

Final Belgian list:

(Last update 31/01/2025)

Marketing name	Active substance	MAH	Reason on list
ABECMA	IDECABTAGENE VICLEUCEL	BRISTOL-MYERS SQUIBB PHARMA EEIG	New Biological, New AS, PASS
ABEVMY	BEVACIZUMAB	BIOSIMILAR COLLABORATIONS IRELAND LIMITED	New biological
ABRYSVO	RESPIRATORY SYNCYTIAL VIRUS VACCINE (BIVALENT, RECOMBINANT)	PFIZER EUROPE MA EEIG	New biological
ADTRALZA	TRALOKINUMAB	LEO PHARMA A/S	New AS, New Biological
ABSIMKY	USTEKINUMAB	ACCORD HEALTHCARE S.L.U.	New biological
ADYNOVI	RURIOCTOCOG ALFA PEGOL	BAXALTA INNOVATIONS GMBH	PASS
ADZYNMA	rADAMTS13	TAKEDA MANUFACTURING AUSTRIA AG	New AS, New Biological, Auth under excep circumstances
AFLURIA TETRA	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	eMCURE PHARMA UK LTD	New Biological
AFQLIR	AFLIBERCEPT	SANDOZ GMBH	New Biological
AGAMREE	VAMOROLONE	SANTHERA PHARMACEUTICALS (DEUTSCHLAND) GMBH	New AS
AHZANTIVE	AFLIBERCEPT	KLINGE BIOPHARMA GMBH	New biological
AKLIEF	TRIFAROTENE	GALDERMA NORDIC AB	New AS
ALHEMO	CONCIZUMAB	NOVO NORDISK A/S	New AS, New Biological
ALTUVOCT	EFANESOCTOCOG ALFA	SWEDISH ORPHAN BIOVITRUM AB (publ)	New AS, New Biological
ALYMSYS	BEVACIZUMAB	MABXIENCE RESEARCH SL	New Biological
AMVUTTRA	VUTRISIRAN	ALNYLAM NETHERLANDS B.V.	New AS
ANZUPGO	DELGOCITINIB	LEO PHARMA A/S	New AS
APRETUDE	CAPOTEGRAVIR	VIIV HEALTHCARE BV	New AS
AQUIPTA	ATOGEPAANT	ABBVIE DEUTSCLAND GMBH & CO. KG	New AS
AREXVY	RESPIRATORY SYNCYTIAL VIRUS (RSV) VACCINE (RECOMBINANT, ADJUVANTED)	GLAXOSMITHKLINE BIOLOGICALS S.A.	New AS, New Biological
ARTESUNATE AMIVAS	ARTESUNATE	AMIVAS IRELAND LTD	New AS
ASPAVELI	PEGCETACOPLAN	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	New AS
ATGAM	ANTI-HUMAN T-LYMPHOCYTE IMMUNOGLOBULIN	PFIZER PHARMA GMBH	New Biological
ATRIANCE	NELARABINE	SANDOZ PHARMACEUTICALS D.D.	Auth under excep circumstances
AUGTYRO	REPOTRECTINIB	BRISTOL MYERS SQUIBB PHARMA EEIG	New AS, conditional auth
AWIQLI	INSULIN ICODEC	NOVO NORDISK A/S	New AS, New Biological
AYBINTIO	BEVACIZUMAB	SAMSUNG BIOEPIS NL B.V.	New Biological
AYVAKYT	AVAPRITINIB	BLUEPRINT MEDICINES (NETHERLANDS) B.V.	New AS, Conditional auth
AVZIVI	BEVACIZUMAB	FGK REPRESENTATIVE SERVICE GMBH	New Biological
BAIAMA	AFLIBERCEPT	FORMYCON AG	New biological
BALVERSA	ERDAFITINIB	JANSSSEN-CILAG INTERNATIONAL NV	New AS

BAVENCIO	AVELUMAB	MERCK EUROPE B.V.	New AS, Conditional auth, New Biological
BEKEMV	ECULIZUMAB	AMGEN TECHNOLOGY (IRELAND) UC	New Biological
BENLYSTA	BELIMUMAB	GLAXO GROUP LTD	New AS
BEYFORTUS	NIRSEVIMAB	SANOFI WINTHROP INDUSTRIE	New AS, New biological
BIMERVAX	COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)	HIPRA HUMAN HEALTH, S.L.U.	New AS, New Biological
BIMZELX	BIMEKIZUMAB	UCB PHARMA S.A.	New AZ, New biological
BLINCYTO	BLINATUMOMAB	AMGEN EUROPE BV	PASS
BYOOVIZ	RANIBIZUMAB	SAMSUNG BIOEPIS NL B.V.	New Biological
BRETARIS GENUAIR	ACLIDINIUM BROMIDE	ASTRAZENECA AB	PASS
BREYANZI	LISOCABTAGENE MARALEUCEL	BRISTOL-MYERS SQUIBB PHARMA EEIG	New Biological, New AS, PASS
BRIMICA GENUAIR	ACLIDINIUM BROMIDE/ FORMOTEROL FUMARATE-DIHYDRATE	COVIS PHARMA EUROPE B.V.	PASS
BRINEURA	CERLIPONASE ALFA	BIOMARIN INTERNATIONAL LTD	Auth under excep circumstances, PASS
BRIUMVI	UBLITUXIMAB	NEURAXPHARM PHARMACEUTICALS, S.L.	New AS, New Biological
BYFAVO	REMIMAZOLAM	PAION DEUTSCHLAND GMBH	New AS
BRUKINSA	ZANUBRUTINIB	BEIGENE IRELAND LIMITED	New AS
BYLVAY	ODEVIXIBAT	IPSEN PHARMA	New AS, Auth under excep circumstances
CALQUENCE	ACALABRUTINIB	ASTRAZENECA AB	New AS
CAMZYOS	MAVACAMTEN	BRISTOL MYERS SQUIBB PHARMA EEIG	New AS
CARVYKTI	CILTACABTAGENE AUTOLEUCEL	JANSSEN-CILAG INTERNATIONAL NV	New AS, New Biological
CASGEVY	EXAGAMGLOGENE AUTOTEMCEL	VERTEX PHARMACEUTICALS (IRELAND) LIMITED	New AS, new Biological, Conditional Auth, PASS
CELLEDMIC	ZOONOTIC INFLUENZA VACCINE (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)	SEQIRUS NETHERLANDS B.V.	New AS, New Biological
CEJEMLY	SUGEMALIMAB	SFL PHARMACEUTICALS DEUTSCHLAND GMBH	New AS, New Biological
CEPLENE	HISTAMINE DIHYDROCHLORIDE	LABORATOIRES DELBERT	Auth under excep circumstances
CERDELGA	ELIGLUSTAT	GENZYME EUROPE B.V.	PASS
CEVENFACTA	EPTACOG BETA (ACTIVATED)	LABORATOIRE FRANÇAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES	New AS, New Biological
CHENODEOXYCHOLIC ACID LEADIANT (previously known as chenodeoxycholic acid sigma-tau)	CHENODEOXYCHOLIC ACID	SIGMA-TAU ARZNEIMITTEL GmbH	Auth under excep circumstances, PASS
CHORIONGONADOTROPHIN GENEVRIER	CHORIONIC GONADOTROPIN	LABORATOIRES GENEVRIER	New Biological
CIBINQO	ABROCITINIB	PFIZER EUROPE MA EEIG	New AS
CIDOFOVIR	CIDOFOVIR	EMCURE PHARMA UK LTD	PASS
CINRYZE	C1-INHIBITOR, HUMAN	TAKEDA MANUFACTURING AUSTRIA AG	PASS
COLEVANCE	ENOXAPARIN SODIUM	VENIPHARM	New Biological

COLUMVI	GLOFITAMAB	ROCHE REGISTRATION GMBH	New AS, New Biological, Conditional Auth
COMIRNATY JN.1	COVID-19 mRNA VACCINE (nucleoside modified)	BIONTECH MANUFACTURING GmbH	New AS, New Biological
COPIKTRA	DUVELISIB	VERASTERN EUROPE GMBH	New AS
CONVULEX	VALPROIC ACID	TAKEDA BELGIUM	PASS
CRYSVITA	BUROSUMAB	KYOWA KIRIN HOLDINGS B.V.	New AS, New Biological
CRUSIA	ENOXAPARIN SODIUM	LABORATORIOS FARMACEUTICOS ROVI S.A.	New Biological
DAURISMO	GLASDEGIB	PFIZER EUROPE MA EEIG	New AS
DECTOVA	ZANAMIVIR	GLAXOSMITHKLINE TRADING SERVICES B.V.	Auth under excep circumstances
DEFITELIO	DEFIBROTIDE	GENTIUM S.P.A	New Biological, Auth under excep circumstances
DELTYBA	DELAMANID	OTSUKA NOVEL PRODUCTS GMHB	New AS, Conditional auth
DEPAKINE	SODIUM VALPROATE	SANOFI BELGIUM	PASS
DEPAKINE CHRONO	SODIUM VALPROATE, VALPROIC ACID	SANOFI BELGIUM	PASS
DEPAKINE CHRONO	SODIUM VALPROATE, VALPROIC ACID	PI-PHARMA NV	PASS
DEPAKINE ENTERIC	SODIUM VALPROATE	SANOFI BELGIUM	PASS
DEPAKINE IV	SODIUM VALPROATE	SANOFI BELGIUM	PASS
DOVPRELA (previously PRETOMANID FGK)	PRETOMANID	MYLAN IRE HEALTHCARE LIMITED	New AS
DROVELIS	DROSPIRENONE/ ESTETROL	GEDEON RICHTER PLC.	New AS
DUAKLIR-GENUAIR	ACLIDINIUM BROMIDE/ FORMOTEROL FUMARATE-DIHYDRATE	COVIS-PHARMA EUROPE B.V.	PASS
DURVEQTIX	EDANACOGENE ELAPARVOVEC	PFIZER EUROPE MA EEIG	New AS, New Biological
EBGLYSS	LEBRIKIZUMAB	ALMIRALL S.A.	New AS, New Biological
EBVALLO	TABECLUCEL	PIERRE FABRE MEDICAMENT	New AS, New Biological, Auth under excep circumstances
EFLUELDA	TRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOFI WINTHROP	New Biological
EFLUELDA TETRA	QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOFI WINTHROP	New Biological
EKLIRA-GENUAIR	ACLIDINIUM (BROMURE)	COVIS-PHARMA EUROPE B.V.	PASS
EKSUNBI	USTEKINUMAB	SAMSUNG BIOEPIS NL B.V.	New Biological
ELADYNOS	ABALOPARATIDE	THERAMEX IRELAND LIMITED	New AS
ELAPRASE	IDURSULFASE	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	Auth under excep circumstances
ELFABRIO	PEGUNIGALSIDASE ALFA	CHIESI FARMACEUTICI S.P.A	New AS, New Biological
ELUCIREM	GADOPICLENOL	GUERBET	New AS
ELREXFIO	ELRANATAMAB	PFIZER EUROPE MA EEIG	New biological, New AS , Conditional auth

EFLUELDA	QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOFI PASTEUR	New Biological
ELAHERE	MIRVETUXIMAB SORAVTANSINE	ABBVIE DEUTSCLAND GMBH & CO. KG	New Biological
ELZONRIS	TAGRAXOFUSP	STEMLINE THERAPEUTICS B.V.	New AS, New Biological, Auth under excep circumstances
ENHERTU	TRASTUZUMAB DERUXTECAN	DAIICHI SANKYO EUROPE GmbH	New AS, New Biological, Conditional auth
ENOXAPARINE LEDRAXEN	ENOXAPARIN SODIUM	VENIPHARM	New Biological
ENJAYMO	SUTIMLIMAB	GENZYME EUROPE B.V.	New AS, New Biological
ENRYLAZE	CRISANTASPASE	PAZZ PHARMACEUTICALS IRELAND LIMITED	New AS, New Biological
ENSPRYNG	SATRALIZUMAB	ROCHE REGISTRATION GMBH	New AS, New Biological
EPYSQLI	ECULIZUMAB	SAMSUNG BIOEPIS NL B.V.	New Biological
ERVEBO	EBOLA ZAIRE VACCINE (rVSVΔG-ZEBOV-GP,live)	MERCK SHARP & DOHME B.V.	New AS, New Biological
ESPEROCT	TUROCTOCOG ALFA PEGOL	NOVO NORDISK A/S	PASS
EVKEEZA	EVINACUMAB	ULTRAGENYX GERMANY GMBH	New AS, New Biological, PASS, Auth under excep circumstances
EVOLTRA	CLOFARABINE	GENZYME EUROPE B.V.	Auth under excep circumstances
EVRENZO	ROXADUSTAT	ASTELLAS PHARMA EUROPE BV	New AS
EVRYSDI	RISDIPLAM	ROCHE REGISTRATION GMBH	New AS, Conditional auth
EVUSHELD	TIXAGEVIMAB, CILGAVIMAB	ASTRAZENECA AB	New AS, New Biological
EXBLIFEP	CEFEPIME / ENMETAZOACTAM	ADVANZ PHARMA LIMITED	New AS
EXJADE	DEFERASIROX	NOVARTIS EUROPHARM LIMITED	PASS
FABHALTA	IPTACOPAN	NOVARTIS EUROPHARM LIMITED	New AS
FETCROJA	CEFIDEROCOL	SHIONOGI B.V.	New AS
FILSPARI	SPARSENTAN	VIFOR France S.A.	New AS, Conditional auth
FINTEPLA	FENFLURAMINE	UCB PHARMA S.A.	PASS
FIRDAPSE	AMIFAMPRIDINE (PHOSPHATE)	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS
FLUAD TETRA	INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVATED, ADJUVANTED)	SEQRUS NETHERLANDS B.V.	New Biological
FRUZAQLA	FRUQUINTINIB	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	New AS
FYMSKINA	USTEKINUMAB	BORMYCON AG	New Biological
GHEMAXAN	ENOXAPARIN SODIUM	EFFIK	New AS
GIAPREZA	ANGIOTENSIN II ACETATE	PAION PHARMA GMBH	New AS
GOHIBIC	VILOBELIMAB	INFLARX GMBH	New AS, New Biological, Auth under excep circumstances
GONASI SET	CHORIONIC GONADOTROPHIN	IBSA FARMACEUTICI ITALIA S.R.L	New Biological
HEMGENIX	ETRANACOGENE DEZAPARVOVEC	CSL Behring GmbH	New Biological, New AS, Conditional auth, PASS
HEPCLUDEX	BULEVIRTIDE	GILEAD SCIENCES IRELAND UC	New AS

HEPLISAV B	HEPATITIS B SURFACE ANTIGEN	DYNAVAX GMBH	New Biological
HERWENDA	TRASTUZUMAB	SANDOZ GMBH	New Biological
HOLOCLAR	EX VIVO EXPENDED AUTOLOGOUS HUMAN CORNEAL EPITHELIAL CELLS CONTAINING STEM CELLS	HOLOSTEM S.R.L	New AS, Conditional auth, New Biological
HUKYNDRA	ADALIMUMAB	STADA ARZNEIMITTEL AG	New Biological
HYMPAVZI	MARSTACIMAB	PFIZER EUROPE MA EEIG	New biological, New AS and PASS
IDEFIRIX	IMLIFIDASE	HANSA BIOPHARMA AB	New biological
IMCIVREE	SETMELANOTIDE	RHYTHM PHARMACEUTICALS NETHERLANDS B.V.	New AS
IMJUDO	TREMELIMUMAB	ASTRAZENECA AB	New AS, New Biological
IMNOVID (POMALIDOMIDE CELGENE)	POMALIDOMIDE	CELGENE EUROPE LIMITED	PASS
IMULDOSA	USTEKINUMAB	ACCORD HEALTHCARE S.L.U.	New biological
IMVANEX	SMALLPOX AND MONKEYPOX VACCINE (LIVE MODIFIED VACCINIA VIRUS ANKARA)	BAVARIAN NORDIC A/S	Auth under excep circumstances
INAQOVI	DECITABINE/ CEDAZURIDINE	ØTSUK PAHRMACEUTICAL NETHERLANDS B.V.	New AS
INCELLIPAN	PANDEMIC INFLUENZA VACCINE (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)	SEQIRUS NETHERLANDS B.V.	New AS, Conditional auth
INCRELEX	MECASERMIN	IPSEN PHARMA	Auth under excep circumstances, PASS
INREBIC	FEDRATINIB	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS
INSULIN ASPART SANOFI	INSULIN ASPART	SANOFI WINTHROP INDUSTRIE	New Biological
INTUNIV	GUANFACINE	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	PASS
IQYMUNE	HUMAN NORMAL IMMUNOGLOBULIN	LABORATOIRE FRANÇAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES	New Biological
IQIRVO	ELAFIBRANOR	IPSEN PHARMA	New AS, Conditional auth
ITULAZAX	STANDARDISED ALLERGEN EXTRACT FROM BIRCH	ALK-ABELLO A/S	New Biological
ITUXREDI	RITUXIMAB	REDDY HOLDING GMBH	New Biological
IXCHIQ	CHIKUNGUNYA VACCINE (live)	VALNEVA AUSTRIA GMBH	New AS, New Biological
JAYDESS	LEVONORGESTREL 13.50 MG	BAYER AB	PASS
JAYPIRCA	PIRTOBRUTINIB	ELI LILLY NEDERLAND B.V.	New AS, Conditional auth
JEMPERLI	DOSTARLIMAB	GLAXOSMITHKLINE (IRELAND) LIMITED	New AS, New Biological
JERAYGO	APROCITENTAN	IDORSIA PHARMACEUTICALS DEUTSCHLAND GMBH	New AS, PASS
JINARC	TOLVAPTAN	OTSUKA PHARMACEUTICAL EUROPE LTD	PASS
JUBBONTI	DENOSUMAB	SANDOZ GMBH	New Biological
JYSELECA	FILGOTINIB	ALFASIGMA S.p.A.	New AS
KAFTRIO	IVACAFTOR/ TEZACAFTOR/ ELEXACAFTOR	VERTEX PHARMACEUTICALS (IRELAND) LIMITED	New AS
KANUMA	SEBELIPASE ALFA	ALEXION EUROPE SAS	New AS, PASS, New Biological
KAPRUVIA	DIFELIKEFALIN	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	New AS

KAULIV	TERIPARATIDE	STRIDES PHARMA (CYPRUS) LTD.	New Biological
KAYFANDA	ODEVIXIBAT	IPSEN PHARMA	Auth under excep circumstances
KERENDIA	FINERENONE	BAYER AG	New AS
KESIMPTA	OFATUMUMAB	NOVARTIS IRELAND LIMITED	New AS, New Biological
KETOCONAZOLE HRA	KETOCONAZOLE	HRA PHARMA RARE DISEASES	PASS
KIMMTRAK	TEBENTAFUSP	IMMUNOCORE IRELAND LIMITED	New AS, New Biological
KIRSTY (previously Kixelle)	INSULIN ASPART	MYLAN IRE HEALTHCARE LIMITED	New Biological
KLISYRI	TIRBANIBULIN	ALMIRALL, S.A.	New AS, PASS
KOSELUGO	SELUMETINIB	ASTRAZENECA AB	New AS, Conditional auth, PASS
KRAZATI	ADAGRASIB	BRISTOL MYERS SQUIBB PHARMA EEIG	New AS, Conditional Auth
KYMRIAH	TISAGENLECLEUCEL	NOVARTIS EUROPHARM LIMITED	PASS
LAMZEDE	VELMANASE ALFA	CHIESI FARMACEUTICI S.P.A.	Auth under excep circumstances
LEMTRADA	ALEMTUZUMAB	SANOFI BELGIUM	PASS
LEQVIO	INCLISIRAN	NOVARTIS EUROPHARM LIMITED	New AS
LIBMELDY	autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene	ORCHARD THERAPEUTICS (NETHERLANDS) B.V.	New AS, New Biological, PASS
LIBMYRIS	ADALIMUMAB	STADA ARZNEIMITTEL AG	New Biological
LIBTAYO	CEMIPLIMAB	REGENERON IRELAND U.C.	New AS, New Biological
LITFULO	RITLECITINIB	PFIZER EUROPE MA EEIG	New AS
LIMAXENTIN 4 MG/ML INJEKTIONSLOSUNG	METHACETIN	HUMEDICS GMBH	New AS
LIVMARLI	MARALIXIBAT CHLORIDE	MIRUM PHARMACEUTICALS INTERNATIONAL BV	New AS, Auth under excep circumstances
LIVOGIVA	TERIPARATIDE	THERAMEX IRELAND LIMITED	New Biological
LIVTENCITY	MARIBAVIR	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	New AS
LYTENAVA	BEVACIZUMAB GAMMA	OUTLOOK THERAPEUTICS LIMITED	New AS, New Biological
LOARGYS	PEGZILARGINASE	IMMEDICA PHARMA AB	New AS, New Biological, PASS
LOCAMETZ	GOZETOTIDE	NOVARTIS EUROPHARM LIMITED	New AS
LOJUXTA	LOMITAPIDE (MESYLATE)	CHIESI FARMACEUTICI S.p.A.	New AS, Auth under excep circumstances
LONAPEGSOMATROPIN ASCENDIS PHARMA	LONAPEGSOMATROPIN	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	New AS, New Biological
LORVIQUA	LORLATINIB	PFIZER EUROPE MA EEIG	New AS, Conditional auth
LUNSUMIO	MOSUNETUZUMAB	ROCHE REGISTRATION GMBH	New AS, New Biological, Conditional auth
LOQTORZI	TORIPALIMAB	TMC Pharma (EU) Ltd	New AS, New Biological
LUMYKRAS	SOTORASIB	AMGEN EUROPE B.V.	New AS, Conditional auth

LUPKYNIS	VOCLOSPORIN	OTSUKA PHARMACEUTICAL NETHERLANDS B.V.	New AS
LUXTURNA	VORETIGENE NEPARVOVEC	NOVARTIS EUROPHARM LIMITED	New AS, PASS, New Biological
LYDISILKA	DROSPIRENONE/ ESTETROL	CERES PHARMA	New AS
LYFNUA	GEFAPIXANT	MERCK SHARP & DOHME B.V.	New AS
LYTGObI	FUTIBATNIB	TAIHO PHARMA NETHERLANDS B.V.	New AS, New biological, Conditional auth
LYUMJEV	INSULIN LISPRO	ELI LILLY NEDERLAND B.V.	New Biological
MEDIKINET RETARD	METHYLPHENIDATE HYDROCHLORIDE	MEDICE ARZEIMITTEL PÜTTNER GMBH CO. KG	PASS
MENQUADFI	MENINGOCOCCAL GROUP A, C, W and Y CONJUGATE VACCINE	SANOFI WINTHROP INDUSTRIE	New Biological
MEPSEVII	VESTRONIDASE ALFA	ULTRAGENYX GERMANY GMBH	Auth under excep circumstances
MINJUVI	TAFASITAMAB	INCYTE BIOSCIENCES DISTRIBUTION B.V.	New AS, New Biological, Auth under excep circumstances
MOUNJARO	TIRZEPATIDE	ELI LILLY NEDERLAND B.V.	New AS
MRESVIA	Single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation	MODERNA BIOTECH SPAIN, S.L.	New AS, New Biological
MVABEA	EBOLA VACCINE (MVA-BN-Filo [recombinant])	JANSSEN-CILAG INTERNATIONAL NV	New AS, New biological, Auth under excep circumstances
MYALEPTA	METRELEPTIN	CHIESI FARMACEUTICI S.p.A.	Auth under excep circumstances
MYSIMBA	NALTREXONE, BUPROPION	OREXIGEN THERAPEUTICS IRELAND LIMITED	PASS
NADROPARINE CALCIQUE ASPEN	NADROPARIN CALCIUM	ASPEN PHARMA TRADING LIMITED	New Biological
NATPAR	PARATHYROID HORMONE	SHIRE PHARMACEUTICALS IRELAND LTD	Conditional auth
NEPEXTO	ETANERCEPT	BIOSIMILAR COLLABORATIONS IRELAND LIMITED	New Biological
NEXPOVIO	SELINEXOR	KARYOPHARM EUROPE GMBH	New AS
NEXVIADYME	AVALGLUCOSIDASE ALFA	GENZYME EUROPE B.V.	New AS, New Biological
NGENLA	SOMATROGON	PFIZER EUROPE MA EEIG	New AS, New Biological
NULIBRY	FOSDENOPTERIN	TMC PHARMA (EU) Limited	New AS, Auth under excep circumstances
NUVAXOVID	SARS-COV-2 RECOMBINANT SPIKE PROTEIN	NOVAVAX CZ, a.s.	New AS, New Biological
NYVEPRIA	PEGFILGRASTIM	PFIZER EUROPE MA EEIG	New Biological
OBGESMA	VIBEGRON	PIERRE FABRE MEDICAMENT	New AS
OBIZUR	SUSOCTOCOG ALFA	BAXALTA INNOVATIONS GMBH	Auth under excep circumstances
OCALIVA	OBETICHOLIC ACID	ADVANZ PHARMA LIMITED	Conditional auth
ONDEXXYA	ANDEXANET ALFA	ASTRAZENECA AB	New AS, New Biological, Conditinal auth
ONTOZRY	CENOBAMATE	ANGELINI PHARMA SPA	New AS
OMJJARA	MOMELOTINIB	LAXOSMITHKLINE TRADING SERVICES LIMITED	New AS
OMLYCLO	OMALIZUMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
OMVOH	MIRIKIZUMAB	ELI LILLY NEDERLAND B.V.	New AS, New Biological
OPDUALAG	NIVOLUMAB/ RELATLIMAB	BRISTOL MYERS SQUIBB PHARMA EEIG	New AS, New Biological

ORGOVYX	RELUGOLIX	MYOVANT SCIENCES IRELAND LIMITED	New AS
OPUVIZ	AFLIBERCEPT	SAMSUNG BIOEPIS NL B.V.	New Biological
ORDSPONO	ODRONEXTAMAB	REGENERON IRELAND DESIGNATED ACTIVITY COMPANY (DAC)	New AS, New Biological, Conditional auth
ORLADEYO	BEROTRALSTAT	BIOCRYS T IRELAND LIMITED	New AS
ORPHACOL	CHOLIC ACID	LABORATOIRES CTRS	Auth under excep circumstances
ORSERDU	ELACESTRANT	STEMLINE THERAPEUTICS B.V.	New AS
ORYLMYTE	ALLERGEN EXTRACT FROM HOUSE DUST MITES (DERMATOPHAGOIDES PTERONYSSINUS AND DERMATOPHAGOIDES FARINAE)	STALLERGENES	New Biological
OXBRYTA	VOXELOTOR	PFIZER EUROPE MA EEIG	New AS
OXLUMO	LUMASIRAN	ALNYLAM NETHERLANDS BV	New AS
OTULFI	USTEKINUMAB	FRESENIUS KABI DEUTSCHLAND GmbH	New Biological
OYAVAS	BEVACIZUMAB	STADA ARZNEIMITTEL AG	New Biological
OZADUB	OZENAXACIN	FERRER INTERNACIONAL S.A.	New AS
PADCEV	ENFORTUMAB VEDOTIN	ASTELLAS PHARMA EUROPE BV	New AS, New Biological
PANDEMIC INFLUENZA VACCINE H5N1 ASTRAZENECA	PANDEMIC INFLUENZA VACCINE (H5N1)(live attenuated, nasal)	ASTRAZENECA AB	Conditional auth
PAXLOVID	RITONAVIR/ (1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido) butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide	PFIZER EUROPE MA EEIG	New AS
PEMAZYRE	PEMIGATINIB	INCYTE BIOSCIENCES DISTRIBUTION B.V.	New AS, Conditional auth
PENBRAYA	Meningococcal groups A, C, W, Y conjugate and group B vaccine (recombinant, adsorbed)	PFIZER EUROPE MA EEIG	New biological
PERCOLOZIN	ENOXAPARIN SODIUM	VENIPHARM	New Biological
PHESGO	PERTUZUMAB/ TRASTUZUMAB	ROCHE REGISTRATION GMBH	New Biological
PIASKY	CROVALIMAB	ROCHE REGISTRATION GMBH	New AS, New Biological
PIQRAY	ALPELISIB	NOVARTIS EUROPHARM LIMITED	New AS
PLASMAVOLUME REDIBAG 6%	HYDROXYETHYL STARCH	BAXTER S.A.	Outcome Referral Art 31, PASS
PLUVICTO	LUTETIUM (177Lu) VIPIVOTIDE TETRAXETAN	NOVARTIS EUROPHARM LIMITED	New AS
POLIVY	POLATUZUMAB VEDOTIN	ROCHE REGISTRATION GMBH	New AS, New Biological
PONVORY	PONESIMOD	LABORATOIRES JUVISE PHARMACEUTICALS	New AS
POMBILITI	CIPAGLUCOSIDASE ALPHA	AMICUS THERAPEUTICS EUROPE LIMITED	New AS, New Biological
PREVENAR (voordien Apexxnar)	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (20-VALENT, ADSORBED)	PFIZER EUROPE MA EEIG	New Biological
PYLCLARI	PIFLUFOLASTAT (18F)	CURIUM PET FRANCE	New AS
PYRUKYND	MITAPIVAT	AGIOS NETHERLANDS B.V.	New AS
PYZCHIVA	USTEKINUMAB	SAMSUNG BIOEPIS NL B.V.	New Biological
QALSODY	TOFERSEN	BIOGEN NETHERLANDS B.V.	New AS, PASS

QARZIBA	DINUTUXIMAB BETA	EUSA PHARMA UK LTD	Auth under excep circumstances
QDENG	DENGUE TETRAVALENT VACCINE (live, attenuated)	TAKEDA GMBH	New Biological
QINLOCK	RIPRETINIB	DECIPHERA PHARMACEUTICALS (NETHERLANDS) B.V.	New AS
QUVIVIQ	DARIDOREXANT	IDORSIA PHARMACEUTICALS DEUTSCHLAND GMBH	New AS
RANIBIZUMAB MIDAS	RANIBIZUMAB	MIDAS PHARMA GMBH	New Biological
RANIVISIO	RANIBIZUMAB	MIDAS PHARMA GMBH	New Biological
RAXONE	IDEBENONE	CHIESI FARMACEUTICI S.P.A.	Auth under excep circumstances
RAYVOW	LASMIDITAN	ELI LILLY NEDERLAND B.V.	New AS
REBLOZYL	LUSPATERCEPT	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS
REFIXIA	NONACOG BETA PEGOL	NOVO NORDISK A/S	PASS
REGKIRONA	REGDANVIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New AS, New Biological
REKAMBYS	RILPIVIRINE	JANSSEN-CILAG INTERNATIONAL NV	PASS
RETSEVMO	SELPERCATINIB	ELI LILLY NEDERLAND B.V.	New AS, Conditional auth
REVESTIVE	TEDUGLUTIDE	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	PASS
REVLIMID	LENALIDOMIDE	BRISTOL-MYERS SQUIBB PHARMA EEIG	PASS
REZZAYO	REZAFUNGIN	MUNDIPHARMA GMBH	New AS
RIMMYRAH	RANIBIZUMAB	QILU PHARMA SPAIN S.L.	New Biological
ROCLANDA	LATANOPROST/ NETARSUDIL	SANTEN OY	New AS
ROCTAVIAN	VALOCTOCOGENE ROXAPARVOVEC	BIOMARIN INTERNATIONAL LTD	New AS, New Biological, Cond auth, PASS
RONAPREVE	CASIRIVIMAB/ IMDEVIMAB	ROCHE REGISTRATION GMBH	New AS, New Biological
ROZLYTREK	ENTRECTINIB	ROCHE REGISTRATION GMBH	New AS, Conditional auth
RUKOBIA	FOSTEMSAVIR	VIIV HEALTHCARE BV	New AS
RUXIENCE	RITUXIMAB	PFIZER EUROPE MA EEIG	New Biological
RYBREVANT	AMIVANTAMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS, New Biological
RYEQO	RELUGOLIX/ ESTRADIOL/ NORETHISTERONE ACETATE	GEDEON RICHTER Plc	New AS
RYSTIGGO	ROZANOLIXIZUMAB	UCB PHARMA S.A.	New AS, New Biological
RYZNEUTA	EFBEMALENOGRASTIM ALFA	EVIVE BIOTECHNOLOGY IRELAND LTD	New AS, New Biological
SAPHNELO	ANIFROLUMAB	ASTRAZENECA AB	New AS, New Biological
SARCLISA	ISATUXIMAB	SANOFI WINTHROP INDUSTRIE	New AS, New Biological
SCEMBLIX	ASCIMINIB	NOVARTIS EUROPHARM LIMITED	New AS
SCENESSE	AFAMELANOTIDE	CLINUVEL UK LIMITED	New AS, Auth under excep circumstances
SIILTBCY	rdESAT-6 and rCFP-10	SERUM LIFE SCIENCE EUROPE GMBH	New AS, New Biological
SIXMO	BUPRENORPHINE	L.MOLTENI & C. dei F.lli Alitti Soc.Es.S.p.A.	PASS
SKYCLARYS	OMAVELOXOLONE	BIOGEN NETHERLANDS B.V.	New AS
SOGROYA	SOMAPACITAN	NOVO NORDISK A/S	New AS, New Biological
SONDELBAY	TERIPARATIDE	ACCORD HEALTHCARE S.L.U.	New Biological

SOTYKTU	DEUCRAVACITINIB	BRISTOL MYERS SQUIBB PHARMA EEIG	New AS
SPEVIGO	SPESOLIMAB	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS, New Biological, Conditional auth
SPIKEVAX (previously COVID-19 VACCINE MODERNA)	ELASOMERAN (formally COVID-19 mRNA VACCINE (nucleoside modified))	MODERNA BIOTECH SPAIN, S.L.	New AS, New Biological
SPIKEVAX BIVALENT ORIGINAL/OMICRON BA1	ELASOMERAN (formally COVID-19 mRNA VACCINE (nucleoside modified))	MODERNA BIOTECH SPAIN, S.L.	New AS, New Biological
STEQEYMA	USTEKINUMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
STIMUFEND	PEGFILGRASTIM	FRESENIUS KABI DEUTSCHLAND GmbH	New Biological
STRENSIQ	ASFOTASE ALFA	ALEXION EUROPE SAS	New AS, Aut under excep circumstances
STRIMVELIS	AUTOLOGOUS CD34 + ENRICHED CELL FRACTION THAT CONTAINS CD34 + CELLS TRANSDUCED WITH RETROVIRAL VECTOR THAT ENCODES FOR THE HUMAN ADA Cdna SEQUENCE	FONDAZIONE TELETHON ETS	PASS
SUBLIVAC BAUME	ALLERGEN EXTRACT OF POLLEN FROM BIRCH, ALDER AND HAZEL	HAL ALLERGIE GMBH	New Biological
SUBLIVAC BIRKE	ALLERGEN EXTRACT OF POLLEN FROM BIRCH	HAL ALLERGIE GMBH	New Biological
SUNLENCA	LENACAPAVIR	GILEAD SCIENCES IRELAND UC	New AS
SUNOSI	SOLRIAMFETOL	ATNAHS PHARMA NETHERLANDS B.V.	New AS
SYLVANT	SILTUXIMAB	EUSA PHARMA NETHERLANDS B.V.	New AS
TABRECTA	CAPMATINIB	NOVARTIS EUROPHARM LIMITED	New AS
TALVEY	TALQUETAMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS, New Biological and Conditional auth
TAVNEOS	AVACOPAN	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	New AS
TAUVID	FLORTAUCIPIR (18F)	ELI LILLY NEDERLAND B.V.	New AS
TECARTUS	autologous anti-CD19-transduced CD3+ cells	GILEAD SCIENCES IRELAND UC	New AS, New Biological, Conditional auth, PASS
TECOVIRIMAT SIGA	TECOVIRIMAT MONOHYDRATE	SIGA TECHNOLOGIES NETHERLANDS B.V.	New AS, Auth under excep circumstances
TECVAYLI	TECLISTAMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS, New Biological, Conditional auth
TEPKINLY	EPCORITAMAB	ABBVIE DEUTSCHLAND GMBH & CO. KG	New AS, New Biological and Conditional auth
TEPMETKO	TEPOTINIB HYDROCHLORIDE MONOHYDRATE	MERCK EUROPE B.V.	New AS
TETRASPAN 10%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
TETRASPAN 6%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
TEVIMBRA	TISLELIZUMAB	BEIGENE IRELAND LIMITED	New Biological
TEZSPIRE	TEZPELUMAB	ASTRAZENECA AB	New AS, New Biological

THIOSIX	TIOGUANIN	TEVA NEDERLAND B.V.	Auth under excep circumstances
TIBSOVO	IVOSIDENIB	LES LABORATOIRES SERVIER	New AS
TOFIDENCE	TOCILIZUMAB	BIOGEN NETHERLANDS B.V.	New Biological
TOPAMAX	TOPIRAMATE	JANSSEN-CILAG NV	PASS
TOPIRAMATE EG	TOPIRAMATE	EUROGENERICS N.V./S.A.	PASS
TRANSLARNA	ATALUREN	PTC THERAPEUTICS LTD	New AS, Conditional auth
TRIVALENT INFLUENZA VACCINE	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOFI PASTEUR	New Biological
TRODELVY	SACITUZUMAB GOVITECAN	GILEAD SCIENCES IRELAND UC	New AS, New Biological
TRUQAP	CAPIVASERTIB	ASTRAZENECA AB	New AS, PASS
TUKYSA	TUCATINIB	PFIZER EUROPE MA EEIG	New AS
TUZNUE	TRASTUZUMAB	PRESTIGE BIOPHARMA BELGIUM BVBA	New Biological
TYENNE	TOCILIZUMAB	FRESENIUS KABI DEUTSCHLAND GMBH	New Biological
TYRUKO	NATALIZUMAB	SANDOZ GMBH	New Biological
UPLIZNA	INEBILIZUMAB	VIELA BIO B.V.	New AS, New Biological
UPSTAZA	ELADOCAGENE EXUPARVOVEC	PTC THERAPEUTICS INTERNATIONAL LTD	New AS, New biological, Auth under excep circumstances
UZPRUVO	USTEKINUMAB	STADA Arzneimittel AG	New Biological
VABYSMO	FARICIMAB	ROCHE REGISTRATION GMBH	New AS, New Biological
VAFSEO	VADADUSTAT	AKEBIA EUROPE LIMITED	New AS
VALPROATE MYLAN	SODIUM VALPROATE	MYLAN BVBA	PASS
VALPROATE RETARD EG	SODIUM VALPROATE, VALPROIC ACID	EUROGENERICS N.V.	PASS
VALPROATE RETARD MYLAN	SODIUM VALPROATE	MYLAN BVBA	PASS
VALPROATE SANDOZ	SODIUM VALPROATE, VALPROIC ACID	SANDOZ NV	PASS
VANFLYTA	QUIZARTINIB	DAIICHI SANKYO EUROPE GMBH	New AS
VAXCHORA	CHOLERA VACCINE (RECOMBINANT, LIVE, ORAL)	BAVARIAN NORDIC A/S	New AS, New biological
VAXIGRIP TETRA	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOFI PASTEUR EUROPE	New Biological
VAXNEUVANCE	PNEUMOCOCCAL POLYSACCHARIDE	MERCK SHARP & DOHME B.V.	New AS, New Biological
VAZKEPA	ICOSAPENT ETHYL	AMARIN PHARMACEUTICAL IRELAND LIMITED	New AS
VEDROP	TOCOPHEROL D-ALPHA (AS TOCOFERSOLAN)	RECORDATI RARE DISEASES	Auth under excep circumstances, PASS
VEGZELMA	BEVACIZUMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
VEKLURY	REMDESIVIR	GILEAD SCIENCES IRELAND UC	New AS
VENOHES 6%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
VELSIPITY	ETRASIMOD	PFIZER EUROPE MA EEIG	New AS
VERQUVO	VERICIGUAT	BAYER AG	New AS
VEOZA	BEZOLINETANT	ASTELLAS PHARMA Europe B.V.	New AS
VIMIZIM	ELOSULFASE ALFA	BIOMARIN INTERNATIONAL LTD	New AS, PASS
VITRAKVI	LAROTRECTINIB	BAYER AG	Conditional auth, New AS
VOCABRIA	CABOTEGRAVIR	VIIV HEALTHCARE BV	New AS, PASS
VOLULYTE 6%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS
VOLUVEN 10%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS
VOLUVEN 6%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS

VORAXAZE	GLUCARPIDASE	SERB SAS	New AS, New Biological, Auth under excep circumstances
VOXZOGO	VOSORITIDE	BIOMARIN INTERNATIONAL LTD	New AS, New Biological
VOYDEYA	DANICOPAN	ALEXION EUROPE SAS	New AS
VUEWAY	GADOPICLENOL	BRACCO IMAGING SPA	New AS
VYDURA	RIMEGEPANT	PFIZER EUROPE MA EEIG	New AS
VYEPTI	EPTINEZUMAB	H. LUNDBECK A/S	New Biological
VYLOY	ZOLBETUXIMAB	ASTELLAS PHARMA EUROPE B.V.	New Biological
VYNDAQEL	TAFAMIDIS (MEGLUMINE)	PFIZER EUROPE MA EEG	Auth under excep circumstances, New AS, PASS
VYVGART	EFGARTIGIMOD ALFA	ARGENX B.V.	New AS, New Biological
WAKIX	PITOLISANT HYDROCHLORIDE	BIOPROJET PHARMA	PASS
WAYLIVRA	VOLANESORSEN	AKCEA THERAPEUTICS IRELAND LTD	New AS, Conditional auth
WEGOVY	SEMAGLUTIDE	NOVO NORDISK A/S	New Biological
WEZENLA	USTEKINUMAB	AMGEN TECHNOLOGY (IRELAND) UC	New Biological
WINREVAIR	SOTATERCEPT	MERCK SHARP & DOHME B.V.	New AS, New biological
WYOST	DENOSUMAB	SANDOZ GMBH	New Biological
XEMBIFY	HUMAN NORMAL IMMUNOGLOBULIN	INSTITUTO GRIFOLS S.A.	New Biological
XENLETA	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	New AS
XENPOZYME	OLIPUDASE ALFA	GENZYME EUROPE B.V.	New AS, New Biological
XEVUDY	SOTROVIMAB	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS, New Biological
XIMLUCI	RANIBIZUMAB	STADA ARZNEIMITTEL AG	New Biological
XOFIGO	Radium Ra 223 dichloride	BAYER PHARMA AG	PASS
XOFLUZA	BALOXAVIR MARBOXIL	ROCHE REGISTRATION GMBH	New AS
YESAFILI	AFLIBERCEPT	BIOSIMILAR COLLABORATIONS IRELAND LIMITED	New Biological
YESCARTA	AXICABTAGENE CILOLEUCEL	KITE PHARMA EU BV	PASS
YIMMUGO	HUMAN NORMAL IMMUNOGLOBULIN	BIOTEST PHARMA GMBH	New Biological
YORVIPATH	PALOPEGTERIPARATIDE	ASCENDIS PHARMA BONE DISEASES A/S	New AS
YSELTY	LINZAGOLIX CHOLINE	THERAMEX IRELAND LIMITED	New AS
YUFLYMA	ADALIMUMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
ZABDENO	EBOLA VACCINE (Ad26.ZEBOV-GP [recombinant])	JANSSEN-CILAG INTERNATIONAL NV	New AS, New Biological, Auth under excep circumstances
ZEGALOGUE	DASIGLUCAGON	NOVO NORDISK A/S	New AS
ZERCEPAC	TRASTUZUMAB	ACCORD HEALTHCARE S.L.U.	New AS, New Biological
ZEPOSIA	OZANIMOD	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS
ZOKINVY	LONAFARNIB	TMC PHARMA (EU) LIMITED	New AS, Auth under excep circumstances
ZOLGENSMA	ONASEMNOGENE ABEPARVOVEC	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
ZTALMY	GANAXOLONE	MARINUS PHARMACEUTICALS EMERALD LIMITED	New AS
ZILBRYSQ	ZILUCOPLAN	UCB PHARMA S.A.	New AS

ZYNLONTA	LONCASTUXIMAB TESIRINE	ADC THERAPEUTICS (NL) BV	New AS, New Biological, Conditional Auth
ZYNYZ	RETIFANLIMAB	INCYTE BIOSCIENCES DISTRIBUTION B.V.	New AS, New biological

NOTE	
In Red	commercialised / commercialisé / gecommmercialiseerd
in Black	not commercialised / pas commercialisé / niet gecommmercialiseerd
in blue	info not yet available / info pas encore disponible / info nog niet beschikbaar
in grey	New addition of this month / nouvelle addition de ce mois / nieuwe toevoeging van deze maand
New AS	nouvelle substance active / nieuw actief bestanddeel
New Biological	nouveau médicament biologique / nieuwe biologische geneesmiddel
PASS	Etude de sécurité post-autorisation / post-autorisatie veiligheidsstudies
Conditional auth	Autorisé sous certaines conditions / vergund onder bepaalde voorwaarden
Auth under excep circumstances	autorisé sous circonstances exceptionnelles / vergund onder uitzonderlijke omstandigheden

Product informations / informations : informations sur les produits/productinformatie

http://www.fagg-afmps.be/search?language=fr&search_field=notice