



RWANDA FDA
Rwanda Food and Drugs Authority

DEPARTMENT OF DRUG AND FOOD ASSESSMENT AND REGISTRATION

TITLE: HUMAN BIOLOGICAL PRODUCTS REGISTER

Doc. N^o: DAR/FOM/170
Revision N^o: 1
Effective Date: 21 Feb. 2022
Ref: Doc: DAR/SOP/043

S/N	REGISTRATION NO.	PRODUCT BRAND NAME	GENERIC NAME	DOSAGE STRENGTH	DOSAGE FORM	PACK SIZE	PACKAGING TYPE	SHELF LIFE	MANUFACTURER'S NAME AND ADDRESS	MANUFACTURER COUNTRY	MARKETING AUTHORIZATION HOLDER (MAH)	LOCAL TECHNICAL REPRESENTATIVE-LTR	REGISTRATION DATE	EXPIRY DATE
1	Rwanda FDA-HBP-MA-0001	ERVEBO	EBOLA ZAIRE VACCINE	72 MILLION PFU/ML	SOLUTION FOR INJECTION	1 SINGLE DOSE VIAL	USP TYPE 1 GLASS	36 Months	MSD SITE-BURGWEDEL BIOTECH GMBH Langen Felde 5, Burgwedel 3093, Germany	GERMANY	MSD MAROC	N/A	05/03/2020	05/03/2025
2	Rwanda FDA-HMP-MA-0040	TRICLOFEM	MEDROXYPROGESTERONE ACETATE	150MG/ML	SUSPENSION FOR INJECTION	2ML CLEAR TUBULAR	USP TYPE I GLASS VIAL, capped with 13mm red bromobutyl rubber stopper and sealed with 13mm purple flip-cap aluminium seal	60 Months	PT TUNGGAL IDAMAN ABDI, HORMONE INJECTION PLANT-2 J1, JENDERAL, AHMADYANI NO & JAKARTA TIMUR	INDONESIA	MISSION PHARMA A/S	KIPHARMA LTD	14/11/2020	14/11/2025
3	Rwanda FDA-HMP-MA-0050	PDXANE®8000	ENOXAPARIN SODIUM	8000 ANTI-XA IU/0.8 ML	SOLUTION FOR INJECTION	1ML PREFILLED GRADUATED SYRINGE	Colorless TYPE 1 Borosilicate Glass pre-filled syringe fitted with an injection needle and needle cap.	24 Months	POOYESH DAROU BIO PHARMACEUTICAL CO. 18 Fanavari Street, Pardis Tech-Park, Abali high way, 15th Tehran, IRAN	IRAN	HELVETIC BIOPHARMA SA	MNR EAST AFRICA LIMITED	17/03/2021	17/03/2026
4	Rwanda FDA-HMP-MA-0055	SANTOCYN	OXYTOCIN	10 IU/ML	SOLUTION FOR INJECTION	10 X 1ML AMPOULE	CLEAR TYPE I GLASS	18 Months	PT SANBE FARMA STERILE PREPARATION PLANT Unit 3, Jl. Industri Cimarene No. 8, Desa Cimareme, Kecamatan Ngamprah, Kabupaten Bandung Barat – Indonesia	INDONESIA	PT. SANBE FARMA	AFRI HEALTH CARE LTD	27/04/2021	27/04/2026
5	Rwanda FDA-HMP-MA-0062	PDXANE®4000	ENOXAPARIN SODIUM	40MG(4000 ANTI-XA)	SOLUTION FOR INJECTION	0.4 ML	Prefilled syringe, type I glass syringe barrel, Buthyl rubber stopper+ plunger rod+ hypodermic needle & needle shield. PVC/aluminum blister + paper box	24 Months	POOYESH DAROU BIO PHARMACEUTICAL CO. 18 Fanavari Street, Pardis Tech-Park, Abali high way, 15th Tehran, IRAN	IRAN	HELVETIC BIOPHARMA SA	MNR EAST AFRICA LIMITED	01/06/2021	01/06/2026

6	Rwanda FDA-HMP-MA-0063	DERISE-25	DARBEPOETIN ALFA	25MCG/0.42 ML	SOLUTION FOR INJECTION	1ML	1 ML PREFILLED SYRINGE BARREL WITH NEEDLE, 1 ML PLUNGER STOPPER AND 1 ML PLUNGER ROD	36 Months	HETERO BIOPHARMA LIMITED Sy. No. 458 (part), TSIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar (Disrtict)-509 301, Telangana State, India	INDIA	HETERO BIOPHARMA LIMITED	VINE PHARMA LIMITED	01/06/2021	01/06/2026
7	Rwanda FDA-HMP-MA-0064	DERISE-40	DARBEPOETIN ALFA	40MCG/0.4 ML	SOLUTION FOR INJECTION	1ML	1 ML PREFILLED SYRINGE BARREL WITH NEEDLE, 1 ML PLUNGER STOPPER AND 1 ML PLUNGER ROD	36 Months	HETERO BIOPHARMA LIMITED Sy. No. 458 (part), TSIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar (Disrtict)-509 301, Telangana State, India	INDIA	HETERO BIOPHARMA LIMITED	VINE PHARMA LIMITED	01/06/2021	01/06/2026
8	Rwanda FDA-HMP-MA-0099	U-TRYP	Ulinastatin J.P I. U (Lyophilized)	100,000 i.u	Powder For Injection	5ml	Clear, colourless, USP type I (neutral borosilicate) tubular glass vial with concave bottom	24 Months	BHARAT SERUMS & VACCINES LTD. Plot No. K-27, Jambivili Villaga, Anand Nagar, Additional M.ID.C, Ambernath (East). India	INDIA	BHARAT SERUMS & VACCINES LTD, INDIA	WESSEX PHARMACEUTICALS (RWANDA) LTD	05/08/2021	05/08/2026
9	Rwanda FDA-HBP-MA-002	REPOITIN 4000	ERYTHROPOIETIN CONCENTRATED SOLUTION B.P	4000 IU/0.4 ML.	SOLUTION FOR INJECTION	UNIT PACK	PRE-FILLED SYRINGE	24 Months	SERUM INSTITUTE OF INDIA PVT. LTD 212/2, HADAPSAR, Pune -411028, India	INDIA	SERUM INSTITUTE OF INDIA PVT. LTD	SUN ENTERPRISES LTD	08/09/2021	08/09/2026
10	Rwanda FDA-HBP-MA-003	BCG VACCINE (FREEZE-DRIED)	LIVE ATTENUATED STRAINS OF MYCOBACTERIUM BOVIS	2 X 10 ⁵ AND 8 X 10 ⁵ C.F.U.	LYOPHILIZED INJECTION	50X1ML	VIAL HYDROLYTIC CLASS-I GLASS OF 4 ML + DILUENTS.	24 Months	SERUM INSTITUTE OF INDIA PVT. LTD 212/2, HADAPSAR, Pune -411028, India	INDIA	SERUM INSTITUTE OF INDIA PVT. LTD	SUN ENTERPRISES LTD	08/09/2021	08/09/2026
11	Rwanda FDA-HBP-MA-004	MEASLES VACCINE, LIVE ATTENUATED (FREEZE-DRIED)	CLARIFIED VIRUS POOL OF MEASLES VIRUS	1000 CCID50 OF MEASLES VIRUS/ 0.5ML.	LYOPHILIZED INJECTION	VIALS + DILUENT 10 DOSE	AMBER VIAL TYPE I with rubber stopper in grey bromobutyl and orange (pantone) aluminum caps	24 Months	SERUM INSTITUTE OF INDIA PVT. LTD 212/2, HADAPSAR, Pune -411028, India	INDIA	SERUM INSTITUTE OF INDIA PVT. LTD	SUN ENTERPRISES LTD	08/09/2021	08/09/2026
12	Rwanda FDA-HBP-MA-005	BEVAAS 100	BEVACIZUMAB	100MG/4ML	CONCENTRATE FOR SOLUTION FOR INJECTION	4ML VIAL	USP TYPE I CLEAR GLASS	24 Months	HETERO BIOPHARMA LIMITED Sy. No. 458 (part), TSIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar (Disrtict)-509 301, Telangana State, India	INDIA	HETERO BIOPHARMA LIMITED	VINE PHARMA LIMITED	18/07/2022	17/07/2027
13	Rwanda FDA-HBP-MA-006	BEVAAS 400	BEVACIZUMAB	400MG/16ML	CONCENTRATE FOR SOLUTION FOR INJECTION	16ML VIAL	USP TYPE I CLEAR GLASS	24 Months	HETERO BIOPHARMA LIMITED Sy. No. 458 (part), TSIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar (Disrtict)-509 301, Telangana State, India	INDIA	HETERO BIOPHARMA LIMITED	VINE PHARMA LIMITED	18/07/2022	17/07/2027

14	Rwanda FDA-HBP-MA-007	CARBETOCIN FERRING	CARBETOCIN 100MICROGRAMS/ML	100MICROGRAMS/ML	SOLUTION FOR INJECTION	1MLX10 AMPOULES	TYPE I GLASS AMPOULES WITH A WHITE ONE POINT CUT (OPC) DOT	48 Months	FERRING PHARMACEUTICALS (CHINA) Co., Ltd, No.6, Hui Ling Lu (Ferring Road), National Health Technology Park, Zhongshan City, Guangdong Province, People's Republic of China.	PEOPLE'S REPUBLIC OF CHINA.	FERRING INTERNATIONAL CENTER SA	MULTIPHAR UNIPHARM-RWANDA LTD	21/12/2022	20/12/2027
15	Rwanda FDA-HBP-MA- 008	LEVEMIR FLEXPEN	INSULIN DETEMIR 100 U/ML	100 U/ml	SOLUTION FOR INJECTION	5X3 ML IN CARTRIDGE (TYPE 1 GLASS)	Cartridge (type 1 glass) with a plunger and a rubber closure contained in a pre-filled multidose disposable pen made of polypropylene	30 Months	NOVO NORDISK PRODUCTION SAS, 45 Avenue d'Orléans F-28000 Chartres, France and NOVO NORDISK A/S, Novo Allé, DK-2880 Bagsværd, Denmark	DENMARK	NOVO NORDISK A/S, DENMARK	WESSEX PHARMACEUTICALS (RWANDA) LTD	25/01/2023	24/01/2028
16	Rwanda FDA-HBP-MA- 009	TETGLOB 250 I.U.	TETANUS IMMUNOGLOBULIN BULK POWDER 250 IU	250 IU	Liquid Injection Clear or slightly opalescent, colorless or pale-yellow or light brown liquid	2 ML TUBULAR FLINT GLASS VIAL	Tubular Flint Glass vial, Rubber Bung 13mm Chlorobutyl plain and Aluminum Flip off Seal 13mm yellow	36 Months	BHARAT SERUMS & VACCINES LTD. Address: Plot No. K-27, K-27 part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421501 Maharashtra State, India	INDIA	BHARAT SERUMS AND VACCINES LIMITED	WESSEX PHARMACEUTICALS (RWANDA) LTD	25/01/2023	24/01/2028
17	Rwanda FDA-HBP-MA-0010	ZABDENO SUSPENSION FOR INJECTION. EBOLA VACCINE (AD26.ZEBOV-GP [RECOMBINANT]) AND MVABEA SUSPENSION FOR INJECTION. EBOLA VACCINE (MVA-BN-FILO [RECOMBINANT])	Ad26.ZEBOV, MVA-BN-Filo, 0.5 mL, NLT 0.7x108 Infectious units	0.5 mL, NLT 0.7x108 Infectious units	Suspension for Injection	Single dose	Type I glass Vial, with a rubber stopper, aluminium crimp and red plastic cap for Zabdeno and with yellow plastic cap for Mvabea	48 Months	IDT BIOLOGIKA GmbH, Am Pharmapark 06861 Dessau-Rosslau, Germany	GERMANY	JANSSEN-CILAG INTERNATIONAL NV, BELGIUM	KIPHARMA LTD	13/03/2023	12/03/2028
18	Rwanda FDA-HBP-MA-0011	ABEVMYTM 100	Bevacizumab 100 mg/4 ml	100 mg/4 ml	Concentrate for solution for infusion	20 ml USP/EP Type-I clear glass vial	USP/EP Type-I clear glass vials, plugged with 20 mm grey colored flurotec coated, chlorobutyl serum stoppers and sealed with red color Aluminium flip-off seals	36 Months	BIOCON BIOLOGICS INDIA LIMITED, B1, B2, B3, Q13 of Q1, and Unit S18, 1st Floor, B4 block, Special Economic Zone, Plot Nos. 2, 3, 4 & 5, Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru-560 099, India.	INDIA	MYLAN PHARMACEUTICALS PRIVATE LIMITED, INDIA.	PYRAMID PHARMA LIMITED	12/05/2023	11/05/2028
19	Rwanda FDA-HBP-MA-0012	ABEVMYTM 400	Bevacizumab, 400 mg/16ml	400 mg/16ml	Concentrate for solution for infusion	20 ml USP/EP Type-I clear glass vial	USP/EP Type-I clear glass vials, plugged with 20 mm grey colored flurotec coated, chlorobutyl serum stoppers and sealed with red color Aluminium flip-off seals	36 Months	BIOCON BIOLOGICS INDIA LIMITED, B1, B2, B3, Q13 of Q1, and Unit S18, 1st Floor, B4 block, Special Economic Zone, Plot Nos. 2, 3, 4 & 5, Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru-560 099, India.	INDIA	MYLAN PHARMACEUTICALS PRIVATE LIMITED, INDIA.	PYRAMID PHARMA LIMITED	12/05/2023	11/05/2028

20	Rwanda FDA-HBP-MA- 0013	ZARZIO 30 MU/0.5 ML SOLUTION FOR INJECTION OR INFUSION IN PRE-FILLED SYRINGE	Filgrastim 30 MU/0.5 mL	30 MU/0.5 mL	Solution for injection or infusion	1, 3, 5 or 10 pre-filled syringes containing 0.5 ml solution	1, 3, 5 or 10 pre-filled syringes (type I glass) with injection needle (stainless steel), with or without a needle safety guard, containing 0.5 ml solution	36 Months	SANDOZ GmbH Biochemiestr 10 A-6336 Langkampfen Austria	AUSTRIA	SANDOZ PHARMACEUTICALS D.D.	SURGIPHARM (RWANDA) LTD	12/05/2023	11/05/2028
21	Rwanda FDA-HBP-MA- 0014	ZARZIO 48 MU/0.5 ML SOLUTION FOR INJECTION OR INFUSION IN PRE-FILLED SYRINGE	Filgrastim 48 MU/0.5 mL	48 MU/0.5 mL	Solution for injection or infusion	1, 3, 5 or 10 pre-filled syringes containing 0.5 ml solution	1, 3, 5 or 10 pre-filled syringes (type I glass) with injection needle (stainless steel), with or without a needle safety guard, containing 0.5 ml solution	36 Months	SANDOZ GmbH Biochemiestr 10 A-6336 Langkampfen Austria	AUSTRIA	SANDOZ PHARMACEUTICALS D.D.	SURGIPHARM (RWANDA) LTD	12/05/2023	11/05/2028
22	Rwanda FDA-HBP-MA- 0015	THYMOGAM	Anti-thymocyte Globulin (Equine),250 mg / 5ml liquid injection	250 mg / 5ml	Liquid for Injection	5 ml vial	Vial made from USP Type I, neutral, colorless glass	24 Months	BHARAT SERUMS & VACCINES LTD Plot No. K-27, K-27 part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421501 Maharashtra State, India	INDIA	BHARAT SERUMS AND VACCINES LIMITED	WESSEX PHARMACEUTICALS (RWANDA) LTD	12/05/2023	11/05/2028
23	Rwanda FDA-HBP-MA- 0016	PATIZRA 10 MG/ML SOLUTION FOR INJECTION	Ranibizumab 10 mg/mL	10 mg/mL	Solution for injection	Vial with filter needle -0.23 mL	Glass vial (colorless type I glass) with chlorobutyl rubber stopper and filter needle. Pre-filled syringe-0.165 mL sterile solution in a pre-filled syringe (type I glass)	36 Months	ALCON-COUVREUR NV Rijksweg 14 Puurs, 2870, Belgium	BELGIUM	NVS KENYA LIMITED	SURGIPHARM (RWANDA) LTD	12/05/2023	11/05/2028
24	Rwanda FDA-HBP-MA- 0017	ACTRAPID®100I U/ML ,10 ML VIAL	Human Insulin(rDNA) 100UI/ml	100UI/ml	Aqueous solution	1 and 5 vials of 10ml	Vial 10HN	30 Months	NOVO NORDISK A/S, NOVO ALLE, DK-2880 Bagsvaerd, Denmark and Novo Nordisk Production SAS, 45 Avenue d'Orléans, F-28000 Chartres, France	DENMARK , FRANCE	NOVO NORDISK PHARMA GULF FZ-LLC/DUBAI, UAE	WESSEX PHARMACEUTICALS (RWANDA) LTD	12/05/2023	11/05/2028
25	Rwanda FDA-HBP-MA- 0018	NOVOMIX 30 FLEXPEN	Insulin Aspart 100 U/ml	100 U/ml	Suspension for Injection	5x3 ml in cartridge	Cartridge (type 1 glass) with a plunger (bromobutyl) and a rubber closure (bromobutyl/polyisoprene) contained in a pre-filled multidose disposable pen made of polypropylene	30 Months	NOVO NORDISK PRODUCTION SAS, 45 Avenue d'Orléans F-28000 Chartres, France and Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	FRANCE, DENMARK	NOVO NORDISK A/S, DENMARK	WESSEX PHARMACEUTICALS (RWANDA) LTD	12/05/2023	11/05/2028

26	Rwanda FDA-HBP-MA- 0019	BSV HUMOG 75 HP	Menotrophin BP, 75 I.U	75 I.U	Lyophilized injection white powder or cake	2 ml Vial. Each vial is accompanied by an ampoule containing 1ml of chloride injection BP	USP Type I, Tubular Flint Vial of 2 ml containing sterile, freeze dried white powder having 75 I.U, activity of each FSH and LH.	36 Months	BHARAT SERUMS AND VACCINES LIMITED, Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India.	INDIA	BHARAT SERUMS AND VACCINES LIMITED,	WESSEX PHARMACEUTICALS (RWANDA) LTD	12/05/2023	11/05/2028
27	Rwanda FDA-HBP-MA- 0020	FOLIGRAF 75 I.U (FREEZE DRIED)	Recombinant - Human Follicle Stimulating Hormone for Injection, 75 I.U	75 I.U	Lyophilized injection, white to off white or cake	2 ml Vial	USP Type I clear, colorless tubular flint glass vial of 2 ml	24 Months	BHARAT SERUMS AND VACCINES LIMITED, Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India	INDIA	BHARAT SERUMS AND VACCINES LIMITED,	WESSEX PHARMACEUTICALS (RWANDA) LTD	12/05/2023	11/05/2028
28	Rwanda FDA-HBP-MA-0021	MIXTARD (R) 30, 100IU/ML	Insulin Human, 100IU/ML	100IU/ML	Suspension for injection	10ml in the glass vial	Vial 10 ml, [glass type I] and rubber closure with snap-off cap	30 Months	NOVO NORDISK PRODUCTION SAS, 45 Avenue d'Orleans, F-28000 Chartes, France.	FRANCE	NOVO NORDISK SAS, DENMARK	WESSEX PHARMACEUTICALS (RWANDA) LTD	12/05/2023	11/05/2028
29	Rwanda FDA-HBP-MA- 0022	NOVORAPID FLEXPEN	1 ml of the solution contains 100 U of insulin aspart (equivalent to 3.5 mg).1 pre-filled pen contains 3 ml equivalent to 300 U	100U/ML & 300U/ML	Solution for injection	3 ml solution in cartridge	Cartridge (type I glass) with a plunger (bromobutyl) and a rubber closure (bromobutyl/ polyisoprene) contained in a pre-filled multidose disposable pen made of polypropylene	30 Months	NOVO NORDISK PRODUCTION SAS, 45 Avenue d'Orléans F-28000 Chartres, France and Novo Nordisk A/S Novo Allé DK-2880 Bagsværd, Denmark	FRANCE, DENMARK	NOVO NORDISK S/A	WESSEX PHARMACEUTICALS (RWANDA) LTD	26/06/2023	25/06/2028
30	Rwanda FDA-HBP-MA-0023	RITUXIMAB (RIXIMYO)	Rituximab, 100mg/10ml	100mg/10ml	Solution for infusion	2 or 3 vials of 10ml	Clear Type I glass vials with butyl rubber stopper	36 Months	LEK PHARMACEUTICALS D.D. Ljubljana Verovskova 57 1526 Ljubljana, Slovenia and Batch release by Sandoz GmbH Schaftebau Biochemiestrasse 10 6336 Langkampfen, Austria	AUSTRIA	SANDOZ PHARMACEUTICALS D.D.	SURGIPHARM (RWANDA) LTD	08/07/2023	07/07/2028
31	Rwanda FDA-HBP-MA-0024	RITUXIMAB (RIXIMYO)	Rituximab, 500mg/ 50ml	500mg/ 50ml	Solution for infusion	1 or 2 vials of 50ml	Clear Type I glass vials with butyl rubber stopper	36 Months	LEK PHARMACEUTICALS D.D. Ljubljana Verovskova 57 1526 Ljubljana, Slovenia and Batch release by Sandoz GmbH Schaftebau Biochemiestrasse 10 6336 Langkampfen, Austria	AUSTRIA	SANDOZ PHARMACEUTICALS D.D.	SURGIPHARM (RWANDA) LTD	08/07/2023	07/07/2028
32	Rwanda FDA-HMP-MA-0025	PHESGO®	Pertuzumab 1200 mg + Trastuzumab 600 mg	1200 mg + 600 mg	Solution for injection	15 ml Vial	20 mL USP/ Ph. Eur.JP Type I borosilicate glass, colorless, tapered with fluororesin-laminated rubber stopper	18 Months	F. HOFFMANN-LA ROCHE LTD, Wurmisweg, 4303 Kaiseraugst, Switzerland	SWITZERLAND	F. HOFFMANN-LA ROCHE LTD	KIPHARMA LTD	08/07/2023	07/07/2028
33	Rwanda FDA-HMP-MA-0026	PHESGO®	Pertuzumab 600 mg + Trastuzumab 600 mg	600 mg + 600 mg	Solution for injection	15 ml Vial	20 mL USP/ Ph. Eur.JP Type I borosilicate glass, colorless, tapered with fluororesin-	18 Months	F. HOFFMANN-LA ROCHE LTD, Wurmisweg, 4303 Kaiseraugst, Switzerland	SWITZERLAND	F. HOFFMANN-LA ROCHE LTD	KIPHARMA LTD	08/07/2023	07/07/2028

							laminated rubber stopper							
34	Rwanda FDA-HMP-MA-0027	HERCEPTIN SOLUTION FOR INJECTION 600MG/5ML	Trastuzumab 600mg/5ml	600mg/5ml	Solution for injection	6 mL Vial	Glass vial (type 1 glass) closed by means of a rubber. Stopper (rubber laminated with fluoro-resin) and an aluminum Overseal with flip-off disk	21 Months	F. HOFFMANN-LA ROCHE LTD, Wurmisweg, 4303 Kaiseraugst, Switzerland	SWITZERLAND	F. HOFFMANN-LA ROCHE LTD	KIPHARMA LTD	08/07/2023	07/07/2028
35	Rwanda FDA-HMP-MA-0028	GAMMA IV- 5	Human Normal Immunoglobulin for Intravenous use BP (Bulk).5g / Vial	5g/Vial	Solution for injection	100 ml Vial	USP Type – I, moulded flint glass vial.	24 Months	BHARAT SERUMS & VACCINES LTD, Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India	INDIA	BHARAT SERUMS & VACCINES LTD, INDIA	WESSEX PHARMACEUTICALS (RWANDA) LTD	08/07/2023	07/07/2028
36	Rwanda FDA-HMP-MA-0371	EQUIRAB 1000IU	Rabies Antiserum Equine 1000 I.U.	1000 I.U.	Solution for injection	5ml Vial	Clear colorless Glass USP Type I Moulded flint Vial covered a Rubber Bung 20mm clotted chlorobutyl and a 20mm Aluminium Flip off seal Violet	36 Months	BHARAT SERUMS AND VACCINES LIMITED, Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath East, Thane 421506, Maharashtra, India	INDIA	BHARAT SERUMS & VACCINES LTD, INDIA	WESSEX PHARMACEUTICALS (RWANDA) LTD	08/07/2023	07/07/2028
37	Rwanda FDA-HBP-MA-0029	AMPHONEX-50	Amphotericin B 50mg/vial Lyophilized Powder for injection	50mg/vial	Lyophilized powder for injection	20ml Vial	20ml clear, colorless, USP-Type I (Neutral Borosilicate) Tubular Vial	36 Months	BHARAT SERUMS & VACCINES LTD, Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath East, Thane 421506, Maharashtra, India	INDIA	BHARAT SERUMS & VACCINES LTD, INDIA	WESSEX PHARMACEUTICALS (RWANDA) LTD	24/08/2023	23/08/2028
38	Rwanda FDA-HBP-MA-0033	INSULATARD®	Insulin Human 100 IU/ml	100 IU/ml	Suspension for injection	10ml, Vial	Glass vial	30 Months	NOVO NORDISK PRODUCTION SAS, 45 Avenue d'Orléans F-28000 Chartres, France and Novo Nordisk A/S Novo Allé DK-2880 Bagsværd, Denmark	FRANCE AND DENMARK	NOVO NORDISK A/S	WESSEX PHARMACEUTICALS (RWANDA) LTD	11/09/2023	10/09/2028
39	Rwanda FDA-HBP-MA-0037	BORTEZOMIB NEAPOLIS 3.5MG	Bortezomib 3.5mg	3.5mg	Solution for injection	10 ml Vial	Type I transparent glass vial with a grey bromobutyl stopper diameter 20 mm and aluminium seal with a flip off cap diameter 20 mm	24 Months	NEAPOLIS PHARMA, Route de Tunis, Km7-B.P.206, 8000 Nabeul, Tunisia	TUNISIA	NEAPOLIS PHARMA, TUNISIA	KIPHARMA LTD	13/10/2023	12/10/2028
40	Rwanda FDA-HBP-MA-0100	POLY-MXB	Polymyxin B Sulphate USP 500000 Units	500000 Units	cake/powder for reconstitution	5 ml Glass vial	Amber coloured, USP Type-I (neutral borosilicate) tubular glass vial	36 months	BHARAT SERUMS AND VACCINES LIMITED, Plot No. K-27, K-27 part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421501 Maharashtra State, India	INDIA	BHARAT SERUMS & VACCINES LTD, INDIA	WESSEX PHARMACEUTICAL (RWANDA) LTD	10/12/2023	09/12/2028
41	Rwanda FDA-HBP-MA-0101	LUPRODEX 3.75	Leuprolide Acetate 3.75 mg	3.75 mg	Lyophilized powder for Injection	5 ml Glass vial	Clear, Colourless, USP Type I Glass vial	36 months	BHARAT SERUMS AND VACCINES LIMITED, Plot No. K-27, K-27 part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421501 Maharashtra State, India	INDIA	BHARAT SERUMS & VACCINES LTD, INDIA	WESSEX PHARMACEUTICAL (RWANDA) LTD	10/12/2023	09/12/2028

42	Rwanda FDA-HBP-MA-0103	ADSORBED TETANUS VACCINE B.P TETANUS TOXOID 1 DOSE	Tetanus Toxoid, Each single 0.5 ml human dose contains: Tetanus Toxoid ≥ 5 Lf (≥ 40 IU) Adsorbed onto Aluminium Phosphate, $Al_3 \leq 1.25$ mg 0.5ml/1 dose	≥ 40 IU, $\pm \leq 1.25$ mg 0.5ml/1 dose	Suspension for Injection	1 blister containing 10 ampoules	1 blister containing 10 OPC Type I glass ampoules (Single dose) packed in a corrugated box	36 Months	SERUM INSTITUTE OF INDIA PVT. LTD 212/2, Hadapsar Pune- 411028, India	INDIA	SERUM INSTITUTE OF INDIA PVT. LTD	SUN ENTERPRISE LTD	30/12//2023	29/12/2028
43	Rwanda FDA-HBP-MA-0104	BINOCRIT 4000IU/0.4ML	Epoetin alfa 4000IU per 0.4ml	4000IU per 0.4ml	Sterile solution for injection	1 and 6 in pre-filled syringes	Glass type I pre-filled syringes	24 Months	IDT BIOLOGIKA GmbH, Am Pharma Park 06861 Dessau-Rosslau Germany	GERMANY	SANDOZ PHARMACEUTICALS D.D.	SURGIPHARM (RWANDA) LTD	30/12//2023	29/12/2028
44	Rwanda FDA-HBP-MA-0105	BINOCRIT 10,000 IU/1 ML SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE	Epoetin alfa where it is 10000 IU per 1ml corresponding to 84.0 micrograms per 1mL	10000 IU per 1ml	Solution for injection	1 or 6 in pre-filled syringes	Pre-filled syringes	24 Months	IDT BIOLOGIKA GmbH, Am Pharmapark 06861 DessauRosslau, Germany	GERMANY	SANDOZ PHARMACEUTICALS D.D., SLOVENIA	SURGIPHARM (RWANDA) LTD	15/01/2024	14/01/2029
45	Rwanda FDA-HBP-MA-0106	PAGENAX SOLUTION FOR INJECTION 120MG/ML	Brolucizumab, Solution for injection 120mg/ml	120mg/ml	Solution for injection	1 vial and 1 filter needle	1 vial and 1 filter needle	24 Months	NOVARTIS PHARMA STEIN AG, Schaffhauserstrasse, 4332 Stein, Switzerland	SWITZERLAND	NVS KENYA LIMITED	SURGIPHARM (RWANDA) LTD	15/01/2024	14/01/2029
46	Rwanda FDA-HBP-MA-0107	RILAST 500	Rituximab 500mg/50 mL	500mg/50 mL	Concentrate for solution for injection	50 ml vial	Clear glass vial neutral (USP Type 1) with butyl rubber stopper	30 Months	HETERO BIOPHARMA LIMITED; Sy. No. 458 (part), TSIICFormulation SEZ, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar (District) – 509 301, Telangana State, India	INDIA	M/S HETERO BIOPHARMA LIMITED, INDIA	VINE PHARMA LIMITED	05/01/2024	04/01/2029
47	Rwanda FDA-HBP-MA-0108	RILAST 100	Rituximab 100mg/10 mL	100mg/10 mL	Concentrate for solution for injection	10 ml vial	Clear glass vial neutral (USP Type 1) with butyl rubber stopper	30 Months	HETERO BIOPHARMA LIMITED; Sy. No. 458 (part), TSIICFormulation SEZ, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar (District) – 509 301, Telangana State, India	INDIA	M/S HETERO BIOPHARMA LIMITED, INDIA	VINE PHARMA LIMITED	05/01/2024	04/01/2029
48	Rwanda FDA-HBP-MA-0109	BINOCRIT 2000IU/1ML	Epoetin alfa 2000IU per 1ml	2000IU/1ml	Sterile solution for injection	1 and 6 pre-filled syringes,	re-filled syringes, glass type I	24 Months	IDT BIOLOGIKA GmbH, Am Pharmapark 06861 Dessau-Rosslau, Germany	GERMANY	SANDOZ PHARMACEUTICALS D.D., SLOVENIA	SURGIPHARM (RWANDA) LTD	15/01/2024	14/01/2029
49	Rwanda FDA-HBP-MA-0110	BINOCRIT 8000IU/0.8ML	Epoetin alfa 8000IU per 0.8ml	8000IU/0.8ML	Solution for injection	6 syringes	Pre-filled in type I colorless glass syringes, closed with bromobutyl rubber stoppers which are laminated with a fluorocarbon layer. Such 6 syringes are packed in a carton	24 Months	IDT BIOLOGIKA GmbH, Am Pharmapark 06861 DessauRoßlau, Germany	GERMANY	SANDOZ PHARMACEUTICALS D.D., SLOVENIA	SURGIPHARM (RWANDA) LTD	30/12//2023	29/12/2028
50	Rwanda FDA-HBP-MA-0111	HEPATITIS B VACCINE (rDNA) (ADULT) 1 DOSE	Hepatitis B Surface Antigen (Aqueous), 20mcg/1ml	20mcg/1ml	Suspension for injection	Box of 50 vials of 4ml	Tubular Flint Vial (Type I Glass) with a gray plain bromobutyl rubber stopper and aluminium flip off cap	36 Months	SERUM INSTITUTE OF INDIA PVT. LTD 2122, Hadapsar, Pune411028, India	INDIA	SERUM INSTITUTE OF INDIA PVT. LTD	SUN ENTERPRISES LTD	17/02/2024	16/02/2029
51	Rwanda FDA-HBP-MA-0112	FOLISURGE 1200	Follitropin Alpha 1200 IU/1.92 mL	1200 IU/1.92 mL	Solution for Injection.	1 Vial of 2ml	Type I Glass Vial	24 Months	INTAS PHARMACEUTICALS LIMITED, Plot No. 423/P/A Sarkhej - Bavla Highway. Moraiya,	INDIA	INTAS PHARMACEUTICALS LIMITED	VINE PHARMA LTD	26/02/2024	25/02/2029

									Taluka: Sanand Ahmedabad – 382 213 Gujarat, India					
52	Rwanda FDA-HBP- MA-0113	GLARITUS 100 IU/ML	Insulin glargine Injection USP, 100 IU/mL (r-DNA origin)	100 IU/mL	Solution for Injection.	10 ml vial, 3ml Cartridge	Type I Glass Vial, Cartridge and Dispopen	36 Months	WOCKHARDT LIMITED, Biotech Park, H-14/2, MIDC, Waluj, Aurangabad-431136, India	INDIA	WOCKHARD T LIMITED, INDIA	ABACUS PHARMA (A) LTD	26/02/2024	25/02/2029
53	Rwanda FDA-HBP- MA-0115	ACURIN 5000IU/ML	Heparin sodium BP 5000IU/ml	5000IU/ml	Solution for injection	5 ml vial	Amber Glass Vial USP Type I closed with grey bromobutyl rubber stopper sealed with flip off seal	24 Months	ACULIFE HEALTHCARE PRIVATE LTD, Village- Sachana, Tal- Virangam, City: Sachana-382 150, Dist: Ahmedabad Gujarat State, India	INDIA	ACULIFE HEALTHCAR E PRIVATE LTD, INDIA	SUN ENTERPRISES LTD	26/02/2024	25/02/2029
54	Rwanda FDA-HBP-MA- 0117	TETANUS ANTITOXIN	Tetanus Antitoxin BP 1500 IU	1500 IU	Liquid for injection	1 ml Ampoule	1 ml white USP type I One Point Cut (OPC) ampoule with liquid injection	24 Months	SERUM INSTITUTE OF INDIA PVT. LTD. 212/2 Hadapsar, Pune- 411 0028, India	INDIA	SERUM INSTITUTE OF INDIA PVT. LTD, INDIA	SUN ENTERPRISES LTD	23/02/2024	22/02/2029

Prof. Emile BIENVENU
Director General