

Authorisation Number	Route	Submission Category	Active Substance Name	Date Received	Validate Case Sub Validated	Effective Date of Granting	Authorisation Holder Company Name	Licensed Product Name
PLGB 08265/0048	NATIONAL	NEW ACTIVE SUBSTANCE	TRASTUZUMAB DERUXTECAN	08/01/2021	02/02/2021	12/02/2021	DAICHI SANKYO UK LIMITED	ENHERTU 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 34503/0001	NATIONAL	NEW ACTIVE SUBSTANCE	TUCATINIB HEMIETHANOLATE	13/01/2021	27/01/2021	19/02/2021	SEAGEN U.K.LTD.	TUKYSA 50 MG FILM COATED TABLETS
PLGB 34503/0002	NATIONAL	NEW ACTIVE SUBSTANCE	TUCATINIB HEMIETHANOLATE	13/01/2021	27/01/2021	19/02/2021	SEAGEN U.K.LTD.	TUKYSA 150 MG FILM COATED TABLETS
PLGB 14895/0311	NATIONAL	NEW ACTIVE SUBSTANCE	SELPERCATINIB	20/01/2021	26/01/2021	26/02/2021	ELI LILLY NEDERLAND B.V.	RETSEVMO 400MG HARD CAPSULE
PLGB 14895/0312	NATIONAL	NEW ACTIVE SUBSTANCE	SELPERCATINIB	20/01/2021	26/01/2021	26/02/2021	ELI LILLY NEDERLAND B.V.	RETSEVMO 800MG HARD CAPSULE
PLGB 53732/0002	RELANCE	NEW ACTIVE SUBSTANCE	CX-32414	26/03/2021	30/03/2021	31/03/2021	MODERNA BIOTECH SPAIN SL	COVID-19 VACCINE MODERNA DISPERSION FOR INJECTION
PLGB 42338/0008	RELANCE	NEW ACTIVE SUBSTANCE	PEMGATINIB	09/02/2021	22/02/2021	07/04/2021	INCYTE BIOSCIENCES UK LIMITED	PEMAZYRE 4.5 MG TABLETS
PLGB 42338/0009	RELANCE	NEW ACTIVE SUBSTANCE	PEMGATINIB	09/02/2021	22/02/2021	07/04/2021	INCYTE BIOSCIENCES UK LIMITED	PEMAZYRE 9 MG TABLETS
PLGB 42338/0010	RELANCE	NEW ACTIVE SUBSTANCE	PEMGATINIB	09/02/2021	22/02/2021	07/04/2021	INCYTE BIOSCIENCES UK LIMITED	PEMAZYRE 13.5 MG TABLETS
PLGB 35728/0058	NATIONAL	NEW ACTIVE SUBSTANCE	FOSTEMSAVIR TROMETHAMINE	22/01/2021	22/02/2021	13/04/2021	VIV HEALTHCARE UK LIMITED	RUKOBA 600 MG PROLONGED-RELEASE TABLETS
PLGB 50412/0002	NATIONAL	NEW ACTIVE SUBSTANCE	FEDRATINIB DIHYDROCHLORIDE MONOHYDRATE	12/02/2021	16/02/2021	16/04/2021	CELGENE EUROPE B.V.	INREBIC 100 MG CAPSULE, HARD
PLGB 51241/0002	RELANCE	NEW ACTIVE SUBSTANCE	ICOSAPENT ETHYL	02/02/2021	13/02/2021	20/04/2021	AMARIN PHARMACEUTICALS IRELAND LIMITED	VAZEPPA 988 MG SOFT CAPSULES
PLGB 50690/0001	RELANCE	NEW ACTIVE SUBSTANCE	BERTRALSTAT DIHYDROCHLORIDE	10/03/2021	15/04/2021	12/05/2021	BIOCRYST IRELAND LIMITED	ORLADEYO 150 MG HARD CAPSULES
PLGB 00031/0020	RELANCE	NEW ACTIVE SUBSTANCE	RSD3PLAM	22/03/2021	24/03/2021	20/05/2021	ROCHE PRODUCTS LIMITED	EVRYSDIO 75 MGML POWDER FOR ORAL SOLUTION
PLGB 44238/0001	RELANCE	NEW ACTIVE SUBSTANCE	SELNEXOR	28/02/2021	18/03/2021	28/05/2021	KARYOPHARM EUROPE GMBH	NEKPOVID 20 MG FILM COATED TABLET
PLGB 53690/0005	RELANCE	NEW ACTIVE SUBSTANCE	DUVELSIB	01/04/2021	08/04/2021	26/05/2021	SECURA BIO LIMITED	COPKTRA 15MG HARD CAPSULES
PLGB 53690/0006	RELANCE	NEW ACTIVE SUBSTANCE	DUVELSIB	01/04/2021	08/04/2021	26/05/2021	SECURA BIO LIMITED	COPKTRA 25MG HARD CAPSULES
PLGB 04854/0187	RELANCE	NEW ACTIVE SUBSTANCE	DROSIPRENONE	10/02/2021	09/04/2021	27/05/2021	GEDEON RICHTER PLC	DROVELIS 3 MG/14.2 MG FILM COATED TABLETS
PLGB 00242/0142	RELANCE	NEW ACTIVE SUBSTANCE	RECOMBINANT REPLICATION-INCOMPETENT ADENOVIRUS SEROTYPE 26 VECTOR ENCODING THE SARS-COV-2 SPIKE PROTEIN PER C8 CELL LINE	09/04/2021	20/04/2021	28/05/2021	JANSEN-CLAG LIMITED	COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION
PLGB 19494/0297	RELANCE	NEW ACTIVE SUBSTANCE	DOSTARLIMAB	05/03/2021	10/05/2021	04/06/2021	GLAXOSMITHKLINE UK LIMITED	JEMPERLI 500 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 53287/0001	RELANCE	NEW ACTIVE SUBSTANCE	CENOBAMATE	29/01/2021	01/04/2021	04/06/2021	ARVELLE THERAPEUTICS NETHERLANDS B.V.	ONTOZRY 12.5 MG TABLETS
PLGB 53287/0002	RELANCE	NEW ACTIVE SUBSTANCE	CENOBAMATE	29/01/2021	01/04/2021	04/06/2021	ARVELLE THERAPEUTICS NETHERLANDS B.V.	ONTOZRY 25MG FILM COATED TABLETS
PLGB 53287/0003	RELANCE	NEW ACTIVE SUBSTANCE	CENOBAMATE	29/01/2021	01/04/2021	04/06/2021	ARVELLE THERAPEUTICS NETHERLANDS B.V.	ONTOZRY 50MG FILM COATED TABLETS
PLGB 53287/0004	RELANCE	NEW ACTIVE SUBSTANCE	CENOBAMATE	29/01/2021	01/04/2021	04/06/2021	ARVELLE THERAPEUTICS NETHERLANDS B.V.	ONTOZRY 100MG FILM COATED TABLETS
PLGB 53287/0005	RELANCE	NEW ACTIVE SUBSTANCE	CENOBAMATE	29/01/2021	01/04/2021	04/06/2021	ARVELLE THERAPEUTICS NETHERLANDS B.V.	ONTOZRY 150MG FILM COATED TABLETS
PLGB 53287/0006	RELANCE	NEW ACTIVE SUBSTANCE	CENOBAMATE	29/01/2021	01/04/2021	04/06/2021	ARVELLE THERAPEUTICS NETHERLANDS B.V.	ONTOZRY 200MG FILM COATED TABLETS
PLGB 53287/0007	RELANCE	NEW ACTIVE SUBSTANCE	CENOBAMATE	29/01/2021	01/04/2021	04/06/2021	ARVELLE THERAPEUTICS NETHERLANDS B.V.	ONTOZRY 12.5MG TABLETS AND ONTOZRY 25 MG FILM COATED TABLETS TREATMENT INITIATION PACK
PLGB 05293/0182	RELANCE	NEW ACTIVE SUBSTANCE	TRALOKINUMAB	23/04/2021	14/05/2021	21/06/2021	LEO PHARMA AS	ADTRALZA 150 MG SOLUTION FOR INJECTION IN PRE FILLED SYRINGE
PLGB 17901/0355	NATIONAL	NEW ACTIVE SUBSTANCE	CHADOX1 NCOV-19	22/03/2021	31/03/2021	24/06/2021	ASTRAZENECA UK LIMITED	COVID-19 VACCINE ASTRAZENECA, SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT])
PLGB 54212/0001	RELANCE	NEW ACTIVE SUBSTANCE	REMMAZOLAM BESYLATE	02/02/2021	01/04/2021	28/06/2021	PAIDN NETHERLANDS B.V.	BYFAVO 20 MG POWDER FOR SOLUTION FOR INJECTION
PLGB 00070/0748	RELANCE	NEW ACTIVE SUBSTANCE	VERICIGLAT	25/05/2021	20/05/2021	19/07/2021	BAYER PLC	VERQUIVO 2.9MG FILM COATED TABLETS
PLGB 00010/0749	RELANCE	NEW ACTIVE SUBSTANCE	VERICIGLAT	25/05/2021	20/05/2021	19/07/2021	BAYER PLC	VERQUIVO 5MG FILM COATED TABLETS
PLGB 00242/0759	NATIONAL	NEW ACTIVE SUBSTANCE	PONESMOD	22/04/2021	02/07/2021	29/07/2021	JANSEN-CLAG LIMITED	PONVORY 20MG FILM COATED TABLET
PLGB 00242/0743	NATIONAL	NEW ACTIVE SUBSTANCE	PONESMOD	22/04/2021	02/07/2021	29/07/2021	JANSEN-CLAG LIMITED	PONVORY 2MG, 3MG, 4MG, 5MG, 6MG, 7MG, 8MG, 9MG, 10MG FILM COATED TABLETS
PLGB 16973/0043	RELANCE	NEW ACTIVE SUBSTANCE	TYRANIBULIN	28/05/2021	11/06/2021	02/08/2021	ALMRALL SA	KLBYRI 10MG/G OINTMENT
PLGB 04854/0186	RELANCE	NEW ACTIVE SUBSTANCE	ESTRADIOL HEMHYDRATE	02/06/2021	14/06/2021	09/08/2021	GEDEON RICHTER PLC	RYEOD 40 MG/1 MG0.5 MG FILM COATED TABLETS
PLGB 17901/0356	RELANCE	NEW ACTIVE SUBSTANCE	SELLUMETINIB HYDROGEN SULFATE	27/04/2021	11/05/2021	09/08/2021	ASTRAZENECA UK LIMITED	KOSELUGO 100MG HARD CAPSULE
PLGB 17901/0357	RELANCE	NEW ACTIVE SUBSTANCE	SELLUMETINIB HYDROGEN SULFATE	27/04/2021	11/05/2021	09/08/2021	ASTRAZENECA UK LIMITED	KOSELUGO 25 MG HARD CAPSULES
PLGB 00031/0025	NATIONAL	NEW ACTIVE SUBSTANCE	CASIRIVIMAB	26/02/2021	09/02/2021	19/08/2021	ROCHE PRODUCTS LIMITED	RONAPREVIE 120 MGML SOLUTION FOR INJECTION OR INFUSION
PLGB 00039/0802	RELANCE	NEW ACTIVE SUBSTANCE	BIMKEZUMAB	28/07/2020	08/07/2021	25/08/2021	UCB PHARMA LIMITED	BIMZELX 180 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 00039/0803	RELANCE	NEW ACTIVE SUBSTANCE	BIMKEZUMAB	28/07/2020	08/07/2021	25/08/2021	UCB PHARMA LIMITED	BIMZELX 180 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 00166/0427	RELANCE	NEW ACTIVE SUBSTANCE	ROXADUSTAT	05/07/2021	10/08/2021	27/08/2021	ASTELLAS PHARMA LIMITED	EVRENZO 20 MG FILM COATED TABLETS
PLGB 00166/0428	NATIONAL	NEW ACTIVE SUBSTANCE	ROXADUSTAT	05/07/2021	10/08/2021	27/08/2021	ASTELLAS PHARMA LIMITED	EVRENZO 50 MG FILM COATED TABLETS
PLGB 00166/0429	NATIONAL	NEW ACTIVE SUBSTANCE	ROXADUSTAT	05/07/2021	10/08/2021	27/08/2021	ASTELLAS PHARMA LIMITED	EVRENZO 70 MG FILM COATED TABLETS
PLGB 00166/0430	NATIONAL	NEW ACTIVE SUBSTANCE	ROXADUSTAT	05/07/2021	10/08/2021	27/08/2021	ASTELLAS PHARMA LIMITED	EVRENZO 100 MG FILM COATED TABLETS
PLGB 00166/0431	NATIONAL	NEW ACTIVE SUBSTANCE	ROXADUSTAT	05/07/2021	10/08/2021	27/08/2021	ASTELLAS PHARMA LIMITED	EVRENZO 150 MG FILM COATED TABLETS
PLGB 36216/0001	RELANCE	NEW ACTIVE SUBSTANCE	ODEVXIBAT SESQUIHYDRATE	24/05/2021	15/06/2021	07/09/2021	ALBIREO AB	BYLVAY 200 MICROGRAMS HARD CAPSULE
PLGB 36216/0002	RELANCE	NEW ACTIVE SUBSTANCE	ODEVXIBAT SESQUIHYDRATE	24/05/2021	15/06/2021	07/09/2021	ALBIREO AB	BYLVAY 400 MICROGRAMS HARD CAPSULE
PLGB 36216/0003	RELANCE	NEW ACTIVE SUBSTANCE	ODEVXIBAT SESQUIHYDRATE	24/05/2021	15/06/2021	07/09/2021	ALBIREO AB	BYLVAY 600 MICROGRAMS HARD CAPSULE
PLGB 36216/0004	RELANCE	NEW ACTIVE SUBSTANCE	ODEVXIBAT SESQUIHYDRATE	24/05/2021	15/06/2021	07/09/2021	ALBIREO AB	BYLVAY 1200 MICROGRAMS HARD CAPSULE
PLGB 00057/1703	NATIONAL	NEW ACTIVE SUBSTANCE	ABROCIITINIB	20/04/2021	11/05/2021	08/09/2021	PFIZER LIMITED	CIBINQO 50 MG FILM COATED TABLETS
PLGB 00057/1704	NATIONAL	NEW ACTIVE SUBSTANCE	ABROCIITINIB	20/04/2021	11/05/2021	08/09/2021	PFIZER LIMITED	CIBINQO 100 MG FILM COATED TABLETS
PLGB 00057/1705	NATIONAL	NEW ACTIVE SUBSTANCE	ABROCIITINIB	20/04/2021	11/05/2021	08/09/2021	PFIZER LIMITED	CIBINQO 200 MG FILM COATED TABLETS
PLGB 13832/0051	ORBS	NEW ACTIVE SUBSTANCE	SOTORA5IB	14/01/2021	29/01/2021	08/09/2021	AMGEN LIMITED	LUMYKRAS 120 MG FILM COATED TABLETS
PLGB 22901/0001	ORBS	NEW ACTIVE SUBSTANCE	SACITUZUMAB GOVITECAN	22/01/2021	28/01/2021	08/09/2021	IMMUNOMEDICS GMBH	TRODELYV 180MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 18813/0004	RELANCE	NEW ACTIVE SUBSTANCE	PITOLISANT HYDROCHLORIDE	10/08/2021	13/08/2021	15/09/2021	BIOPROJET UK LIMITED	OZAWADE 4.5MG FILM COATED TABLET
PLGB 18813/0005	NATIONAL	NEW ACTIVE SUBSTANCE	PITOLISANT HYDROCHLORIDE	10/08/2021	13/08/2021	15/09/2021	BIOPROJET UK LIMITED	OZAWADE 18MG FILM COATED TABLET
PLGB 54365/0001	RELANCE	NEW ACTIVE SUBSTANCE	SETMELANOTIDE	01/06/2021	23/06/2021	15/09/2021	RHYTHM PHARMACEUTICALS LIMITED	MCVREE 10 MGML SOLUTION FOR INJECTION
PLGB 11648/0291	ORBS	NEW ACTIVE SUBSTANCE	TEPOTINIB HYDROCHLORIDE HYDRATE	08/02/2021	12/02/2021	24/09/2021	MERCK SERONO LIMITED	TEPMETRO 225 MG FILM COATED TABLETS
PLGB 42338/0016	RELANCE	NEW ACTIVE SUBSTANCE	TAFASITAMAB	02/07/2021	02/08/2021	08/10/2021	INCYTE BIOSCIENCES UK LIMITED	MNJIUV 200 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 53425/0001	RELANCE	NEW ACTIVE SUBSTANCE	TAGRAXOFUSP	16/06/2021	01/07/2021	15/10/2021	STEMLINE THERAPEUTICS B.V.	ELZONRIS 1 MGML CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 04668/0434	RELANCE	NEW ACTIVE SUBSTANCE	SOMAPACITAN	08/06/2021	27/08/2021	22/10/2021	NOVO NORDISK AS	SOGROYA 10 MG/1.5 ML SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 53095/0089	NATIONAL	NEW ACTIVE SUBSTANCE	MOLNUPRAVIR	30/06/2021	01/07/2021	04/11/2021	MERCK SHARP & DOHME (UK) LIMITED	LAGEVIRIO 200 MG HARD CAPSULES
PLGB 00242/0740	ORBS	NEW ACTIVE SUBSTANCE	AMVANTAMAB	01/03/2021	12/03/2021	15/11/2021	JANSEN-CLAG LIMITED	RYBREVANT 50 MGML CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 19494/0301	NATIONAL	NEW ACTIVE SUBSTANCE	SOTROVIMAB	21/07/2021	21/07/2021	01/12/2021	GLAXOSMITHKLINE UK LIMITED	XEVUDY 500 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 53789/0002	RELANCE	NEW ACTIVE SUBSTANCE	ZANUBRUTINIB	22/09/2021	19/10/2021	08/12/2021	BECOME MEDICINES UK LTD.	BRUKINSA 80 MG HARD CAPSULES
PLGB 53856/0090	RELANCE	NEW ACTIVE SUBSTANCE	PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 14 CONJUGATED TO CRM197	18/10/2021	02/11/2021	15/12/2021	MERCK SHARP & DOHME UK LIMITED	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (15-VALENT, ADSORBED)
PLGB 50265/0004	RELANCE	NEW ACTIVE SUBSTANCE	PIPIETINIB	18/10/2021	02/11/2021	20/12/2021	DECIPIERA PHARMACEUTICALS (NETHERLANDS) B.V.	ONLOCK 50 MG TABLETS
PLGB 53632/0004	RELANCE	NEW ACTIVE SUBSTANCE	TOZINAMERAN	19/11/2021	23/11/2021	22/12/2021	BIOTECH MANUFACTURING GMBH	COMPNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)
PLGB 00057/1710	NATIONAL	NEW ACTIVE SUBSTANCE	PF-07321332	24/11/2021	02/12/2021	31/12/2021	PFIZER LIMITED	PAXLOVID 150MG/100MG FILM COATED TABLETS
PLGB 00031/0029	RELANCE	NEW ACTIVE SUBSTANCE	PRALSETINIB MONOHYDRATE	28/10/2021	15/11/2021	14/01/2022	ROCHE PRODUCTS LIMITED	GAVRETO 100 MG HARD CAPSULES
PLGB 00458/0314	RELANCE	NEW ACTIVE SUBSTANCE	EPTINEZUMAB	15/11/2021	18/11/2021	26/01/2022	LUNDBECK LIMITED	VEYPTI 100 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 54180/0002	NATIONAL	NEW ACTIVE SUBSTANCE	NVX-COV2373	07/06/2021	15/06/2021	03/02/2022	NOVAVAX CZ A.S.	NUVAXOVID DISPERSION FOR INJECTION COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)
PLGB 30941/0022	RELANCE	NEW ACTIVE SUBSTANCE	PEGCE TACOPLAN	19/10/2021	08/11/2021	24/02/2022	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	ASPAREVI 1 080 MG SOLUTION FOR INFUSION
PLGB 00010/0751	RELANCE	NEW ACTIVE SUBSTANCE	FINERENONE	17/12/2021	11/01/2022	07/03/2022	BAYER PLC	KERENDIA 10 MG FILM COATED TABLETS
PLGB 00010/0752	RELANCE	NEW ACTIVE SUBSTANCE	FINERENONE	17/12/2021	11/01/2022	07/03/2022	BAYER PLC	KERENDIA 20 MG FILM COATED TABLETS
PLGB 00057/1711	RELANCE	NEW ACTIVE SUBSTANCE	PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 1	23/12/2021	18/01/2022	11/03/2022	PFIZER LIMITED	APFODNAR SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCIN
PLGB 16189/0124	ORBS	NEW ACTIVE SUBSTANCE	MOBOCERTINIB SUCCINATE	04/06/2021	10/06/2021	17/03/2022	TAKEDA UK LIMITED	EXKIVITY 40 MG HARD CAPSULES
PLGB 17901/0360	NATIONAL	NEW ACTIVE SUBSTANCE	CLGAVIMAB	07/10/2021	11/10/2021	17/03/2022	ASTRAZENECA UK LIMITED	EVUSHELD
PLGB 17901/0361	RELANCE	NEW ACTIVE SUBSTANCE	ANIFROLUMAB	21/12/2021	11/01/2022	18/03/2022	ASTRAZENECA UK LIMITED	SAPHNELO 300 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 00057/1712	RELANCE	NEW ACTIVE SUBSTANCE	SOMATROGON	21/12/2021	11/01/2022	25/03/2022	PFIZER LIMITED	NGENLA 24 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 00057/1713	RELANCE	NEW ACTIVE SUBSTANCE	SOMATROGON	21/12/2021	11/01/2022	25/03/2022	PFIZER LIMITED	NGENLA 60 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PL 43185/0002	NATIONAL	NEW ACTIVE SUBSTANCE	SARS-COV-2 VIRUS (INACTIVATED, ADSORBED)	20/08/2021	14/09/2021	13/04/2022	VALNEVA AUSTRIA GMBH	COVID-19 VACCINE (INACTIVATED, ADJUVANTED, ADSORBED)
PLGB 00166/0432	RELANCE	NEW ACTIVE SUBSTANCE	ENFORTUMAB VEDOTIN	21/12/2021	11/01/2022	20/04/2022	ASTELLAS PHARMA LIMITED	PACDEV 20 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 00166/0433	RELANCE	NEW ACTIVE SUBSTANCE	ENFORTUMAB VEDOTIN	21/12/2021	11/01/2022	20/04/2022	ASTELLAS PHARMA LIMITED	PACDEV 50 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 50784/0009	RELANCE	NEW ACTIVE SUBSTANCE	DIFELKIFALIN ACETATE	01/03/2022	07/03/2022	29/04/2022	VIFOR FRESSENU MEDICAL CARE RENAL PHARMA FRANCE	KAPRIVIA 50 MICROGRAMSML SOLUTION FOR INJECTION
PLGB 55184/0002	RELANCE	NEW ACTIVE SUBSTANCE	ARTESUNATE	23/09/2021	06/12/2021	29/04/2022	AMVAS IRELAND LIMITED	ARTESUNATE AMVAS 110 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 50784/0008	RELANCE	NEW ACTIVE SUBSTANCE	AVACOPAN	18/11/2021	10/01/2022	06/05/2022	VIFOR FRESSENU MEDICAL CARE RENAL PHARMA FRANCE	TAVNEOS 10 MG HARD CAPSULES
PLGB 00031/0927	ACCESS	NEW ACTIVE SUBSTANCE	FARICIMAB	21/06/2021	28/06/2021	16/05/2022	ROCHE PRODUCTS LIMITED	VABYSMO 120MGML SOLUTION FOR INJECTION

PLGB 530950087	ORBS	NEW ACTIVE SUBSTANCE	BELZUTIFAN	24/02/2021	26/02/2021	31/05/2022	MERCK SHARP & DOHME (UK) LIMITED	WELIREG 40 MG FILM-COATED TABLETS
PLGB 367810001	ORBS	NEW ACTIVE SUBSTANCE	TEBENTAFUSP	29/07/2021	24/08/2021	07/06/2022	IMMUNOCORE LIMITED	KIMTRAK 200 MICROGRAMS/ ML CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 552450001	RELANCE	NEW ACTIVE SUBSTANCE	RIMEGEPANT SULFATE	02/03/2022	08/03/2022	10/06/2022	BIOHAVEN PHARMACEUTICAL IRELAND DESIGNATED ACTIVITY COMPANY	VYDURA 75MG ORAL YOLPHUSATE
PL 213440029	RELANCE	NEW ACTIVE SUBSTANCE	LANDILOL HYDROCHLORIDE	10/03/2022	15/03/2022	14/06/2022	AOP ORPHAN PHARMACEUTICALS GMBH	RAPBLOC 300 MG POWDER FOR SOLUTION FOR INFUSION
PLGB 001011207	ACCESS	NEW ACTIVE SUBSTANCE	ASCMBIN	28/07/2021	27/08/2021	15/06/2022	NOVARTIS PHARMACEUTICALS UK LIMITED	SCENBLUX 20 MG FILM-COATED TABLETS
PLGB 001011208	ACCESS	NEW ACTIVE SUBSTANCE	ASCMBIN	28/07/2021	27/08/2021	15/06/2022	NOVARTIS PHARMACEUTICALS UK LIMITED	SCENBLUX 40 MG FILM-COATED TABLETS
PLGB 504120023	RELANCE	NEW ACTIVE SUBSTANCE	DECABTAGENE VICIUECEL	29/06/2021	15/07/2021	24/06/2022	CELGENE EUROPE B.V.	ABECCA 200 - 500 X 10 ⁶ CELLS DISPERSION FOR INFUSION
PLGB 431150001	RELANCE	NEW ACTIVE SUBSTANCE	LINZAGOLX CHOLINE	21/12/2021	21/01/2022	27/06/2022	OBSOVA IRELAND LIMITED	YSELTU 100 MG FILM-COATED TABLETS
PLGB 431150002	NATIONAL	NEW ACTIVE SUBSTANCE	LINZAGOLX CHOLINE	21/12/2021	21/01/2022	27/06/2022	OBSOVA IRELAND LIMITED	YSELTU 200 MG FILM-COATED TABLETS
PLGB 567080001	RELANCE	NEW ACTIVE SUBSTANCE	TECOVRIMAT MONOHYDRATE	27/05/2022	27/05/2022	30/06/2022	SIGA TECHNOLOGIES NETHERLANDS B.V.	TECOVRIMAT SIGA 200 MG HARD CAPSULES
PLGB 539040001	ORBS	NEW ACTIVE SUBSTANCE	BELLUMOSULI MESYLATE	26/11/2020	17/04/2021	07/07/2022	KADMON INTERNATIONAL LTD	REZUKRO 200 MG FILM-COATED TABLETS
PLGB 044250000	RELANCE	NEW ACTIVE SUBSTANCE	DUPILUMAB	16/05/2022	18/05/2022	20/07/2022	AVENTIS PHARMA LIMITED	DUPIXENT 100 MG SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE
PLGB 549810001	RELANCE	NEW ACTIVE SUBSTANCE	VOXELOTOR	22/12/2021	25/03/2022	25/07/2022	GLOBAL BLOOD THERAPEUTICS UK LIMITED	OXBRYTA 500MG FILM-COATED TABLETS
PLGB 044250001	RELANCE	NEW ACTIVE SUBSTANCE	GLUPIDASE ALFA	24/05/2022	30/05/2022	01/08/2022	AVENTIS PHARMA LIMITED	XENPOZYME 20MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 359303002	NATIONAL	NEW ACTIVE SUBSTANCE	GOZETOTIDE	28/10/2021	15/11/2021	10/08/2022	ADVANCED ACCELERATOR APPLICATIONS (UK & IRELAND) LIMITED	GOZETOTIDE SOLUTION FOR INJECTION 25 MG
PLGB 359303003	NATIONAL	NEW ACTIVE SUBSTANCE	LUTETIUM (Lu-177)	28/10/2021	15/11/2021	10/08/2022	ADVANCED ACCELERATOR APPLICATIONS (UK & IRELAND) LIMITED	PLUVICTO 1.000 MBQ/ML SOLUTION FOR INJECTION/INFUSION
PLGB 210390072	RELANCE	NEW ACTIVE SUBSTANCE	HUMAN CHORIONIC GONADOTROPIN	11/03/2022	17/03/2022	17/08/2022	BSA FARMACEUTICI ITALIA S.R.L.	ZIVAFERT PFS 5000 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 119720058	RELANCE	NEW ACTIVE SUBSTANCE	LENACAPAVIR SODIUM	24/06/2022	14/07/2022	24/08/2022	GILEAD SCIENCES LTD	SUNLENCA 484 MG SOLUTION FOR INJECTION
PLGB 119720059	NATIONAL	NEW ACTIVE SUBSTANCE	LENACAPAVIR SODIUM	24/06/2022	14/07/2022	24/08/2022	GILEAD SCIENCES LTD	SUNLENCA 300 MG FILM-COATED TABLETS
PLGB 567090001	RELANCE	NEW ACTIVE SUBSTANCE	LONAFARNIB	02/06/2022	20/06/2022	24/08/2022	EIGERBIO EUROPE LIMITED	ZOKINNVY 50 MG HARD CAPSULES
PLGB 567090002	RELANCE	NEW ACTIVE SUBSTANCE	LONAFARNIB	02/06/2022	20/06/2022	24/08/2022	EIGERBIO EUROPE LIMITED	ZOKINNVY 75 MG HARD CAPSULES
PLGB 477930003	RELANCE	NEW ACTIVE SUBSTANCE	EVNACUMAB	01/07/2022	12/07/2022	26/08/2022	UL TRAGENYX GERMANY GMBH	EVEKEZA 150 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 487110002	RELANCE	NEW ACTIVE SUBSTANCE	DARODRENTAN HYDROCHLORIDE	08/06/2022	26/06/2022	26/09/2022	DOERSA PHARMACEUTICALS DEUTSCHLAND GMBH	DOVARTIS 50 MG FILM-COATED TABLETS
PLGB 487110003	RELANCE	NEW ACTIVE SUBSTANCE	DARODRENTAN HYDROCHLORIDE	08/06/2022	26/06/2022	26/09/2022	DOERSA PHARMACEUTICALS DEUTSCHLAND GMBH	DOVARTIS 50 MG FILM-COATED TABLETS
PLGB 002402744	RELANCE	NEW ACTIVE SUBSTANCE	BEDAQULINE FUMARATE	17/08/2021	05/11/2021	15/09/2022	JANSEN-CLAG LIMITED	BIRTURO 20 MG TABLETS
PLGB 505970008	RELANCE	NEW ACTIVE SUBSTANCE	VUTRISIRAN SODIUM	28/07/2022	16/08/2022	16/09/2022	ALNYLAM NETHERLANDS B.V.	AMVUTTRA 25 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 179010365	RELANCE	NEW ACTIVE SUBSTANCE	TEZPELUMAB	02/09/2022	01/08/2022	23/09/2022	ASTRAZENCA UK LIMITED	TEZSPRE 210 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 148950317	RELANCE	NEW ACTIVE SUBSTANCE	TRZEPATIDE	26/07/2022	03/08/2022	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 2.5 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 148950318	NATIONAL	NEW ACTIVE SUBSTANCE	TRZEPATIDE	26/07/2022	03/08/2022	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 5 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 148950320	NATIONAL	NEW ACTIVE SUBSTANCE	TRZEPATIDE	26/07/2022	03/08/2022	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 7.5 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 148950321	NATIONAL	NEW ACTIVE SUBSTANCE	TRZEPATIDE	26/07/2022	03/08/2022	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 10 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 148950322	NATIONAL	NEW ACTIVE SUBSTANCE	TRZEPATIDE	26/07/2022	03/08/2022	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 15 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 148950323	NATIONAL	NEW ACTIVE SUBSTANCE	TRZEPATIDE	26/07/2022	03/08/2022	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 15 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 000310903	RELANCE	NEW ACTIVE SUBSTANCE	MOSUNETUZUMAB	01/07/2022	01/08/2022	04/10/2022	ROCHE PRODUCTS LIMITED	LUNSUMO 1 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 000310904	RELANCE	NEW ACTIVE SUBSTANCE	MOSUNETUZUMAB	01/07/2022	01/08/2022	04/10/2022	ROCHE PRODUCTS LIMITED	LUNSUMO 30 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 474970001	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 3 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 474970002	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 3.6 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 474970003	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 4.3 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 474970004	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 5.2 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 474970005	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 6.3 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 474970006	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 7.4 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 474970007	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 9.1 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 474970008	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 11 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 474970009	RELANCE	NEW ACTIVE SUBSTANCE	LONAPEGSOMATROPIN	11/12/2021	29/06/2022	17/10/2022	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A-S	LONAPEGSOMATROPIN ASCENDIS PHARMA 13.3 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN CARTRIDGE
PLGB 179010370	RELANCE	NEW ACTIVE SUBSTANCE	NIRSEVIMAB	20/09/2022	04/10/2022	07/11/2022	ASTRAZENCA UK LIMITED	BEYFORTUS 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 179010371	NATIONAL	NEW ACTIVE SUBSTANCE	NIRSEVIMAB	20/09/2022	04/10/2022	07/11/2022	ASTRAZENCA UK LIMITED	BEYFORTUS 100 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 002426751	RELANCE	NEW ACTIVE SUBSTANCE	TECLISTAMAB	18/08/2022	07/09/2022	09/11/2022	JANSEN-CLAG LIMITED	TECVAYLI 10 MG/ML SOLUTION FOR INJECTION
PLGB 002426752	NATIONAL	NEW ACTIVE SUBSTANCE	TECLISTAMAB	18/08/2022	07/09/2022	09/11/2022	JANSEN-CLAG LIMITED	TECVAYLI 90 MG/ML SOLUTION FOR INJECTION
PLGB 536230012	RELANCE	NEW ACTIVE SUBSTANCE	FAMOTIZUMERAN	07/10/2022	21/10/2022	09/11/2022	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.45 (1515 MICROGRAMS)/DOSE DISPERSION FOR INJECTION
PLGB 161990127	RELANCE	NEW ACTIVE SUBSTANCE	MARBIVIR	26/09/2022	26/09/2022	26/09/2022	TAKEDA UK LIMITED	TAHEDI 120 MG FILM-COATED TABLETS
PLGB 042210008	RELANCE	NEW ACTIVE SUBSTANCE	ELADOCAGENE EXUPARVOVEC	24/05/2022	02/09/2022	17/11/2022	PTC THERAPEUTICS INTERNATIONAL LIMITED	UPSTAZA 2.8X10 ¹¹ VECTOR GENOMES (VGV) 5 ML SOLUTION FOR INFUSION
PLGB 506970002	RELANCE	NEW ACTIVE SUBSTANCE	VOLOSOPORIN	25/07/2022	27/07/2022	29/11/2022	OTSUKA PHARMACEUTICAL NETHERLANDS BV	LUPKYNIS 7.9 MG SOFT CAPSULES
PLGB 466020028	RELANCE	NEW ACTIVE SUBSTANCE	SARS-COV-2 PREFUSION SPIKE DELTA TM PROTEIN, RECOMBINANT	11/11/2022	17/11/2022	20/12/2022	SANOFI PASTEUR EUROPE	COVID-19 VACCINE
PLGB 527790001	RELANCE	NEW ACTIVE SUBSTANCE	MITAPIVAT SULFATE	20/09/2022	14/10/2022	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 5 MG FILM-COATED TABLETS
PLGB 527790002	RELANCE	NEW ACTIVE SUBSTANCE	MITAPIVAT SULFATE	20/09/2022	14/10/2022	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 20 MG FILM-COATED TABLETS
PLGB 527790003	RELANCE	NEW ACTIVE SUBSTANCE	MITAPIVAT SULFATE	20/09/2022	14/10/2022	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 50 MG FILM-COATED TABLETS
PLGB 527790004	RELANCE	NEW ACTIVE SUBSTANCE	MITAPIVAT SULFATE	04/11/2022	29/11/2022	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 20 MG FILM-COATED TABLETS
PLGB 527790005	RELANCE	NEW ACTIVE SUBSTANCE	MITAPIVAT SULFATE	04/11/2022	29/11/2022	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 20 MG FILM-COATED TABLETS
PLGB 002403745	RELANCE	NEW ACTIVE SUBSTANCE	CLTACABTAGENE AUTOUECEL	01/07/2022	01/08/2022	04/01/2022	JANSEN-CLAG LIMITED	CARVYKTI 3.2 X 10 ⁶ - 1.0 X 10 ⁶ CELLS DISPERSION FOR INFUSION
PLGB 161990125	RELANCE	NEW ACTIVE SUBSTANCE	DENGUE VIRUS SEROTYPE 2 EXPRESSING DENGUE VIRUS SEROTYPE 1 SURFACE PROTEINS LIVE ATTENUATED	18/10/2022	17/01/2023	26/01/2023	TAKEDA UK LIMITED	QDENGA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 161990126	NATIONAL	NEW ACTIVE SUBSTANCE	DENGUE VIRUS SEROTYPE 2 EXPRESSING DENGUE VIRUS SEROTYPE 1 SURFACE PROTEINS LIVE ATTENUATED	18/10/2022	17/01/2023	26/01/2023	TAKEDA UK LIMITED	QDENGA POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 567550001	RELANCE	NEW ACTIVE SUBSTANCE	LONCASTUXIMAB TESIRINE	20/09/2022	28/09/2022	07/02/2023	ADC THERAPEUTICS (NL) B.V.	ZYNLONTA 10 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 566420001	RELANCE	NEW ACTIVE SUBSTANCE	MARALKIBAT CHLORIDE	17/10/2022	20/12/2022	10/02/2023	MIRUM PHARMACEUTICALS INTERNATIONAL B.V.	LMARLI 9.5 MG/ML ORAL SOLUTION
PLGB 537200006	RELANCE	NEW ACTIVE SUBSTANCE	DAVESOMERAN	22/11/2022	22/12/2022	21/02/2023	MODERNA BIOTECH SPAIN SL	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 (50 MICROGRAMS/50 MICROGRAMS)ML DISPERSION FOR INJECTION
PLGB 537200007	NATIONAL	NEW ACTIVE SUBSTANCE	DAVESOMERAN	22/11/2022	22/12/2022	21/02/2023	MODERNA BIOTECH SPAIN SL	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 25 MICROGRAMS/25 MICROGRAMS DISPERSION FOR INJECTION
PLGB 471040004	RELANCE	NEW ACTIVE SUBSTANCE	EFGRATIGMAD ALFA	20/10/2022	17/01/2023	14/03/2023	ARGENX	VYVGART 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION
PL 186020047	NATIONAL	NEW ACTIVE SUBSTANCE	RUBIDULI CHLORIDE	29/10/2021	07/12/2021	15/03/2023	BRACCO UK LIMITED	OMVOGEN-32 3.3-5.6 GBG RADIONUCLIDE GENERATOR
PLGB 150360160	RELANCE	NEW ACTIVE SUBSTANCE	ETNANACOGENE DEZAPARVOVEC	09/09/2023	17/01/2023	22/03/2023	C.S. BERNING GMBH	COVIR-19 VACCINE (RECOMBINANT, ADJUVANTED)
PLGB 001011217	ORBS	NEW ACTIVE SUBSTANCE	CAPMATINIB DRYHYDROCHLORIDE MONOHYDRATE	26/07/2022	14/08/2022	27/03/2023	NOVARTIS PHARMACEUTICALS UK LIMITED	TABRECTA 150 MG FILM-COATED TABLETS
PLGB 001011218	NATIONAL	NEW ACTIVE SUBSTANCE	CAPMATINIB DRYHYDROCHLORIDE MONOHYDRATE	26/07/2022	14/08/2022	27/03/2023	NOVARTIS PHARMACEUTICALS UK LIMITED	TABRECTA 200 MG FILM-COATED TABLETS
PLGB 000310928	RELANCE	NEW ACTIVE SUBSTANCE	BALOXAVIR MARBOXIL	20/05/2022	02/09/2022	19/04/2023	ROCHE PRODUCTS LIMITED	XOFIENZA 80 MG FILM-COATED TABLETS
PLGB 151050179	RELANCE	NEW ACTIVE SUBSTANCE	DEUCRAVACITINIB	31/01/2023	04/05/2023	10/05/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	SOTYKTU 8 MG FILM-COATED TABLETS
PLGB 462380004	ACCESS	NEW ACTIVE SUBSTANCE	VADADUSTAT	01/03/2022	18/03/2022	19/05/2023	AKEBIA EUROPE LIMITED	VADADUSTAT 150 MG FILM-COATED TABLETS
PLGB 462380005	ACCESS	NEW ACTIVE SUBSTANCE	VADADUSTAT	01/03/2022	18/03/2022	19/05/2023	AKEBIA EUROPE LIMITED	VADADUSTAT 300 MG FILM-COATED TABLETS
PLGB 462380006	ACCESS	NEW ACTIVE SUBSTANCE	VADADUSTAT	01/03/2022	18/03/2022	19/05/2023	AKEBIA EUROPE LIMITED	VADADUSTAT 450 MG FILM-COATED TABLETS
PLGB 522970001	RELANCE	NEW ACTIVE SUBSTANCE	TABRECTA EUCEL	17/10/2022	08/12/2022	22/05/2023	ATARA BIOTHERAPEUTICS IRELAND LIMITED	DAVIDOL 2.8 X 10 ⁷ - 7.3 X 10 ⁷ CELLS/ML DISPERSION FOR INJECTION
PLGB 336110029	NATIONAL	NEW ACTIVE SUBSTANCE	RECOMBINANT SARS-COV-2 S NANOPARTICLE	09/07/2022	09/07/2022	09/07/2022	SK CHEMICALS GMBH	SK-CH2019 VACCINE (RECOMBINANT, ADJUVANTED)
PLGB 179010368	RELANCE	NEW ACTIVE SUBSTANCE	TREMELIMUMAB	29/12/2022	31/03/2023	06/06/2023	ASTRAZENCA UK LIMITED	TABRECTA 150 MG FILM-COATED TABLETS
PLGB 184420002	RELANCE	NEW ACTIVE SUBSTANCE	GLUCARIPIDASE	25/02/2022	21/07/2022	15/06/2023	PROTHERICS MEDICINES DEVELOPMENT LIMITED	VORAXAZE 1000 UNITS POWDER FOR SOLUTION FOR INJECTION
PLGB 148950324	RELANCE	NEW ACTIVE SUBSTANCE	MIRKIZUMAB	16/09/2022	18/04/2023	28/06/2023	ELI LILLY NEDERLAND B.V.	OMVOH 300 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 148950325	RELANCE	NEW ACTIVE SUBSTANCE	MIRKIZUMAB	16/09/2022	18/04/2023	28/06/2023	ELI LILLY NEDERLAND B.V.	OMVOH 100 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 148950326	RELANCE	NEW ACTIVE SUBSTANCE	MIRKIZUMAB	16/09/2022	18/04/2023	28/06/2023	ELI LILLY NEDERLAND B.V.	OMVOH 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 258230003	RELANCE	NEW ACTIVE SUBSTANCE	CPAGLUCOSIDASE ALFA	19/12/2022	17/01/2023	30/06/2023	AMUS THERAPEUTICS UK LIMITED	POMBLITI 105 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 058150120	RELANCE	NEW ACTIVE SUBSTANCE	VOSENB	26/02/2023	11/05/2023	05/07/2023	LES LABORATOIRES SERVIER	TIBSOVO 250 MG FILM COATED TABLETS
PLGB 148640216	RELANCE	NEW ACTIVE SUBSTANCE	RECOMBINANT RESPIRATORY SYNCYTIAL VIRUS PRE-FUSION F PROTEIN	26/04/2023	05/06/2023	07/07/2023	GLAXOSMITHKLINE UK LIMITED	AREXVY POWDER AND SUSPENSION FOR SUSPENSION FOR INJECTION
PLGB 145860228	RELANCE	NEW ACTIVE SUBSTANCE	EPISOLIMAB	17/01/2023	30/01/2023	27/07/2023	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SPREVED 450MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 151050180	RELANCE	NEW ACTIVE SUBSTANCE	NAVACAMTEN	26/04/2023	19/05/2023	28/07/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	CAMZYOS 2.5MG HARD CAPSULES
PLGB 151050181	RELANCE	NEW ACTIVE SUBSTANCE	NAVACAMTEN	26/04/2023	19/05/2023	28/07/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	CAMZYOS 5MG HARD CAPSULES
PLGB 151050182	RELANCE	NEW ACTIVE SUBSTANCE	NAVACAMTEN	26/04/2023	19/05/2023	28/07/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	CAMZYOS 10MG HARD CAPSULES
PLGB 151050183	RELANCE	NEW ACTIVE SUBSTANCE	NAVACAMTEN	26/04/2023	19/05/2023	28/07/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	CAMZYOS 15MG HARD CAPSULES
PLGB 563460002	RELANCE	NEW ACTIVE SUBSTANCE	RECOMBINANT SARS-COV-2 B.1.351 AND B.1.1.7 VARIANT SPIKE PROTEIN RECEPTOR BINDING DOMAIN FUSION HETEROIDIMER	04/04/2023	18/04/2023	31/07/2023	HPRA HUMAN HEALTH S.L.	BIMERVAX EMULSION FOR INJECTION
PLGB 412250001	REL							

PLGB 410420088	NATIONAL	NEW ACTIVE SUBSTANCE	ATOGEPAANT MONOHYDRATE	28/06/2022	21/07/2022	30/08/2023	ABBVIE LTD	AQUIPTA 10 MG TABLETS
PLGB 410420089	NATIONAL	NEW ACTIVE SUBSTANCE	ATOGEPAANT MONOHYDRATE	28/06/2022	21/07/2022	30/08/2023	ABBVIE LTD	AQUIPTA 80 MG TABLETS
PLGB 536320026	RELANCE	NEW ACTIVE SUBSTANCE	RAXTOZINAMERAN	09/08/2023	11/08/2023	04/09/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 (30 MICROGRAMS)/DOSE DISPERSION FOR INJECTION
PLGB 536320032	RELANCE	NEW ACTIVE SUBSTANCE	RAXTOZINAMERAN	09/08/2023	11/08/2023	04/09/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 (10 MICROGRAMS)/DOSE DISPERSION FOR INJECTION
PLGB 537200011	NATIONAL	NEW ACTIVE SUBSTANCE	ANDUSOMERAN	22/06/2023	28/06/2023	14/09/2023	MODERNA BIOTECH SPAIN SL	SPIREXAX XBB.1.5 0.1 MG/ML DISPERSION FOR INJECTION
PLGB 536320028	RELANCE	NEW ACTIVE SUBSTANCE	RAXTOZINAMERAN	12/09/2023	28/09/2023	04/10/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 (30 MICROGRAMS)/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VAL
PLGB 536320030	RELANCE	NEW ACTIVE SUBSTANCE	RAXTOZINAMERAN	12/09/2023	28/09/2023	04/10/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION
PLGB 536320034	RELANCE	NEW ACTIVE SUBSTANCE	RAXTOZINAMERAN	12/09/2023	28/09/2023	04/10/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION, SINGLE DOSE VAL
PLGB 002420755	RELANCE	NEW ACTIVE SUBSTANCE	TALQUETAMAB	25/07/2023	02/08/2023	09/10/2023	JANSSEN-CLAG LIMITED	TALVEY 2 MG/ML SOLUTION FOR INJECTION
PLGB 002420756	RELANCE	NEW ACTIVE SUBSTANCE	TALQUETAMAB	25/07/2023	02/08/2023	09/10/2023	JANSSEN-CLAG LIMITED	TALVEY 40 MG/ML SOLUTION FOR INJECTION
PLGB 506070033	RELANCE	NEW ACTIVE SUBSTANCE	CEDAZURIDINE	28/07/2023	02/08/2023	11/10/2023	OTSUKA PHARMACEUTICAL NETHERLANDS BV	INAQOVI 35 MG/100 MG FILM-COATED TABLETS
PLGB 000310931	RELANCE	NEW ACTIVE SUBSTANCE	GLOFITAMAB	22/05/2023	13/06/2023	16/10/2023	ROCHE PRODUCTS LIMITED	COLUMVI 2.5 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 000310932	RELANCE	NEW ACTIVE SUBSTANCE	GLOFITAMAB	22/05/2023	13/06/2023	16/10/2023	ROCHE PRODUCTS LIMITED	COLUMVI 10 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 410420092	NATIONAL	NEW ACTIVE SUBSTANCE	EPCORTAMAB	24/11/2022	08/12/2022	20/10/2023	ABBVIE LTD	TEPRKNLY 4 MG/50 ML CONCENTRATE FOR SOLUTION FOR INJECTION
PLGB 410420093	NATIONAL	NEW ACTIVE SUBSTANCE	EPCORTAMAB	24/11/2022	08/12/2022	20/10/2023	ABBVIE LTD	TEPRKNLY 48 MG SOLUTION FOR INJECTION
PLGB 445300001	RELANCE	NEW ACTIVE SUBSTANCE	UBILUXIMAB	25/05/2023	23/06/2023	23/10/2023	PROPHARMA GROUP THE NETHERLANDS B.V.	BRUMMI 150 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 151050192	RELANCE	NEW ACTIVE SUBSTANCE	LISOCABTAGENE MARALEUCEL	15/12/2022	03/03/2023	28/10/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	BREYANZI 1.1-70 X 10 ⁹ CELLS/ML / 1.1-70 X 10 ⁹ CELLS/ML DISPERSION FOR INFUSION
PLGB 000571715	NATIONAL	NEW ACTIVE SUBSTANCE	RITLICTINIB TOSYLATE	26/07/2022	02/09/2022	31/10/2023	PFIZER LIMITED	LITULO 50 MG HARD CAPSULES
PLGB 561540001	NATIONAL	NEW ACTIVE SUBSTANCE	ADAGRASIB	25/08/2022	11/09/2022	03/11/2023	MIRATI THERAPEUTICS B.V.	KRAZATI 200 MG FILM-COATED TABLETS
PLGB 223520019	NATIONAL	NEW ACTIVE SUBSTANCE	EXAGAMGLOGENE AUTOTEMCEL	28/12/2022	26/01/2023	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	CASGEVY 4-13 X 10 ⁹ CELLS/ML DISPERSION FOR INFUSION
PLGB 000310916	RELANCE	NEW ACTIVE SUBSTANCE	SATRALIZUMAB	30/06/2023	28/09/2023	21/11/2023	ROCHE PRODUCTS LIMITED	ENSPRYNG 120 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 000571722	RELANCE	NEW ACTIVE SUBSTANCE	RESPIRATORY SYNCYTIAL VIRUS SUBGROUP A STABILISED PREFUSION F PROTEIN	10/07/2023	02/08/2023	21/11/2023	PFIZER LIMITED	ABRYSO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 524200020	RELANCE	NEW ACTIVE SUBSTANCE	ELACESTRANT DIHYDROCHLORIDE	26/07/2023	11/08/2023	06/12/2023	STEDIM THERAPEUTICS B.V.	KORBERDU 80 MG FILM-COATED TABLETS
PLGB 524250004	RELANCE	NEW ACTIVE SUBSTANCE	ELACESTRANT DIHYDROCHLORIDE	26/07/2023	12/09/2023	06/12/2023	STEDIM THERAPEUTICS B.V.	KORBERDU 345 MG FILM-COATED TABLETS
PLGB 123080014	RELANCE	NEW ACTIVE SUBSTANCE	GADOPICLENOL	17/10/2023	25/10/2023	12/12/2023	GUERBET	ELUCIREM 0.5 MMOL/ML SOLUTION FOR INJECTION
PLGB 123080034	RELANCE	NEW ACTIVE SUBSTANCE	GADOPICLENOL	17/10/2023	25/10/2023	12/12/2023	GUERBET	ELUCIREM 0.5 MMOL/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 001011216	RELANCE	NEW ACTIVE SUBSTANCE	TISLELIZUMAB	30/06/2022	25/07/2023	13/12/2023	NOVARTIS PHARMACEUTICALS UK LIMITED	TEVIMBRA 100 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 001066437	RELANCE	NEW ACTIVE SUBSTANCE	FEZOLINETANT	17/10/2023	14/11/2023	14/12/2023	ASTELLAS PHARMA LIMITED	VEOZA 45 MG FILM-COATED TABLETS
PLGB 169730048	RELANCE	NEW ACTIVE SUBSTANCE	LEBRKIZUMAB	21/09/2023	28/09/2023	19/12/2023	ALMRALL SA	EBGLYSS 250 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 169730049	RELANCE	NEW ACTIVE SUBSTANCE	LEBRKIZUMAB	21/09/2023	28/09/2023	19/12/2023	ALMRALL SA	EBGLYSS 250 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 534870007	RELANCE	NEW ACTIVE SUBSTANCE	PEGZLAGRANSE	17/10/2023	24/10/2023	20/12/2023	IMMEDICA PHARMA AB	LOARGYS 5 MG/ML SOLUTION FOR INJECTION/INFUSION
PLGB 533950091	RELANCE	NEW ACTIVE SUBSTANCE	GEFAPRANT CITRATE	24/07/2023	21/08/2023	21/12/2023	MEYOR SHARP & SCHMIE (UK) LIMITED	L17PNU 45 MG FILM-COATED TABLET
PLGB 151050192	ORBSIS	NEW ACTIVE SUBSTANCE	NICOLIZUMAB	01/02/2023	24/03/2023	27/12/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	OPROULAG 240 MG/80 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 000571723	RELANCE	NEW ACTIVE SUBSTANCE	ELRANATAMAB	17/10/2023	28/10/2023	04/01/2024	PFIZER LIMITED	ELREXFIO 40 MG/ML SOLUTION FOR INJECTION
PLGB 258350005	RELANCE	NEW ACTIVE SUBSTANCE	VAMOROLONE	27/02/2023	31/03/2023	11/01/2024	SANTHERA PHARMACEUTICALS (DEUTSCHLAND) GMBH	AGAMREE 40 MG/ML ORAL SUSPENSION
PLGB 000390805	RELANCE	NEW ACTIVE SUBSTANCE	ZILUCOPLAN SODIUM	18/09/2023	22/09/2023	15/01/2024	UCB PHARMA LIMITED	ZLBRYSO 16.6 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 000390806	RELANCE	NEW ACTIVE SUBSTANCE	ZILUCOPLAN SODIUM	18/09/2023	22/09/2023	15/01/2024	UCB PHARMA LIMITED	ZLBRYSO 23 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 000390807	RELANCE	NEW ACTIVE SUBSTANCE	ZILUCOPLAN SODIUM	18/09/2023	22/09/2023	15/01/2024	UCB PHARMA LIMITED	ZLBRYSO 32.4 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 189200050	RELANCE	NEW ACTIVE SUBSTANCE	GADOPICLENOL	19/10/2023	27/10/2023	19/01/2024	BRACCO UK LIMITED	VUEWAY 0.5 MMOL/ML SOLUTION FOR INJECTION
PLGB 189200051	RELANCE	NEW ACTIVE SUBSTANCE	GADOPICLENOL	19/10/2023	27/10/2023	19/01/2024	BRACCO UK LIMITED	VUEWAY 0.5 MMOL/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 189200050	RELANCE	NEW ACTIVE SUBSTANCE	NEZAFURON ACETATE	19/10/2023	23/10/2023	29/09/2024	NAPP PHARMACEUTICALS UK LIMITED	REZZAYO 200 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 194940318	RELANCE	NEW ACTIVE SUBSTANCE	NOMELOTINB DIHYDROCHLORIDE MONOHYDRATE	14/11/2023	14/12/2023	30/01/2024	GLAXOSMITHKLINE UK LIMITED	OKJARA 100 MG FILM-COATED TABLETS
PLGB 194940322	RELANCE	NEW ACTIVE SUBSTANCE	NOMELOTINB DIHYDROCHLORIDE MONOHYDRATE	14/11/2023	14/12/2023	30/01/2024	GLAXOSMITHKLINE UK LIMITED	OKJARA 150 MG FILM-COATED TABLETS
PLGB 194940323	RELANCE	NEW ACTIVE SUBSTANCE	NOMELOTINB DIHYDROCHLORIDE MONOHYDRATE	14/11/2023	14/12/2023	30/01/2024	GLAXOSMITHKLINE UK LIMITED	OKJARA 200 MG FILM-COATED TABLETS
PL 191560168	RELANCE	NEW ACTIVE SUBSTANCE	RUBIDIUM-82 CHLORIDE	18/02/2022	27/04/2022	06/03/2024	JUBLANT PHARMACEUTICALS NV	RUBY-FIL(RUBIDIUM RB 82 GENERATOR) 3.145 GBq-4.255 GBq *82SR PER GENERATOR,RADIONUCLIDE GENERATOR
PLGB 443010003	RELANCE	NEW ACTIVE SUBSTANCE	PILUFOLASTAT	12/07/2023	15/08/2023	06/03/2024	CURIUM PHARMA UK LIMITED	PYLCLARI 1 000 MBQ/ML SOLUTION FOR INJECTION
PLGB 443010004	RELANCE	NEW ACTIVE SUBSTANCE	PILUFOLASTAT	13/07/2023	15/08/2023	06/03/2024	CURIUM PHARMA UK LIMITED	PYLCLARI 1 500 MBQ/ML SOLUTION FOR INJECTION
PLGB 000390808	RELANCE	NEW ACTIVE SUBSTANCE	ROZANOLIZUMAB	13/11/2023	27/11/2023	07/03/2024	UCB PHARMA LIMITED	RYSTIGGO 140 MG/ML SOLUTION FOR INJECTION
PLGB 556200001	RELANCE	NEW ACTIVE SUBSTANCE	GANAXOLONE	30/06/2023	09/08/2023	07/03/2024	MARINUS PHARMACEUTICALS EMERALD LIMITED	ZTALMY 50 MG/ML ORAL SUSPENSION
PLGB 000571723	RELANCE	NEW ACTIVE SUBSTANCE	ETRASIMODIL LARGINEINE	24/10/2023	04/01/2024	07/03/2024	DAIICHI SANKYO UK LIMITED	DAIICHI 240 MG FILM-COATED TABLETS
PLGB 082650047	RELANCE	NEW ACTIVE SUBSTANCE	QUIZARTINB DIHYDROCHLORIDE	22/09/2023	24/10/2023	11/03/2024	DAIICHI SANKYO UK LIMITED	VANFLYTA 17.7 MG FILM-COATED TABLETS
PLGB 082650048	RELANCE	NEW ACTIVE SUBSTANCE	QUIZARTINB DIHYDROCHLORIDE	22/09/2023	24/10/2023	11/03/2024	DAIICHI SANKYO UK LIMITED	VANFLYTA 26.5 MG FILM-COATED TABLETS
PLGB 567340009	IRP Route A	NEW ACTIVE SUBSTANCE	CEFEPIME DIHYDROCHLORIDE MONOHYDRATE	02/02/2024	09/02/2024	04/04/2024	ADVANC PHARMA LIMITED	EXBIFEP 2 G/0.5 G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 245760009	RELANCE	NEW ACTIVE SUBSTANCE	FOSDENOPTERN HYDROBROMIDE DIHYDRATE	08/09/2023	16/10/2023	09/04/2024	TMC PHARMA SERVICES LIMITED	NULIBRY 5 MG POWDER FOR SOLUTION FOR INJECTION
PLGB 511270001	RELANCE	NEW ACTIVE SUBSTANCE	PALOPEGTERIPARATIDE	19/09/2023	14/12/2023	23/04/2024	ASCENDIS PHARMA BONE DISEASES A/S	YORVPATH 168 MICROGRAMS/0.56 ML SOLUTION FOR INJECTION IN PRE FILLED PEN
PLGB 511270002	RELANCE	NEW ACTIVE SUBSTANCE	PALOPEGTERIPARATIDE	19/09/2023	14/12/2023	23/04/2024	ASCENDIS PHARMA BONE DISEASES A/S	YORVPATH 294 MICROGRAMS/0.98 ML SOLUTION FOR INJECTION IN PRE FILLED PEN
PLGB 511270003	RELANCE	NEW ACTIVE SUBSTANCE	PALOPEGTERIPARATIDE	19/09/2023	14/12/2023	23/04/2024	ASCENDIS PHARMA BONE DISEASES A/S	YORVPATH 420 MICROGRAMS/1.4 ML SOLUTION FOR INJECTION IN PRE FILLED PEN
PL 370900005	NATIONAL	NEW ACTIVE SUBSTANCE	ITOPRIDE HYDROCHLORIDE	18/05/2020	12/11/2020	14/08/2024	PRO MED CS PHARMA AS	PROGIT 50 MG FILM-COATED TABLETS
PLGB 006030269	IRP Route A	NEW ACTIVE SUBSTANCE	VIBEGRON	13/05/2024	21/05/2024	17/07/2024	PIERRE FABRE LIMITED	OSSEMA 75 MG FILM-COATED TABLETS
PLGB 179010373	ORBSIS	NEW ACTIVE SUBSTANCE	CAPIVASERTIB	28/04/2023	23/05/2023	17/07/2024	ASTRAZENECA UK LIMITED	TRUQAQ 180 MG FILM -COATED TABLETS
PLGB 179010374	NATIONAL	NEW ACTIVE SUBSTANCE	CAPIVASERTIB	28/04/2023	23/05/2023	17/07/2024	ASTRAZENECA UK LIMITED	TRUQAQ 200 MG FILM -COATED TABLETS
PLGB 536320042	IRP Route A	NEW ACTIVE SUBSTANCE	BRETOVAMERAN	11/06/2024	18/06/2024	24/07/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY.JN.1 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION
PLGB 536320046	IRP Route A	NEW ACTIVE SUBSTANCE	BRETOVAMERAN	11/06/2024	18/06/2024	24/07/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY.JN.1 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 536320052	IRP Route A	NEW ACTIVE SUBSTANCE	BRETOVAMERAN	11/06/2024	18/06/2024	24/07/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY.JN.1 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VAL
PLGB 536320056	IRP Route A	NEW ACTIVE SUBSTANCE	BRETOVAMERAN	11/06/2024	18/06/2024	24/07/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY.JN.1 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION, 3-DOSE VAL
PLGB 001011231	IRP Route B	NEW ACTIVE SUBSTANCE	PTACOPAN HYDROCHLORIDE MONOHYDRATE	10/04/2024	29/04/2024	02/08/2024	NOVARTIS PHARMACEUTICALS UK LIMITED	FABHALTA 200 MG HARD CAPSULES
PLGB 311870023	IRP Route B	NEW ACTIVE SUBSTANCE	DANICOPAN	14/03/2024	03/05/2024	02/08/2024	ALEXON EUROPE SAS	KOZYREYA 50 MG FILM-COATED TABLETS
PLGB 311870024	IRP Route B	NEW ACTIVE SUBSTANCE	DANICOPAN	14/03/2024	03/05/2024	02/08/2024	ALEXON EUROPE SAS	KOZYREYA 100MG FILM-COATED TABLETS
PLGB 000310943	IRP Route A	NEW ACTIVE SUBSTANCE	CROVALIMAB	09/07/2024	09/07/2024	07/08/2024	ROCHE PRODUCTS LIMITED	PIASKY 340 MG SOLUTION FOR INJECTION/INFUSION
PLGB 001066439	NATIONAL	NEW ACTIVE SUBSTANCE	ZOLBETUXIMAB	26/01/2024	14/02/2024	14/08/2024	ASTELLAS PHARMA LIMITED	VLYDO 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 536320044	IRP Route A	NEW ACTIVE SUBSTANCE	BRETOVAMERAN	02/08/2024	08/08/2024	20/08/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY.JN.1 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VAL
PLGB 536320048	IRP Route A	NEW ACTIVE SUBSTANCE	BRETOVAMERAN	02/08/2024	08/08/2024	20/08/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY.JN.1 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION
PLGB 536320050	IRP Route A	NEW ACTIVE SUBSTANCE	BRETOVAMERAN	02/08/2024	08/08/2024	20/08/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY.JN.1 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION
PLGB 536320054	IRP Route A	NEW ACTIVE SUBSTANCE	BRETOVAMERAN	02/08/2024	08/08/2024	20/08/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY.JN.1 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION
PLGB 339670027	NATIONAL	NEW ACTIVE SUBSTANCE	LECANEVIMAB	18/05/2023	02/06/2023	22/08/2024	EISA EUROPE LIMITED	LEDEMBI 100 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 537200015	NATIONAL	NEW ACTIVE SUBSTANCE	SARS-COV-2-JN.1 MRNA (MODERNATX)	06/05/2024	10/05/2024	02/09/2024	MODERNA BIOTECH SPAIN SL	SPIREXAX.JN.1 0.1 MG/ML DISPERSION FOR INJECTION
PL 161890146	ACCESS	NEW ACTIVE SUBSTANCE	FRUGUQUINTINB	29/06/2023	29/06/2023	20/09/2024	TAKEDA UK LIMITED	FABALTA 1 MG HARD CAPSULES
PL 161890147	ACCESS	NEW ACTIVE SUBSTANCE	FRUGUQUINTINB	29/06/2023	29/10/2023	20/09/2024	TAKEDA UK LIMITED	FRIUZAQA 5 MG HARD CAPSULES
PLGB 330100001	IRP Route B	NEW ACTIVE SUBSTANCE	LENOLISB PHOSPHATE	29/02/2024	08/04/2024	25/09/2024	PHARMING TECHNOLOGIES BV	JOENUA 70 MG FILM-COATED TABLETS
PLGB 345260029	NATIONAL	NEW ACTIVE SUBSTANCE	ELAFIBRANOR	16/11/2023	28/11/2023	04/10/2024	IPSEN LIMITED	QIRVO 80 MG FILM-COATED TABLETS
PLGB 536320058	IRP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, OMICRON VARIANT KP.2, SPIKE PROTEIN	11/06/2024	25/09/2024	10/10/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY KP.2 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION
PLGB 536320062	IRP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, OMICRON VARIANT KP.2, SPIKE PROTEIN	27/09/2024	02/10/2024	10/10/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY KP.2 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 179010377	NATIONAL	NEW ACTIVE SUBSTANCE	EPLONTENSEN SODIUM	13/10/2023	13/11/2023	14/10/2024	ASTRAZENECA UK LIMITED	WANZUA 45 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 002420768	IRP Route A	NEW ACTIVE SUBSTANCE	ERDAFITINIB	12/07/2024	21/08/2024	17/10/2024	JANSSEN-CLAG LIMITED	BALVERSA 3 MG FILM-COATED TABLETS
PLGB 002420769	IRP Route A	NEW ACTIVE SUBSTANCE	ERDAFITINIB	12/07/2024	21/08/2024	17/10/2024	JANSSEN-CLAG LIMITED	BALVERSA 4 MG FILM-COATED TABLETS
PLGB 002420770	IRP Route A	NEW ACTIVE SUBSTANCE	ERDAFITINIB	12/07/2024	21/08/2024	17/10/2024	JANSSEN-CLAG LIMITED	BALVERSA 5 MG FILM-COATED TABLETS
PLGB 148650038	NATIONAL	NEW ACTIVE SUBSTANCE	DONANEMAB	28/07/2023	21/08/2023	23/10/2024	ELIJLY NEDERLAND B.V.	KISUNA 350 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 542800003	NATIONAL	NEW ACTIVE SUBSTANCE	SUGEMALIMAB	31/10/2022	07/12/2022	30/10/2024	SFL PHARMACEUTICALS DEUTSCHLAND GMBH	EQUJBI 30 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 152400005	IRP Route B	NEW ACTIVE SUBSTANCE	SPARSENTAN	01/03/2024	22/05/2024	06/11/2024	VIFOR FRANCE	FLSPARI 200 MG FILM-COATED TABLETS
PLGB 152400006	IRP Route B	NEW ACTIVE SUBSTANCE	SPARSENTAN	01/03/2024	22/05/2024	06/11/2024	VIFOR FRANCE	FLSPARI 400 MG FILM-COATED TABLETS
PLGB 536320060	IRP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, OMICRON VARIANT KP.2, SPIKE PROTEIN	10/10/2024	14/10/2024	11/11/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY KP.2 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VAL
PLGB 536320064	IRP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, OMICRON VARIANT KP.2, SPIKE PROTEIN	16/10/2024	28/10/2024	11/11/2024	BIONTECH MANUFACTURING GMBH	COMIRNATY KP.2 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION

PLGB 536320066	RP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, OMICRON VARIANT KP.2, SPIKE PROTEIN	15/10/2024	28/10/2024	11/11/2024	BIONTECH MANUFACTURING GMBH	COMRNATY KP.2 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL
PLGB 536320068	RP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, OMICRON VARIANT KP.2, SPIKE PROTEIN	16/10/2024	28/10/2024	11/11/2024	BIONTECH MANUFACTURING GMBH	COMRNATY KP.2 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION, 3-DOSE VIAL
PLGB 541600004	RP Route A	NEW ACTIVE SUBSTANCE	NVX-COV2373	11/07/2024	14/10/2024	13/11/2024	NOVAVAX CZ A.S.	NOVAVOXD JN.1 DISPERSION FOR INJECTION COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)
PLGB 245760010	RP Route A	NEW ACTIVE SUBSTANCE	TORPALIMAB	06/08/2024	12/09/2024	16/11/2024	TMC PHARMA SERVICES LIMITED	LOOTORZ 240 MG CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 148950329	NATIONAL	NEW ACTIVE SUBSTANCE	FLORTAUFCPR (18F)	31/03/2023	14/04/2023	27/11/2024	ELI LILLY NEDERLAND B.V.	TAUVO 1 800 MBQ/Ml. SOLUTION FOR INJECTION
PLGB 148950330	NATIONAL	NEW ACTIVE SUBSTANCE	FLORTAUFCPR (18F)	31/03/2023	14/04/2023	27/11/2024	ELI LILLY NEDERLAND B.V.	TAUVO 800 MBQ/Ml. SOLUTION FOR INJECTION
PLGB 052930191	RP Route B	NEW ACTIVE SUBSTANCE	DELGOCTINB	16/09/2024	01/10/2024	29/11/2024	LED PHARMA AS	ANZUPGO 20 MG/G CREAM
PLGB 132970107	RP Route B	NEW ACTIVE SUBSTANCE	GIVNOSTAT HYDROCHLORIDE MONOHYDRATE	10/07/2024	24/07/2024	20/12/2024	ITALFARMACO SPA	DUVYZAT 8.86 MG/Ml. ORAL SUSPENSION
PLGB 530950104	RP Route B	NEW ACTIVE SUBSTANCE	NO ACTIVES PRESENT	03/09/2024	12/09/2024	27/12/2024	MERCK SHARP & DOHME (UK) LIMITED	WINREVAR 45 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 530950105	RP Route B	NEW ACTIVE SUBSTANCE	NO ACTIVES PRESENT	03/09/2024	12/09/2024	27/12/2024	MERCK SHARP & DOHME (UK) LIMITED	WINREVAR 60 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 530950106	RP Route B	NEW ACTIVE SUBSTANCE	SOTATERCEPT	03/09/2024	12/09/2024	27/12/2024	MERCK SHARP & DOHME (UK) LIMITED	WINREVAR 45 MG POWDER FOR SOLUTION FOR INJECTION
PLGB 530950107	RP Route B	NEW ACTIVE SUBSTANCE	SOTATERCEPT	03/09/2024	12/09/2024	27/12/2024	MERCK SHARP & DOHME (UK) LIMITED	WINREVAR 60 MG POWDER FOR SOLUTION FOR INJECTION
PLGB 138320083	ORBSIS	NEW ACTIVE SUBSTANCE	TARLATAMAB	10/11/2023	24/11/2023	31/12/2024	AMGEN LIMITED	IMDYLTRA 1 MILLIGRAM POWDER FOR CONCENTRATE AND SOLUTION FOR INFUSION
PLGB 138320084	ORBSIS	NEW ACTIVE SUBSTANCE	TARLATAMAB	10/11/2023	24/11/2023	31/12/2024	AMGEN LIMITED	IMDYLTRA 10 MILLIGRAM POWDER FOR CONCENTRATE AND SOLUTION FOR INFUSION
PL 487110008	RP Route B	NEW ACTIVE SUBSTANCE	APROCOTENTAN	05/08/2024	21/08/2024	09/01/2025	ICORSIA PHARMACEUTICALS DEUTSCHLAND GMBH	JERAYGO 12.5 MG FILM-COATED TABLETS
PL 487110009	RP Route B	NEW ACTIVE SUBSTANCE	APROCOTENTAN	05/08/2024	21/08/2024	09/01/2025	ICORSIA PHARMACEUTICALS DEUTSCHLAND GMBH	JERAYGO 25 MG FILM-COATED TABLETS
PLGB 507290001	NATIONAL	NEW ACTIVE SUBSTANCE	SELADELPAR LYSINE DIIHYDRATE	30/01/2024	19/02/2024	16/01/2025	CYMBARY IRELAND, LIMITED	LADLZ1 10MG CAPSULES
PLGB 150360161	ACCESS	NEW ACTIVE SUBSTANCE	GARADACIMAB	22/11/2023	08/12/2023	24/01/2025	CSL BEHRING GMBH	ANDEMBRY 200 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 150360162	ACCESS	NEW ACTIVE SUBSTANCE	GARADACIMAB	22/11/2023	21/12/2023	24/01/2025	CSL BEHRING GMBH	ANDEMBRY 200 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PL 252580425	RP Route B	NEW ACTIVE SUBSTANCE	CLASCOTERONE	29/02/2024	09/04/2024	30/01/2025	GLENMARK PHARMACEUTICALS EUROPE LIMITED	WINLEV1 10 MG/G CREAM
PLGB 431650007	RP Route B	NEW ACTIVE SUBSTANCE	CHIKUNGUNYA VIRUS, STRAIN CHIKV LIVE ATTENUATED	12/06/2024	08/08/2024	04/02/2025	VALNEVA AUSTRIA GMBH	IXCHIG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 309410024	RP Route B	NEW ACTIVE SUBSTANCE	EFANESOCITOCOG ALFA	08/05/2024	31/05/2024	14/02/2025	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	ALTUVCT 250 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 309410025	RP Route B	NEW ACTIVE SUBSTANCE	EFANESOCITOCOG ALFA	08/05/2024	31/05/2024	14/02/2025	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	ALTUVCT 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 309410026	RP Route B	NEW ACTIVE SUBSTANCE	EFANESOCITOCOG ALFA	08/05/2024	31/05/2024	14/02/2025	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	ALTUVCT 750 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 309410027	RP Route B	NEW ACTIVE SUBSTANCE	EFANESOCITOCOG ALFA	08/05/2024	31/05/2024	14/02/2025	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	ALTUVCT 1000 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 309410028	RP Route B	NEW ACTIVE SUBSTANCE	EFANESOCITOCOG ALFA	08/05/2024	31/05/2024	14/02/2025	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	ALTUVCT 2000 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 309410029	RP Route B	NEW ACTIVE SUBSTANCE	EFANESOCITOCOG ALFA	08/05/2024	31/05/2024	14/02/2025	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	ALTUVCT 3000 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PLGB 309410030	RP Route B	NEW ACTIVE SUBSTANCE	EFANESOCITOCOG ALFA	08/05/2024	31/05/2024	14/02/2025	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	ALTUVCT 4000 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PL 105900075	ACCESS	NEW ACTIVE SUBSTANCE	NEMOLIZUMAB	18/03/2024	24/04/2024	17/02/2025	GALDERMA (UK) LIMITED	NEMLUVIO 30 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PL 105900076	ACCESS	NEW ACTIVE SUBSTANCE	NEMOLIZUMAB	18/03/2024	24/04/2024	17/02/2025	GALDERMA (UK) LIMITED	NEMLUVIO 30 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 537200014	NATIONAL	NEW ACTIVE SUBSTANCE	SINGLE-STRANDED 5'-CAPPED MRNA ENCODING THE RSV-A GLYCOPROTEIN F STABILISED IN THE PREFUSION CONFORMATION	24/07/2023	17/08/2023	27/02/2025	MODERNA BIOTECH SPAIN SL	MRESVA 50 MICROGRAMS DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE
PL 275690001	RELEVANCE	NEW ACTIVE SUBSTANCE	LIPSPMA-107	28/12/2023	19/01/2024	03/03/2025	ABU ADVANCED BIOCHEMICAL COMPOUNDS - BIOMEDIZINISCHE FORSCHUNG	RAVELIMAB 200 MBQ/Ml. SOLUTION FOR INJECTION
PLGB 002420763	ORBSIS	NEW ACTIVE SUBSTANCE	LAZERTINB MESILATE MONOHYDRATE	19/01/2024	22/01/2024	06/03/2025	JANSSEN-Cilag LIMITED	LACZULIZE 80 MG FILM COATED TABLETS
PLGB 002420764	ORBSIS	NEW ACTIVE SUBSTANCE	LAZERTINB MESILATE MONOHYDRATE	19/01/2024	22/01/2024	06/03/2025	JANSSEN-Cilag LIMITED	LACZULIZE 240 MG FILM COATED TABLETS
PL 223520024	NATIONAL	NEW ACTIVE SUBSTANCE	DEUTIVACAFTOR	17/05/2024	02/07/2024	07/03/2025	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	ALYTREX 50 MG/20 MG/4 MG FILM-COATED TABLETS
PL 223520025	NATIONAL	NEW ACTIVE SUBSTANCE	DEUTIVACAFTOR	17/05/2024	02/07/2024	07/03/2025	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	ALYTREX 125 MG/50 MG/10 MG FILM-COATED TABLETS
PL 533730002	NATIONAL	NEW ACTIVE SUBSTANCE	TECHNETIUM (99mTc) TROFOLASTAT CHLORIDE	28/04/2023	11/05/2023	27/03/2025	ROTOP RADIOPHARMACY GMBH	ROTECPISMA 80 MICROGRAMS KIT FOR RADIOPHARMACEUTICAL PREPARATION
PLGB 000571730	RP Route B	NEW ACTIVE SUBSTANCE	MARSTACIMAB	01/10/2024	23/10/2024	17/04/2025	PFIZER LIMITED	HYMPAVZI 150 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 000571731	RP Route B	NEW ACTIVE SUBSTANCE	MARSTACIMAB	01/10/2024	23/10/2024	17/04/2025	PFIZER LIMITED	HYMPAVZI 150 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PLGB 224070033	RP Route B	NEW ACTIVE SUBSTANCE	OMAVELOXOLONE	01/11/2024	28/11/2024	23/04/2025	BIODEN NETHERLANDS BV	SKYCLARYS 50 MG HARD CAPSULES
PL 1071607025	RP Route A	NEW ACTIVE SUBSTANCE	ACQRAMERB HYDROCHLORIDE	26/02/2023	26/02/2023	24/04/2025	BAYER PLC	BEVORTINRA 360 MG FILM-COATED TABLETS
PLGB 461130001	NATIONAL	NEW ACTIVE SUBSTANCE	OBCACITAGENE AUTOLEUCIEL	26/07/2024	09/08/2024	25/04/2025	AUTOLIS LIMITED	AUCALZYL 410 X 10 ⁶ CELLS DISPERSION FOR INFUSION
PL 402650008	RP Route A	NEW ACTIVE SUBSTANCE		26/02/2025	06/03/2025	01/05/2025	BAVARIAN NORDISK AS	VAKIUNYA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE CHIKUNGUNYA VACCINE (RECOMBINANT, ADSORBED)
PLGB 138320098	NATIONAL	NEW ACTIVE SUBSTANCE	TEPROTUMUMAB	18/03/2024	30/05/2024	07/05/2025	AMGEN LIMITED	TEPEZZA 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PL 161890148	RP Route B	NEW ACTIVE SUBSTANCE	APADAMTASE ALFA	31/10/2024	05/12/2024	12/05/2025	TAKEDA UK LIMITED	ADZYNMA 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PL 161890149	RP Route B	NEW ACTIVE SUBSTANCE	APADAMTASE ALFA	31/10/2024	05/12/2024	12/05/2025	TAKEDA UK LIMITED	ADZYNMA 1 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
PL 360780007	RP Route B	NEW ACTIVE SUBSTANCE	POLIHEXANIDE	08/12/2024	22/01/2025	15/05/2025	SIFI S.P.A.	AKANTOR 0.8 MG/Ml. EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER
PLGB 530950108	RP Route A	NEW ACTIVE SUBSTANCE	PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE CONJUGATED TO CRM197	05/03/2025	10/03/2025	15/05/2025	MERCK SHARP & DOHME (UK) LIMITED	CAPVAXIME SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PLGB 542600002	NATIONAL	NEW ACTIVE SUBSTANCE	AJUMOLERTINB MESILATE	03/06/2022	10/06/2022	03/06/2025	SFL PHARMACEUTICALS DEUTSCHLAND GMBH	AUMISEQA 55 MG FILM-COATED TABLETS
PL 200791599	RP Route B	NEW ACTIVE SUBSTANCE	SERRULUMAB	09/10/2024	21/11/2024	20/06/2025	ACCORD HEALTHCARE LIMITED	HETRONIFY 100MG/Ml. CONCENTRATE FOR SOLUTION FOR INFUSION
PL 598490001	RP Route B	NEW ACTIVE SUBSTANCE	NOGAPENDENX ALFA	01/12/2024	19/02/2025	04/07/2025	SERUM LIFE SCIENCE EUROPE GMBH	AKNTIVA 400 MICROGRAMS CONCENTRATE FOR INTRAVESICAL SOLUTION
PL 000100759	ACCESS	NEW ACTIVE SUBSTANCE	ELINZANETANT	29/08/2024	27/09/2024	08/07/2025	BAYER PLC	LYNKUET 60 MG SOFT CAPSULES
PL 463260001	ACCESS	NEW ACTIVE SUBSTANCE	SEBETRALSTAT	23/09/2024	30/10/2024	15/07/2025	KALVISTA PHARMACEUTICALS LIMITED	EXTERLYN 300 MG FILM-COATED TABLETS
PL 410420100	RP Route B	NEW ACTIVE SUBSTANCE	MIRVETUXIMAB SORAVANTASINE	08/02/2025	14/03/2025	24/07/2025	ABRIEVE LTD	ELAHERE 5 MG/Ml. CONCENTRATE FOR SOLUTION FOR INFUSION
PL 536320071	RP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, VARIANT LP.8.1, SPIKE PROTEIN, PRE-FUSION STABILISED	18/07/2025	22/07/2025	12/08/2025	BIONTECH MANUFACTURING GMBH	COMRNATY LP.8.1 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE
PL 536320073	RP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, VARIANT LP.8.1, SPIKE PROTEIN, PRE-FUSION STABILISED	17/07/2025	23/07/2025	12/08/2025	BIONTECH MANUFACTURING GMBH	COMRNATY LP.8.1 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL
PL 536320074	RP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, VARIANT LP.8.1, SPIKE PROTEIN, PRE-FUSION STABILISED	17/07/2025	22/07/2025	12/08/2025	BIONTECH MANUFACTURING GMBH	COMRNATY LP.8.1 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION, 3-DOSE VIAL
PL 128950353	RP Route B	NEW ACTIVE SUBSTANCE	PIRTORUTINIB	11/03/2025	04/04/2025	13/08/2025	ELI LILLY NEDERLAND B.V.	JAYPRICA 50 MG FILM-COATED TABLETS
PL 148950354	RP Route B	NEW ACTIVE SUBSTANCE	PIRTORUTINIB	11/03/2025	04/04/2025	13/08/2025	ELI LILLY NEDERLAND B.V.	JAYPRICA 100 MG FILM-COATED TABLETS
PLGB 044250908	RP Route B	NEW ACTIVE SUBSTANCE	TEPLUZUMAB	30/08/2024	24/01/2025	14/08/2025	AVENTIS PHARMA LIMITED	TZELD 2 MG/2 ML CONCENTRATE FOR SOLUTION FOR INFUSION
PLGB 194940317	NATIONAL	NEW ACTIVE SUBSTANCE	GEPTODACIN MESILATE DIHYDRATE	09/08/2024	16/08/2024	27/08/2025	GLAXOSMITHKLINE UK LIMITED	BLIUEPA 750 MG FILM-COATED TABLETS
PLGB 224070030	RP Route B	NEW ACTIVE SUBSTANCE	ZURANCLONE	29/07/2024	13/09/2024	27/08/2025	BIODEN NETHERLANDS BV	ZURZUVAE 20 MG HARD CAPSULES
PLGB 224070031	RP Route B	NEW ACTIVE SUBSTANCE	ZURANCLONE	29/07/2024	13/09/2024	27/08/2025	BIODEN NETHERLANDS BV	ZURZUVAE 25 MG HARD CAPSULES
PLGB 224070032	RP Route B	NEW ACTIVE SUBSTANCE	ZURANCLONE	29/07/2024	13/09/2024	27/08/2025	BIODEN NETHERLANDS BV	ZURZUVAE 30 MG HARD CAPSULES
PL 058150122	ORBSIS	NEW ACTIVE SUBSTANCE	VORASIDENIB CITRATE	08/04/2025	11/04/2025	16/09/2025	LES LABORATOIRES SERVIER	VORANGO 10 MG FILM-COATED TABLETS
PL 058150123	ORBSIS	NEW ACTIVE SUBSTANCE	VORASIDENIB CITRATE	08/04/2025	11/04/2025	16/09/2025	LES LABORATOIRES SERVIER	VORANGO 40 MG FILM-COATED TABLETS
PLGB 530950099	NATIONAL	NEW ACTIVE SUBSTANCE	MOLXURIPAVR	23/08/2024	19/02/2025	24/09/2025	MERCK SHARP & DOHME (UK) LIMITED	LAKERV 200 MG HARD CAPSULES
PL 046680458	RP Route B	NEW ACTIVE SUBSTANCE	CONCIZUMAB	06/05/2025	11/06/2025	06/10/2025	NOVO NORDISK AS	ALHEMO 15 MG/1.5 ML SOLUTION FOR INJECTION IN PRE-FILLED PEN
PL 046680457	RP Route B	NEW ACTIVE SUBSTANCE	CONCIZUMAB	06/05/2025	11/06/2025	06/10/2025	NOVO NORDISK AS	ALHEMO 80 MG/1.5 ML SOLUTION FOR INJECTION IN PRE-FILLED PEN
PL 046680458	RP Route B	NEW ACTIVE SUBSTANCE	CONCIZUMAB	06/05/2025	11/06/2025	06/10/2025	NOVO NORDISK AS	ALHEMO 150 MG/1.5 ML SOLUTION FOR INJECTION IN PRE-FILLED PEN
PL 046680459	RP Route B	NEW ACTIVE SUBSTANCE	CONCIZUMAB	06/05/2025	11/06/2025	06/10/2025	NOVO NORDISK AS	ALHEMO 300 MG/3 ML SOLUTION FOR INJECTION IN PRE-FILLED PEN
PL 593090001	RP Route A	NEW ACTIVE SUBSTANCE	RCFP-10	08/08/2025	03/09/2025	31/10/2025	SERUM LIFE SCIENCES LTD	SILTBEY (0.5 MCG + 0.5 MCG)/ML SOLUTION FOR INJECTION MYCOBACTERIUM TUBERCULOSIS DERIVED ANTIGENS
PL 536320072	RP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, VARIANT LP.8.1, SPIKE PROTEIN, PRE-FUSION STABILISED	10/08/2025	13/10/2025	14/11/2025	BIONTECH MANUFACTURING GMBH	COMRNATY LP.8.1 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION
PL 000310946	RP Route A	NEW ACTIVE SUBSTANCE	INAVOLISB	15/08/2025	29/08/2025	26/11/2025	ROCHE PRODUCTS LIMITED	ITOVEBI 3 MG FILM-COATED TABLETS
PL 000310947	RP Route A	NEW ACTIVE SUBSTANCE	INAVOLISB	15/08/2025	29/08/2025	26/11/2025	ROCHE PRODUCTS LIMITED	ITOVEBI 9 MG FILM-COATED TABLETS
PL 198490308	RP Route B	NEW ACTIVE SUBSTANCE	TISOTUMAB VEDOTIN	30/07/2024	31/07/2025	02/12/2025	GENMAB AS	TIVDAR 40 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
PL 593090003	RP Route B	NEW ACTIVE SUBSTANCE	MIRDAMETINB	11/07/2025	29/07/2025	11/12/2025	SPRINGWORKS THERAPEUTICS IRELAND LIMITED	EZMEKLY 1 MG DISPERSIBLE TABLETS
PL 593090004	RP Route B	NEW ACTIVE SUBSTANCE	MIRDAMETINB	11/07/2025	29/07/2025	11/12/2025	SPRINGWORKS THERAPEUTICS IRELAND LIMITED	EZMEKLY 1 MG HARD CAPSULES
PL 593090005	RP Route B	NEW ACTIVE SUBSTANCE	MIRDAMETINB	11/07/2025	29/07/2025	11/12/2025	SPRINGWORKS THERAPEUTICS IRELAND LIMITED	EZMEKLY 2 MG HARD CAPSULES
PL 194940328	NATIONAL	NEW ACTIVE SUBSTANCE	DEPEMOKIMAB	05/02/2025	27/03/2025	15/12/2025	GLAXOSMITHKLINE UK LIMITED	EXDENSUR 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
PL 194940329	NATIONAL	NEW ACTIVE SUBSTANCE	DEPEMOKIMAB	05/02/2025	27/03/2025	15/12/2025	GLAXOSMITHKLINE UK LIMITED	EXDENSUR 100 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
PL 536320070	RP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, VARIANT LP.8.1, SPIKE PROTEIN, PRE-FUSION STABILISED	11/11/2025	18/11/2025	17/12/2025	BIONTECH MANUFACTURING GMBH	COMRNATY LP.8.1 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION
PL 536320075	RP Route A	NEW ACTIVE SUBSTANCE	5'-CAPPED MRNA ENCODING SARS-COV-2, VARIANT LP.8.1, SPIKE PROTEIN, PRE-FUSION STABILISED	20/11/2025	24/11/2025	17/12/2025	BIONTECH MANUFACTURING GMBH	COMRNATY LP.8.1 FRIDGE 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION