

AUT-F0061

FORM

VERSION 2

EFFECTIVE DATE 12 FEBRUARY 2023

HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 03/11/2023

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	PA1347/063/002	CRN00DCXW	Septabene Lemon and Honey 3 mg/1 mg lozenges	BENZYDAMINE HYDROCHLORIDE Cetylpyridinium chloride	KRKA, d.d., Novo mesto
2	PA2315/148/001	CRN00DH0D	Aprepitant Accord 80 mg hard capsules	Aprepitant	Accord Healthcare Ireland Ltd.
3	PA2315/148/002	CRN00DH0D	Aprepitant Accord 125 mg hard capsules	Aprepitant	Accord Healthcare Ireland Ltd.
4	PA2315/148/003	CRN00DH0D	Aprepitant Accord 125 mg/80 mg hard capsules	Aprepitant Aprepitant	Accord Healthcare Ireland Ltd.
5	PA22720/006/001	CRN00DMCL	Melphalan Tillomed 50 mg powder and solvent for solution for injection/infusion	Melphalan Hydrochloride	Tillomed Pharma GmbH
6	PA22624/001/001	CRN00DMM5	Utrogestan Vaginal 200 mg vaginal capsule, soft	PROGESTERONE MICRONISED	Besins Healthcare Ireland Limited

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VERSION 3

EFFECTIVE DATE 12 FEBRUARY 2023

HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 27/10/2023

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	PA2239/022/002	CRN00CV5R	Seroquel 100 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/002	AstraZeneca AB
2	PA2239/022/003	CRN00CV5R	Seroquel 200 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/003	AstraZeneca AB
3	PA2239/022/001	CRN00CV5R	Seroquel 25 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/001	AstraZeneca AB
4	PA2239/022/004	CRN00CV5R	Seroquel 300 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/004	AstraZeneca AB
5	PA2239/022/006	CRN00CV5R	Seroquel XR 150mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/006	AstraZeneca AB
6	PA2239/022/007	CRN00CV5R	Seroquel XR 200mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/007	AstraZeneca AB
7	PA2239/022/008	CRN00CV5R	Seroquel XR 300mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/008	AstraZeneca AB
8	PA2239/022/009	CRN00CV5R	Seroquel XR 400mg prolonged-release tablets.	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/009	AstraZeneca AB

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<b>NO.</b>	<b>PA NUMBER</b>	<b>CASE NUMBER</b>	<b>NAME OF PRODUCT</b>	<b>PROPOSED NEW PA HOLDER</b>	<b>TRANSFERRED FROM PA NUMBER</b>	<b>EXISTING PA HOLDER</b>
9	PA2239/022/005	CRN00CV5R	Seroquel XR 50mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA1019/019/005	AstraZeneca AB
10	PA22587/003/002	CRN00DK2N	Haldol Decanoate 100mg/ml Solution for Injection	Essential Pharma Limited	PA22612/007/002	Janssen Sciences Ireland UC
11	PA22587/003/001	CRN00DK2N	Haldol Decanoate 50mg/ml Solution for Injection	Essential Pharma Limited	PA22612/007/001	Janssen Sciences Ireland UC
12	PA2262/003/001	CRN00DWTM	Chlorphenamine 10 mg/ml Solution for Injection	Evolan Pharma AB	PA2288/001/002	Kyowa Kirin Holdings B.V.
13	PA25244/001/002	CRN00DWVX	Espestesin 40 mg/ml + 5 microgram/ml solution for injection	Pierrel S.p.A	PA1762/001/002	3M Deutschland GmbH
14	PA25244/001/001	CRN00DWVX	Espestesin Forte 40 mg/ml + 10 microgram/ml solution for injection	Pierrel S.p.A	PA1762/001/001	3M Deutschland GmbH