, HERTFORDSHIRE, UNITED KINGDOM</p> <p>Laboratory: FPRC: GLAXO OPERATIONS UK LTD T/A GLAXO WELLCOME OPERATIONS, WARE, HERTFORDSHIRE, UNITED KINGDOM</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	MRF-15
MRF-15	<p>Registration number: 4877.1/0040</p> <p>Name of medicine: VASCOLOK 10 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 18 FEBRUARY 2016</p>	MRF-15

MRF 15	MRF 15	MRF 15
<p>Registration number: 487.1/0585</p> <p>Name of medicine: AMLODIPINE HETERO 10</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: HETERO DRUGS SA</p> <p>Manufacturer: HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Packer: HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR DISTRICT, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR DISTRICT, ANDHRA PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICAL (PTY) LTD, NORTH-RIDING, RANDBURG, RSA</p> <p>FPRC: HETERO DRUGS SA, CENTURION, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 483215/0715</p> <p>Name of medicine: XOFIGO</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: RADIUM Ra 223 DICHLORIDE 1 000.0 KBq</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BAYER (PTY) LTD</p> <p>Manufacturer: INSTITUTE FOR ENERGY TECHNOLOGY, KJELLER, NORWAY</p> <p>Packer: INSTITUTE FOR ENERGY TECHNOLOGY, KJELLER, NORWAY</p> <p>Laboratory: FPRC: INSTITUTE FOR ENERGY TECHNOLOGY, KJELLER, NORWAY ALGETA ASA, OSLO, NORWAY EUROFINS PHARMA A/S, GLOSTRUP, DENMARK PROXY LABORATORIES B.V., LEIDEN, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRC: BAYER (PTY) LTD, ISANDO, JOHANNESBURG, RSA</p> <p>Shelf-life: 28 days</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Registration number: 48/20.1.2/1122</p> <p>Name of medicine: CAMOX CO-AMOXICLAV ES 600</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH 5.0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 600.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 42.9 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: CAMOX PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY</p> <p>Packer: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY</p> <p>Laboratory: FPRC: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRC: CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXT 3, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>

MRF 15	MRF 15	MRF 15	
<p>Registration number: 48/20.1.2/1123</p> <p>Name of medicine: AUSTELL CO-AMOXICLAV ES 600</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH 5.0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 600.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 42.9 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p>	<p>Registration number: 48/20.1.2/1124</p> <p>Name of medicine: APEX CO-AMOXICLAV ES 600</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH 5.0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 600.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 42.9 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p>	<p>Registration number: 48/20.1.1/1047</p> <p>Name of medicine: AKLIV IV</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: LINEZOLID 2.0 mg</p>	
<p>Applicant: CAMOX PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY</p> <p>Packer: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY</p> <p>Laboratory: FPRC: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXT 3, JOHANNESBURG, RSA</p>	<p>Applicant: CAMOX PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY</p> <p>Packer: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY</p> <p>Laboratory: FPRC: DEVA HOLDINGS A.S., TEKIRDAG, TURKEY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXT 3, JOHANNESBURG, RSA</p>	<p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AKACIA HEALTHCARE (PTY) LTD</p> <p>Manufacturer: CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA PHARMADOX HEALTHCARE LTD, PAOLA, MALTA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENGAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA</p>	
<p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	<p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 18 FEBRUARY 2016</p>	

MRF 15		MRF 15		MRF 15	
Registration number:	13/3.1.2/04	Registration number:	13/3.1.2/09	Registration number:	09/17.1/15
Name of medicine:	EQUICAM INJECTION 2 %	Name of medicine:	VETCAM INJECTION 2 %	Name of medicine:	AQUAFLOX 50 %
Dosage form:	SOLUTIO FOR INJECTION	Dosage form:	SOLUTIO FOR INJECTION	Dosage form:	ORAL PREMIX POWDER
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: MELOXICAM 20.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: MELOXICAM 20.0 mg	Active ingredients:	EACH 1.0 kg POWDER CONTAINS: FLORFENICOL 500.0 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, 16, 17
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	INTERVET SOUTH AFRICA (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IX,VERNA SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT IX,VERNA SALCETTE, GOA, INDIA	Manufacturer:	SCHERING-PLOUGH ANIMAL HEALTH CORPORATION, BARON ROUGE, LOS ANGELES, USA
Packer:	CIPLA LTD, UNIT IX,VERNA SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT IX,VERNA SALCETTE, GOA, INDIA	Packer:	SCHERING-PLOUGH ANIMAL HEALTH CORPORATION, BARON ROUGE, LOS ANGELES, USA
Laboratory, FPRC:	CIPLA LTD, UNIT IX,VERNA SALCETTE, GOA, INDIA	Laboratory, FPRC:	CIPLA LTD, UNIT IX,VERNA SALCETTE, GOA, INDIA	Laboratory, FPRC:	KHULILEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INTERVET SOUTH AFRICA (PTY) LTD, SPARTAN, ISANDO, RSA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN PARK, BELLVILLE, CAPE TOWN, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN PARK, BELLVILLE, CAPE TOWN, RSA	FPRR:	INTERVET SOUTH AFRICA (PTY) LTD, SPARTAN, ISANDO, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	36 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15	MRF15	MRF 15
<p>Registration number: 417, 1.3/1112</p> <p>Name of medicine: ASPEN VALSARTAN 80 mg</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: PHARMACARE LIMITED</p> <p>Manufacturer: ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Packer: ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Laboratory: FPRC : ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>FPRR: PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 417, 1.3/1113</p> <p>Name of medicine: ASPEN VALSARTAN 160 mg</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: PHARMACARE LIMITED</p> <p>Manufacturer: ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Packer: ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Laboratory: FPRC: ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>FPRR: PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 427, 1.3/0640</p> <p>Name of medicine: ASPEN VALSARTAN 40 mg</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: PHARMACARE LIMITED</p> <p>Manufacturer: ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Packer: ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Laboratory: FPRC ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>FPRR: PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 43/7.1.3/0521</p> <p>Name of medicine: RINTEZEX 320</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 320,0 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 STEIN AG, STEIN, SWITZERLAND</p> <p>Packer: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND</p> <p>Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 43/7.1.3/0522</p> <p>Name of medicine: ZOMEVEK 320 TABLET</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 320,0 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 STEIN AG, STEIN, SWITZERLAND</p> <p>Packer: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND</p> <p>Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 43/7.1.3/0523</p> <p>Name of medicine: MIGROBEN 320 TABLET</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: VALSARTAN 320,0 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 STEIN AG, STEIN, SWITZERLAND</p> <p>Packer: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND</p> <p>Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>



MRF 15	MRF15	F 15
<p>Registration number: 43/7.1.3/0547</p> <p>Name of medicine: DYNAVAL 40 mg</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, 8</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN</p> <p>Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 43/7.1.3/0548</p> <p>Name of medicine: DYNAVAL 80 mg</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, 8</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN</p> <p>Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 43/7.1.3/0549</p> <p>Name of medicine: DYNAVAL 160 mg</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, 8</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN</p> <p>Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 4377.1.3/0550</p> <p>Name of medicine: DYNA VALSARTAN 40 mg</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, 8</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN</p> <p>Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 4377.1.3/0551</p> <p>Name of medicine: DYNA VALSARTAN 80 mg</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, 8</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN</p> <p>Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 4377.1.3/0552</p> <p>Name of medicine: DYNA VALSARTAN 160 mg</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, 8</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN</p> <p>Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15

Registration number:	437.1.3/0949	43/20.1.1/1180	43/7.1.3/0950
Name of medicine:	PHARMA DYNAMICS VALSARTAN 80 mg	CRITPEME 500 mg	PHARMA DYNAMICS VALSARTAN 160 mg
Dosage form:	TABLET	POWDER FOR SOLUTION FOR INJECTION OR INFUSION	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg	EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 500,0 mg	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD	SANDOZ SA (PTY) LTD	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LUPIN LTD, VERNA SALCETTE, GOA, INDIA	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA	LUPIN LTD, VERNA SALCETTE, GOA, INDIA
Packer:	LUPIN LTD, VERNA SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA	LUPIN LTD, VERNA SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA ATLASVILLE, BOKSBURG, RSA
Laboratory: FPRC	LUPIN LTD, VERNA SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	SANDOZ GmbH, KUNDL, AUSTRIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	LUPIN LTD, VERNA SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA
Shelf-life:	24 months (provisional)	24 months (provisional)	24 months (provisional)
Date of registration:	21 APRIL 2016	21 APRIL 2016	21 APRIL 2016

MRF 15	5	MRF 15	5
<p>Registration number: 43/20.1.1/1181</p> <p>Name of medicine: CRITPEME 1 000 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 1 000,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY</p> <p>Packer: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 43/20.1.1/1182</p> <p>Name of medicine: CRITPEME 2 000 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 2 000,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY</p> <p>Packer: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 43/20.1.1/1183</p> <p>Name of medicine: SANDOZ CEFEPIME 500 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY</p> <p>Packer: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 43/20.1.1/1182</p> <p>Name of medicine: CRITPEME 2 000 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 2 000,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY</p> <p>Packer: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 43/20.1.1/1184</p> <p>Name of medicine: SANDOZ CEFEPIME 1 000 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 1 000,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Packer: SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 43/20.1.1/1185</p> <p>Name of medicine: SANDOZ CEFEPIME 2 000 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 2 000,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Packer: SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 44/18.2/0283</p> <p>Name of medicine: SANDOZ CLOPIDOGREL 75</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI/MUMBAI, MAHARASHTRA, INDIA</p> <p>Packer: SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI/MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Laboratory: FPRC: SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI/MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 44/8.2/0284</p> <p>Name of medicine: PLAHIP</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA</p> <p>Packer: SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA</p> <p>Laboratory: FPRC: SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA</p> <p>FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 44/2.6.5/0673</p> <p>Name of medicine: RISPIDE 0.5</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: ABEX PHARMACEUTICA (PTY) LTD</p> <p>Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE</p> <p>Packer: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE</p> <p>FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE</p> <p>PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE</p> <p>DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE INDUSTRIAL, JOHANNESBURG, RSA</p> <p>PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE</p> <p>Laboratory: FPRC: SPECFARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 44/2.6.5/0674</p> <p>Name of medicine: RISPIDE 1</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: ABEX PHARMACEUTICA (PTY) LTD</p> <p>Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE</p> <p>Packer: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE</p> <p>FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE</p> <p>PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE</p> <p>DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE INDUSTRIAL, JOHANNESBURG, RSA</p> <p>PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE</p> <p>Laboratory: FPRC: SPECFARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	44/2.6.5/0675	44/2.6.5/0676	44/2.6.5/0677
Name of medicine:	RISPIDE 2	RISPIDE 3	RISPIDE 4
Dosage form:	TABLET	TABLET	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 mg	EACH TABLET CONTAINS: RISPERIDONE 3,0 mg	EACH TABLET CONTAINS: RISPERIDONE 4,0 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:	ABEX PHARMACEUTICA (PTY) LTD	ABEX PHARMACEUTICA (PTY) LTD	ABEX PHARMACEUTICA (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory, FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
Shelf-life:	36 months	36 months	36 months
Date of registration:	21 APRIL 2016	21 APRIL 2016	21 APRIL 2016
Registration number:			
Name of medicine:			
Dosage form:			
Active ingredients:			
Conditions of registration:			
Applicant:			
Manufacturer:			
Packer:			
Laboratory, FPRC:			
Shelf-life:			
Date of registration:			

Registration number:	44/2.6.5/0678	Registration number:	44/21.12/0850	Registration number:	44/20.2.8/1050
Name of medicine:	RISPIDE 6	Name of medicine:	DUODART	Name of medicine:	TENOLAM
Dosage form:	TABLET	Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 6.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: DUTASTERID 0.5 mg TAMSULOSIN HYDROCHLORIDE 0.4 mg	Active ingredients:	EACH TABLET CONTAINS: TENOFIVIR DISPROXIL FUMARATE 300.0 mg LAMIVUDINE 300.0 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
Applicant:	ABEX PHARMACEUTICA (PTY) LTD	Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	Manufacturer:	CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY CATALENT FRANCE BEINHEIM SA, BEINHEIM, FRANCE (DUTASTERIDE INTERMEDIATE) ROTTENDORF PHARMA GmbH, ENNINGERLOH, GERMANY (TAMSULOSIN HCI INTERMEDIATE)	Manufacturer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA ASPEN OSD (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A. LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	Packer:	CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY CATALENT FRANCE BEINHEIM SA, BEINHEIM, FRANCE ROTTENDORF PHARMA GmbH, ENNINGERLOH, GERMANY GLAXOSMITHKLINE SA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA	Packer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA ASPEN OSD (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOXSBURG, RSA	Laboratory:	FPRC: CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY CATALENT FRANCE BEINHEIM SA, BEINHEIM, FRANCE ROTTENDORF PHARMA GmbH, ENNINGERLOH, GERMANY QUINTA-ANALYTICA s.r.o., PRAGUE HOSTIVAR, CZECH REPUBLIC SYNTHON HIPANIA S.L., SAINT BOI DE LLOBREGAT, SPAIN GLAXOSMITHKLINE SA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA	Laboratory:	FPRC: MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA ASPEN OSD (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENGAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
Shelf-life:	36 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016
FPRC:	ABEX PHARMACEUTICA (PTY) LTD, MORELETA PARK, PRETORIA, RSA	FPRC:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA	FPRC:	ASPEN OSD (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA



Registration number:	457.1.3/0106	Registration number:	45/20.2.8/0099	Registration number:	45/20.2.8/0098
Name of medicine:	VOLIBRIS 5 mg	Name of medicine:	MEDPRO LOPINAVIR & RITONAVIR 80/20 mg/ml	Name of medicine:	CIPLA LOPINAVIR & RITONAVIR 80/20 mg/ml
Dosage form:	TABLET	Dosage form:	ORAL SOLUTION	Dosage form:	ORAL SOLUTION
Active ingredients:	EACH TABLET CONTAINS: AMBRISENTAN 5.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LOPINAVIR 80.0 mg RITONAVIR 20.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LOPINAVIR 80.0 mg RITONAVIR 20.0 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
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	Applicant:	CIPLA LIFE SCIENCES (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	PATHEON INC. MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA
Packer:	PATHEON INC. MISSISSAUGA, ONTARIO, CANADA GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING, INDUSTRIA, CAPE TOWN, RSA	Packer:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA
Laboratory:	PATHEON INC. MISSISSAUGA, ONTARIO, CANADA GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING, INDUSTRIA, CAPE TOWN, RSA	Laboratory:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Laboratory:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA
		FPRR:	FPRR: CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA
		FPRR:		FPRR:	
Shelf-life:	48 months	Shelf-life:	48 months	Shelf-life:	48 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/20.1.1/0417</p> <p>Name of medicine: MERTIC 500 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OF INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 500,0 mg</p> <p>Conditions of registration: 1. 2. 3. 4. 5. 6. 7. 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA</p> <p>Packer: SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Laboratory: FPRC: SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/20.1.1/0418</p> <p>Name of medicine: MERTIC 1 g</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OF INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 1,0 g</p> <p>Conditions of registration: 1. 2. 3. 4. 5. 6. 7. 8</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA</p> <p>Packer: SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Laboratory: FPRC: SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>FPRC/FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/20.1.1/0419</p> <p>Name of medicine: MEROPENEM SANDOZ 500 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION OF INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 500,0 mg</p> <p>Conditions of registration: 1. 2. 3. 4. 5. 6. 7. 8</p> <p>Manufacturer: SANDOZ SA (PTY) LTD</p> <p>Packer: SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Laboratory: FPRC: SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	45/10.2.2/0668	45/10.2.2/0687	45/20.1./10420
Name of medicine:	LUCAN CHEW 5 mg	LUCAN CHEW 4 mg	MEROPENEM SANDOZ 1 g
Dosage form:	CHEWABLE TABLET	CHEWABLE TABLET	POWDER FOR SOLUTION FOR INJECTION OF INFUSION
Active ingredients:	EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg	EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MYLAN (PTY) LTD	MYLAN (PTY) LTD	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA
Laboratory:	FPRC	FPRC	FPRC
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (provisional)	24 months (provisional)	24 months (provisional)
Date of registration:	21 APRIL 2016	21 APRIL 2016	21 APRIL 2016

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/20.2.6/0828</p> <p>Name of medicine: METRONIDAZOLE DEZZO 200</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: METRONIDAZOLE 200,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Packer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Laboratory: FPRC: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/20.2.6/0829</p> <p>Name of medicine: METRONIDAZOLE DEZZO 400</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: METRONIDAZOLE 400,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Packer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Laboratory: FPRC: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/20.2.6/0830</p> <p>Name of medicine: FLAMET 200</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: METRONIDAZOLE 200,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Packer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Laboratory: FPRC: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	MRF 15	MRF 15	MRF 15
<p>Registration number: 45/11.4.3/0930</p> <p>Name of medicine: GASTRI-EZE IV</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: PANTOPRAZOLE SODIUM SESQUHYDRATE EQUIVALENT TO PANTOPRAZOLE 40.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ABEX PHARMACEUTICA (PTY) LTD</p> <p>Manufacturer: SIRTON PHARMACEUTICALS S.A., VILLA GUARDIA ITALY</p> <p>Packer: SIRTON PHARMACEUTICALS S.A., VILLA GUARDIA ITALY</p> <p>Laboratory: FPRC SPECHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: SPECHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/20.2.3/0844</p> <p>Name of medicine: MACLEODS PYRAZINAMIDE 500</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: PYRAZINAMIDE 500.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MECLIODS PHARMACEUTICALS SA (PTY) LTD</p> <p>Manufacturer: MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA</p> <p>Packer: MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA</p> <p>Laboratory: FPRC MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA</p> <p>FPRR: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>Shelf-life: 48 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/20.2.6/0831</p> <p>Name of medicine: FLAMET 400</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: METRONIDAZOLE 400.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Packer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Laboratory: FPRC KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>FPRR: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/20.2.6/0831</p> <p>Name of medicine: FLAMET 400</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: METRONIDAZOLE 400.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Packer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>Laboratory: FPRC KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/8.3/0166</p> <p>Name of medicine: MonoFer 100 mg</p> <p>Dosage form: SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL OF AMPOULE CONTAINS: IRON (III) ISOMALTOSE 1 000 EQUIVALENT TO IRON 100.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMAPLAN (PTY) LTD</p> <p>Manufacturer: SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY</p> <p>Packer: SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY SCANPHARM A/S, BIRKERØED, DENMARK</p> <p>Laboratory: FPRC: PHARMACOSMOS A/S, HOLBAEK, DENMARK CONSULTING CHEMICAL LABORATORIES (PTY) LTD, MIDRAND, RSA ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/8.3/0167</p> <p>Name of medicine: MonoFer 500 mg</p> <p>Dosage form: SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL OF AMPOULE CONTAINS: IRON (III) ISOMALTOSE 1 000 EQUIVALENT TO IRON 500.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMAPLAN (PTY) LTD</p> <p>Manufacturer: SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY</p> <p>Packer: SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY SCANPHARM A/S, BIRKERØED, DENMARK</p> <p>Laboratory: FPRC: PHARMACOSMOS A/S, HOLBAEK, DENMARK CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: 45/8.3/0168</p> <p>Name of medicine: MonoFer 1 000 mg</p> <p>Dosage form: SOLUTION FOR INJECTION OR INFUSION</p> <p>Active ingredients: EACH VIAL OF AMPOULE CONTAINS: IRON (III) ISOMALTOSE 1 000 EQUIVALENT TO IRON 1 000.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PHARMAPLAN (PTY) LTD</p> <p>Manufacturer: SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY</p> <p>Packer: SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY SCANPHARM A/S, BIRKERØED, DENMARK</p> <p>Laboratory: FPRC: PHARMACOSMOS A/S, HOLBAEK, DENMARK CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	<p>Registration number: 473.10467</p> <p>Name of medicine: ORENCIA 125 mg</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: ABATACEPT 125,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD</p> <p>Manufacturer: BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, MANATI, PUERTO RICO</p> <p>Packer: BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, MANATI, PUERTO RICO</p> <p>Laboratory: FPRC: BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, MANATI, PUERTO RICO</p> <p>FPRR: SYRACUSE NEW YORK, USA COVANCE LABORATORIES LTD, HARROGATE, NORTH YORKSHIRE, UNITED KINGDOM</p> <p>FPRR: BRISTOL-MYERS SQUIBB (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 21 APRIL 2016</p>	MRF15	<p>Registration number: 48/20.2.8/0083</p> <p>Name of medicine: HETLATEF</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg LAMIVUDINE 300,0 mg TENOFVIR DISOPROXIL FUMARATE 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: HETERO DRUGS SA</p> <p>Manufacturer: HETERO LABS LIMITED, UNIT II, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: HETERO LABS LIMITED, UNIT II, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: HETERO LABS LIMITED, UNIT II, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD NORTH RIDING, RANDBURG, RSA</p> <p>FPRR: HETERO DRUGS SA, CENTURION, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>
MRF15	<p>Registration number: 48/20.1.1/0434</p> <p>Name of medicine: LINEZOLID FRESENIUS 600 mg/300 ml</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH 300,0 ml SOLUTION CONTAINS: LINEZOLID 600,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 18</p> <p>Applicant: FRESENIUS KABI SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY</p> <p>Packer: FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY</p> <p>Laboratory: FPRC: FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY KHULULEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 21 APRIL 2016</p>	MRF15	<p>Registration number: 49/20.1.1/0434</p> <p>Name of medicine: LINEZOLID FRESENIUS 600 mg/300 ml</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH 300,0 ml SOLUTION CONTAINS: LINEZOLID 600,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 18</p> <p>Applicant: FRESENIUS KABI SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY</p> <p>Packer: FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY</p> <p>Laboratory: FPRC: FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY KHULULEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 21 APRIL 2016</p>

MRF 15	<p>Registration number: 49/20.2.8/0097</p> <p>Name of medicine: TRELAVUE</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 50,0 mg ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 600,0 mg LAMIVUDINE 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: GLAXO OPERATIONS UK LTD (T/A GLAXO WELLCOME OPERATIONS), WARE, HERTFORDSHIRE, UNITED KINGDOM</p> <p>Packer: GLAXO OPERATIONS UK LTD (T/A GLAXO WELLCOME OPERATIONS), WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOWELLCOME S.A., ARANDA DE DUERO, BURGOS, SPAIN</p> <p>Laboratory: FPRC: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA</p> <p>FPRC: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA</p> <p>24 months (provisional)</p> <p>21 APRIL 2016</p>	<p>Registration number: 49/20.2.8/0374</p> <p>Name of medicine: LAMIVUDINE SANDOZ</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: LAMIVUDINE 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTIA, JOHANNESBURG, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Laboratory: FPRC: JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>24 months</p> <p>21 APRIL 2016</p>	<p>Registration number: 49/20.2.8/0503</p> <p>Name of medicine: ZIDOVUDINE SANDOZ 300 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ZIDOVUDINE 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTIA, JOHANNESBURG, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>Laboratory: FPRC: HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA</p> <p>24 months</p> <p>21 APRIL 2016</p>
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MRF 15	<p>Registration number: 49/21.1/0708                  Name of medicine: BASAGLAR                  Dosage form: SOLUTION FOR INJECTION                  Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: INSULIN GLARGINE 3.64 mg                  Conditions of registration: 1, 2, 3, 4, 5, 6, 7                  Applicant: ELI LILLY (S.A.) (PTY) LTD                  Manufacturer: ELI LILLY FRANCE, FEGERSHEIM, FRANCE                  Packer: ELI LILLY FRANCE, FEGERSHEIM, FRANCE                  ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA                  Laboratory: FPRC: SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p>	<p>Registration number: A40/21.10/0263                  Name of medicine: LEUPROLIDE HEXAL 5                  Dosage form: IMPLANT                  Active ingredients: EACH IMPLANT CONTAINS: LEUPROLIDE ACETATE EQUIVALENT TO LEUPROLIDE 5.0 mg                  Conditions of registration: 1, 2, 3, 4, 5, 6, 7                  Applicant: SANDOZ SA (PTY) LTD                  Manufacturer: JENAHEXAL PHARMA GmbH, JENA, GERMANY                  ReUSCH STERILISATION SERVICE GmbH, KERNEN, GERMANY                  GAMMA-SERVICE PRODUKTBESTRAHLUNG GmbH, RADEBERG, GERMANY                  Packer: JENAHEXAL PHARMA GmbH, JENA, GERMANY                  SALUTAS PHARM GmbH, BARLEBEN, GERMANY                  DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA                  TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA                  Laboratory: FPRC: JENAHEXAL PHARMA GmbH, JENA, GERMANY                  SALUTAS PHARM GmbH, BARLEBEN, GERMANY                  CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA                  FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA                  Shelf-life: 48 months                  Date of registration: 21 APRIL 2016</p>	<p>Registration number: A40/1.2/0477                  Name of medicine: ROXET 10 mg                  Dosage form: TABLET                  Active ingredients: EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 10.0 mg                  Conditions of registration: 1, 2, 3, 4, 5, 6, 7                  Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD                  Manufacturer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA                  Packer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA                  DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA                  TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA                  Laboratory: FPRC: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA                  TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA                  M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA                  FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA                  Shelf-life: 36 months                  Date of registration: 21 APRIL 2016</p>
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MRF 15	MRF 15	MRF 15
<p>Registration number: A40/1.2/0478</p> <p>Name of medicine: ROXET 20 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 20,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA</p> <p>Packer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRR: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA</p> <p>M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number: A40/1.2/0479</p> <p>Name of medicine: ROXET 30 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 30,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA</p> <p>Packer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRR: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA</p> <p>M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 21 APRIL 2016</p>	<p>Registration number:</p> <p>Name of medicine:</p> <p>Dosage form:</p> <p>Active ingredients:</p> <p>Conditions of registration:</p> <p>Applicant:</p> <p>Manufacturer:</p> <p>Packer:</p> <p>Laboratory: FPRR:</p> <p>Shelf-life:</p> <p>Date of registration:</p>

MRF 15	F 15	MRF 15
<p>Registration number: 07/3.1/13</p> <p>Name of medicine: TOLFEDINE 6 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: TOLFENAMIC ACID 6.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD</p> <p>Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Laboratory: FPRC: BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA</p> <p>FPRR: AFRIVET BUSINESS MANAGEMENT (PTY) LTD, HAZELDEAN, PRETORIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 07/3.1/14</p> <p>Name of medicine: TOLFEDINE 20 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: TOLFENAMIC ACID 20.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD</p> <p>Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Laboratory: FPRC: BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA</p> <p>FPRR: AFRIVET BUSINESS MANAGEMENT (PTY) LTD, HAZELDEAN, PRETORIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 07/3.1/15</p> <p>Name of medicine: TOLFEDINE 60 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: TOLFENAMIC ACID 60.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD</p> <p>Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Laboratory: FPRC: BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA</p> <p>FPRR: AFRIVET BUSINESS MANAGEMENT (PTY) LTD, HAZELDEAN, PRETORIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	15	MRF 15	MRF 15
<p>Registration number: 07/3-1/16</p> <p>Name of medicine: TOLFEDINE 120 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: TOLFENAMIC ACID 120,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD</p> <p>Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Laboratory: FPRC : BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 10/17.1.6/16</p> <p>Name of medicine: BAXIN 100 mg/ml</p> <p>Dosage form: INJECTION</p> <p>Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: ENROFLOXACIN 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 10/17.1.6/15</p> <p>Name of medicine: EVANIX 100 mg/ml</p> <p>Dosage form: INJECTION</p> <p>Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: ENROFLOXACIN 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 10/17.1.6/16</p> <p>Name of medicine: BAXIN 100 mg/ml</p> <p>Dosage form: INJECTION</p> <p>Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: ENROFLOXACIN 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF-15	MRF-15	MRF-15	MRF-15
<p>Registration number: A063/1/08</p> <p>Name of medicine: TOLFEDINE INJECTABLE</p> <p>Dosage form: INJECTION</p> <p>Active ingredients: EACH 100,0 ml SOLUTION CONTAINS: TOLFENAMIC ACID 4,0 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD</p> <p>Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Laboratory: FPRC: BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA</p> <p>Shelf-life: 36 months (in-use) 28 days</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 4177./10661</p> <p>Name of medicine: ACCORD AMLODIPINE 5</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATETE EQUIVALENT TO AMLODIPINE 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 4177./10662</p> <p>Name of medicine: ACCORD AMLODIPINE 10</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: A063/1/08</p> <p>Name of medicine: TOLFEDINE INJECTABLE</p> <p>Dosage form: INJECTION</p> <p>Active ingredients: EACH 100,0 ml SOLUTION CONTAINS: TOLFENAMIC ACID 4,0 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD</p> <p>Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE</p> <p>Laboratory: FPRC: BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA</p> <p>Shelf-life: 36 months (in-use) 28 days</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	Registration number:	Name of medicine:	Dosage form:	Active ingredients:	Conditions of registration:	Applicant:	Manufacturer:	Packer:	Laboratory:	FPRC:	Shelf-life:	Date of registration:	
	41/13.2/0408	ALOVELL TABLET	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONATE 10,0 mg	1, 2, 3, 4, 5, 6, 7, 8	GULF DRUG COMPANY (PTY) LTD PT NOVELL PHARMACEUTICAL LABORATORIES, SENAYAN, JAKARTA, INDONESIA	PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA	PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA	PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA	PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA	WRAPSA (PTY) LTD, HENNOFSPARK, CENTURION, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA WEST JOHANNESBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA	24 months (provisional)	09 JUNE 2016
	41/26/0910	OXALIPLATIN EBEWE 50 mg	POWDER FOR SOLUTION FOR INFUSION EACH VIAL CONTAINS: OXALIPLATIN 50,0 mg	1, 2, 3, 4, 5, 6, 7, 8	SANDOZ SA (PTY) LTD ONCOTEC PHARMA PRODUCTION GmbH, RODLIBEN, GERMANY	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+S AG, BAD BOCKLET, GERMANY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	24 months (provisional)	09 JUNE 2016	
	41/26/1129	OXALIPLATIN EBEWE 100 mg	POWDER FOR SOLUTION FOR INFUSION EACH VIAL CONTAINS: OXALIPLATIN 100,0 mg	1, 2, 3, 4, 5, 6, 7, 8	SANDOZ SA (PTY) LTD ONCOTEC PHARMA PRODUCTION GmbH, RODLIBEN, GERMANY	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+S AG, BAD BOCKLET, GERMANY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	24 months (provisional)	09 JUNE 2016		

<p>Registration number: 42/5.8.0223</p> <p>Name of medicine: SINUPHEN SINUS PAIN</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: PHENYLEPHRINE HYDROCHLORIDE 5.0 mg PARACETAMOL 500.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: JOHNSON &amp; JOHNSON (PTY) LTD</p> <p>Manufacturer: JOHNSON &amp; JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA</p> <p>Packer: JOHNSON &amp; JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA</p> <p>Laboratory: FPRC: JOHNSON &amp; JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 42/20.1.2/0225</p> <p>Name of medicine: CLAVAMI SR</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 1 000.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 62,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE</p> <p>Packer: GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE</p> <p>Laboratory: FPRC: GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 42/20.1.2/0226</p> <p>Name of medicine: GSK AMOXICILLIN/CLAVULANATE SR</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 1 000.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 62,5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE</p> <p>Packer: GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE</p> <p>Laboratory: FPRC: GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>
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MRF 15	MRF 15	MRF 15
<p>Registration number: 42/11.5/0412</p> <p>Name of medicine: PURGOLENE</p> <p>Dosage form: POWDER FOR ORAL SOLUTION</p> <p>Active ingredients: EACH SACHET CONTAINS: MACROGOL (PEG) 3350 13,125 g SODIUM BICARBONATE 178,5 mg SODIUM CHLORIDE 350,7 mg POTASSIUM CHLORIDE 46,6 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ANMARATE (PTY) LTD</p> <p>Manufacturer: DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA (PTY) LTD, HENNOPSPARK, CENTURION, RSA</p> <p>Packer: DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA (PTY) LTD, HENNOPSPARK, CENTURION, RSA</p> <p>Laboratory: FPRC: INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, BOKSBURG, RSA</p> <p>FPRR: ANMARATE (PTY) LTD, GEORGE, RSA</p> <p>Shelf-life: 48 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 42/11.5/0413</p> <p>Name of medicine: PURGOPEL</p> <p>Dosage form: POWDER FOR ORAL SOLUTION</p> <p>Active ingredients: EACH SACHET CONTAINS: MACROGOL (PEG) 3350 6,563 g SODIUM BICARBONATE 89,3 mg SODIUM CHLORIDE 175,4 mg POTASSIUM CHLORIDE 23,3 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ANMARATE (PTY) LTD</p> <p>Manufacturer: DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA (PTY) LTD, HENNOPSPARK, CENTURION, RSA</p> <p>Packer: DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA (PTY) LTD, HENNOPSPARK, CENTURION, RSA</p> <p>Laboratory: FPRC: INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: ANMARATE (PTY) LTD, GEORGE, RSA</p> <p>Shelf-life: 48 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 43/2.1/0392</p> <p>Name of medicine: TORRANE</p> <p>Dosage form: LIQUID FOR INHALATION</p> <p>Active ingredients: EACH BOTTLE CONTAINS: DESFLURANE 250,0 ml</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: SAFELINE PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA</p> <p>Packer: MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA</p> <p>Laboratory: FPRC: MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA</p> <p>FPRR: SAFELINE PHARMACEUTICALS (PTY) LTD, WELTEVREDEN PARK, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>



MRF 15	MRF 15	MRF 15
<p>Registration number: 43/13.1/1057</p> <p>Name of medicine: BARRS MERCUROCHROME 1% SOLUTION</p> <p>Dosage form: SOLUTION</p> <p>Active ingredients: EACH 20.0 ml SOLUTION CONTAINS: MERCUROCHROME 0,20 g</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BARRS PHARMACEUTICAL INDUSTRIES cc</p> <p>Manufacturer: BARRS PHARMACEUTICAL INDUSTRIES cc, N'DABENI, CAPE TOWN, RSA</p> <p>Packer: BARRS PHARMACEUTICAL INDUSTRIES cc, N'DABENI, CAPE TOWN, RSA</p> <p>Laboratory: FPRC: BARRS PHARMACEUTICAL INDUSTRIES cc, N'DABENI, CAPE TOWN, RSA</p>	<p>Registration number: 43/21.13/0829</p> <p>Name of medicine: GLYPRESSIN</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: TERLIPRESSIN ACETATE EQUIVALENT TO TERLIPRESSIN 0,1 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: FERRING (PTY) LTD</p> <p>Manufacturer: ZENTIVA A.S., PRAGUE, CZECH REPUBLIC</p> <p>Packer: ZENTIVA A.S., PRAGUE, CZECH REPUBLIC</p> <p>Laboratory: FPRC: ZENTIVA A.S., PRAGUE, CZECH REPUBLIC</p> <p>FERRING-LECVIA A.S., JESENICE U PRAHY, CZECH REPUBLIC ITEST PLUS S.R.O., HRADEC KRALOVE, CZECH REPUBLIC FRESENIUS HEMOCARE CZ S.R.O., ZVERINEK, CZECH REPUBLIC CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA</p>	<p>Registration number: 43/8.2/0763</p> <p>Name of medicine: VASPID</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CLOPIDOGREL BESYLATE EQUIVALENT TO CLOPIDOGREL 75,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: AKACIA HEALTHCARE (PTY) LTD</p> <p>Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE</p> <p>SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p>
<p>FPRR: BARRS PHARMACEUTICAL INDUSTRIES cc, N'DABENI, CAPE TOWN, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>FPRR: FERRING (PTY) LTD, IRENE, PRETORIA, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>FPRR: AKACIA HEALTHCARE (PTY) LTD, ISANIDO JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 43/26/1067</p> <p>Name of medicine: CAMPTO CSV 300 mg/15 ml</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: IRINOTECAN HYDROCHLORIDE TRIHYDRATE 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: PFIZER LABORATORIES (PTY) LTD</p> <p>Manufacturer: PFIZER PERTH (PTY) LIMITED, BENTLEY, AUSTRALIA</p> <p>Packer: PFIZER PERTH (PTY) LTD, BENTLEY, AUSTRALIA</p> <p>Laboratory: FPRC: PFIZER PERTH (PTY) LTD, BENTLEY, AUSTRALIA, KHULILEKANI LABORATORY cc, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRC: PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 43/21.5/1143</p> <p>Name of medicine: MACLEODS HYDROCORTISONE INJECTION</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: HYDROCORTISONE SODIUM SUCCINATE EQUIVALENT TO HYDROCORTISONE 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MACLEODS PHARMACEUTICALS SA (PTY) LTD</p> <p>Manufacturer: MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA</p> <p>Packer: MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA</p> <p>Laboratory: FPRC: MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA</p> <p>FPRC: MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 44/21.12/0190</p> <p>Name of medicine: ZETRA</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</p> <p>Applicant: PHARMAPLAN (PTY) LTD</p> <p>Manufacturer: DOUGLAS PHARMACEUTICALS LTD, NADI, FIJI</p> <p>Packer: DOUGLAS PHARMACEUTICALS LTD, NADI, FIJI DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND</p> <p>Laboratory: FPRC: DOUGLAS PHARMACEUTICALS LTD, MARTINAR, NADI, FIJI CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRC: PHARMAPLAN (PTY) LTD, MIDRAND, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 44/20.1.2/0471</p> <p>Name of medicine: LICAX 250 mg INJECTION</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: CLOXACILLIN SODIUM EQUIVALENT TO CLOXACILLIN 250,0 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 XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULILEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 44/20.1.2/0472</p> <p>Name of medicine: LICAX 500 mg INJECTION</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: CLOXACILLIN SODIUM EQUIVALENT TO CLOXACILLIN 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 XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Packer: AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA</p> <p>Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULILEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 44/26/0548</p> <p>Name of medicine: REVOLADE 25 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: ELTROMBOPAG OLAMINE EQUIVALENT TO ELTROMBOPAG 25,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM</p> <p>Packer: GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA</p> <p>Laboratory: FPRC: GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA</p> <p>FPRR: NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA</p> <p>Shelf-life: 48 months</p> <p>Date of registration: 09 JUNE 2016</p>

Registration number: Name of medicine: Dosage form: Active ingredients: Conditions of registration: Applicant: Manufacturer: Packer: Laboratory: FPRC: Shelf-life: Date of registration:	44/20.1.2/0970 GDC CO AMOXICLAV 1 000/200 INJECTION EACH VIAL CONTAINS: AMOXICILLIN 1 000.0 mg CLAVULANIC ACID 200.0 mg 1, 2, 3, 4, 5, 6, 7 GULF DRUG COMPANY (PTY) LTD LABORATORIO REIG JOFRE, TOLEDO, SPAIN LABORATORIO REIG JOFRE, TOLEDO, SPAIN LABORATORIO REIG JOFRE, TOLEDO, SPAIN FPRC 36 months 09 JUNE 2016
Registration number: Name of medicine: Dosage form: Active ingredients: Conditions of registration: Applicant: Manufacturer: Packer: Laboratory: FPRC: Shelf-life: Date of registration:	44/20.1.2/0969 GDC CO AMOXICLAV 500/100 INJECTION EACH VIAL CONTAINS: AMOXICILLIN 500.0 mg CLAVULANIC ACID 100.0 mg 1, 2, 3, 4, 5, 6, 7 GULF DRUG COMPANY (PTY) LTD LABORATORIO REIG JOFRE, TOLEDO, SPAIN LABORATORIO REIG JOFRE, TOLEDO, SPAIN LABORATORIO REIG JOFRE, TOLEDO, SPAIN FPRC 36 months 09 JUNE 2016
Registration number: Name of medicine: Dosage form: Active ingredients: Conditions of registration: Applicant: Manufacturer: Packer: Laboratory: FPRC: Shelf-life: Date of registration:	44/20/0549 REVOLADE 50 mg TABLET EACH TABLET CONTAINS: ELTROMBOPAG OLAMINE EQUIVALENT TO ELTROMBOPAG 50,0 mg 1, 2, 3, 4, 5, 6, 7 GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD GLAXO OPERATIONS UK LTD, HERTFORDSHIRE, UNITED KINGDOM GLAXO OPERATIONS UK LTD, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA GLAXO OPERATIONS UK LTD, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA FPRC GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA 48 months 09 JUNE 2016

MRF 15	Registration number:	Name of medicine:	Dosage form:	Active ingredients:	Conditions of registration:	Applicant:	Manufacturer:	Packer:	Laboratory:	FPRR:	Shelf-life:	Date of registration:
	44/18.8/1033	GDC CLOMIFENE 50	TABLET	EACH TABLET CONTAINS: CLOMPHENE CITRATE EQUIVALENT TO CLOMPHENE 50.0 mg	1, 2, 3, 4, 5, 6, 7, 8	GULF DRUG COMPANY (PTY) LTD	OMAN	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	LABORATORIO REIG JOFRE, TOLEDO, SPAIN WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SWIFT MICROLABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA	FPRR:	24 months (provisional)	09 JUNE 2016
	44/18.8/1034	FERTAB	TABLET	EACH TABLET CONTAINS: CLOMPHENE CITRATE EQUIVALENT TO CLOMPHENE 50.0 mg	1, 2, 3, 4, 5, 6, 7, 8	GULF DRUG COMPANY (PTY) LTD	OMAN	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	LABORATORIO REIG JOFRE, TOLEDO, SPAIN WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SWIFT MICROLABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA	FPRR:	24 months (provisional)	09 JUNE 2016
	4515.4/0142	DORZOTIM	EYE DROPS	EACH SOLUTION CONTAINS: DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 20.0 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5.0 mg	1, 2, 3, 4, 5, 6, 7, 8	LITHA PHARMA (PTY) LTD	FAMAR S.A., ALIMOS, ATHENS, GREECE	FAMAR S.A., ALIMOS, ATHENS, GREECE PHARMATEN S.A., PALLINI, ATTIKIS, GREECE	FAMAR S.A., ALIMOS, ATHENS, GREECE PHARMATEN S.A., PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	FPRR:	24 months (provisional)	09 JUNE 2016

RF 15

MRF15

MRF 15

Registration number:	45/26/0268	Registration number:	45/26/0269	Registration number:	45/7.1.3/0608
Name of medicine:	HEMADAUN	Name of medicine:	CIPLA DAUNORUBICIN 20	Name of medicine:	MICATEL 40
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: DAUNORUBICIN HYDROCHLORIDE EQUIVALENT TO DAUNORUBICIN 20.0 mg	Active ingredients:	EACH VIAL CONTAINS: DAUNORUBICIN HYDROCHLORIDE EQUIVALENT TO DAUNORUBICIN 20.0 mg	Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 40.0 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:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA LIFE SCIENCES (PTY) LTD	Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Manufacturer:	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Packer:	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC::	CIPLA MEDPRO (PTY) LTD, ROSENPAK, BELLVILLE, CAPE TOWN, RSA	FPRC/FPRC:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPAK, BELLVILLE, CAPE TOWN, RSA	FPRC:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (provisional)
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/10.2.2/0662</p> <p>Name of medicine: WATSON MONTELUKAST 5</p> <p>Dosage form: CHEWABLE TABLET</p> <p>Active ingredients: EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: SPECIFAR SA, VARVARA, ATHENS, GREECE</p> <p>Packer: SPECIFAR SA, VARVARA, ATHENS, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC SPECIFAR SA, VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/10.2.2/0661</p> <p>Name of medicine: WATSON MONTELUKAST 4</p> <p>Dosage form: CHEWABLE TABLET</p> <p>Active ingredients: EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: SPECIFAR SA, VARVARA, ATHENS, GREECE</p> <p>Packer: SPECIFAR SA, VARVARA, ATHENS, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC SPECIFAR SA, VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/7.1.3/0609</p> <p>Name of medicine: MICATEL 80</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: TELMISARTAN 80,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: RANBAXY (SA) (PTY) LTD</p> <p>Manufacturer: RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA</p> <p>Packer: RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA</p> <p>Laboratory: FPRC RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: RANBAXY (SA) (PTY) LTD, CENTURION, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/2.5/0698</p> <p>Name of medicine: GABAPENTIN TEVA 100</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: GABAPENTIN 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: TEVA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL</p> <p>Packer: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED COMPANY, PALLAFI UT, DEBRECEN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL PHARMACHEMIE B.V., SWENSWEG, HAARLEM SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENGAMI, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPFR: TEVA PHARMACEUTICALS (PTY) LTD, RUIMSIG, ROODEPOORT, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/2.5/0699</p> <p>Name of medicine: GABAPENTIN TEVA 300</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: TEVA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL</p> <p>Packer: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED COMPANY, PALLAFI UT, DEBRECEN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL PHARMACHEMIE B.V., SWENSWEG, HAARLEM SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENGAMI, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPFR: TEVA PHARMACEUTICALS (PTY) LTD, RUIMSIG, ROODEPOORT, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/2.5/0700</p> <p>Name of medicine: GABAPENTIN TEVA 400</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: TEVA PHARMACEUTICALS (PTY) LTD</p> <p>Manufacturer: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL</p> <p>Packer: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED COMPANY, PALLAFI UT, DEBRECEN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC: TEVA PHARMAC EUTICALS INDUSTRIES LTD, KFAR SABA, ISRAEL PHARMACHEMIE B.V., SWENSWEG, HAARLEM SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENGAMI, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA</p> <p>FPFR: TEVA PHARMACEUTICALS (PTY) LTD, RUIMSIG, ROODEPOORT, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>



MRF 15	MRF 15	MRF 15
<p>Registration number: 45/16.4/0808</p> <p>Name of medicine: SEPTOLETE CHERRY LOZENGE</p> <p>Dosage form: LOZENGE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: CETYLPRYRIDINIUM 1,2 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BLISS PHARMACEUTICALS cc</p> <p>Manufacturer: KRKA d.d., NOVO MESTO, SLOVENIA</p> <p>Packer: KRKA d.d., NOVO MESTO, SLOVENIA</p> <p>Laboratory: FPRC: M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: BLISS PHARMACEUTICALS c. WOODMEAD, WOODMEAD, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/16.4/0809</p> <p>Name of medicine: SEPTOLETE LEMON LOZENGE</p> <p>Dosage form: LOZENGE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: CETYLPRYRIDINIUM 1,2 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BLISS PHARMACEUTICALS cc</p> <p>Manufacturer: KRKA d.d., NOVO MESTO, SLOVENIA</p> <p>Packer: KRKA d.d., NOVO MESTO, SLOVENIA</p> <p>Laboratory: FPRC: M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: BLISS PHARMACEUTICALS c. WOODMEAD, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/16.4/0810</p> <p>Name of medicine: SEPTOLETE APPLE LOZENGE</p> <p>Dosage form: LOZENGE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: CETYLPRYRIDINIUM 1,2 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: BLISS PHARMACEUTICALS cc</p> <p>Manufacturer: KRKA d.d., NOVO MESTO, SLOVENIA</p> <p>Packer: KRKA d.d., NOVO MESTO, SLOVENIA</p> <p>Laboratory: FPRC: M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: BLISS PHARMACEUTICALS c. WOODMEAD, JOHANNESBURG, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 45/34/1025</p> <p>Name of medicine: REBIF 22 MULTIDOSE</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH PRE FILLED CONTAINS: INTERFERON BETA-1 a 1.5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MERCK (PTY) LTD</p> <p>Manufacturer: MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND</p> <p>Packer: MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND</p> <p>Laboratory: FPRC: MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND</p> <p>FPRR: MERCK (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/34/1026</p> <p>Name of medicine: REBIF 44 MULTIDOSE</p> <p>Dosage form: SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH PRE FILLED CONTAINS: INTERFERON BETA-1 a 1.5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: MERCK (PTY) LTD</p> <p>Manufacturer: MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND</p> <p>Packer: MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND</p> <p>Laboratory: FPRC: MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND</p> <p>FPRR: MERCK (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/15.4/1080</p> <p>Name of medicine: GOZOPT</p> <p>Dosage form: EYE DROPS</p> <p>Active ingredients: EACH DROP CONTAINS: DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 5.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: CIPLA MEDPRO (PTY) LTD</p> <p>Manufacturer: CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA</p> <p>Packer: CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA</p> <p>Laboratory: FPRC: CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA</p> <p>FPRR: CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF-15	MRF-15	MRF-15
<p>Registration number: 45/26/0212</p> <p>Name of medicine: OPLAXIN 50 mg</p> <p>Dosage form: CONCENTRATE SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH 50 mg SOLUTION CONTAINS: OXALIPLATIN 50,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 45/26/0213</p> <p>Name of medicine: OPLAXIN 100 mg</p> <p>Dosage form: CONCENTRATE SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH 50 mg SOLUTION CONTAINS: OXALIPLATIN 100,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: ACCORD HEALTHCARE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 46/7_3/0217</p> <p>Name of medicine: RIZATRIPTAN MYLAN ODT 5 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RIZATRIPTAN BENZOATE EQUIVALENT TO RIZATRIPTAN 5,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</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 (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 467.3/0218</p> <p>Name of medicine: RIZATRIPTAN MYLAN ODT 10 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: RIZATRIPTAN BENZOATE EQUIVALENT TO RIZATRIPTAN 10.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</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 (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 465.3/0404</p> <p>Name of medicine: NEPIZEL 5</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</p> <p>Applicant: UNICHEM SA (PTY) LTD</p> <p>Manufacturer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA</p> <p>Packer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA</p> <p>Laboratory: FPRC: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENGAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 465.3/0405</p> <p>Name of medicine: NEPIZEL 10</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</p> <p>Applicant: UNICHEM SA (PTY) LTD</p> <p>Manufacturer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA</p> <p>Packer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA</p> <p>Laboratory: FPRC: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENGAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 46/34/0696</p> <p>Name of medicine: AFINITOR 2.5 mg</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: EVEROLIMUS 2.5 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: NOVARTIS PHARMA AG, BASEL, SWITZERLAND NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND</p> <p>Packer: NOVARTIS PHARMA AG, BASEL, SWITZERLAND NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND ALLPACK GROUP AG, REINACH, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND PROMLOG AG, PRATTELN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA DRA PHARMACEUTICALS cc, IRENE, CENTURION, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA</p> <p>Laboratory: FPRC</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 46/5.3/0407</p> <p>Name of medicine: DONEPEZIL UNICHEM 10 mg</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</p> <p>Applicant: UNICHEM SA (PTY) LTD</p> <p>Manufacturer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA</p> <p>Packer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA</p> <p>Laboratory: FPRC</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 46/5.3/0406</p> <p>Name of medicine: DONEPEZIL UNICHEM 5 mg</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</p> <p>Applicant: UNICHEM SA (PTY) LTD</p> <p>Manufacturer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA</p> <p>Packer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA</p> <p>Laboratory: FPRC</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 48/20.1.1/0814</p> <p>Name of medicine: CEFALXIN ASCENDIS 250</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: CEFALXIN MONOHYDRATE EQUIVALENT TO CEFALXIN 250,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA</p> <p>Packer: ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA</p> <p>Laboratory: FPRC: ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 48/20.1.1/0815</p> <p>Name of medicine: CEFALXIN ASCENDIS 500</p> <p>Dosage form: CAPSULE</p> <p>Active ingredients: EACH CAPSULE CONTAINS: CEFALXIN MONOHYDRATE EQUIVALENT TO CEFALXIN 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA</p> <p>Packer: ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA</p> <p>Laboratory: FPRC: ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 48/32.2/1152</p> <p>Name of medicine: IMUGRAFT 500</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: INGWE LIFESCIENCE (PTY) LTD</p> <p>Manufacturer: INTAS PHARMACEUTICALS LIMITED, MATODA, GUJARAT, INDIA INTAS PHARMA LTD, VILLAGE MATODA, AHMEDABAD, GUJARAT, INDIA</p> <p>Packer: INTAS PHARMACEUTICALS LIMITED, MATODA, GUJARAT, INDIA INTAS PHARMA LTD, VILLAGE MATODA, AHMEDABAD, GUJARAT, INDIA</p> <p>Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, MATODA, GUJARAT, INDIA INTAS PHARMA LTD, VILLAGE MATODA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA SPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: INGWE LIFESCIENCE (PTY) LTD, MOOI RIVER, KWAZULU NATAL, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 49/20.1/0171</p> <p>Name of medicine: COTRIMOX ASCENDIS DS</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: SULFAMETHOXAZOLE 800.0 mg TRIMETHOPRIM 100.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA</p> <p>Manufacturer: SVIZERA LABS LTD., TURBHE, NAVI MUMBAI, INDIA</p> <p>Packer: SVIZERA LABS LTD., TURBHE, NAVI MUMBAI, INDIA</p> <p>Laboratory: FPRC: SVIZERA LABS LTD., TURBHE, NAVI MUMBAI, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA</p> <p>FPRR: DEZZO TRADING 392 (PTY) LTD, T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 49/20.1/10899</p> <p>Name of medicine: LINZAI IV</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: LINEZOLID 2.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: PHARMA DYNAMICS (PTY) LTD</p> <p>Manufacturer: CLARIS INJECTABLES LIMITED, CHACHARWADI-VASANA, AHMEDABAD, INDIA</p> <p>Packer: CLARIS INJECTABLES LIMITED, CHACHARWADI-VASANA, AHMEDABAD, INDIA PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA</p> <p>Laboratory: FPRC: CLARIS INJECTABLES LIMITED, CHACHARWADI-VASANA, AHMEDABAD, INDIA PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMADOX HEALTHCARE LTD, PAOLA PLA, MALTA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&amp;L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</p> <p>FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: 49/26/1045</p> <p>Name of medicine: CAPECITABINE SPECIPHARM 150</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CAPECITABINE 150.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SPECIPHARM (PTY) LTD</p> <p>Manufacturer: REMEDICA LTD, LIMASSOL, CYPRUS</p> <p>Packer: REMEDICA LTD, LIMASSOL, CYPRUS SPECIPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: REMEDICA LTD, LIMASSOL, CYPRUS SPECIPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</p> <p>FPRR: SPECIPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>

MRF 15	MRF 15	MRF 15
<p>Registration number: 49/26/1046</p> <p>Name of medicine: CAPECITABINE SPECPHARM 500</p> <p>Dosage form: TABLET</p> <p>Active ingredients: EACH TABLET CONTAINS: CAPECITABINE 500.0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SPECPHARM (PTY) LTD</p> <p>Manufacturer: REMEDICA LTD, LIMASSOL, CYPRUS</p> <p>Packer: REMEDICA LTD, LIMASSOL, CYPRUS SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Laboratory: FPRC: REMEDICA LTD, LIMASSOL, CYPRUS SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>FPRC: SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 36 months</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: A39/20.1.1/0166</p> <p>Name of medicine: CEFUROXIME FRESENIUS 750 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFUROXIME SODIUM 750,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: FRESENIUS KABI SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Packer: SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA</p> <p>Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA</p> <p>FPRC: FRESENIUS KABI SOUTH (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>	<p>Registration number: A39/20.1.1/0167</p> <p>Name of medicine: CEFUROXIME FRESENIUS 1 500 mg</p> <p>Dosage form: POWDER FOR SOLUTION FOR INJECTION</p> <p>Active ingredients: EACH VIAL CONTAINS: CEFUROXIME SODIUM 1 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8</p> <p>Applicant: FRESENIUS KABI SOUTH AFRICA (PTY) LTD</p> <p>Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA</p> <p>Packer: SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA</p> <p>Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA</p> <p>FPRC: FRESENIUS KABI SOUTH (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA</p> <p>Shelf-life: 24 months (provisional)</p> <p>Date of registration: 09 JUNE 2016</p>



MRF 15

Registration number:	A39/20.1.1/0175	Registration number:		Registration number:	
Name of medicine:	CEFUROXIME FRESENIUS 250 mg	Name of medicine:		Name of medicine:	
Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:		Dosage form:	
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM 250.0 mg	Active ingredients:		Active ingredients:	
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:		Conditions of registration:	
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD	Applicant:		Applicant:	
Manufacturer:	SANDOZ GmbH, KUNDL, AUSTRIA	Manufacturer:		Manufacturer:	
Packer:	SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA	Packer:		Packer:	
Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA	Laboratory: FPRC:		Laboratory: FPRC:	
FPRR:	FRESENIUS KABI SOUTH (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRR:		FPRR:	
Shelf-life:	24 months (provisional)	Shelf-life:		Shelf-life:	
Date of registration:	09 JUNE 2016	Date of registration:		Date of registration:	





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