

## LIST

of the medicines not recommended for the registration by the Center according to the meeting decision N 12-1/24 on December 16, 2024

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	Entocid	thick extract of cuminum-cyminum, thick extract of vitisvinifera, thick extract of foeniculumvulgare, thick extract of menthapiperita, thick extract of berberisaristata, thick extract of mesuaferrea, thick extract of glycyrrhizaglabra, thick extract of cinnamomumtamala, thick extract of amomumsubulatum, thick extract of coriandrum-sativum	syrup	20mg+20mg+20mg+20mg+12mg+12mg+24mg+9mg+3mg+2mg; 120ml glass bottle	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Pakistan	OTC	22559 16.12.2024
2	ZEVIYA	cisplatin	concentrate for solution for infusion	50mg/50ml; glass vial	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kvality Pharmaceuticals Ltd, 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra (H.P.), India- bulk manufacturer, packager, quality control (physicochemical and microbiological)	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	22560 16.12.2024
3	Droxa	doxorubicin (doxorubicin hydrochloride)	powder lyophilized for solution for infusion	10mg; glass vial	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kvality Pharmaceuticals Ltd, 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra (H.P.), India- bulk manufacturer, packager, quality control (physicochemical and microbiological)	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	22561 16.12.2024

## LIST

of the medicines not recommended for the re-registration by the Center according to the meeting decision N 12-1/24 on December 16, 2024

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	Ethambutol Hydrochloride	ethambutol (ethambutol hydrochloride)	tablets film-coated	100mg; (100/10x10) in blister	Macleods Pharmaceuticals Ltd., Phase-II, Plot No 25-27, Sr. No 366, Premier Ind. Estate, Kachigam, Daman-396210	India	Macleods Pharmaceuticals Ltd., 304, Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai-400 059	India	PoM	22609 16.12.2024

## LIST

of the medicines not recommended for the variations not requiring reformulation of certificate for registration approved by the Center according to the meeting decision N 12-1/24 on December 16, 2024

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	Ketonal Extra 25mg granules for oral solution	ketoprofen (ketoprofen lysine)	granules for oral solution	25mg; (15) sachets, (30) sachets,	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana-batch releaser, Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG), Italy-bulk manufacturer, packager, quality control	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	18773/2 16.12.2024
2	Cerebrolysin	porcine brain peptides	solution for injection	215,2mg/ml; (5/1x5) ampoules 20ml in blister	EVER Neuro Pharma GmbH, Oberburgau 3, 4866 Unterach am Attersee- quality control, batch releaser, EVER Pharma Jena GmbH, Otto-Schott-Strasse 15, 07745 Jena,Thuringen, Germany- bulk manufacturer, primary packager, EVER Pharma Jena GmbH, Bruesseler Strasse 18, 07747 Jena, Thuringen, Germany- secondary packager	Austria	EVER Neuro Pharma GmbH, Oberburgau 3, 4866 Unterach am Attersee	Austria	PoM	22034/1 16.12.2024