

LIST

of the medicines not recommended for the registration by the Center according to the meeting decision N 04-1/25 on April 16, 2025

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	Indotrex	cetorelix (cetorelix acetate)	solution for s/c injection	0,25mg/0,5ml; pre-filled syringe 0,5ml	Gufic Biosciences Limited, Survey No. 171, N. H. No. 8, Near Grid, Kabilpore Navsari - 396424, Gujarat-bulk manufacturer, packager, quality control, batch releaser	India	Gufic Biosciences Ltd., National Highway No. 8, Near Grid, Kabilpore-396424, Navsari, Gujarat	India	PoM	22991 16.04.2025
2	Montol	montelukast (montelukast sodium)	tablets film-coated	10mg; (28/2x14) in blister	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081, Lefkosia- secondary packaging, batch releaser, Saneca Pharmaceuticals. a.s., Nitrianska 100, 92027 Hlohovec, Slovakia-bulk manufacturer, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-primary packaging	Cyprus	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081, Lefkosia	Cyprus	PoM	22992 16.04.2025