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Information and Notices

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Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2022 to 30 September 2022 (*Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council or Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council*)

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IV

*(Notices)*NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND
AGENCIES

EUROPEAN COMMISSION

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 September 2022 to 30 September 2022***(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of
the Council ⁽¹⁾ or Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council ⁽²⁾)*

(2022/C 419/01)

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.⁽²⁾ OJ L 4, 7.1.2019, p. 43.

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
15.9.2022	Amvuttra	vutrisiran	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/22/1681	Solution for injection	N07XX18	16.9.2022
15.9.2022	Celdoxome pegylated liposomal	doxorubicin hydrochloride	YES Pharmaceutical Development Services GmbH Bahnstrasse 42-46, 61381 Friedrichsdorf, Deutschland	EU/1/22/1666	Concentrate for dispersion for infusion	L01DB01	22.9.2022
15.9.2022	ilLuzyce	lutetium (¹⁷⁷ Lu) chloride	Billev Pharma ApS Slotsmarken 10, 2970 Hørsholm, Danmark	EU/1/22/1680	Radiopharmaceutical precursor, solution	V10X	16.9.2022
15.9.2022	Lupkynis	voclosporin	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/22/1678	Capsule, soft	L04AD03	19.9.2022
15.9.2022	Mounjaro	tirzepatide	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/22/1685	Solution for injection	Pending	19.9.2022
15.9.2022	NULIBRY	fosdenopterin	Comharsa Life Sciences Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Co. Dublin, Ireland	EU/1/22/1684	Powder for solution for injection	A16AX	16.9.2022
15.9.2022	Opdualag	nivolumab/ relatlimab	Bristol Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland	EU/1/22/1679	Concentrate for solution for infusion	L01XY03	16.9.2022
15.9.2022	Vabysmo	Faricimab	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach- Wyhlen, Deutschland	EU/1/22/1683	Solution for injection	S01LA09	16.9.2022

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
19.9.2022	Tezspire	tezepelumab	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1677	Solution for injection	R03DX11	20.9.2022
19.9.2022	Thalidomide Lipomed	Thalidomide	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland	EU/1/22/1676	Coated tablet	L04AX02	26.9.2022
21.9.2022	CRYSVITA	Burosumab	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/17/1262	Solution for injection	M05BX	29.9.2022

— **Modification of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
1.9.2022	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	1.9.2022
1.9.2022	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España	EU/1/20/1507	1.9.2022
2.9.2022	Aprovel	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/97/046	5.9.2022
2.9.2022	CoAprovel	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/98/086	5.9.2022
2.9.2022	Copalia HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/575	5.9.2022
2.9.2022	Dafiro HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/574	5.9.2022
2.9.2022	Dupixent	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/17/1229	5.9.2022
2.9.2022	Imcivree	Rhythm Pharmaceuticals Netherlands B.V. Radarweg 29, 1043 NX Amsterdam, Nederland	EU/1/21/1564	5.9.2022
2.9.2022	Januvia	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/07/383	7.9.2022
2.9.2022	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	5.9.2022
2.9.2022	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	5.9.2022
2.9.2022	Zolgensma	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1443	12.9.2022
6.9.2022	Nuvaxovid	Novavax CZ, a.s. Bohumil 138, 281 63 Jevany, Česká republika	EU/1/21/1618	7.9.2022

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
9.9.2022	Ceplene	Laboratoires Delbert 49 rue Rouelle, 75015 Paris, FRANCE	EU/1/08/477	12.9.2022
12.9.2022	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	12.9.2022
13.9.2022	Buvidal	Camurus AB Ideon Science Park, 223 70 Lund, Sverige	EU/1/18/1336	14.9.2022
13.9.2022	Exforge HCT	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/569	14.9.2022
13.9.2022	GAVRETO	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1555	15.9.2022
13.9.2022	Izba	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/905	14.9.2022
13.9.2022	JEMPERLI	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1538	14.9.2022
13.9.2022	Karvea	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/97/049	14.9.2022
13.9.2022	Karvezide	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/98/085	14.9.2022
13.9.2022	Ninlaro	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/16/1094	19.9.2022
13.9.2022	Oncaspar	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes Cedex, France	EU/1/15/1070	14.9.2022
13.9.2022	Temozolomide HEXAL	Hexal AG Industriestraße 25, 83607 Holzkirchen, Deutschland	EU/1/10/616	19.9.2022
13.9.2022	Temozolomide Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/10/617	16.9.2022
13.9.2022	Tigecycline Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/19/1394	14.9.2022

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
13.9.2022	Xeljanz	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/17/1178	14.9.2022
15.9.2022	Corlantor	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes CEDEX, France	EU/1/05/317	19.9.2022
15.9.2022	Fasenra	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1252	16.9.2022
15.9.2022	Hemlibra	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach- Wyhlen, Deutschland	EU/1/18/1271	16.9.2022
15.9.2022	Intrarosa	Endoceutics S.A. Rue Belliard 40, 1040 Bruxelles, Belgique/ Belliardstraat 40, 1040 Brussel, België	EU/1/17/1255	18.9.2022
15.9.2022	Kinpeygo	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/22/1657	19.9.2022
15.9.2022	Nyxoid	Mundipharma Corporation (Ireland) Limited Millbank House, Arkle Road, Sandyford Industrial Estate, Dublin 18, Ireland	EU/1/17/1238	16.9.2022
15.9.2022	Oxlumo	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/20/1496	16.9.2022
15.9.2022	PREZISTA	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/06/380	16.9.2022
15.9.2022	Procoralan	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes CEDEX, France	EU/1/05/316	19.9.2022
15.9.2022	Stribild	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/13/830	19.9.2022
16.9.2022	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	19.9.2022
16.9.2022	EVUSHELD	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/22/1651	16.9.2022
16.9.2022	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España	EU/1/20/1507	19.9.2022

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
16.9.2022	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	19.9.2022
19.9.2022	Miglustat Gen.Orph	Gen.Orph 185 Bureaux de la Colline, 92213 Saint Cloud Cedex, France	EU/1/17/1232	21.9.2022
19.9.2022	Reblozyl	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1452	23.9.2022
19.9.2022	SomaKit TOC	Advanced Accelerator Applications 20 rue Diesel, 01630 Saint-Genis-Pouilly, France	EU/1/16/1141	21.9.2022
19.9.2022	TAGRISSO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1086	20.9.2022
19.9.2022	Tarceva	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/05/311	21.9.2022
21.9.2022	Betmiga	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/12/809	26.9.2022
21.9.2022	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/07/419	26.9.2022
21.9.2022	Dafiro	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/371	23.9.2022
21.9.2022	Daxas	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/636	23.9.2022
21.9.2022	Efficib	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/457	26.9.2022
21.9.2022	Evrysdi	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/21/1531	23.9.2022
21.9.2022	InductOs	Medtronic BioPharma B.V. Earl Bakkenstraat 10, 6422 PJ Heerlen, Nederland	EU/1/02/226	23.9.2022
21.9.2022	Inlyta	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/777	26.9.2022

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
21.9.2022	Lyrica	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/04/279	27.9.2022
21.9.2022	Mvasi	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/17/1246	26.9.2022
21.9.2022	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	23.9.2022
21.9.2022	Ozempic	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1251	23.9.2022
21.9.2022	Rubraca	Clovis Oncology Ireland Limited Regus Dublin Airport, Skybridge House - Dublin Airport, Swords, Co. Dublin, K67 P6K2, Ireland	EU/1/17/1250	23.9.2022
21.9.2022	Tegsedi	Akcea Therapeutics Ireland Ltd Regus House, Harcourt Centre, Harcourt Road, Dublin 2, Ireland	EU/1/18/1296	23.9.2022
21.9.2022	Tesavel	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/07/435	26.9.2022
21.9.2022	Travatan	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/01/199	26.9.2022
21.9.2022	Tybost	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/13/872	28.9.2022
21.9.2022	Ultomiris	Alexion Europe SAS 103-105 Rue Anatole France, 92300 Levallois-Perret, France	EU/1/19/1371	23.9.2022
21.9.2022	Verkazia	Santen Oy Niittyhaankatu 20, 33720 Tampere, Suomi	EU/1/17/1219	26.9.2022
21.9.2022	Zabdeno	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1444	27.9.2022
26.9.2022	Cometriq	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/13/890	27.9.2022

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
26.9.2022	Gencebok	Gennisium Pharma Swen Parc de Vitrolles, Chemin de la Bastide Blanche, 13127 Vitrolles, France	EU/1/20/1465	28.9.2022
26.9.2022	Lamivudine / Zidovudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/663	27.9.2022
26.9.2022	Lutathera	Advanced Accelerator Applications 20 rue Diesel, 01630 Saint-Genis-Pouilly, France	EU/1/17/1226	28.9.2022
26.9.2022	Pirfenidone axunio	axunio Pharma GmbH Van-der-Smissen-Straße 1, 22767 Hamburg, Deutschland	EU/1/22/1655	27.9.2022
26.9.2022	Pregabalin Pfizer	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/14/916	27.10.2022
26.9.2022	Rybrevant	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	27.9.2022
26.9.2022	TOOKAD	Steba Biotech S.A 7 Place du Théâtre, 2613 Luxembourg, Luxembourg	EU/1/17/1228	6.10.2022
27.9.2022	COVID-19 Vaccine (inactivated, adjuvanted) Valneva	Valneva Austria GmbH Campus Vienna Biocenter 3, 1030 Wien, Österreich	EU/1/21/1624	29.9.2022
27.9.2022	Jorveza	Dr Falk Pharma GmbH Leinenweberstraße 5, 79041 Freiburg im Breisgau, Deutschland	EU/1/17/1254	28.9.2022
29.9.2022	ABILIFY MAINTENA	Otsuka Pharmaceutical Netherlands B.V. Herikerbergweg 292, 1101 CT, Amsterdam, Nederland	EU/1/13/882	3.10.2022
29.9.2022	Byooviz	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/21/1572	4.10.2022
29.9.2022	CABOMETYX	Ipsen Pharma 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/16/1136	30.9.2022
29.9.2022	Copalia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/372	30.9.2022

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
29.9.2022	Dupixent	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/17/1229	30.9.2022
29.9.2022	Efient	SUBSTIPHARM 24 rue Erlanger, 75016 Paris, France	EU/1/08/503	30.9.2022
29.9.2022	Entresto	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/15/1058	3.10.2022
29.9.2022	Exforge	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/370	30.9.2022
29.9.2022	IVEMEND	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/07/437	3.10.2022
29.9.2022	Janumet	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/455	29.9.2022
29.9.2022	Lydisilka	Estetra SRL Rue Saint Georges 5-7, 4000 Liège, Belgique	EU/1/21/1548	3.10.2022
29.9.2022	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	30.9.2022
29.9.2022	PHELINUN	ADIENNE S.r.l.S.U. Via Galileo Galilei 19, 20867 Caponago (MB), Italia	EU/1/20/1487	30.9.2022
29.9.2022	Ristaben	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/10/621	30.9.2022
29.9.2022	Ristfor	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/10/620	29.9.2022
29.9.2022	Simbrinza	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/14/933	3.10.2022
29.9.2022	TAKHZYRO	Takeda Pharmaceuticals International AG Ireland Branch Block 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland	EU/1/18/1340	3.10.2022

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
29.9.2022	Vaniqa	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/01/173	3.10.2022
29.9.2022	Velmetia	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/456	30.9.2022
30.9.2022	Evrenzo	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/21/1574	3.10.2022
30.9.2022	Lamivudine Teva Pharma B.V.	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/596	3.10.2022

— **Withdrawal of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
15.9.2022	Temozolomide HEXAL	Hexal AG Industriestraße 25, 83607 Holzkirchen, Deutschland	EU/1/10/616	19.9.2022
15.9.2022	Temozolomide Sandoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/10/617	21.9.2022

— **Issuing of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
13.9.2022	Lotilaner Elanco	lotilaner	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/22/288	Chewable tablet	QP53BE04	14.9.2022

— **Modification of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
2.9.2022	Aivlosin	ECO Animal Health Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, Ireland	EU/2/04/044	14.9.2022
2.9.2022	Zenalpha	Vetcare Oy P.O. Box 99, 24101 Salo, Suomi	EU/2/21/279	5.9.2022
13.9.2022	Equisolon	Le Vet B.V. Wilgenweg 7, 3421 TV Oudewater, Nederland	EU/2/14/161	30.9.2022
13.9.2022	Poulvac E. coli	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/12/140	16.9.2022
13.9.2022	Suiseng Diff/A	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/21/278	15.9.2022
15.9.2022	Bonqat	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/2/21/273	16.9.2022
15.9.2022	Nobivac LeuFel	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/17/217	28.9.2022
15.9.2022	Sileo	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/2/15/181	16.9.2022
19.9.2022	Suprelorin	VIRBAC S.A. 1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France	EU/2/07/072	22.9.2022
26.9.2022	Clomicalm	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/98/007	28.9.2022
26.9.2022	Leucofeligen FeLV/RCP	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/09/097	28.9.2022
26.9.2022	Meloxoral	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/10/111	27.9.2022
26.9.2022	Vaxxitek HVT + IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/02/032	28.9.2022
29.9.2022	Arti-Cell Forte	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/18/228	5.10.2022

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
29.9.2022	Bovilis Blue-8	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/218	30.9.2022
29.9.2022	Leucogen	Virbac 1ère Avenue - 2065 m - L.I.D., 06516 Carros CEDEX, France	EU/2/09/096	4.10.2022
29.9.2022	PREVEXXION RN	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/254	4.10.2022
29.9.2022	PREVEXXION RN +HVT+IBD	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/20/255	4.10.2022
29.9.2022	Suvaxyn Circo + MH RTU	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la- Neuve, Belgique	EU/2/15/190	4.10.2022

— **Withdrawal of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council)

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
29.9.2022	Activyl Tick Plus	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/11/137	30.9.2022
29.9.2022	Nobilis OR inac	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/02/036	30.9.2022

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

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