

AUT-F0059**FORM****VERSION 2****EFFECTIVE DATE 12 FEBRUARY 2023****HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 27/10/2023****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	PA22992/007/001	CRN00CQZG	Escitalopram Grindeks 5 mg film-coated tablets	Escitalopram oxalate	AS Grindeks
2	PA22992/007/002	CRN00CQZG	Escitalopram Grindeks 10 mg film-coated tablets	Escitalopram oxalate	AS Grindeks
3	PA22992/007/003	CRN00CQZG	Escitalopram Grindeks 20 mg film-coated tablets	Escitalopram oxalate	AS Grindeks
4	PA0979/082/001	CRN00CRR4	Gaviscon Extra Mixed Berries Flavour Chewable Tablets Sodium alginate 250 mg Sodium hydrogen carbonate 106.5 mg Calcium carbonate 187.5 mg	Sodium alginate Sodium hydrogen carbonate Calcium carbonate	Reckitt Benckiser Ireland Ltd
5	PA0711/324/001	CRN00D0RH	Azelastine hydrochloride /Fluticasone propionate Rowex 137 micrograms/50 micrograms per actuation, nasal spray suspension	Azelastine hydrochloride Fluticasone propionate	Rowex Ltd

AUT-F0061**FORM****VERSION 2****EFFECTIVE DATE 12 FEBRUARY 2023****HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 27/10/2023****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	PA2059/011/001	CRN008TK0	Linezolid 2 mg/ ml solution for infusion	Linezolid	Fresenius Kabi Deutschland GmbH
2	PA1347/076/001	CRN00CVGZ	Vildagliptin Krka 50 mg tablets	Vildagliptin	KRKA, d.d., Novo mesto
3	PA22874/003/001	CRN00D7ZS	Nithiodote Solution for Injection	SODIUM NITRITE Sodium thiosulfate	Hope Pharmaceuticals Ltd
4	PA1347/086/001	CRN00DT43	TANYZ 400 micrograms hard modified-release capsule	Tamsulosin hydrochloride	KRKA, d.d., Novo mesto
5	PA1347/087/001	CRN00DT45	Tamzeltos 400 micrograms prolonged-release tablets	Tamsulosin hydrochloride	KRKA, d.d., Novo mesto
6	PA22639/002/001	CRN00DX5P	Colecalciferol 800 IU capsules, soft	Colecalciferol	Strides Pharma (Cyprus) Limited

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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	PA0711/327/005	CRN00DRQ6	Zofran Zydis 4 mg oral lyophilisate	Rowex Ltd	PA0896/036/007	Novartis Ireland Limited
2	PA0711/327/006	CRN00DRQ6	Zofran Zydis 8 mg oral lyophilisate	Rowex Ltd	PA0896/036/008	Novartis Ireland Limited
3	PA0126/381/001	CRN00DTT2	Opticrom 2 % w/v Eye Drops, solution	Clonmel Healthcare Ltd	PA23180/010/001	Opella Healthcare France SAS T/A Sanofi
4	PA0126/381/002	CRN00DTT2	Opticrom allergy 2% w/v eye drops, solution	Clonmel Healthcare Ltd	PA23180/010/002	Opella Healthcare France SAS T/A Sanofi
5	PA0126/381/003	CRN00DTT2	Opticrom Allergy Single Dose 2% w/v eye drops, solution	Clonmel Healthcare Ltd	PA23180/010/003	Opella Healthcare France SAS T/A Sanofi

AUT-F0136**FORM****VERSION 3****EFFECTIVE DATE 9 FEBRUARY 2023****HPRA LEADERSHIP TEAM – LICENSING AND REGULATORY MEETING 27/10/2023****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	PPA1463/215/001	CRN00DPQF	Atozet 10 mg/40 mg film-coated tablets	Ezetimibe Atorvastatin	IMED Healthcare Ltd.
2	PPA1463/215/002	CRN00DPQF	Atozet 10 mg/80 mg film-coated tablets	Ezetimibe Atorvastatin	IMED Healthcare Ltd.

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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	CRN00DMQ4	Apixaban	31/07/2023	IC0124-018-003 2.5mg / Film-coated Tablets	9	07/11/2023
2	CRN00DMQ5	Apixaban	31/07/2023	IC0124-001-003 5mg / Film-coated Tablets	9	07/11/2023

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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	ASRV13068/00001	Alivira Animal Health Limited 16 Glenoaks Close Glenconner Clonmel Co. Tipperary E91 T8Y6	Alivira Animal Health Limited 16 Glenoaks Close Glenconner Clonmel Co. Tipperary E91 T8Y6	Importation: <ul style="list-style-type: none"> • Procurement Distribution: <ul style="list-style-type: none"> • Supply 	New Vet ASR