Policy Decisions Taken by the Medicines Evaluation Committee in Year 2025

Name of Product/Category	Decision	MEC Number	Date of the meeting
Ramipril Modified Release dosage forms	Ramipril Modified Release dosage forms are not accepted as Ramipril has a long half-life which anyway allows for once daily dosing and there is no particular advantage of having a modified release.	98	28/01/2025
Oral dosage forms of Cloxacillin	Not to register new products and not to renew existing products of Oral dosage forms of Cloxacillin because of poor bioavailability.	98	28/01/2025
Chloramphenicol Eye Ointment	Not to register new products and not to renew existing products of Chloramphenicol Eye Ointment under "Need" clause.	98	28/01/2025
Bisoprolol Fumarate tablets	Only Bisoprolol Fumarate tablets are accepted for registration in Sri Lanka but not Bisoprolol Hemifumarate tablets as there is no any added advantage of Bisoprolol Hemifumarate tablets.	98	28/01/2025
Ketorolac Tablets	Not to register new product and not to renew existing products of Ketorolac Tablets and recall existing registrations.	98	28/01/2025
Cilnidipine	Not to register new product and not to renew existing products of Cilnidipine and recall existing registrations.	98	28/01/2025
Deflazacort Tablets 30mg.	Not to accept new registration applications and not to renew applications of Deflazacort Tablets 30mg.	99	25/02/2025
Orciprenaline Tablet BP 10mg	Not to accept new applications, not to renew applications of Orciprenaline Tablet 10mg	99	25/02/2025

Losartan Potassium Tablet 50 mg Amlodipine Besylate Tablet 5 mg Hydrochlorothiazide Tablet 25 mg Metformin Tablet 500 mg Gliclazide Tablet 40 mg and 80 mg.	Only blister packs are accepted for registration of the following drug products. 1. Losartan Potassium Tablet 50 mg 2. Amlodipine Besylate Tablet 5 mg 3. Hydrochlorothiazide Tablet 25 mg 4. Metformin Tablet 500 mg 5. Gliclazide Tablet 40 mg and 80 mg.	101	29/04/2025
All medicine products	Stem of INN should not be used in or as a brand name	102	03/06/2025
Sevelamer Tablets	A report of comparative study with the innovator product for phosphate binding capacity is needed for Sevelamer.	102	03/06/2025
Cough syrups	Cough syrups conotaining Codeine can be sold in limited pharmacies as practiced earlier and cough syrups containing Dextromethorphan can be sold in any pharmacy	103	24/06/2025
All medicine products	If any drug product is available in Ph. Eur., BP, IP and USP monographs, such drug products should not be registered in any other specification including Inhuose specifications.	103	24/06/2025
Whitfield's ointment	Not to import Whitfield's ointment and only local manufacturing and extemporaneous preparation is allowed.	103	24/06/2025
Drug products for HIV	WHO prequalified product should be used as the comparator for BE or Biowaiver studies of drug products for HIV	103	24/06/2025

All new multivitamins and multiminerals containing products	All new multivitamins and multiminerals containing products should be submitted to the Borderline Products Regulatory Division for classification.	103	24/06/2025
Hydroxyprojesterone	Not to accept new applications of Hydroxyprogesterone and not to renew existing registrations.	104	22/07/2025
Oral liquid dosage forms	A measuring cup is mandatory for the oral liquid dosage forms	105	26/08/2025
Cloxacillin Sodium for Oral Solution 125mg/5ml	Not to register new products and not to renew existing products of Cloxacillin Sodium for Oral Solution 125mg/5ml	105	26/08/2025
Indapamide/ Perindopril Arginine Tablets 2.5 mg/ 10 mg	Not to register new products and not to renew existing products of Indapamide/ Perindopril Arginine Tablets 2.5 mg/ 10 mg	105	26/08/2025
Oral Liquid Drug Products	NMQAL report for DEG and EG contamination of the finished product of oral liquid drug products should be available for granting registration for such products.	105	26/08/2025
Isotretinoin and Acitretin products	A risk management plan needs to be provided by the manufacturer for Isotretinoin and Acitretin products at the time of registration.	108	02/12/2025
Skin drug preperations	The maximum accepted amount for skin drug preperations is 30 g	108	02/12/2025
Quality failure reported drug product	The applicant can reapply for product registration of the quality failure reported drug product after two years.	108	02/12/2025

Angiotensin II receptor blockers, histamine-2 blockers (ranitidine and nizatidine), antidiabetic medications (metformin and sitagliptin), antibiotics (rifampin and rifapentine), and smoking cessation medications (varenicline)	Nitrosamine impurity tests results for the following products should be submitted, in accordance with US FDA guidance. 1. Angiotensin II receptor blockers 2. Histamine-2 blockers (ranitidine and nizatidine) 3. Antidiabetic medications (metformin and sitagliptin) 4. Antibiotics (rifampin and rifapentine) 5. Smoking cessation medications (varenicline)	108	02/12/2025
Multivitamin and Multimineral products	A product will be categorized as a medicine only if all APIs exceed the established therapeutic level for each respective API.	108	02/12/2025
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 purpose.	109	30/12/2025