

LIST

of the medicines not recommended for the registration by the Center according to the meeting decision N 08-2/22 on August 30, 2022

President _____ E. Amroyan

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Vinracin injection 1mg	vincristine (vincristine sulfate)	solution for injection	1mg/ml; vial 1ml	KOREA UNITED PHARM. INC., 107, Gongdan-ro, Yeonseo-myeon, Sejong-si	Korea South	KOREA UNITED PHARM. INC., 107, Gongdan-ro, Yeonseo-myeon, Sejong-si	Korea South	PoM	20876 30.08.2022
2	ESOMEZOLE-PROMO	esomeprazole (esomeprazole magnesium)	capsules gastro-resistant	20mg; (30/3x10/) in blister	Fredun Pharmaceuticals Ltd, Plot No 14,15,16, Zorabian Industrial Complex, Veoor Village, Tal Palghar (E), Thane, Maharashtra state 401404	India	RIAYU REMEDIES PVT.LTD, Flat N102, 1st Floor, Sharda Prem Building, Kopri Road, Thane, Maharashtra 400603	India	PoM	20877 30.08.2022
3	Promoconazole-150	fluconazole	capsules hard	150mg; (1) in blister	Fredun Pharmaceuticals Ltd, Plot No 14,15,16, Zorabian Industrial Complex, Veoor Village, Tal Palghar (E), Thane, Maharashtra state 401404	India	RIAYU REMEDIES PVT.LTD, Flat N102, 1st Floor, Sharda Prem Building, Kopri Road, Thane, Maharashtra 400603	India	PoM	20878 30.08.2022

4	TROGE Ibuprofen 400mg film-coated tablets	ibuprofen	tablets film-coated	400mg; (100/10x10/) in blister	Medopharm, No. 34-B, Industrial Area, Malur-563 160, Karnataka	India	Troge Medical GmbH, Milchstrasse 19, 20148 Hamburg	Germany	OTC	13632/1 30.08.2022
5	Kepxan Oral	levamisole (levamisole hydrochloride), oxyclozanide	suspension oral	30mg/ml+60mg/ml; plastic container 100ml, plastic container 1000ml	Kepto BV, Maagdenburgstraat 17, 7421 ZA Deventer- batch releaser, secondary packager, Kepto BV, Forellenweg 16, 4941SJ Raamsdonksveer, the Netherlands- bulk manufacturer, primary packager	the Netherlands	Kepto BV, Maagdenburgstraa t 17, 7421 ZA Deventer	the Netherland	PoM	20879 30.08.2022