

## Decisions for New Molecular Entities

	<b>Application No</b>	<b>New Molecular Entity Name</b>	<b>Decision</b>
1	MEC/195/23	Denosumab solution for Injection PFS 60mg/ml	Molecule was accepted.
2	MEC/196/23	Doxofyline Tablets 400mg	Molecule was not accepted.
3	MEC/197/23	Dolutegrovir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets 50/300/300mg	Molecule was accepted.
4	MEC/198/23	Teneligliptin Tablet 20mg	Molecule was not accepted.
5	MEC/199/23	Darunavir Tablets 300mg	Molecule was accepted.
6	MEC/200/23	Darunavir Tablets 600mg	Molecule was accepted.
7	MEC/201/23	Darunavir Tablets 800mg	Molecule was accepted.
8	MEC/202/23	Denosumab Injection 120mg	Molecule was accepted.
9	MEC/203/23	Etanercept Solution for Injection 25mg/0.5ml in PFS	Molecule was accepted.
10	MEC/204/23	Desidustat Tablets 25mg	Molecule was accepted.
11	MEC/205/23	Calfactant 35mg/1ml	Molecule was accepted.
12	MEC/206/23	Desidustat Tablets 50mg	Molecule was accepted.
13	MEC/207/23	Desvenlafaxine Extended Release Tablets 50 mg	Molecule was accepted.
14	MEC/208/23	Vonoprazan Fumarate Tablet 20mg	Molecule was not accepted.
15	MEC/209/23	Vonoprazan Fumarate Tablet 10mg	Molecule was not accepted.
16	MEC/210/23	Azelnidipine Tablets 8mg	Molecule was not accepted.
17	MEC/211/23	Afatinib Dimaleate tablets 40mg	Molecule was accepted.
18	MEC/212/23	Vonoprazan Fumarate Tablets 20mg	Molecule was not accepted.
19	MEC/213/23	Vonoprazan Fumarate Tablets 10mg	Molecule was not accepted.
20	MEC/214/23	Doxophylline INN tablets 400 mg	Molecule was not accepted.
21	MEC/215/23	Luliconazole Cream 1% w/w	Molecule was not accepted.
22	MEC/216/23	Cabazitaxel concentrate and solvent for solution for infusion 60mg	Molecule was accepted.
23	MEC/217/23	Dolutegravir Sodium Tablets 50 mg	Molecule was accepted.

24	MEC/218/23	Vonoprazan Tablets 10 mg	Molecule was not accepted.
25	MEC/219/23	Vonoprazan Tablets 20 mg	Molecule was not accepted.
26	MEC/220/23	Rasagiline Mesylate Tablets 1mg	Molecule was accepted.
27	MEC/221/23	Plerixafor solution for Injection 20mg	Molecule was accepted.
28	MEC/222/23	Semaglutide Tablets 7mg	Molecule was accepted.
29	MEC/223/23	Semaglutide Tablets 3mg	Molecule was accepted.
30	MEC/224/23	Semaglutide Tablets 14mg	Molecule was accepted.
31	MEC/225/23	Dexketoprofen Trometamol 36.90 mg	Molecule was not accepted.
32	MEC/226/23	Dexlansoprazole Delayed Release Capsules 30 mg	Molecule was accepted.
33	MEC/227/23	Etanercept Injectable solution in prefilled syringe	Molecule was accepted.
34	MEC/228/23	Fomepizole Injection 1.5mg/1.5 ml	Molecule was accepted.
35	MEC/229/23	Roflumilast Tablets 500mcg	Molecule was accepted.
36	MEC/230/23	Durvalumab Injection 500mg/10ml(50mg/ml)	Molecule was accepted.
37	MEC/231/23	Durvalumab Injection 120mg/2.4ml(50mg/ml)	Molecule was accepted.
38	MEC/232/23	Micafungin Sodium for injection 100mg	Molecule was accepted.
39	MEC/233/23	Etanercept Solution for Injection 25mg/0.5ml	Molecule was accepted.
40	MEC/234/23	Tedizolid Phosphate INN 200mg	Molecule was accepted.
41	MEC/235/23	Anagrelide Capsules USP 0.5 mg	Molecule was accepted.
42	MEC/236/23	Dexlansoprazole Delayed Release Capsules 30 mg	Molecule was accepted.
43	MEC/237/23	Semaglutide INN 1.34mg	Molecule was accepted.
44	MEC/238/23	Brivaracetam Tablets 25mg	Molecule was accepted.
45	MEC/239/23	Brivaracetam Tablets 75mg	Molecule was accepted.
46	MEC/240/23	Brivaracetam Tablets 50mg	Molecule was accepted.
47	MEC/241/23	Brivaracetam Tablets 100mg	Molecule was accepted.
48	MEC/242/23	Semaglutide Tablets 3mg	Molecule was accepted.
49	MEC/243/23	Semaglutide Tablets 7mg	Molecule was accepted.
50	MEC/244/23	Semaglutide Tablets 14mg	Molecule was accepted.
51	MEC/245/23	Bilastine Tablet 20mg	Molecule was not accepted.
52	MEC/246/23	Luliconazole Cream 1% w/w	Molecule was accepted.
53	MEC/247/23	Cinacalcet Film Coated Tablets 30mg	Molecule was accepted.

54	MEC/248/23	Cinacalcet Film Coated Tablets 60mg	Molecule was accepted.
55	MEC/249/23	Brivaracetam Tablets 10mg	Molecule was accepted.
56	MEC/250/23	Brivaracetam Tablets 25mg	Molecule was accepted.
57	MEC/251/23	Brivaracetam Tablets 50mg	Molecule was accepted.
58	MEC/252/23	Brivaracetam Tablets 75mg	Molecule was accepted.
59	MEC/253/23	Brivaracetam Tablets 100mg	Molecule was accepted.
60	MEC/254/23	Rasagilin Tablet 1mg	Molecule was accepted.
62	MEC/255/23	Levocartinine Injection USP 1g/5ml	Molecule was accepted.
63	MEC/256/23	L-Ornithine L-Aspartate Infusion 5g/10ml	Molecule was accepted.
64	MEC/257/23	Ferric Carboxymaltose Injection 1g/20ml	Molecule was accepted.
65	MEC/258/23	Ulinastatin for Injection 100000IU	Molecule was not accepted.
66	MEC/259/23	Imeglimin Hydrochloride Tablets 1000mg	Molecule was not accepted.
67	MEC/260/23	Imeglimin Hydrochloride Tablets 500mg	Molecule was not accepted.
68	MEC/261/23	Atazanavir Capsulets 300mg	Molecule was accepted.
69	MEC/262/23	Teneligliptin Tablets IP 20mg	Molecule was not accepted.
70	MEC/263/23	Vonoprazan Tablets 20mg	Molecule was not accepted.
71	MEC/264/23	Butenafine Cream 1% w/w	Molecule was not accepted.
72	MEC/265/23	Rizatriptan Benzoate Tablets 10mg	Molecule was accepted.
73	MEC/266/24	Lurasidone Hydrochloride Tablets 40mg,80mg	Molecule was accepted.
74	MEC/267/24	Obeticholoic Acid Tablets 10mg	Molecule was accepted.
75	MEC/268/24	Bilastine Tablet 20mg	Molecule was not accepted.
76	MEC/269/24	Atazanavir & Ritonavir Tablets	Molecule was accepted.
77	MEC/270/24	Fosfomycin Trometamol Powder for oral solution 3gm	Molecule was accepted.
78	MEC/271/24	Brilliant Blue G Ophthalmic Solution 0.05%w/v/1ml	Molecule was accepted.
79	MEC/272/24	Sugammadex Injection 200mg/2ml	Molecule was accepted.
80	MEC/273/24	Vardenafil Tablets 20 mg	Molecule was accepted.
81	MEC/274/24	Vardenafil Tablets 10 mg	Molecule was accepted.
82	MEC/275/24	Parecoxib Sodium Lyophilized Powder for Solution for IV/TM Injection	Molecule was accepted.
83	MEC/276/24	Carbetocin Solution for Injection 100mcg	Molecule was accepted.
84	MEC/277/24	Caffeine Citrate Solution for Injection USP 20mg/ml	Molecule was accepted.

85	MEC/278/24	Pitavastatin Film Coated Tablet 4mg	Molecule was not accepted.
86	MEC/279/24	Artemether Injection 80mg/1ml	Pending
87	MEC/280/24	Semaglutide Injection 6.7mg/5ml	Molecule was accepted.
88	MEC/281/24	Alogliptin Tablets 12.5mg	Molecule was not accepted.
89	MEC/282/24	Alogliptin Tablets 25mg	Molecule was not accepted.
90	MEC/283/24	Semaglutide Injection 2mg/1.5ml (1.34mg/ml) Pre-Filled Pen), Semglutide Injection 4mg/3ml (1.34mg/ml) pre-filled pen	Molecule was accepted.
91	MEC/284/24	Ferric Carboxymaltose Injection 500mg	Molecule was accepted.
92	MEC/285/24	Vonoprazan Fumarate Tablets 10mg	Molecule was not accepted.
93	MEC/286/24	Nitisinone Capsules 10mg	Molecule was accepted.
94	MEC/287/24	Ertugliflozin Tablets 5 mg	Molecule was not accepted.
95	MEC/288/24	Ertugliflozin Tablets 15 mg	Molecule was not accepted.
96	MEC/289/24	Cerebrolysin concentrate 215.2 mg solution for solution for infusion/solution for injection	Molecule was not accepted.
97	MEC/290/24	Brivaracetam Tablet 50mg	Molecule was accepted.
98	MEC/291/24	Risdiplam Powder for Oral Solution 0.75mg/ml	Molecule was accepted.
99	MEC/292/24	Faricimab 6mg/0.05ml solution for intravitreal injection, 120mg/ml solution in a single-dose vial with filter transfer needle	Molecule was accepted.
100	MEC/293/24	Ocrelizumab 300mg concentrate for solution for infusion 300mg/10ml (30mg/ml) in a single dose vial	Molecule was accepted.
101	MEC/294/2024	Luliconazole Cream 1% w/w	Molecule was accepted.
102	MEC/295/2024	Ertugliflozin 5 mg + Sitagliptin 100 mg Tablets	Molecule was not accepted.
103	MEC/296/2024	Ertugliflozin 15 mg + Sitagliptin 100 mg Tablets	Molecule was not accepted.
104	MEC/297/2024	Mirabegron Extended-Release Tablets 25mg and Mirabegron Extended- Release Tablets 50mg	Molecule was accepted.
105	MEC/298/2024	Pentosan polysulfate sodium capsules 100 mg	Molecule was accepted.
106	MEC/299/2024	Racecadotril Dispersible Tablets 30mg	Molecule was not accepted.
107	MEC/300/2024	Racecadotril Dispersible Tablets 10mg	Molecule was not accepted.
108	MEC/301/2024	Desvenlafaxine Succinate Monohydrate Coated Controlled Release Tablets 50 Mg/100 Mg	Molecule was not accepted.

109	MEC/302/2024	RASAGILINE TABLETS 1MG	Molecule was accepted.
110	MEC/303/2024	MACITENTAN TABLETS 10 MG	Molecule was accepted.
111	MEC/304/2024	Roflumilast Tablets 500mcg	Molecule was accepted.
112	MEC/305/2024	Lurasidone Hydrochloride Tablets 40 mg & 80 mg	Molecule was accepted.
113	MEC/306/2024	Butorphanol Tartrate Injection USP 1mg	Molecule was accepted.
114	MEC/307/2024	Bromfenac Ophthalmic Solution 0.09% w/v	Molecule was accepted.
115	MEC/308/2024	Bepotastine Besilate Ophthalmic Solution 1.5% w/v	Molecule was not accepted.
116	MEC/309/2024	Bilastine Tablets 20 mg	Molecule was not accepted.
117	MEC/310/2024	Nitisinone Suspension 4mg/ml	Molecule was accepted.
118	MEC/311/2024	Estradiol Valerate/ Dienogest Tablets	Molecule was accepted.
119	MEC/312/2024	Dienogest Tablets 2 mg	Molecule was accepted.
120	MEC/313/2024	Butamirate Citrate Syrup 15 mg/5 ml	Molecule was not accepted.
121	MEC/314/2024	Glycyrrhizine 20mg/10ml, Glycine 200mg/10ml, L-cysteine hydrochloride Solution for Injection 10mg/10ml	Molecule was not accepted.
122	MEC/315/2024	Itopride hydrochloride 50mg Flim coated tablets	Molecule was not accepted.
123	MEC/316/2024	Ixekizumab Injection 80 mg/ml	Molecule was accepted.
124	MEC/317/2024	Semaglutide Tablets 3mg/7mg/14mg	Molecule was accepted.
125	MEC/318/2024	Vonoprazan Tablets 20mg	Molecule was not accepted.
126	MEC/319/2024	Alectinib Capsules 150mg	Molecule was accepted.
127	MEC/320/2024	Finerenone Tablets 20 mg	Molecule was accepted.
128	MEC/321/2024	Finerenone Tablets 10 mg	Molecule was accepted.
129	MEC/322/2024	Sofosbuvir 400mg + Velpatavir 100 mg Tablets	Molecule was accepted.
130	MEC/323/2024	Cladribine Tablets 10mg	Molecule was accepted.
131	MEC/324/2025	Semaglutide Pre-filled Syringe Injection 0.25mg/0.188ml	Molecule was accepted.
132	MEC/325/2025	Fosfomycin Trometamol 3 g granules for oral solution	Molecule was accepted.
133	MEC/326/2025	Aflibercept Injection	Molecule was accepted.
134	MEC/327/2025	Flibanserin Flim coated Tablets 100mg	Molecule was not accepted.
135	MEC/328/2025	Elagolix Sodium Film Coated Tablets 150mg	Molecule was not accepted.
136	MEC/329/2025	Carisoprodol Tablets 350mg	Molecule was not accepted.
137	MEC/330/2025	Semaglutide tablets 7mg	Molecule was accepted.

138	MEC/331/2025	Semaglutide 4mg/3ml	Molecule was accepted.
139	MEC/332/2025	Semaglutide 2mg/1.5m	Molecule was accepted.
140	MEC/333/2025	Elagolix Sodium Film Coated Tablets 200mg	Molecule was not accepted.
141	MEC/334/2025	Prucalopride Tablets	Molecule was accepted.
142	MEC/335/2025	Crovalimab Injection 340mg/2ml (170mg/ml)	Molecule was accepted.
143	MEC/336/2025	Niraparib Capsule 100mg	Molecule was accepted.
144	MEC/337/2025	Racecadotril Capsules 100mg and Racecadotril Sachet 30mg &10mg	Molecule was not accepted.
145	MEC/338/2025	Finerenone Film Coated Tablets	Molecule was accepted.
146	MEC/339/2025	Fenticonazole Nitrate 2% cream	Molecule was not accepted.
147	MEC/340/2025	Lercanidipine Hydrochloride Tablet 20mg	Molecule was not accepted.
148	MEC/341/2025	Pomalidomide Capsules	Molecule was accepted.
149	MEC/342/2025	Bempedoic Acid Tablets 180mg	Molecule was accepted.
150	MEC/343/2025	Vonoprazan Tablets 20mg	Molecule was not accepted.
151	MEC/344/2025	Ibrutinib Capsules	Molecule was accepted.
152	MEC/345/2025	Venetoclax Tablets	Molecule was accepted.
153	MEC/346/2025	Raltegravir Tablets USP 400mg	Molecule was accepted.
154	MEC/347/2025	Vericiguat Tablets 2.5mg	Pending
155	MEC/348/2025	Vonoprazan Fumarate Tablets 10mg	Molecule was not accepted.
156	MEC/349/2025	Abemaciclib Tablets 50mg, 100mg,150mg and 200mg	Pending
157	MEC/350/2025	Resmetirom INN 80mg	Molecule was not accepted.
158	MEC/351/2025	Prucalopride Succinate INN 10mg	Molecule was accepted.
159	MEC/352/2025	Finerenone INN 10mg	Molecule was accepted.
160	MEC/353/2025	Eladiol Tablets range 150-200mg	Molecule was not accepted.
161	MEC/354/2025	Mirogabalin Tablet 5mg	Molecule was not accepted.
162	MEC/355/2025	Brivaracetam Tablets 25mg, 50mg, 75mg, 100mg, Injection 50mg/5ml	Molecule was accepted.
163	MEC/356/2025	Finerenone Tablets 10mg, 20mg	Molecule was accepted.
164	MEC/357/2025	Finerenone Film Coafed Tablets 10mg	Molecule was accepted.
165	MEC/358/2025	Carbetocin Injection 100mcg/ 1ml	Molecule was accepted.
166	MEC/366/2025	Diazoxide Tablets BP 50mg	Molecule was accepted.