

LIST OF MEDICINAL PRODUCTS RECEIVED UNDER THE EAC MRH PROGRAMM FOR JOINT ASSESSMENT (OCTOBER 2015 TO APRIL 2017)

S/N	REFERENCE NO.	EAC REFERENCE NUMBER	DATE RECEIVED	BRAND NAME	STRENGTH	DOSAGE FORM	APPLICANT NAME	EAC ASSESSMENT SESSION	STATUS MARCH 31 ST, 2017
1	TFDA0015/HM/0322	EAC15/HM/001	21-Jul-15	Avastin 100mg / 4ml	100 mg/4ml	Injection	F.Hoffmann-La Roche Limited	EAC 1st Joint Assessment 19th to 23rd October 2015	Registered
2	TFDA0015/HM/0323	EAC15/HM/002	21-Jul-15	Avastin 400mg / 16ml	25 mg/ml	Injection	F.Hoffmann-La Roche Limited		Registered
3	TFDA0015/HM/0324	EAC15/HM/003	21-Jul-15	Herceptin 150mg	150 mg	Lyophilized Injection	F.Hoffmann-La Roche Limited		Registered
4	TFDA0015/HM/0325	EAC15/HM/004	21-Jul-15	Herceptin 440mg	440 mg	Lyophilized Injection	F.Hoffmann-La Roche Limited		Registered
5	TFDA0015/HM/0399	EAC15/HM/005	11-Sep-15	Cardisar HT 160/12.5	160 + 12.5 mg	Tablet	Mylan Pharmaceuticals Pvt Ltd		Queried
6	TFDA0015/HM/0400	EAC15/HM/006	11-Sep-15	Cardisar HT 160/25	160 + 25 mg	Tablet	Mylan Pharmaceuticals Pvt Ltd		Queried
7	TFDA0015/HM/0401	EAC15/HM/007	11-Sep-15	Cardisar HT 80/12.5	80 + 12.5 mg	Tablet	Mylan Pharmaceuticals Pvt Ltd		Queried
8	TFDA0015/HM/0402	EAC15/HM/008	11-Sep-15	Vaclovir 500	500 mg	Tablet	Mylan Pharmaceuticals Pvt Ltd		Queried
9	TFDA0015/HM/0431	EAC15/HM/009	22-Oct-15	Abacavir Sulfate and Lamivudine	60 + 30 mg	Tablet, Dispersible	Mylan Laboratories Limited	EAC 2nd Joint Assessment 23rd to 27th May 2016	Queried
10	TFDA0016/HM/0032	EAC16/HM/001	15-Jan-16	Nexavar	200 mg	Tablet	Bayer East Africa Limited		Recommended for registration pending GMP positive outcome

11	TFDA0016/HM/0042	EAC16/HM/002	27-Jan-16	Tamoxifen	20 mg	Tablet, Film-coated	Sandoz GmbH Kundl		Queried
12	TFDA0016/HM/0043	EAC16/HM/003	27-Jan-16	Metformin Sandoz	1000 mg	Tablet, coated	Sandoz GmbH Kundl		Queried
13	TFDA0016/HM/0044	EAC16/HM/004	27-Jan-16	Metformin Sandoz	500 mg	Tablet, Film-coated	Sandoz GmbH Kundl		Queried
14	TFDA0016/HM/0045	EAC16/HM/005	27-Jan-16	Amlodipine	10 mg	Tablet	Sandoz GmbH Kundl		Queried
15	TFDA0016/HM/0046	EAC16/HM/006	27-Jan-16	Amlodipine	5 mg	Tablet	Sandoz GmbH Kundl		Queried
16	TFDA0016/HM/0062	EAC16/HM/007	9-Feb-16	Sirturo	100 mg	Tablet	Janssen-Cilag International NV	EAC 3rd Joint Assessment - 8th to 12th August 2016	Recommended for registration pending GMP positive outcome
17	TFDA0016/HM/0142	EAC16/HM/008	6-Apr-16	Bisoprolol	2.5 mg	Tablet, Film-coated	Sandoz GmbH Kundl		Queried
18	TFDA0016/HM/0143	EAC16/HM/009	6-Apr-16	Bisoprolol	5 mg	Tablet, Film-coated	Sandoz GmbH Kundl		Queried
19	TFDA0016/HM/0144	EAC16/HM/010	6-Apr-16	Bisoprolol	10 mg	Tablet, Film-coated	Sandoz GmbH Kundl		Queried
20	TFDA0016/HM/0145	EAC16/HM/011	6-Apr-16	Anastrozole Sandoz	1 mg	Tablet, Film-coated	Sandoz GmbH Kundl		Queried
21	TFDA0016/HM/0146	EAC16/HM/012	6-Apr-16	Furosemide	40 mg	Tablet	Sandoz GmbH Kundl		Queried

22	TFDA0016/HM/0164	EAC16/HM/013	20-Apr-16	Ec- Pram 10	10 mg	Tablet	Hetero Labs Limited	4th Joint assessment 5th to 8th December 2016	Queried
23	TFDA0016/HM/0165	EAC16/HM/014	20-Apr-16	Prega 150	150 mg	Tablet	Hetero Labs Limited		Queried
24	TFDA0016/HM/0166	EAC16/HM/015	20-Apr-16	Prega 75	75 mg	Tablet	Hetero Labs Limited		Queried
25	TFDA0016/HM/0209	EAC16/HM/016	18-May-16	Simvastatin	40 mg	Tablet, Film-coated	Sandoz GmbH Kundl		Queried
26	TFDA0016/HM/0210	EAC16/HM/017	18-May-16	Hydrochlorothiazide	25 mg	Tablet	Sandoz GmbH Kundl		Queried
27	TFDA0016/HM/0211	EAC16/HM/018	18-May-16	Simvastatin	20 mg	Tablet, Film-coated	Sandoz GmbH Kundl		Queried
28	TFDA0016/HM/0358	EAC16/HM/019	15-Jul-16	Cetuximab 5 mg/ml	5 mg/ml	Erbitux Solution for Infusion	Merck (Pty) Limited, South Africa		Queried
29	TFDA0016/HM/0388	EAC16/HM/020	29-Jul-16	Ablevox Solution for Infusion		Levofloxacin	Abacus Parenteral Drugs Ltd (APDL), Uganda	Queried	
30	TFDA0016/HM/0389	EAC16/HM/021	29-Jul-16	Abpara Solution for infusion	Paracetamol 1%	Solution for infusion	Abacus Parenteral Drugs Ltd (APDL), Uganda	Queried	

31	TFDA0016/HM/05 46	EAC16/HM/022	17-Oct-16	Chlorhexidine Digluconate gel	Chlorhexidine Digluconate gel 7.1% USP	gel	Universal Corporation Ltd, Kenya		Queried
32	TFDA0016/HM/05 88	EAC16/HM/023	8-Nov-16	Kemoxyl DT 250	Amoxicillin dispersible tablets 250 mg	Dispersible Tablets	Laboratory and Allied Limited, Kenya		Queried
33	TFDA0017/HM/01 09	EAC17/HM/001	3-Mar-17	Mycamine 100 Powder for Solution for Infusion	Micafungin 100 mg correspondin g to 101.73mg as Sodium salt	Powder for Solution for Infusion	Astellas Pharma (Pty) Ltd, South Africa	5th Joint assessment 18 th to 22 nd April 2017	New
34	TFDA0017/HM/01 10	EAC17/HM/002	3-Mar-17	Mycamine 50 Powder for Solution for Infusion	Micafungin 50 mg correspondin g to 50.86 mg as Sodium salt	Powder for Solution for Infusion	Astellas Pharma (Pty) Ltd, South Africa		New