Policy Decisions Taken by the Medicines Evaluation Committee

(109th to 113th MEC Meetings)

MEC No.	Date of the meeting	Name of Product/Category	Decision
109	30.12.2025	Glutathione intravenous preparations	Not to accept Glutathione intravenous preparations, either alone or in combination with other preparations, and Vitamin C intravenous preparations for skin lightening purposes.
109	30.12.2025	Batch-specific COA requirement for WOR applications	Batch-specific Certificates of Analysis (COA) need not be submitted during the WOR application review stage. Applicants shall submit the batch-specific COA to the NMRA prior to distribution of the respective product lot.
111	24.02.2026	Phenylephrine containing products	Phenylephrine cannot be used for nasal decongestant. Grant one-year registration for all products containing phenylephrine as a nasal decongestant and instruct applicants to reformulate by removing phenylephrine.
111	24.02.2026	Site change applications	Site change applications shall be considered as variation applications where the change involves a change in manufacturing site within the same manufacturer; • Sites operating under the same management; • Subsidiaries of the same manufacturer;

			• An additional, upgraded, or alternative site of the same manufacturer; and • Contract manufacturers of the legal manufacturer For biological products, such variations shall be accepted only if the manufacturer is approved by a stringent regulatory authority or holds registration in a PIC/S member country. However, for insulin and enoxaparin products, site change applications may be accepted as variations even if the manufacture is not from a stringent regulatory authority .
111	24.02.2026	Methylcobalamin	Not to accept methylcobalamin either alone or in combination with other products.
111	24.02.2026	Orlistat Capsules	Bioequivalence (BE) study reports are not required for Orlistat Capsules. Comparative dissolution studies with the market leader or innovator product may be considered.
111	24.02.2026	Bioequivalence (BE) studies	MEC recommended following policy decision regarding BE studies **1. Local Manufacturers**

			The decision regarding the requirement of Bioequivalence (BE) studies for locally manufactured products is as follows: <u>Products requiring BE studies:</u> ❖ Products belonging to BCS Class II and Class IV ❖ Extended-release products ❖ Modified-release products ❖ BCS Class I and III products with a Narrow Therapeutic Index, where safety and effectiveness cannot be adequately monitored <u>Products not requiring BE studies:</u> Products belonging to BCS Class I and Class III <u>Special considerations for Narrow Therapeutic Index (NTI) drugs:</u> BCS Class I and III products with a Narrow Therapeutic Index, where safety and effectiveness can be adequately monitored, do not require BE studies. <u>Antibiotics:</u> Oral antibiotics belonging to BCS Class I and III do not require BE studies.

			2. Imported Products Products requiring BE studies: ● Oral antibiotics ● Products with a Narrow Therapeutic Index ● Extended-release and modified-release products ● Products belonging to BCS Class II and Class IV Products requiring comparative dissolution studies: ● Products belonging to BCS Class I and Class III
111	24.02.2026	Oseltamivir distribution	Distribution and availability of Oseltamivir shall be restricted to Government Osusala outlets, pharmacies of private hospitals, and outlets of registered importers.
112	24.03.2026	'Me-Too' NCE policy	Accept new chemical entities except Biologicals only in instances where there is a clearly demonstrated significant clinical advantage and a substantial price advantage over the existing registered me-too products.
113	28.04.2026	Vitamin D 2000 IU preparations	Vitamin D 2000 IU strength products were accepted for evaluation and registration

113	28.04.2026	Methylprednisolone sodium succinate powder for injection combi pack	Not to accept combi packs for Methylprednisolone sodium succinate powder for injection products. Existing registered combi packs shall be removed at the renewal stage.
113	28.04.2026	Vaccines	Vaccines which are in the EPI program or if there is any potential to include to the program should be WHO prequalified.
113	28.04.2026	DEG and EG contaminants	NMQAL test report/ 3rd party accredited laboratory test reports/ WHO prequalified laboratory test report for DEG and EG contamination of the finished product of oral liquid drug products containing any components which have been defined as high risk drug components for DEG and EG according to US. Food and Drug Administration Center for Drug evaluation and Research guideline should be available for granting registration for such products.
113	28.04.2026	Risk Management Plan	Risk Management Plan (RMP) for all biological products is mandatory for grant registration with effect from 01.07.2026. This decision should be applicable for the applications which have been already submitted.
113	28.04.2026	Sunscreen	Sunscreens with SPF greater than 30 be regulated and registered as medicines with effect from 1st January 2027.

113	28.04.2026	Local NCE application	All required data, including stability data covering the entire proposed shelf life, should be submitted at the time of registration for Local NCE applications.
113	28.04.2026	Measuring device	A calibrated measuring device, such as a cup, spoon, syringe, or pipette, should be mandatory for oral liquid dosage forms.