

AUT-F0059**FORM****VERSION 2****EFFECTIVE DATE 12 FEBRUARY 2023****HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 20/10/2023****RECOMMENDATION FOR AUTHORISATION****TABLE 1.2 MR OR DECENTRALISED MARKETING AUTHORISATION FOR A HUMAN MEDICINAL PRODUCT**

NO.	PA NUMBER	CASE NUMBER	NAME OF PRODUCT	ACTIVE SUBSTANCES	PA HOLDER
1	PA0281/263/001	CRN00CQ58	Furosemide Pinewood 20 mg Tablets	Furosemide	Pinewood Laboratories Ltd
2	PA0281/263/002	CRN00CQ58	Furosemide Pinewood 20 mg Tablets	Furosemide	Pinewood Laboratories Ltd
3	PA1986/109/001	CRN00CL7G	Nasusaf 137 micrograms/50 micrograms per actuation nasal spray, suspension	Azelastine hydrochloride Fluticasone propionate	Teva B.V.

AUT-F0061**FORM****VERSION 2****EFFECTIVE DATE 12 FEBRUARY 2023****HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 20/10/2023****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	PA2220/002/003	CRN00DRZ5	Co-amoxiclav 2000 mg/200 mg powder for solution for infusion	Amoxicillin Clavulanic acid	Instituto Biochimico Italiano G. Lorenzini S.p.A.
2	PA2220/002/002	CRN00DRZ5	Co-amoxiclav 1000 mg/200 mg powder for solution for injection/infusion	Amoxicillin Clavulanic acid	Instituto Biochimico Italiano G. Lorenzini S.p.A.
3	PA2220/002/001	CRN00DRZ5	Co-amoxiclav 500 mg/100 mg powder for solution for injection/infusion	Amoxicillin Clavulanic acid	Instituto Biochimico Italiano G. Lorenzini S.p.A.
4	PA2315/120/001	CRN00CRVT	Tacrolimus 0.1% Ointment	Tacrolimus	Accord Healthcare Ireland Ltd.

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NO.	PA NUMBER	CASE NUMBER	NAME OF PRODUCT	PROPOSED NEW PA HOLDER	TRANSFERRED FROM PA NUMBER	EXISTING PA HOLDER
1	PA23490/009/001	CRNOODWFM	Oraldene 0.1% w/v Gargle/Mouthwash	JNTL Consumer Health I (Ireland) Limited	PA0330/024/001	Johnson & Johnson (Ireland) Limited

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RECOMMENDATION FOR AUTHORISATION

TABLE 1.11 NATIONAL APPLICATION FOR REGISTRATION OF A TRADITIONAL HERBAL MEDICINAL PRODUCT

NO.	TR NUMBER	CASE NUMBER	NAME OF PRODUCT	ACTIVE SUBSTANCES	TR HOLDER
1	TR22953/001/001	CRN009L3H	Ellura hard capsules	Cranberry fruit juice refined dry extract	Laboratoire Pharmaceutique Pharmatoka SAS

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RECOMMENDATION FOR PUBLICATION OF NEW IC LIST

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	CRNOODTNK	Pirfenidone	17/10/2023	IC0127 -1 73-009 267 mg I Capsules/Film-Coated Tablets	8	26/10/2023
2	CRNOODTNP	Pirfenidone	17/10/2023	IC0127 -1 7 4-003 534 mg I Film-coated Tablets	4	26/10/2023
3	CRNOODTNQ	Pirfenidone	17/10/2023	IC0127-175-003 801 mg I Film-coated Tablets	7	26/10/2023

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NO.	VPA NUMBER	CASE NUMBER	NAME OF PRODUCT	PROPOSED NEW VPA HOLDER	TRANSFERRED FROM VPA NUMBER	EXISTING VPA HOLDER
1	VPA23462/017/001	CRNOODSGQ	Xylamidor	VetViva Richter GmbH	VPA10801/017/001	Richter Pharma AG
2	VPA10509/008/002	CRNOODWOX	ARIXIL vet 20 mg film-coated tablet for dogs	Industrial Veterinaria S.A.	VPA10516/020/002	Vetpharma Animal Health, S.L.
3	VPA10509/008/001	CRNOODWOX	ARIXIL vet 5 mg film-coated tablet for dogs and cats	Industrial Veterinaria S.A.	VPA10516/020/001	Vetpharma Animal Health, S.L.