

AUT-F0061**FORM****VERSION 2****EFFECTIVE DATE 9 FEBRUARY 2023****HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 21/06/2024****RECOMMENDATION FOR AUTHORISATION****TABLE 1.4 MR OR DECENTRALISED APPLICATIONS FOR RENEWAL OF A MARKETING AUTHORISATION FOR A HUMAN MEDICINAL PRODUCT**

NO.	PA NUMBER	CASE NUMBER	NAME OF PRODUCT	ACTIVE SUBSTANCES	PA HOLDER
1	PA0281/270/001	CRN00DZFD	Duloxetine Pinewood 30 mg hard gastro-resistant capsules	Duloxetine hydrochloride	Pinewood Laboratories Ltd
2	PA0281/270/002	CRN00DZFD	Duloxetine Pinewood 60 mg hard gastro-resistant capsules	Duloxetine hydrochloride	Pinewood Laboratories Ltd

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NO.	PPA NUMBER	CASE NUMBER	NAME OF PRODUCT	ACTIVE SUBSTANCES	PPA HOLDER
1	PPA1463/222/001	CRN00F2QT	Clarityn 10 mg tablets	Loratadine	IMED Healthcare Ltd.
2	PPA0465/506/001	CRN00F688	Saizen 8 mg/ml solution for injection in cartridge	Somatropin	PCO Manufacturing Ltd.

AUT-F0424	FORM
VERSION 4	EFFECTIVE DATE 19 MARCH 2024

**HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 21/06/2024
RECOMMENDATION FOR AUTHORISATION**

TABLE 1.13 RECOMMENDATIONS FOR PUBLICATION OF A NEW INTERCHANGEABLE MEDICINES LIST

NO.	CASE NUMBER	SUBSTANCE	CONSULTATION PERIOD ENDED	INTERCHANGEABLE LISTS FOR PUBLICATION	NO OF PRODUCTS	PROPOSED DATE OF PUBLICATION
1	CRN00FCWZ	Celecoxib	18/06/2024	IC0156-024-001 100mg / Capsules	3	24/06/2024
1	CRN00FCX0	Celecoxib	18/06/2024	IC0156-067-001 200mg / Capsules	4	24/06/2024
2	CRN00FCX1	Ulipristal	18/06/2024	IC0154-033-014 30mg / Film-Coated Tablets/Tablets	3	24/06/2024
3	CRN00FCX3	Desloratadine	18/06/2024	IC0153-001-014 5mg / Film-Coated Tablets/Tablets	10	24/06/2024
3	CRN00FCX4	Desloratadine	18/06/2024	IC0153-155-019 0.5 mg/ml / Oral Solution	4	24/06/2024