

**NOTICE 407 OF 2014****MEDICINES CONTROL COUNCIL****CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS  
OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965  
(ACT 101 OF 1965)**

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

| MRF 15                      |                                                                                                                                          | MRF 15                      |                                                                                                                                          |
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| Registration number:        | 06/17.1.6/07                                                                                                                             | Registration number:        | 47/26/0918                                                                                                                               |
| Name of medicine:           | MRCOBYL 10 %/                                                                                                                            | Name of medicine:           | ZALZEN 200 mg/8 ml                                                                                                                       |
| Dosage form:                | INJECTION                                                                                                                                | Dosage form:                | CONCENTRATE FOR SOLUTION FOR INFUSION                                                                                                    |
| Active ingredients:         | EACH 1.0 ml SOLUTION CONTAINS: MARBOFLOXSCIN 100.0 mg                                                                                    | Active ingredients:         | EACH VIAL CONTAINS: AFLIBERCEPT 200.0 mg                                                                                                 |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                                                                                      | Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                                                                                      |
| Applicant:                  | AFRIVET LOGISTICS(PTY) LTD                                                                                                               | Applicant:                  | WINTHROP PHARMACEUTICALS(PTY) LTD                                                                                                        |
| Manufacturer:               | VETOQUINOL, LURE, CEDEX, FRANCE                                                                                                          | Manufacturer:               | SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY                                                                              |
| Packer:                     | SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY                                                                              | Packer:                     | SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY                                                                              |
| Laboratory: FPRC:           | SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY<br>SA NATIONAL CONTROL LABORATORY FOR BIOLOGICAL PRODUCTS, BLOENFONTEIN, RSA | Laboratory: FPRC:           | SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY<br>SA NATIONAL CONTROL LABORATORY FOR BIOLOGICAL PRODUCTS, BLOENFONTEIN, RSA |
| FPRR:                       | WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA<br>SANOFI-AVENTIS SOUTH AFRICA(PTY) LTD, MIDRAND, RSA                         | FPRR:                       | WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA<br>SANOFI-AVENTIS SOUTH AFRICA(PTY) LTD, MIDRAND, RSA                         |
| Shelf-life:                 | 36 months                                                                                                                                | Shelf-life:                 | 36 months                                                                                                                                |
| Date of registration:       | 10 APRIL 2014                                                                                                                            | Date of registration:       | 10 APRIL 2014                                                                                                                            |

| MRF 15                      |                                                                           | MRF 15                      |                                                                                                     | MRF 15                      |                                                                                                     |
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| Registration number:        | 47/26/0917                                                                | Registration number:        | 46/2.6/5/0085                                                                                       | Registration number:        | 46/2.6/5/0084                                                                                       |
| Name of medicine:           | ZALZEN 100 mg/4 ml                                                        | Name of medicine:           | SPEC QUETIAPINE 300                                                                                 | Name of medicine:           | SPEC QUETIAPINE 200                                                                                 |
| Dosage form:                | CONCENTRATE FOR INFUSION SOLUTION                                         | Dosage form:                | TABLET                                                                                              | Dosage form:                | TABLET                                                                                              |
| Active ingredients:         | EACH VIAL CONTAINS: AFLIBERCEPT 100,0 mg                                  | Active ingredients:         | EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO 300,0 mg                                    | Active ingredients:         | EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO 200,0 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:                  | WINTHROP PHARMACEUTICALS(PTY) LTD                                         | Applicant:                  | SPECPHARM (PTY) LTD                                                                                 | Applicant:                  | SPECPHARM (PTY) LTD                                                                                 |
| Manufacturer:               | SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY               | Manufacturer:               | GENEPHARM SA, PALLINI, GREECE                                                                       | Manufacturer:               | GENEPHARM SA, PALLINI, GREECE                                                                       |
| Packer:                     | SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY               | Packer:                     | GENEPHARM SA, PALLINI, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA             | Packer:                     | GENEPHARM SA, PALLINI, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA             |
| Laboratory: FPRC:           | SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY               | Laboratory: FPRC:           | GENEPHARM SA, PALLINI, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA | Laboratory: FPRC:           | GENEPHARM SA, PALLINI, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA |
| FPRC:                       | SA NATIONAL CONTROL LABORATORY FOR BIOLOGICAL PRODUCTS, BLOENFONTEIN, RSA | FPRC:                       | SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA                                                    | FPRC:                       | SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA                                                    |
| Shelf-life:                 | 36 months                                                                 | Shelf-life:                 | 24 months                                                                                           | Shelf-life:                 | 24 months                                                                                           |
| Date of registration:       | 10 APRIL 2014                                                             | Date of registration:       | 10 APRIL 2014                                                                                       | Date of registration:       | 10 APRIL 2014                                                                                       |

| MRF 15                      |                                                                             | MRF 15                      |                                                                             | MRF 15                      |                                                                             |
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| Registration number:        | 46/2.6/5/0083                                                               | Registration number:        | 46/2.6/5/0082                                                               | Registration number:        | 46/2.6/5/0081                                                               |
| Name of medicine:           | SPEC QUETIAPINE 150                                                         | Name of medicine:           | SPEC QUETIAPINE 100                                                         | Name of medicine:           | SPEC QUETIAPINE 25                                                          |
| Dosage form:                | TABLET                                                                      | Dosage form:                | TABLET                                                                      | Dosage form:                | TABLET                                                                      |
| Active ingredients:         | EACH TABLET CONTAINS:<br>QUETIAPINE FUMARATE<br>EQUIVALENT TO 150.0 mg      | Active ingredients:         | EACH TABLET CONTAINS:<br>QUETIAPINE FUMARATE<br>EQUIVALENT TO 100.0 mg      | Active ingredients:         | EACH TABLET CONTAINS:<br>QUETIAPINE FUMARATE<br>EQUIVALENT TO 25.0 mg       |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                         | Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                         | Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                         |
| Applicant:                  | SPECPHARM (PTY) LTD                                                         | Applicant:                  | SPECPHARM (PTY) LTD                                                         | Applicant:                  | SPECPHARM (PTY) LTD                                                         |
| Manufacturer:               | GENEPHARM SA, PALLINI,<br>GREECE                                            | Manufacturer:               | GENEPHARM SA, PALLINI,<br>GREECE                                            | Manufacturer:               | GENEPHARM SA, PALLINI,<br>GREECE                                            |
| Packer:                     | GENEPHARM SA, PALLINI,<br>GREECE                                            | Packer:                     | GENEPHARM SA, PALLINI,<br>GREECE                                            | Packer:                     | GENEPHARM SA, PALLINI,<br>GREECE                                            |
|                             | SPECPHARM HOLDINGS (PTY)<br>LTD, HALFWAY HOUSE,<br>MIDRAND, RSA             |                             | SPECPHARM HOLDINGS (PTY)<br>LTD, HALFWAY HOUSE,<br>MIDRAND, RSA             |                             | SPECPHARM HOLDINGS (PTY)<br>LTD, HALFWAY HOUSE,<br>MIDRAND, RSA             |
| Laboratory:                 | FPRC:                                                                       | Laboratory:                 | FPRC:                                                                       | Laboratory:                 | FPRC:                                                                       |
|                             | GENEPHARM SA, PALLINI,<br>GREECE                                            |                             | GENEPHARM SA, PALLINI,<br>GREECE                                            |                             | GENEPHARM SA, PALLINI,<br>GREECE                                            |
|                             | CONSULTING CHEMICAL<br>LABORATORIES (PTY) LTD,<br>ATLASVILLE, BOKSBURG, RSA |                             | CONSULTING CHEMICAL<br>LABORATORIES (PTY) LTD,<br>ATLASVILLE, BOKSBURG, RSA |                             | CONSULTING CHEMICAL<br>LABORATORIES (PTY) LTD,<br>ATLASVILLE, BOKSBURG, RSA |
|                             | SPECPHARM HOLDINGS (PTY)<br>LTD, HALFWAY HOUSE, MIDRAND,<br>RSA             |                             | SPECPHARM HOLDINGS (PTY)<br>LTD, HALFWAY HOUSE,<br>MIDRAND, RSA             |                             | SPECPHARM HOLDINGS (PTY)<br>LTD, HALFWAY HOUSE,<br>MIDRAND, RSA             |
| FPRR:                       | SPECPHARM (PTY) LTD,<br>HALFWAY HOUSE, MIDRAND, RSA                         | FPRR:                       | SPECPHARM (PTY) LTD,<br>HALFWAY HOUSE, MIDRAND,<br>RSA                      | FPRR:                       | SPECPHARM (PTY) LTD,<br>HALFWAY HOUSE, MIDRAND,<br>RSA                      |
| Shelf-life:                 | 24 months                                                                   | Shelf-life:                 | 24 months                                                                   | Shelf-life:                 | 24 months                                                                   |
| Date of registration:       | 10 APRIL 2014                                                               | Date of registration:       | 10 APRIL 2014                                                               | Date of registration:       | 10 APRIL 2014                                                               |

| MRF 15                      |                                                                                                                                                                                                                                         | MRF 15                      |                                                                                                                                                                                                                                        | MRF 15                      |                                                                                                                                                                                                                                              |
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| Registration number:        | 43/21.2/0669                                                                                                                                                                                                                            | Registration number:        | 43/7.1.5/0984                                                                                                                                                                                                                          | Registration number:        | 43/7.1.5/0983                                                                                                                                                                                                                                |
| Name of medicine:           | MYLAN METFORMIN 1 000 mg                                                                                                                                                                                                                | Name of medicine:           | VITRIXA 100                                                                                                                                                                                                                            | Name of medicine:           | VITRIXA 50                                                                                                                                                                                                                                   |
| Dosage form:                | TABLET                                                                                                                                                                                                                                  | Dosage form:                | TABLET                                                                                                                                                                                                                                 | Dosage form:                | TABLET                                                                                                                                                                                                                                       |
| Active ingredients:         | EACH TABLET CONTAINS:<br>METFORMIN HYDROCHLORIDE<br>1 000,0 mg                                                                                                                                                                          | Active ingredients:         | EACH TABLET CONTAINS:<br>SILDENAFIL CITRATE EQUIVALENT TO<br>SILDENAFIL 100,0 mg                                                                                                                                                       | Active ingredients:         | EACH TABLET CONTAINS:<br>SILDENAFIL CITRATE<br>EQUIVALENT TO SILDENAFIL<br>50,0 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:                  | MYLAN (PTY) LTD                                                                                                                                                                                                                         | Applicant:                  | LASARA TRADERS (PTY) LTD                                                                                                                                                                                                               | Applicant:                  | LASARA TRADERS (PTY) LTD                                                                                                                                                                                                                     |
| Manufacturer:               | MATRIX LABORATORIES LIMITED,<br>SINNAR, NASHIK, MAHARASHTRA,<br>INDA                                                                                                                                                                    | Manufacturer:               | UNICHEM LABORATORIES LIMITED,<br>PILERNE, GOA, INDIA                                                                                                                                                                                   | Manufacturer:               | UNICHEM LABORATORIES<br>LIMITED, PILERNE, GOA, INDIA                                                                                                                                                                                         |
| Packer:                     | MATRIX LABORATORIES LIMITED,<br>SINNAR, NASHIK, MAHARASHTRA,<br>INDA                                                                                                                                                                    | Packer:                     | UNICHEM LABORATORIES LIMITED,<br>PILERNE, GOA, INDIA<br>PENDOPHARM Inc (Division of<br>Pharmascience Inc), MONTREAL,<br>QUEBEC, CANADA<br>ROPACK Inc, MONTREAL, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD,<br>HALFWAY HOUSE, MIDRAND, RSA | Packer:                     | UNICHEM LABORATORIES<br>LIMITED, PILERNE, GOA, INDIA<br>PENDOPHARM Inc (Division of<br>Pharmascience Inc), MONTREAL,<br>QUEBEC, CANADA<br>ROPACK Inc, MONTREAL,<br>CANADA<br>SPECPHARM HOLDINGS (PTY)<br>LTD, HALFWAY HOUSE,<br>MIDRAND, RSA |
| Laboratory:                 | FPRC :<br>MATRIX LABORATORIES LIMITED,<br>SINNAR, NASHIK, MAHARASHTRA,<br>INDA<br>ACORN PHARMACEUTICALS (PTY)<br>LTD, NORTH RIDING,<br>JOHANNESBURG, RSA<br>CONSULTING CHEMICAL<br>LABORATORIES (PTY) LTD,<br>ATLASVILLE, BOKSBURG, RSA | Laboratory:                 | FPRC:<br>UNICHEM LABORATORIES LIMITED,<br>PILERNE, GOA, INDIA<br>PHARMASCIENCE Inc, MONTREAL,<br>QUEBEC, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD,<br>HALFWAY HOUSE, MIDRAND, RSA                                                        | Laboratory:                 | FPRC<br>UNICHEM LABORATORIES<br>LIMITED, PILERNE, GOA, INDIA<br>PHARMASCIENCE Inc,<br>MONTREAL, QUEBEC, CANADA<br>SPECPHARM HOLDINGS (PTY)<br>LTD, HALFWAY HOUSE,<br>MIDRAND, RSA                                                            |
| FPRR:                       | MYLAN (PTY) LTD, MODDERFONTEIN,<br>GAUTENG, RSA                                                                                                                                                                                         | FPRR:                       | LASARA TRADERS (PTY) LTD,<br>MORELETA PARK, PRETORIA, RSA                                                                                                                                                                              | FPRR:                       | LASARA TRADERS (PTY) LTD,<br>MORELETA PARK, PRETORIA,<br>RSA                                                                                                                                                                                 |
| Shelf-life:                 | 24 months                                                                                                                                                                                                                               | Shelf-life:                 | 24 months                                                                                                                                                                                                                              | Shelf-life:                 | 24 months                                                                                                                                                                                                                                    |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                           | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                          | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                |

| MRF 15                      |                                                                                                                                                                                                                            | MRF 15                      |                                                                                                                                                                                                                            | MRF 15                      |                                                                                                                                                                                                                            |
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| Registration number:        | 43/7.1.5/0982                                                                                                                                                                                                              | Registration number:        | 43/7.1.5/0981                                                                                                                                                                                                              | Registration number:        | 43/7.1.5/0980                                                                                                                                                                                                              |
| Name of medicine:           | VITRIXA 25                                                                                                                                                                                                                 | Name of medicine:           | VIDENA 100                                                                                                                                                                                                                 | Name of medicine:           | VIDENA 50                                                                                                                                                                                                                  |
| Dosage form:                | TABLET                                                                                                                                                                                                                     | Dosage form:                | TABLET                                                                                                                                                                                                                     | Dosage form:                | TABLET                                                                                                                                                                                                                     |
| Active ingredients:         | EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 25,0 mg                                                                                                                                                  | Active ingredients:         | EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 100,0 mg                                                                                                                                                 | Active ingredients:         | EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 50,0 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:                  | LASARA TRADERS (PTY) LTD                                                                                                                                                                                                   | Applicant:                  | LASARA TRADERS (PTY) LTD                                                                                                                                                                                                   | Applicant:                  | LASARA TRADERS (PTY) LTD                                                                                                                                                                                                   |
| Manufacturer:               | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA                                                                                                                                                                          | Manufacturer:               | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA                                                                                                                                                                          | Manufacturer:               | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA                                                                                                                                                                          |
| Packer:                     | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA<br>PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA<br>ROPACK Inc, MONTREAL, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA | Packer:                     | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA<br>PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA<br>ROPACK Inc, MONTREAL, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA | Packer:                     | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA<br>PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA<br>ROPACK Inc, MONTREAL, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA |
| Laboratory: FPRC:           | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA<br>PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA                                                              | Laboratory: FPRC:           | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA<br>PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA                                                              | Laboratory: FPRC:           | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA<br>PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA                                                              |
| FPRR:                       | LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA                                                                                                                                                                     | FPRR:                       | LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA                                                                                                                                                                     | FPRR:                       | LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA                                                                                                                                                                     |
| Shelf-life:                 | 24 months                                                                                                                                                                                                                  | Shelf-life:                 | 24 months                                                                                                                                                                                                                  | Shelf-life:                 | 24 months                                                                                                                                                                                                                  |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                              | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                              | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                              |

| MRF 15                      |                                                                                                                                                                                                                            | MRF 15                      |                                                                                                                                                                                                                                                        | MRF 15                      |                                                                                                                                                                                                                                                        |
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| Registration number:        | 43/7.1.5/0979                                                                                                                                                                                                              | Registration number:        | 43/5.10/0762                                                                                                                                                                                                                                           | Registration number:        | 43/5.10/0761                                                                                                                                                                                                                                           |
| Name of medicine:           | VIDENA 25                                                                                                                                                                                                                  | Name of medicine:           | ENTRAN INJECTION 4 mg/2 ml1                                                                                                                                                                                                                            | Name of medicine:           | ARROW ONDANSETRON INJECTION 4 mg/2 ml1                                                                                                                                                                                                                 |
| Dosage form:                | TABLET                                                                                                                                                                                                                     | Dosage form:                | INJECTION                                                                                                                                                                                                                                              | Dosage form:                | INJECTION                                                                                                                                                                                                                                              |
| Active ingredients:         | EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 25.0 mg                                                                                                                                                  | Active ingredients:         | EACH VIAL CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4.0 mg                                                                                                                                                               | Active ingredients:         | EACH VIAL CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 4.0 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:                  | LASARA TRADERS (PTY) LTD                                                                                                                                                                                                   | Applicant:                  | ARROW PHARMA SOUTH AFRICA (PTY) LTD                                                                                                                                                                                                                    | Applicant:                  | ARROW PHARMA SOUTH AFRICA (PTY) LTD                                                                                                                                                                                                                    |
| Manufacturer:               | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA                                                                                                                                                                          | Manufacturer:               | EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA                                                                                                                                                                                                  | Manufacturer:               | EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA                                                                                                                                                                                                  |
| Packer:                     | UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA<br>PENDOPHARM Inc (Division of Pharmascience Inc), MONTREAL, QUEBEC, CANADA<br>ROPACK Inc, MONTREAL, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA | Packer:                     | EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA                                                      | Packer:                     | EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA                                                      |
| Laboratory:                 | FPRC:<br>UNICHEM LABORATORIES LIMITED, PILERNE, GOA, INDIA<br>PHARMASCIENCE Inc, MONTREAL, QUEBEC, CANADA<br>SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA                                                     | Laboratory:                 | FPRC:<br>EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA<br>SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA | Laboratory:                 | FPRC:<br>EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA<br>SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA |
| FPRC:                       | LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA                                                                                                                                                                     | FPRC:                       | ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA                                                                                                                                                                         | FPRC:                       | ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA                                                                                                                                                                         |
| Shelf-life:                 | 24 months                                                                                                                                                                                                                  | Shelf-life:                 | 24 months                                                                                                                                                                                                                                              | Shelf-life:                 | 24 months                                                                                                                                                                                                                                              |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                              | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                          | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                          |

| MRF 15                      | MRF 15                                                                                                                                                                                                                                                                                                                                                                                  | MRF 15                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Registration number:        | 43/1.2/0699                                                                                                                                                                                                                                                                                                                                                                             | 43/1.2/0698                                                                                                                                                                                                                                                                                                                                                                  |
| Name of medicine:           | BIOTECH TRAZODONE 100                                                                                                                                                                                                                                                                                                                                                                   | BIOTECH TRAZODONE 50                                                                                                                                                                                                                                                                                                                                                         |
| Dosage form:                | CAPSULE                                                                                                                                                                                                                                                                                                                                                                                 | CAPSULE                                                                                                                                                                                                                                                                                                                                                                      |
| Active ingredients:         | EACH CAPSULE CONTAINS: TRAZODONE HYDROCHLORIDE 100,0 mg                                                                                                                                                                                                                                                                                                                                 | EACH CAPSULE CONTAINS: TRAZODONE HYDROCHLORIDE 50,0 mg                                                                                                                                                                                                                                                                                                                       |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                                                                                                                                                                                                                                                                                                                                     | 1, 2, 3, 4, 5, 6, 7                                                                                                                                                                                                                                                                                                                                                          |
| Applicant:                  | BIOTECH LABORATORIES (PTY) LTD                                                                                                                                                                                                                                                                                                                                                          | BIOTECH LABORATORIES (PTY) LTD                                                                                                                                                                                                                                                                                                                                               |
| Manufacturer:               | RIVOPHARM SA, MANNO, SWITZERLAND                                                                                                                                                                                                                                                                                                                                                        | RIVOPHARM SA, MANNO, SWITZERLAND                                                                                                                                                                                                                                                                                                                                             |
| Packer:                     | RIVOPHARM SA, MANNO, SWITZERLAND                                                                                                                                                                                                                                                                                                                                                        | RIVOPHARM SA, MANNO, SWITZERLAND                                                                                                                                                                                                                                                                                                                                             |
| Laboratory: FPRC:           | RIVOPHARM SA, MANNO, SWITZERLAND<br>INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD,<br>(PTY) LTD, SILVERTONDALE, PRETORIA, RSA<br>M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA<br>CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA | RIVOPHARM SA, MANNO, SWITZERLAND<br>INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD,<br>SILVERTONDALE, PRETORIA, RSA<br>M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA<br>CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA |
| FPRR:                       | BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA                                                                                                                                                                                                                                                                                                                                | BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA                                                                                                                                                                                                                                                                                                                     |
| Shelf-life:                 | 36 months                                                                                                                                                                                                                                                                                                                                                                               | 36 months                                                                                                                                                                                                                                                                                                                                                                    |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                                                                                                                                                           | 10 APRIL 2014                                                                                                                                                                                                                                                                                                                                                                |

  

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| Registration number:        | 43/20.1.1/0238                                                                                                                                                                                 |
| Name of medicine:           | SANDOZ LEVOFLOXACIN 500 mg/100 ml                                                                                                                                                              |
| Dosage form:                | SOLUTION FOR INFUSION                                                                                                                                                                          |
| Active ingredients:         | EACH VIAL CONTAINS: LEVOFLOXACIN 500,0 mg                                                                                                                                                      |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                                                                                                                                            |
| Applicant:                  | SANDOZ SA (PTY) LTD                                                                                                                                                                            |
| Manufacturer:               | SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA                                                                                                                                                |
| Packer:                     | SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA<br>SANDAZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA                                                                                             |
| Laboratory: FPRC:           | SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA<br>SANDAZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA<br>SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA |
| FPRR:                       | SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA                                                                                                                                                |
| Shelf-life:                 | 24 months                                                                                                                                                                                      |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                  |

| MRF 15                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | MRF 15                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | MRF 15                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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| <p>Registration number: 43/20.1.1/0233</p> <p>Name of medicine: SANDOZ LEVOFLOXACIN 250 mg/50 ml</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: LEVOFLOXACIN 250,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Packer: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Laboratory: FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 10 APRIL 2014</p> | <p>Registration number: 43/20.1.1/0232</p> <p>Name of medicine: LEVONIC 500 mg/100 ml</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: LEVOFLOXACIN 500,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Packer: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Laboratory: FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 10 APRIL 2014</p> | <p>Registration number: 43/20.1.1/0231</p> <p>Name of medicine: LEVONIC 250 mg/500 ml</p> <p>Dosage form: SOLUTION FOR INFUSION</p> <p>Active ingredients: EACH VIAL CONTAINS: LEVOFLOXACIN 250,0 mg</p> <p>Conditions of registration: 1, 2, 3, 4, 5, 6, 7</p> <p>Applicant: SANDOZ SA (PTY) LTD</p> <p>Manufacturer: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Packer: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Laboratory: FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA</p> <p>Shelf-life: 24 months</p> <p>Date of registration: 10 APRIL 2014</p> |

| MRF 15                      |                                                                   | MRF 15                      |                                                                                                                                                                                  | MRF 15                      |                                                                 |
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| Registration number:        | 36/28/0137                                                        | Registration number:        | A40/32.5/0648                                                                                                                                                                    | Registration number:        | 46/20.2.8/0038                                                  |
| Name of medicine:           | ULTRAVIST 240 10 ml                                               | Name of medicine:           | HYLO-MAX EYE DROPS SOLUTION                                                                                                                                                      | Name of medicine:           | ALVIR 50 mg/5 ml                                                |
| Dosage form:                | SOLUTION FOR INJECTION                                            | Dosage form:                | SOLUTION                                                                                                                                                                         | Dosage form:                | ORAL SUSPENSION                                                 |
| Active ingredients:         | EACH VIAL CONTAINS:<br>IOPROMIDE EQUIVALENT TO<br>IODINE 240,0 mg | Active ingredients:         | EACH 1,0 ml SOLUTION CONTAINS:<br>SODIUM HYALURONATE 1,0 mg                                                                                                                      | Active ingredients:         | EACH 5,0 ml SUSPENSION CONTAINS:<br>NEVIRAPINE 50,0 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:                  | BAYER (PTY) LTD                                                   | Applicant:                  | PHARMAFRICA (PTY) LTD                                                                                                                                                            | Applicant:                  | INGELHEIM PHARMACEUTICALS (PTY) LTD                             |
| Manufacturer:               | BAYER SCHERING PHARMA AG,<br>BERLIN, GERMANY                      | Manufacturer:               | URSAPHARM ARZNEIMITTEL GmbH &<br>Co. KG, SARBRUCKEN, GERMANY                                                                                                                     | Manufacturer:               | BOEHRINGER INGELHEIM ROXANE INC,<br>WILSON ROAD, COLUMBUS, OHIO |
| Packer:                     | BAYER SCHERING PHARMA AG,<br>BERLIN, GERMANY                      | Packer:                     | URSAPHARM ARZNEIMITTEL GmbH &<br>Co. KG, SARBRUCKEN, GERMANY                                                                                                                     | Packer:                     | BOEHRINGER INGELHEIM ROXANE INC,<br>WILSON ROAD, COLUMBUS, OHIO |
| Laboratory:                 | BAYER SCHERING PHARMA AG,<br>BERLIN, GERMANY                      | Laboratory:                 | URSAPHARM ARZNEIMITTEL GmbH &<br>Co. KG, SARBRUCKEN, GERMANY                                                                                                                     | Laboratory:                 | BOEHRINGER INGELHEIM ROXANE INC,<br>WILSON ROAD, COLUMBUS, OHIO |
| FPRC:                       |                                                                   | FPRC:                       | SABS COMMERCIAL (PTY) LTD<br>PHARMACEUTICAL CHEMISTRY<br>DEPARTMENT, GROENKLOOF,<br>PRETORIA, RSA<br>CONSULTING CHEMICAL<br>LABORATORIES (PTY) LTD,<br>ATLASVILLE, BOKSBURG, RSA | FPRC:                       | BOEHRINGER INGELHEIM ROXANE INC,<br>WILSON ROAD, COLUMBUS, OHIO |
| Shelf-life:                 | 24 months                                                         | Shelf-life:                 | 36 months                                                                                                                                                                        | Shelf-life:                 | 36 months                                                       |
| Date of registration:       | 10 APRIL 2014                                                     | Date of registration:       | 10 APRIL 2014                                                                                                                                                                    | Date of registration:       | 10 APRIL 2014                                                   |

| MRF 15                      |                                                                                                                                                                                                                                                                                                                                       | MRF 15                      |                                                                                                                                                                                                                                                                           | MRF 15                      |                                                                                                                                                                                                                                                                        |
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| Registration number:        | 46/20.2.8/0037                                                                                                                                                                                                                                                                                                                        | Registration number:        | 45/5.2/0791                                                                                                                                                                                                                                                               | Registration number:        | 45/5.2/0790                                                                                                                                                                                                                                                            |
| Name of medicine:           | ALVIR 200 mg TABLETS                                                                                                                                                                                                                                                                                                                  | Name of medicine:           | BISBETA 10 mg                                                                                                                                                                                                                                                             | Name of medicine:           | BISBETA 5 mg                                                                                                                                                                                                                                                           |
| Dosage form:                | TABLET                                                                                                                                                                                                                                                                                                                                | Dosage form:                | TABLET                                                                                                                                                                                                                                                                    | Dosage form:                | TABLET                                                                                                                                                                                                                                                                 |
| Active ingredients:         | EACH TABLET CONTAINS:<br>NEVIRAPINE 200.0 mg                                                                                                                                                                                                                                                                                          | Active ingredients:         | EACH TABLET CONTAINS:<br>BISOPROLOL FUMARATE<br>10.0 mg                                                                                                                                                                                                                   | Active ingredients:         | EACH TABLET CONTAINS:<br>BISOPROLOL FUMARATE<br>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:                  | INGELHEIM<br>PHARMACEUTICALS (PTY) LTD                                                                                                                                                                                                                                                                                                | Applicant:                  | AUROBINDO PHARMA (PTY)<br>LTD                                                                                                                                                                                                                                             | Applicant:                  | AUROBINDO PHARMA (PTY) LTD                                                                                                                                                                                                                                             |
| Manufacturer:               | BOEHRINGER INGELHEIM<br>ELLAS A.E., KOROPI, GREECE<br>BOEHRINGER INGELHEIM<br>PHARMA GmbH & Co. KG,<br>INGELHEIM/RIEHN, GERMANY                                                                                                                                                                                                       | Manufacturer:               | AUROBINDO PHARMA LIMITED,<br>UNIT III, QUTHUBULLAPUR<br>MANDAL, RANGA REDDY<br>DISTRICT, ANDHRA PRADESH,<br>INDIA                                                                                                                                                         | Manufacturer:               | AUROBINDO PHARMA LIMITED,<br>UNIT III, QUTHUBULLAPUR<br>MANDAL, RANGA REDDY DISTRICT,<br>ANDHRA PRADESH, INDIA                                                                                                                                                         |
| Packer:                     | BOEHRINGER INGELHEIM<br>ELLAS A.E., KOROPI, GREECE<br>BOEHRINGER INGELHEIM<br>PHARMA GmbH & Co. KG,<br>INGELHEIM/RIEHN, GERMANY                                                                                                                                                                                                       | Packer:                     | AUROBINDO PHARMA LIMITED,<br>UNIT III, QUTHUBULLAPUR<br>MANDAL, RANGA REDDY<br>DISTRICT, ANDHRA PRADESH,<br>INDIA                                                                                                                                                         | Packer:                     | AUROBINDO PHARMA LIMITED,<br>UNIT III, QUTHUBULLAPUR<br>MANDAL, RANGA REDDY DISTRICT,<br>ANDHRA PRADESH, INDIA                                                                                                                                                         |
| Laboratory:                 | FPRC:<br>BOEHRINGER INGELHEIM<br>ELLAS A.E., KOROPI, GREECE<br>BOEHRINGER INGELHEIM<br>PHARMA GmbH & Co. KG,<br>INGELHEIM/RIEHN, GERMANY<br>RESEARCH INSTITUTE FOR<br>INDUSTRIAL PHARMACY<br>INCORPORATING CENQAM,<br>NORTH WEST UNIVERSITY,<br>POTCHEFSTROOM, RSA<br>WINTROP<br>PHARMACEUTICALS (PTY) LTD,<br>WALTLOO, PRETORIA, RSA | Laboratory:                 | FPRC:<br>AUROBINDO PHARMA LIMITED,<br>UNIT III, QUTHUBULLAPUR<br>MANDAL, RANGA REDDY<br>DISTRICT, ANDHRA PRADESH,<br>INDIA<br>M&L LABORATORY SERVICES<br>(PTY) LTD, ORMONDE,<br>JOHANNESBURG, RSA<br>KHULLEKANI LABORATORY<br>SERVICES cc, COVENTRY<br>PARK, MIDRAND, RSA | Laboratory:                 | FPRC:<br>AUROBINDO PHARMA LIMITED,<br>UNIT III, QUTHUBULLAPUR<br>MANDAL, RANGA REDDY DISTRICT,<br>ANDHRA PRADESH, INDIA<br>M&L LABORATORY SERVICES (PTY)<br>LTD, ORMONDE, JOHANNESBURG,<br>RSA<br>KHULLEKANI LABORATORY<br>SERVICES cc, COVENTRY PARK,<br>MIDRAND, RSA |
| Shelf-life:                 | 48 months                                                                                                                                                                                                                                                                                                                             | Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                                                                                                   | Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                                                                                                |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                                                                                                         | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                                             | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                                          |

| MRF 15                      |                                                                                                                                                                                                                                         | MRF 15                      |                                                                                                                                                                                                                                                                             | MRF 15                      |                                                                                                                                                                         |
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| Registration number:        | 45/5.2/0789                                                                                                                                                                                                                             | Registration number:        | 45/20.2.3/0518                                                                                                                                                                                                                                                              | Registration number:        | 44/8.2/1041                                                                                                                                                             |
| Name of medicine:           | BISBETA 2.5 mg                                                                                                                                                                                                                          | Name of medicine:           | DYNA ETHAMBUTOL 400 mg                                                                                                                                                                                                                                                      | Name of medicine:           | BRILINTA                                                                                                                                                                |
| Dosage form:                | TABLET                                                                                                                                                                                                                                  | Dosage form:                | TABLET                                                                                                                                                                                                                                                                      | Dosage form:                | TABLET                                                                                                                                                                  |
| Active ingredients:         | EACH TABLET CONTAINS: BISOPROLOL FUMARATE 2.5 mg                                                                                                                                                                                        | Active ingredients:         | EACH TABLET CONTAINS: ETHAMBUTOL HYDROCHLORIDE 400.0 mg                                                                                                                                                                                                                     | Active ingredients:         | EACH TABLET CONTAINS: TICAGRELOR 90.0 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:                  | AUROBINDO PHARMA (PTY) LTD                                                                                                                                                                                                              | Applicant:                  | PHARMA DYNAMICS (PTY) LTD                                                                                                                                                                                                                                                   | Applicant:                  | ASTRAZENECA PHARMACEUTICALS (PTY) LTD                                                                                                                                   |
| Manufacturer:               | AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA                                                                                                                                   | Manufacturer:               | LUPIN LIMITED, CHIKALTHANA, AURANGABAD, INDIA                                                                                                                                                                                                                               | Manufacturer:               | ASTRAZENECA AB, SODERTALJE, SWEDEN                                                                                                                                      |
| Packer:                     | AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA                                                                                                                                   | Packer:                     | LUPIN LIMITED, CHIKALTHANA, AURANGABAD, INDIA<br>DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA<br>PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, RSA | Packer:                     | ASTRAZENECA AB, SODERTALJE, SWEDEN<br>ASTRAZENECA UK LIMITED, MACCLESFIELD, CHESHIRE, UNITED KINGDOM<br>AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA |
| Laboratory: FPRC:           | AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA<br>M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA<br>KHULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA | Laboratory: FPRC:           | LUPIN LIMITED, CHIKALTHANA, AURANGABAD, INDIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA<br>M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA                  | Laboratory: FPRC:           | ASTRAZENECA AB, SODERTALJE, SWEDEN<br>ASTRAZENECA UK LIMITED, MACCLESFIELD, CHESHIRE, UNITED KINGDOM<br>CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA     |
| FPRR:                       | AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA                                                                                                                                                                                | FPRR:                       | PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA                                                                                                                                                                                                                         | FPRR:                       | ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, JOHANNESBURG, RSA                                                                                                   |
| Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                                                                 | Shelf-life:                 | 48 months )                                                                                                                                                                                                                                                                 | Shelf-life:                 | 24 months                                                                                                                                                               |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                           | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                                               | Date of registration:       | 10 APRIL 2014                                                                                                                                                           |

| MRF 15                      |                                                             | MRF 15                      |                                                      | MRF 15                      |                                                                         |
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| Registration number:        | 43/20.2.8/0355                                              | Registration number:        | 43/20.2.8/0353                                       | Registration number:        | 43/20.2.8/0226                                                          |
| Name of medicine:           | CIPLA EMTRICITABINE                                         | Name of medicine:           | MEDPRO EMTRICITABINE 200 mg                          | Name of medicine:           | APTIVUS 250 mg                                                          |
| Dosage form:                | CAPSULE                                                     | Dosage form:                | CAPSULE                                              | Dosage form:                | CAPSULE                                                                 |
| Active ingredients:         | EACH CAPSULE CONTAINS:<br>EMTRICITABINE 200,0 mg            | Active ingredients:         | EACH CAPSULE CONTAINS:<br>EMTRICITABINE 200,0 mg     | Active ingredients:         | EACH CAPSULE CONTAINS:<br>TIPRANAVIR 250,0 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:                  | CIPLA LIFE SCIENCES (PTY) LTD                               | Applicant:                  | CIPLA MEDPRO (PTY) LTD                               | Applicant:                  | INGELHEIM<br>PHARMACEUTICALS (PTY) LTD                                  |
| Manufacturer:               | CIPLA LTD, UNIT VII, VERNA, GOA,<br>INDIA                   | Manufacturer:               | CIPLA LTD, UNIT VII, VERNA, GOA,<br>INDIA            | Manufacturer:               | CATALENT PHARMA<br>SOLUTIONS, ST PETERSBURG,<br>FLORIDA, USA            |
| Packer:                     | CIPLA LTD, UNIT VII, VERNA, GOA,<br>INDIA                   | Packer:                     | CIPLA LTD, UNIT VII, VERNA, GOA,<br>INDIA            | Packer:                     | BOEHRINGER INGELHEIM<br>ROXANE Inc, WILSON ROAD,<br>COLUMBUS, OHIO, USA |
| Laboratory:                 | CIPLA LTD, UNIT VII, VERNA, GOA,<br>INDIA                   | Laboratory:                 | FPRC:                                                | Laboratory:                 | CATALENT PHARMA<br>SOLUTIONS, ST PETERSBURG,<br>FLORIDA, USA            |
| FPRC:                       | CIPLA LIFE SCIENCES (PTY) LTD,<br>ROSENPARK, BELLVILLE, RSA | FPRC:                       | CIPLA MEDPRO (PTY) LTD,<br>ROSENPARK, BELLVILLE, RSA | FPRC:                       | INGELHEIM<br>PHARMACEUTICALS (PTY)<br>LTD, FERNDALE, RANDBURG,<br>RSA   |
| Shelf-life:                 | 24 months                                                   | Shelf-life:                 | 24 months                                            | Shelf-life:                 | 36 months                                                               |
| Date of registration:       | 10 APRIL 2014                                               | Date of registration:       | 10 APRIL 2014                                        | Date of registration:       | 10 APRIL 2014                                                           |

MRF 15

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| Registration number:        | 417/5/0617                                                                                                                                                                                                                                                                                           | Registration number:        | 34/2.7/0290                                                                         | Registration number:        | A04/2.9/12                                                                                                                    |
| Name of medicine:           | BIOVAC SIMVASTATIN<br>80 mg                                                                                                                                                                                                                                                                          | Name of medicine:           | IBUPROFEN RECKITT 200                                                               | Name of medicine:           | SEDAXYLAN                                                                                                                     |
| Dosage form:                | TABLET                                                                                                                                                                                                                                                                                               | Dosage form:                | TABLET                                                                              | Dosage form:                | SOLUTION FOR INJECTION                                                                                                        |
| Active ingredients:         | EACH TABLET CONTAINS:<br>SIMVASTATIN 80,0 mg                                                                                                                                                                                                                                                         | Active ingredients:         | EACH TABLET CONTAINS:<br>IBUPROFEN 200,0 mg                                         | Active ingredients:         | EACH 1,0 ml SOLUTION<br>CONTAINS:<br>XYLAZINE HYDROCHLORIDE<br>EQUIVALENT TO XYLAZINE<br>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:                  | ARROW PHARMA SOUTH<br>AFRICA (PTY) LTD                                                                                                                                                                                                                                                               | Applicant:                  | RECKITT BENCKISER<br>HEALTHCARE (SA) (PTY) LTD                                      | Applicant:                  | VIRBAC RSA (PTY) LTD                                                                                                          |
| Manufacturer:               | ARROW MANUFACTURING Inc,<br>MISSISSAUGA, ONTARIO,<br>CANADA                                                                                                                                                                                                                                          | Manufacturer:               | RECKITT BENCKISER<br>HEALTHCARE (PTY) LTD,<br>INTERNATIONAL, NOTTINGHAM,<br>ENGLAND | Manufacturer:               | EUROVET ANIMAL HEALTH B.V.,<br>BLADEL, THE NETHERLANDS                                                                        |
| Packer:                     | ARROW MANUFACTURING Inc,<br>MISSISSAUGA, ONTARIO,<br>CANADA<br>CONTRACT<br>PHARMACEUTICALS LTD,<br>MISSISSAUGA, ONTARIO,<br>CANADA<br>QUALITY (BURNLEY) LIMITED,<br>BURNLEY, UNITED KINGDOM                                                                                                          | Packer:                     | RECKITT BENCKISER<br>HEALTHCARE (PTY) LTD,<br>INTERNATIONAL, NOTTINGHAM,<br>ENGLAND | Packer:                     | EUROVET ANIMAL HEALTH B.V.,<br>BLADEL, THE NETHERLANDS                                                                        |
| Laboratory: FPRC:           | ARROW MANUFACTURING Inc,<br>MISSISSAUGA, ONTARIO,<br>CANADA<br>QUALITY (BURNLEY) LIMITED,<br>BURNLEY, UNITED KINGDOM<br>RESEARCH INSTITUTE FOR<br>INDUSTRIAL PHARMACY<br>INCORPORATING CENQAM,<br>NORTH-WEST UNIVERSITY,<br>POTCHEFSTROOM, RSA<br>SEDEK AGRICHEM,<br>SILVERTONDALE, PRETORIA,<br>RSA | Laboratory: FPRC:           | RECKITT BENCKISER<br>HEALTHCARE (PTY) LTD,<br>INTERNATIONAL, NOTTINGHAM,<br>ENGLAND | Laboratory: FPRC:           | EUROVET ANIMAL HEALTH B.V.,<br>BLADEL, THE NETHERLANDS<br>M&L LABORATORY SERVICES<br>(PTY) LTD, ORMONDE,<br>JOHANNESBURG, RSA |
| FPRR:                       | ARROW PHARMA SOUTH<br>AFRICA (PTY) LTD, NORWICH<br>CLOSE, SANDOWN,<br>JOHANNESBURG, RSA<br>36 months                                                                                                                                                                                                 | FPRR:                       | RECKITT BENCKISER<br>PHARMACEUTICALS (PTY) LTD,<br>ELANDSFONTEIN, RSA               | FPRR:                       | VIRBAC RSA (PTY) LTD,<br>CENTURION, RSA                                                                                       |
| Shelf-life:                 | 36 months                                                                                                                                                                                                                                                                                            | Shelf-life:                 | 24 months                                                                           | Shelf-life:                 | 36 months<br>28 days (in-use)                                                                                                 |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                                                                        | Date of registration:       | 10 APRIL 2014                                                                       | Date of registration:       | 10 APRIL 2014                                                                                                                 |

| MRF 15                      |                                                                                                                                                                                             | MRF 15                      |                                                                                                                                                                                                                     | MRF 15                      |                                                                                                                                                                                                                     |
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| Registration number:        | 45/11.4.3/0777                                                                                                                                                                              | Registration number:        | 45/7.1.3/0626                                                                                                                                                                                                       | Registration number:        | 45/7.1.3/0625                                                                                                                                                                                                       |
| Name of medicine:           | TRUSTAN 20 mg                                                                                                                                                                               | Name of medicine:           | ARROW IRBESARTAN 300                                                                                                                                                                                                | Name of medicine:           | ARROW IRBESARTAN 150                                                                                                                                                                                                |
| Dosage form:                | TABLET                                                                                                                                                                                      | Dosage form:                | TABLET                                                                                                                                                                                                              | Dosage form:                | TABLET                                                                                                                                                                                                              |
| Active ingredients:         | EACH TABLET CONTAINS:<br>ESOMEPRAZOLE MAGNESIUM<br>TRIHYDRATE EQUIVALENT TO<br>ESOMEPRAZOLE 20.0 mg                                                                                         | Active ingredients:         | EACH TABLET CONTAINS:<br>IRBESARTAN 300.0 mg                                                                                                                                                                        | Active ingredients:         | EACH TABLET CONTAINS:<br>IRBESARTAN 150.0 mg                                                                                                                                                                        |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                                                                                                                                         | Conditions of registration: | 1, 2, 3, 4, 5, 6, 7, 8                                                                                                                                                                                              | Conditions of registration: | 1, 2, 3, 4, 5, 6, 7, 8                                                                                                                                                                                              |
| Applicant:                  | ASTRAZENECA<br>PHARMACEUTICALS (PTY) LTD                                                                                                                                                    | Applicant:                  | ARROW PHARMA SOUTH AFRICA<br>(PTY) LTD                                                                                                                                                                              | Applicant:                  | ARROW PHARMA SOUTH<br>AFRICA (PTY) LTD                                                                                                                                                                              |
| Manufacturer:               | ASTRAZENECA AB,<br>SODERTALJE, SWEDEN                                                                                                                                                       | Manufacturer:               | ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA                                                                                                                                                    | Manufacturer:               | ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA                                                                                                                                                    |
| Packer:                     | ASTRAZENECA AB,<br>SODERTALJE, SWEDEN<br>ASTRAZENECA UK LIMITED,<br>MACCLESFIELD, CHESHIRE,<br>UNITED KINGDOM                                                                               | Packer:                     | ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA<br>TECHNIKON LABORATORIES<br>(PTY) LTD, ROBERTVILLE,<br>FLORIDA, RSA<br>DIVPHARM MANUFACTURING &<br>PACKAGING (PTY) LTD,<br>LONGDALE, JOHANNESBURG | Packer:                     | ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA<br>TECHNIKON LABORATORIES<br>(PTY) LTD, ROBERTVILLE,<br>FLORIDA, RSA<br>DIVPHARM MANUFACTURING<br>& PACKAGING (PTY) LTD,<br>LONGDALE, JOHANNESBURG |
| Laboratory: FPRC:           | ASTRAZENECA AB,<br>SODERTALJE, SWEDEN<br>CONSULTING CHEMICAL<br>LABORATORIES (PTY) LTD,<br>ATLASVILLE, BOKSBURG, RSA<br>M&L LABORATORY SERVICES<br>(PTY) LTD, ORMONDE,<br>JOHANNESBURG, RSA | Laboratory: FPRC:           | ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA<br>TECHNIKON LABORATORIES<br>(PTY) LTD, ROBERTVILLE,<br>FLORIDA, RSA<br>SEDEK AGRICHEM,<br>SILVERTONDALE, PRETORIA, RSA                            | Laboratory: FPRC:           | ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA<br>TECHNIKON LABORATORIES<br>(PTY) LTD, ROBERTVILLE,<br>FLORIDA, RSA<br>SEDEK AGRICHEM,<br>SILVERTONDALE, PRETORIA,<br>RSA                         |
| FPRR:                       | ASTRAZENECA<br>PHARMACEUTICALS (PTY) LTD,<br>SUNNINGHILL, JOHANNESBURG,<br>RSA                                                                                                              | FPRR:                       | ARROW PHARMA S.A.(PTY) LTD,<br>NORWICH CLOSE, SANDOWN,<br>JOHANNESBURG, RSA                                                                                                                                         | FPRR:                       | ARROW PHARMA S.A.(PTY)<br>LTD, NORWICH CLOSE,<br>SANDOWN, JOHANNESBURG,<br>RSA                                                                                                                                      |
| Shelf-life:                 | 36 months                                                                                                                                                                                   | Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                                             | Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                                             |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                               | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                       | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                       |

| MRF 15                      |                                                                                                                                                                                                   | MRF 15                      |                                                                                                                                                                                                   | MRF 15                      |                                                                                                                                                                                                   |
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| Registration number:        | 45/7.1.3/0624                                                                                                                                                                                     | Registration number:        | 45/7.1.3/0623                                                                                                                                                                                     | Registration number:        | 45/7.1.3/0622                                                                                                                                                                                     |
| Name of medicine:           | ARROW IRBESARTAN 75                                                                                                                                                                               | Name of medicine:           | AROTAN 300                                                                                                                                                                                        | Name of medicine:           | AROTAN 150                                                                                                                                                                                        |
| Dosage form:                | TABLET                                                                                                                                                                                            | Dosage form:                | TABLET                                                                                                                                                                                            | Dosage form:                | TABLET                                                                                                                                                                                            |
| Active ingredients:         | EACH TABLET CONTAINS:<br>IRBESARTAN 75,0 mg                                                                                                                                                       | Active ingredients:         | EACH TABLET CONTAINS:<br>IRBESARTAN 300,0 mg                                                                                                                                                      | Active ingredients:         | EACH TABLET CONTAINS:<br>IRBESARTAN 150,0 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:                  | ARROW PHARMA SOUTH AFRICA (PTY) LTD                                                                                                                                                               | Applicant:                  | ARROW PHARMA SOUTH AFRICA (PTY) LTD                                                                                                                                                               | Applicant:                  | ARROW PHARMA SOUTH AFRICA (PTY) LTD                                                                                                                                                               |
| Manufacturer:               | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA                                                                                                                                        | Manufacturer:               | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA                                                                                                                                        | Manufacturer:               | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA                                                                                                                                        |
| Packer:                     | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG | Packer:                     | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG | Packer:                     | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG |
| Laboratory: FPRC:           | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>SILVERTONDALE, PRETORIA, RSA                                         | Laboratory: FPRC:           | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA                         | Laboratory: FPRC:           | ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA<br>TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA<br>SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA                         |
| FPRC:                       | ARROW PHARMA S.A. (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA                                                                                                                            | FPRC/FPRR:                  | ARROW PHARMA S.A. (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA                                                                                                                            | FPRC:                       | ARROW PHARMA S.A. (PTY) LTD, NORWICH CLOSE, SANDOWN, JOHANNESBURG, RSA                                                                                                                            |
| Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                           | Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                           | Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                           |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                     | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                     | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                     |

| MRF 15                      |                                                                                                                                                                                                                  | MRF 15                      |                                                                   | MRF 15                      |                                                               |
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| Registration number:        | 45/7.1.3/0621                                                                                                                                                                                                    | Registration number:        | 44/20.2.8/0016                                                    | Registration number:        | 44/20.2.8/0015                                                |
| Name of medicine:           | AROTAN 75                                                                                                                                                                                                        | Name of medicine:           | VORIOR                                                            | Name of medicine:           | HEVITREX                                                      |
| Dosage form:                | TABLET                                                                                                                                                                                                           | Dosage form:                | TABLET                                                            | Dosage form:                | TABLET                                                        |
| Active ingredients:         | EACH TABLET CONTAINS:<br>IRBESARTAN 75.0 mg                                                                                                                                                                      | Active ingredients:         | EACH TABLET CONTAINS:<br>VALACICLOVIR 500.0 mg                    | Active ingredients:         | EACH TABLET CONTAINS:<br>VALACICLOVIR 500.0 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:                  | ARROW PHARMA SOUTH AFRICA (PTY) LTD                                                                                                                                                                              | Applicant:                  | BLISS PHARMACEUTICALS cc                                          | Applicant:                  | BLISS PHARMACEUTICALS cc                                      |
| Manufacturer:               | ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA                                                                                                                                                 | Manufacturer:               | HETERO DRUGS LIMITED,<br>JEEDIMETLA, HYDERABAD,<br>INDIA          | Manufacturer:               | HETERO DRUGS LIMITED,<br>JEEDIMETLA, HYDERABAD, INDIA         |
| Packer:                     | ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA<br>TECHNIKON LABORATORIES (PTY)<br>LTD, ROBERTVILLE, FLORIDA, RSA<br>DIVPHARM MANUFACTURING &<br>PACKAGING (PTY) LTD,<br>LONGDALE, JOHANNESBURG | Packer:                     | HETERO DRUGS LIMITED,<br>JEEDIMETLA, HYDERABAD,<br>INDIA          | Packer:                     | HETERO DRUGS LIMITED,<br>JEEDIMETLA, HYDERABAD, INDIA         |
| Laboratory:                 | FPRC:<br>ARROW LABORATORIES LTD,<br>CROYDON SOUTH, VICTORIA,<br>AUSTRALIA<br>TECHNIKON LABORATORIES (PTY)<br>LTD, ROBERTVILLE, FLORIDA, RSA<br>SEDEK AGRICHEM,<br>SILVERTONDALE, PRETORIA, RSA                   | Laboratory:                 | FPRC:<br>HETERO DRUGS LIMITED,<br>JEEDIMETLA, HYDERABAD,<br>INDIA | Laboratory:                 | FPRC<br>HETERO DRUGS LIMITED,<br>JEEDIMETLA, HYDERABAD, INDIA |
| FPRR:                       | ARROW PHARMA S.A.(PTY) LTD,<br>NORWICH CLOSE, SANDOWN,<br>JOHANNESBURG, RSA                                                                                                                                      | FPRR:                       | BLISS PHARMACEUTICALS xx,<br>ORMONDE, JOHANNESBURG,<br>RSA        | FPRR:                       | BLISS PHARMACEUTICALS xx,<br>ORMONDE, JOHANNESBURG,<br>RSA    |
| Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                                          | Shelf-life:                 | 36 months                                                         | Shelf-life:                 | 36 months                                                     |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                    | Date of registration:       | 10 APRIL 2014                                                     | Date of registration:       | 10 APRIL 2014                                                 |

| MRF 15                      |                                                                                                                                                                                                                                                                         | MMRF 15                     |                                                                                                                                                                                                                                                                         |
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| Registration number:        | 43/7.1.3/0445                                                                                                                                                                                                                                                           | Registration number:        | 43/7.1.3/0443                                                                                                                                                                                                                                                           |
| Name of medicine:           | QUINAPRIL ZYDUS 40 mg                                                                                                                                                                                                                                                   | Name of medicine:           | QUINAPRIL ZYDUS 10 mg                                                                                                                                                                                                                                                   |
| Dosage form:                | TABLET                                                                                                                                                                                                                                                                  | Dosage form:                | TABLET                                                                                                                                                                                                                                                                  |
| Active ingredients:         | EACH TABLET CONTAINS:<br>QUINAPRIL HYDROCHLORIDE<br>EQUIVALENT TO QUINAPRIL 40,0 mg                                                                                                                                                                                     | Active ingredients:         | EACH TABLET CONTAINS:<br>QUINAPRIL HYDROCHLORIDE<br>EQUIVALENT TO QUINAPRIL 10,0 mg                                                                                                                                                                                     |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                                                                                                                                                                                                                     | Conditions of registration: | 1, 2, 3, 4, 5, 6, 7                                                                                                                                                                                                                                                     |
| Applicant:                  | ZYDUS HEALTHCARE SA (PTY) LTD                                                                                                                                                                                                                                           | Applicant:                  | ZYDUS HEALTHCARE SA (PTY) LTD                                                                                                                                                                                                                                           |
| Manufacturer:               | ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA                                                                                                                                                                                                      | Manufacturer:               | ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA                                                                                                                                                                                                      |
| Packer:                     | ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA                                                                                                                                                                                                      | Packer:                     | ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA                                                                                                                                                                                                      |
| Laboratory:                 | FPRC: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA<br>INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA | Laboratory:                 | FPRC: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA<br>INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA<br>RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA |
| FPRR:                       | ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA                                                                                                                                                                                                    | FPRR:                       | ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA                                                                                                                                                                                                    |
| Shelf-life:                 | 24 months                                                                                                                                                                                                                                                               | Shelf-life:                 | 24 months                                                                                                                                                                                                                                                               |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                                           | Date of registration:       | 10 APRIL 2014                                                                                                                                                                                                                                                           |

| MRF 15                      |                                                                                                                                          | MRF 15                      |                                                                                                                                          | MRF 15                      |                                                                                                                                                                                |
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| Registration number:        | 43/3.2/0132                                                                                                                              | Registration number:        | 43/3.2/0131                                                                                                                              | Registration number:        | 42/7.1.3/0094                                                                                                                                                                  |
| Name of medicine:           | RISEDRONATE WINTHROP MONTHLY                                                                                                             | Name of medicine:           | ACTONEL ONCE-A-MONTH                                                                                                                     | Name of medicine:           | LOZAAN 12.5 mg                                                                                                                                                                 |
| Dosage form:                | TABLET                                                                                                                                   | Dosage form:                | TABLET                                                                                                                                   | Dosage form:                | TABLET                                                                                                                                                                         |
| Active ingredients:         | EACH TABLET CONTAINS: RISEDRONATE SODIUM EQUIVALENT TO RISEDRONIC ACID 150.0 mg                                                          | Active ingredients:         | EACH TABLET CONTAINS: RISEDRONATE SODIUM EQUIVALENT TO RISEDRONIC ACID 150.0 mg                                                          | Active ingredients:         | EACH TABLET CONTAINS: LOSARTAN POTASSIUM 12.5 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:                  | WINTHROP PHARMACEUTICALS (PTY) LTD                                                                                                       | Applicant:                  | SANOFLAVENTIS SOUTH AFRICA (PTY) LTD                                                                                                     | Applicant:                  | AKACIA HEALTHCARE (PTY) LTD                                                                                                                                                    |
| Manufacturer:               | NORWICH PHARMACEUTICAL INC, NEW YORK, USA<br>PROCTER & GAMBLE PHARMACEUTICALS, PUERTO RICO<br>RICO L.L.C. MANATI, PUERTO RICO            | Manufacturer:               | NORWICH PHARMACEUTICAL INC, NEW YORK, USA<br>PROCTER & GAMBLE PHARMACEUTICALS, PUERTO RICO<br>L.L.C. MANATI, PUERTO RICO                 | Manufacturer:               | SPECIAR S.A., VARVARA, ATHENS, GREECE                                                                                                                                          |
| Packer:                     | PROCTER & GAMBLE PHARMACEUTICALS, GERMANY GmbH, WEITERSTADT, GERMANY<br>WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA       | Packer:                     | PROCTER & GAMBLE PHARMACEUTICALS, GERMANY GmbH, WEITERSTADT, GERMANY<br>WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA       | Packer:                     | SPECIAR S.A., VARVARA, ATHENS, GREECE                                                                                                                                          |
| Laboratory:                 | FPRC: PROCTER & GAMBLE PHARMACEUTICALS, GERMANY GmbH, WEITERSTADT, GERMANY<br>WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA | Laboratory:                 | FPRC: PROCTER & GAMBLE PHARMACEUTICALS, GERMANY GmbH, WEITERSTADT, GERMANY<br>WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA | Laboratory:                 | FPRC: SPECIAR S.A., VARVARA, ATHENS, GREECE<br>CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA<br>AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA |
| FPRR:                       | WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA<br>WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA                           | FPRR:                       | WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA<br>SANOFLAVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA                         | FPRR:                       | AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA                                                                                                                         |
| Shelf-life:                 | 24 months (Provisional)                                                                                                                  | Shelf-life:                 | 24 months (Provisional)                                                                                                                  | Shelf-life:                 | 24 months (Provisional)                                                                                                                                                        |
| Date of registration:       | 10 APRIL 2014                                                                                                                            | Date of registration:       | 10 APRIL 2014                                                                                                                            | Date of registration:       | 10 APRIL 2014                                                                                                                                                                  |

| MRF 15                      |                                                                                                                                                                                      | MMRF 15                     |                                                                                                                                                                                         |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Registration number:        | 42/7.1.3/0095                                                                                                                                                                        | Registration number:        | 42/7.1.3/0097                                                                                                                                                                           |
| Name of medicine:           | LOZAAN 25 mg                                                                                                                                                                         | Name of medicine:           | LOZAAN 100 mg                                                                                                                                                                           |
| Dosage form:                | TABLET                                                                                                                                                                               | Dosage form:                | TABLET                                                                                                                                                                                  |
| Active ingredients:         | EACH TABLET CONTAINS:<br>LOSARTAN POTASSIUM 25 mg                                                                                                                                    | Active ingredients:         | EACH TABLET CONTAINS:<br>LOSARTAN POTASSIUM<br>100.0 mg                                                                                                                                 |
| Conditions of registration: | 1, 2, 3, 4, 5, 6, 7, 8                                                                                                                                                               | Conditions of registration: | 1, 2, 3, 4, 5, 6, 7, 8                                                                                                                                                                  |
| Applicant:                  | AKACIA HEALTHCARE (PTY) LTD                                                                                                                                                          | Applicant:                  | AKACIA HEALTHCARE (PTY)<br>LTD                                                                                                                                                          |
| Manufacturer:               | SPECIAR S.A., VARVARA, ATHENS,<br>GREECE                                                                                                                                             | Manufacturer:               | SPECIAR S.A., VARVARA,<br>ATHENS, GREECE                                                                                                                                                |
| Packer:                     | SPECIAR S.A., VARVARA, ATHENS,<br>GREECE                                                                                                                                             | Packer:                     | SPECIAR S.A., VARVARA,<br>ATHENS, GREECE                                                                                                                                                |
| Laboratory, FPRC:           | SPECIAR S.A., VARVARA, ATHENS,<br>GREECE<br>CONSULTING CHEMICAL<br>LABORATORIES (PTY) LTD,<br>ATLASVILLE, BOKSBURG, RSA<br>AKACIA HEALTHCARE (PTY) LTD,<br>ISANDO, JOHANNESBURG, RSA | Laboratory, FPRC:           | SPECIAR S.A., VARVARA,<br>ATHENS, GREECE<br>CONSULTING CHEMICAL<br>LABORATORIES (PTY) LTD,<br>ATLASVILLE, BOKSBURG, RSA<br>AKACIA HEALTHCARE (PTY)<br>LTD, ISANDO,<br>JOHANNESBURG, RSA |
| FPRR:                       | AKACIA HEALTHCARE (PTY) LTD,<br>ISANDO, JOHANNESBURG, RSA                                                                                                                            | FPRR:                       | AKACIA HEALTHCARE (PTY)<br>LTD, ISANDO,<br>JOHANNESBURG, RSA                                                                                                                            |
| Shelf-life:                 | 24 months (Provisional)                                                                                                                                                              | Shelf-life:                 | 24 months (Provisional)                                                                                                                                                                 |
| Date of registration:       | 10 APRIL 2014                                                                                                                                                                        | Date of registration:       | 10 APRIL 2014                                                                                                                                                                           |