

AUT-F0059

FORM

VERSION 2

EFFECTIVE DATE 9 FEBRUARY 2023

HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 14/06/2024

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	PA23341/001/001	CRN00CSDF	Hydrocortisone Hualan 2.5 mg tablets	Hydrocortisone	Hualan Pharmaceuticals Limited
2	PA23341/001/002	CRN00CSDF	Hydrocortisone Hualan 5 mg tablets	Hydrocortisone	Hualan Pharmaceuticals Limited
3	PA23341/001/003	CRN00CSDF	Hydrocortisone Hualan 10 mg tablets	Hydrocortisone	Hualan Pharmaceuticals Limited
4	PA23341/001/004	CRN00CSDF	Hydrocortisone Hualan 15 mg tablets	Hydrocortisone	Hualan Pharmaceuticals Limited
5	PA23341/001/005	CRN00CSDF	Hydrocortisone Hualan 20 mg tablets	Hydrocortisone	Hualan Pharmaceuticals Limited
6	PA2315/266/001	CRN00D0QS	Paracetamol/Codeine Accord 500 mg/30 mg, effervescent Tablet	Paracetamol Codeine phosphate hemihydrate	Accord Healthcare Ireland Ltd.
7	PA2059/085/001	CRN00D59F	Benzylpenicillin sodium 600 mg powder for solution for injection/infusion	Benzylpenicillin Sodium	Fresenius Kabi Deutschland GmbH

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NO.	PA NUMBER	CASE NUMBER	NAME OF PRODUCT	ACTIVE SUBSTANCES	PA HOLDER
8	PA2059/085/002	CRN00D59F	Benzylpenicillin sodium 1200 mg powder for solution for injection/infusion	Benzylpenicillin Sodium	Fresenius Kabi Deutschland GmbH
9	PA1986/129/001	CRN00D9Z1	Varenicline Teva 0.5 mg film-coated tablets	Varenicline Citrate	Teva B.V.
10	PA1986/129/002	CRN00D9Z1	Varenicline Teva 1 mg film-coated tablets	Varenicline Citrate	Teva B.V.
11	PA1986/129/003	CRN00D9Z1	Varenicline Teva 0.5 mg film-coated tablets Varenicline Teva 1 mg film-coated tablets	Varenicline Citrate Varenicline Citrate	Teva B.V.
12	PA1774/009/001	CRN00DC27	Eribulin EVER Pharma 0.44 mg/ml solution for injection	Eribulin	EVER Valinject GmbH
13	PA1347/114/001	CRN00DHK6	Apremilast Krka 10 mg film-coated tablets Apremilast Krka 20 mg film-coated tablets Apremilast Krka 30 mg film-coated tablets	Apremilast Apremilast Apremilast	KRKA, d.d., Novo mesto

14	PA1347/114/002	CRN00DHK6	Apremilast Krka 30 mg film-coated tablets	Apremilast	KRKA, d.d., Novo mesto
15	PA2315/274/001	CRN00DTYS	Voriconazole Accord 200 mg Powder for Solution for Infusion	Voriconazole	Accord Healthcare Ireland Ltd.

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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	PA23266/026/001	CRN00F6PL	Pravastatin Viatris 10 mg Tablets	Viatris Limited	PA0577/136/001	McDermott Laboratories Ltd., T/A Gerard Laboratories
2	PA23266/026/002	CRN00F6PL	Pravastatin Viatris 20 mg Tablets	Viatris Limited	PA0577/136/002	McDermott Laboratories Ltd., T/A Gerard Laboratories
3	PA23266/026/003	CRN00F6PL	Pravastatin Viatris 40 mg Tablets	Viatris Limited	PA0577/136/003	McDermott Laboratories Ltd., T/A Gerard Laboratories
4	PA23266/029/001	CRN00F6SY	Agomelatine Viatris 25 mg film-coated tablets	Viatris Limited	PA0577/189/001	McDermott Laboratories Ltd., T/A Gerard Laboratories

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RECOMMENDATION FOR AUTHORISATION

TABLE 1.9 NATIONAL APPLICATIONS FOR A PARALLEL IMPORT LICENCE FOR A HUMAN MEDICINAL PRODUCT

NO.	PPA NUMBER	CASE NUMBER	NAME OF PRODUCT	ACTIVE SUBSTANCES	PPA HOLDER
1	PPA1463/218/001	CRN00DV40	Calcichew 500 mg Chewable Tablets	Calcium carbonate	IMED Healthcare Ltd.

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**HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 14/06/2024
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	CRN00FCFR	Pramipexole	11/06/2024	IC0152-181-002 0.088 mg / Tablets	5	17/06/2024
2	CRN00FCFS	Pramipexole	11/06/2024	IC0152-182-002 0.18 mg / Tablets	5	17/06/2024
3	CRN00FCFW	Pramipexole	11/06/2024	IC0152-183-002 0.35 mg / Tablets	4	17/06/2024
4	CRN00FCFZ	Pramipexole	11/06/2024	IC0152-184-002 0.7 mg / Tablets	5	17/06/2024
5	CRN00FCG1	Pramipexole	11/06/2024	IC0152-185-024 0.26 mg / Prolonged Release Tablets	3	17/06/2024
6	CRN00FCG6	Pramipexole	11/06/2024	IC0152-186-024 0.52 mg / Prolonged Release Tablets	3	17/06/2024
7	CRN00FCG7	Pramipexole	11/06/2024	IC0152-187-024 1.05 mg / Prolonged Release Tablets	3	17/06/2024

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NO.	CASE NUMBER	SUBSTANCE	CONSULTATION PERIOD ENDED	INTERCHANGEABLE LISTS FOR PUBLICATION	NO OF PRODUCTS	PROPOSED DATE OF PUBLICATION
8	CRN00FCGD	Pramipexole	11/06/2024	IC0152-188-024 1.57 mg / Prolonged Release Tablets	3	17/06/2024
9	CRN00FCGG	Pramipexole	11/06/2024	IC0152-189-024 2.1 mg / Prolonged Release Tablets	3	17/06/2024
10	CRN00FCGK	Pramipexole	11/06/2024	IC0152-190-024 2.62 mg / Prolonged Release Tablets	3	17/06/2024
11	CRN00FCGL	Pramipexole	11/06/2024	IC0152-191-024 3.15 mg / Prolonged Release Tablets	3	17/06/2024

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RECOMMENDATION FOR AUTHORISATION

TABLE 3.1 APPLICATIONS FOR A MANUFACTURER’S AUTHORISATION FOR HUMAN MEDICINAL PRODUCTS

NO.	AUTHORISATION NO.	NAME AND ADDRESS OF AUTHORISATION HOLDER	NAME AND ADDRESS OF MANUFACTURING SITE	OPERATIONS AUTHORISED	NEW/RENEWAL AUTHORISATION
1.	M11249/00002	AbbVie Ireland NL B.V Manorhamilton Road, Ballytivnan, Sligo, F91 P6P8	AbbVie Ireland NL B.V Ballytivnan Road, Ballytivnan, Sligo, F91 K735	<p>MANUFACTURING OPERATIONS</p> <p>1.1 Sterile Products</p> <p>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</p> <p>1.1.1.2 Lyophilisates</p> <p>1.1.1.4 Small Volume Liquids</p> <p>1.3 Biological medicinal products</p> <p>1.3.1 Biological medicinal products</p> <p>1.3.1.5 Biotechnology Products</p> <p>1.6 Quality control testing</p> <p>1.6.2 Microbiological; Non Sterility</p> <p>1.6.3 Chemical / Physical</p> <p>1.6.4 Biological</p> <p>IMPORTATION OF MEDICINAL PRODUCTS</p> <p>2.3 Other importation activities</p> <p>2.3.3 Biological Active Substance</p>	New

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RECOMMENDATION FOR AUTHORISATION

TABLE 3.2 APPLICATIONS FOR A MANUFACTURER'S LICENCE FOR VETERINARY MEDICINAL PRODUCTS

NO.	LICENCE NO.	NAME AND ADDRESS OF LICENCE HOLDER	NAME AND ADDRESS OF MANUFACTURING SITE	OPERATIONS LICENSED	NEW/RENEWAL LICENCE
1.	V13301/00001	NOD Apiary Ireland Limited Tullow Industrial Estate, Bunclody Road Tullow, Carlow, R93 W0D8	NOD Apiary Ireland Limited Clieveragh Industrial Estate, Listowel, Co. Kerry,	IMPORTATION OF MEDICINAL PRODUCTS 2.2 Batch certification of imported medicinal products. 2.2.2 Non-sterile products 2.3 Other importation activities 2.3.1 Site of physical importation	New