125th Sub Committee of MEC 01/10/2026			
No	**Application No.**	**Application type**	**Decision of Subcommittee**
1.	M/7030/NP/LMP/2025	New	Awaiting additional data
2.	M/7031/NP/LMP/2025	New	Awaiting additional data
3.	M/8225/NP/2026/REL	New	Provisional Registration for two years
4.	MEDREG/2020/00334	New	Provisional Registration for two years
5.	MEDREG/2021/01320	New additional	Awaiting additional data
6.	M/6664/NP/2024	New additional	Awaiting additional data
7.	M/6794/NP/2024	New additional	Awaiting additional data
8.	M/6236/NP/LMP/2023	New additional	Provisional Registration for two years
9.	M/6860/NP	New additional	Provisional Registration for two years
10.	M/7391/NP/LMP/2025	New	Provisional Registration for two years
11.	M/4785/NP/2022	New additional	Provisional Registration for two years
12.	M/6447/NP/LMP	New additional	Awaiting additional data

13.	M/6448/NP/LMP	New additional	Awaiting additional data
14.	M/6449/NP/LMP	New additional	Awaiting additional data
15.	M/6351/NP/2023	New	Provisional Registration for two years
16.	M/5467/NP/2023	New additional	Awaiting additional data
17.	M/5471/NP/2023	New additional	Awaiting additional data
18.	M/5470/NP/2023	New additional	Awaiting additional data
19.	M/6794/NP/2024	New additional	Awaiting additional data
20.	M/6824/NP/2024	New additional	Provisional Registration for two years
21.	M/6622/NP/LMP/2024	New additional	Hold until GMP approval is granted
22.	M/6722/NP/LMP/2024	New additional	Provisional Registration for two years
23.	M/6782/NP/LMP/2024	New	Awaiting additional data
24.	M/5848/NP/LMP/2023	New	Provisional Registration for two years
25.	M/5317/RR-D/2025	Renewal	Full Registration for five years
26.	M/7771/NP/2025	New additional	Awaiting additional data

27.	M5935/NP/LMP/202 3	New additional	Awaiting additional data
28.	M/4703/NP/LMP/202 2	Renewal	Provisional Registration for one year
29.	M/5545/RR-D/2025	Reregistration	Awaiting additional data
30.	M/6656/NP/LMP/202 4	New	Provisional Registration for two years

Renewal Applications

No	Application No.	Application type	Decision of Subcommittee
1.	11473	Renewal	Full Registration for five years.
2.	M/6580/NP/LMP/2024	Renewal	Full Registration for five years.
3.	M/917/NP/LMP	Renewal	Provisional Registration for two years.
4.	M/905/NP/LMP	Renewal	Provisional Registration for two years.
5.	M/5496/NP/LMP/2023	Renewal	Provisional Registration for two years.
6.	M/4183/NP/LMP	Renewal	Provisional Registration for one year.
7.	M/5693/NP/LMP/2023	Renewal	Provisional Registration for two years.
8.	M/4648/NP/LMP/2022	Renewal	Provisional Registration for two years.
9.	M/2075/NP/LMP	Renewal	Provisional Registration for two years.

10.	M/4677/NP/LMP	Renewal	Provisional Registration for two years.
11.	M/6596/NP/LMP/2024	Renewal	Provisional Registration for two years.
12.	M/3135/RR	Renewal	Full Registration for five years.
13.	M/3019/RR	Renewal	Full Registration for five years.
14.	M/2254/NP	Renewal	Full Registration for five years.
Reregistration			
No	**Application No.**	**Application type**	**Decision of Subcommittee**
1.	M/5575/RR/2025	RR	Full Registration for five years.
2.	M/5546/RR/2025	RR	Full Registration for five years.
3.	M/3762/NP	RR	Awaiting additional data

Other matters

1. Registration of Beractant Intratracheal Suspension 25mg/1ml (Beraksurf) - M/7092/NP/BTP/2024

The Committee discussed the registration application for Beractant Intratracheal Suspension 25 mg/1 mL (Beraksurf), M/7092/NP/BTP/2024, manufactured by Tekzima Darou Alborz Co., Iran.

The Committee was informed that the recommended SmPC and pack insert had been forwarded to the representative of the MEC from the College of Paediatricians for her opinion. She has forwarded the documents to Dr. Nishani Lucas, Consultant Neonatologist. The

Thereafter, the recommendation of Dr. Nishani Lucas was communicated to the representative of the MEC from the College of Paediatricians. It was further informed that, if no response was received within two working days, the NMRA would proceed with releasing the evaluation sheet accordingly, accepting the attached PI and SmPC. As no response was received within the two working days, the matter was submitted to the Subcommittee for final consideration and

The Committee therefore recommended granting provisional registration for one year considering the recommendation of Consultant Neonatologist. The Committee further recommended that the Paediatricians and

- Edit and update the currently available monitoring form available at the MSD nd implement strict monitoring of efficacy and safety of the product
- To have a national guideline on which surfactant to be used in RDS

2. Clarification regarding the acceptance of applications M/4744/RR-

The matter was forwarded by the Pricing Unit/NMRA regarding the registration application M/4744/RR-D/BTP/2024 for Canmab (Trastuzumab for Injection [rDNA Origin] 440 mg/vial), submitted by Medmart Pharma (Pvt) Ltd manufactured by Biocon Biologics Limited, India. Also it was noted that the above manufacturer is also the manufacturer of Hertraz 440, under application M/4946/RR-D, submitted by Markss HLC (Pvt) Ltd. The manufacturing address declared for Hertraz 440 is also the same as that declared for the

Accordingly, both products are manufactured by the same manufacturer and have the same strength and presentation, although they
are marketed under different brand names and submitted by two different Local Agents. The Pricing Committee therefore requested clarification and acceptance of The Subcommittee noted the matter and recommended to forwarded it to the MEC

Participants

1. Prof. Rohini Fernandopulle, Senior Professor of Pharmacology (Expert/MEC)
2. Dr. Kapila Gamage, Consultant Surgeon (Member/MEC)
3. Dr. Rohitha Muthugala, Consultant Medical Virologist (Expert MEC)
4. Mr. A.J.M.N. Bandara, PA/NMRA
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19. Ms. C.H.E. Senevirathne, APA/NMRA