

AUT-F0061

FORM

VERSION 2

EFFECTIVE DATE 9 FEBRUARY 2023

HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 07/06/2024

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	PA1347/092/001	CRN00CXSQ	Paliperidone Krka 3 mg prolonged-release tablets	Paliperidone	KRKA, d.d., Novo mesto
2	PA1347/092/002	CRN00CXSQ	Paliperidone Krka 6 mg prolonged-release tablets	Paliperidone	KRKA, d.d., Novo mesto
3	PA1347/092/003	CRN00CXSQ	Paliperidone Krka 9 mg prolonged-release tablets	Paliperidone	KRKA, d.d., Novo mesto
4	PA0281/160/001	CRN00D8V7	Febuxostat Pinewood 80 mg film-coated tablets	Febuxostat	Pinewood Laboratories Ltd
5	PA0281/160/002	CRN00D8V7	Febuxostat Pinewood 120 mg film-coated tablets	Febuxostat	Pinewood Laboratories Ltd
6	PA0577/188/001	CRN00F1TL	Posaconazole Mylan 100 mg gastro-resistant tablets	Posaconazole	McDermott Laboratories Ltd., T/A Gerard Laboratories
7	PA1968/007/002	CRN00F6T5	Phenylephrine 100 micrograms/ml solution for injection/infusion	Phenylephrine hydrochloride	Laboratoire AGUETTANT

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VERSION 3

EFFECTIVE DATE 9 FEBRUARY 2023

HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 07/06/2024

RECOMMENDATION FOR AUTHORISATION

TABLE 1.5 APPLICATIONS FOR TRANSFER OF A MARKETING AUTHORISATION FOR A HUMAN MEDICINAL PRODUCT

NO.	PA NUMBER	CASE NUMBER	NAME OF PRODUCT	PROPOSED NEW PA HOLDER	TRANSFERRED FROM PA NUMBER	EXISTING PA HOLDER
1	PA23311/004/004	CRN00DZ1K	Estradot 100 micrograms/24 hours, transdermal patch	Sandoz Pharmaceuticals d.d.	PA0896/010/004	Novartis Ireland Limited
2	PA23311/004/005	CRN00DZ1K	Estradot 25 micrograms/24 hours, transdermal patch	Sandoz Pharmaceuticals d.d.	PA0896/010/005	Novartis Ireland Limited
3	PA23311/004/001	CRN00DZ1K	Estradot 37.5 micrograms/24 hours, transdermal patch	Sandoz Pharmaceuticals d.d.	PA0896/010/001	Novartis Ireland Limited
4	PA23311/004/002	CRN00DZ1K	Estradot 50 micrograms/24 hours, transdermal patch	Sandoz Pharmaceuticals d.d.	PA0896/010/002	Novartis Ireland Limited
5	PA23311/004/003	CRN00DZ1K	Estradot 75 micrograms/24 hours, transdermal patch	Sandoz Pharmaceuticals d.d.	PA0896/010/003	Novartis Ireland Limited

AUT-F0424	FORM
VERSION 4	EFFECTIVE DATE 19 MARCH 2024

**HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 07/06/2024
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	CRN00F9F6	Icatibant	04/06/2024	IC0148-033-063 30mg / Solution for injection	4	10/06/2024
2	CRN00F9FK	Terbinafine	04/06/2024	IC0150-130-002 250 mg / Tablets	7	10/06/2024
2	CRN00F9FL	Terbinafine	04/06/2024	IC0150-115-067 1% w/w / Cream	3	10/06/2024
3	CRN00F9FQ	Fluconazole	04/06/2024	IC0151-023-001 50mg / Capsules	3	10/06/2024
3	CRN00F9FR	Fluconazole	04/06/2024	IC0151-062-001 150mg / Capsules	5	10/06/2024
3	CRN00F9FT	Fluconazole	04/06/2024	IC0151-067-001 200mg / Capsules	3	10/06/2024

AUT-F0402	FORM
VERSION 6	EFFECTIVE DATE 9 FEBRUARY 2023

HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 07 JUNE 2024
RECOMMENDATION FOR REGISTRATION

TABLE 13.1 APPLICATIONS FOR REGISTRATION OF AN ACTIVE SUBSTANCE MANUFACTURER, IMPORTER OR DISTRIBUTOR

NO.	REGISTRATION NUMBER	NAME AND ADDRESS OF REGISTRANT	NAME AND ADDRESS OF SITE WHERE ACTIVITY OCCURS	REGISTERED ACTIVITY	NEW/ANNUAL COMMUNICATION
1.	ASRV13067/00001	Chanelle Pharmaceuticals Manufacturing Limited Ida Industrial Estate Dublin Road Loughrea H62 FH90	Chanelle Pharmaceuticals Manufacturing Limited Ida Industrial Estate Dublin Road Loughrea H62 FH90	AS-Importer - Procurement - Site of physical importation AS-Distributor - Procurement - Holding	New