

Final Belgian list:

(Last update 2/07/2024)

Marketing name	Active substance	MAH	Reason on list
ABECMA	IDECABTAGENE VICLEUCCEL	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
ADYNOVI	RURIOCTOCOG ALFA PEGOL	BAXALTA INNOVATIONS GMBH	PASS
AFLURIA TETRA	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SEQIRUS NETHERLANDS B.V.	New biological
AGAMREE	VAMOROLONE	SANTHERA PHARMACEUTICALS (DEUTSCHLAND) GMBH	New AS
AKLIEF	TRIFAROTENE	GALDERMA NORDIC AB	New AS
ALTUVOCT	EFANESOCTOCOG ALFA	SWEDISH ORPHAN BIOVITRUM AB (publ)	New AS, New Biological
ALYMSYS	BEVACIZUMAB	MABXIENCE RESEARCH SL	New biological
AMSPARITY	ADALIMUMAB	PFIZER EUROPE MA EEIG	New Biological
AMVUTTRA	VUTRISIRAN	ALNYLAM NETHERLANDS B.V.	New As
ANORO ELLIPTA	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
APEXXNAR	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (20-VALENT, ADSORBED)	PFIZER EUROPE MA EEIG	New Biological
APRETUDE	CAPOTEGRAVIR	VIIV HEALTHCARE BV	NEW AS
AQUIPTA	ATOGEPAANT	ABBVIE DEUTSCHLAND 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
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
BAVENCIO	AVELUMAB	MERCK EUROPE B.V.	New AS, Conditional auth, New biological
BEKEMV	ECULIZUMAB	AMGEN TECHNOLOGY (IRELAND) UC	New Biological
BELLINA	CHLORMADINONE, ETHINYLESTRADIOL	GEDEON RICHTER PLC	PASS
BENLYSTA	BELIMUMAB	GLAXO GROUP LTD	New AS
BEOVU	BROLUCIZUMAB	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
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	ALMIRALL S.A	New AS, PASS
BREYANZI	LISOCABTAGENE MARALEUCEL	BRISTOL-MYERS SQUIBB PHARMA EEIG	New Biological, New AS, PASS
BRIMICA GENUAIR	ACLIDINIUM BROMIDE/ FORMOTERL FUMARATE DIHYDRATE	COVIS PHARMA EUROPE B.V.	New AS, 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 exceptional 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, Cond Auth, PASS
CELLEMIC	ZOONOTIC INFLUENZA VACCINE (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)	SEQIRUS NETHERLANDS B.V.	New AS, New Biological
CEGFILA (previously PEGFILGRASTIM MUNDIPHARMA)	PEGFILGRASTIM	MUNDIPHARMA CORPORATION (IRELAND) LIMITED	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, Cond Auth
COMIRNATY	COVID-19 mRNA VACCINE (nucleoside modified)	BIONTECH MANUFACTURING GmbH	New AS, New Biological

COMIRNATY ORIGINAL/OMICRON BA.1	COVID-19 mRNA VACCINE (nucleoside modified)	BIONTECH MANUFACTURING GmbH	New AS, New Biological
COMIRNATY ORIGINAL/OMICRON BA. 4-5	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/ FORMOTERL FUMARATE DIHYDRATE	COVIS PHARMA EUROPE B.V.	PASS
EBGLYSS	LEBRIKIZUMAB	ALMIRALL S.A.	New AS, New Biological
EBVALLO	TABELECLEUCCEL	PIERRE FABRE MEDICAMENT	New AS, New Biological, Auth under excep circumstances
EKLIRA GENUAIR	ACLIDINIUM (BROMURE)	COVIS PHARMA EUROPE B.V.	New AS, PASS
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
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 BECAT (ALSO KNOWN IN EU COUNTRIES AS LOSIMA, ENOXAPARIN ROVI, CRUSIA AND AROVI)	ENOXAPARIN SODIUM	LABORATORIOS FARMACEUTICOS ROVI SA	New Biological
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
EVENITY	ROMOSOZUMAB	UCB PHARMA S.A.	New AS, New Biological
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)	SEQIRUS NETHERLANDS B.V.	New Biological
GHEMAXAN	ENOXAPARIN SODIUM	EFFIK	New AS
GIAPREZA	ANGIOTENSIN II ACETATE	PAION DEUTSCHLAND GMBH	New AS
GAVRETO	PRALSETINIB	ROCHE REGISTRATION GMBH	New AS, conditional auth
GIVLAARI	GIVOSIRAN	ALNYLAM NETHERLANDS B.V.	New AS
HELEN	CHLORMADINONE, ETHINYLESTRADIOL	CERES PHARMA NV	PASS
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
HEPAXANE	ENOXAPARIN SODIUM	CHEMI S.P.A.	New Biological
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
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
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 Marketing autorisation
INCRELEX	MECASERMIN	IPSEN PHARMA	Auth under excep circumstances, PASS
INCRUSE ELLIPTA	UMECLIDINIUM BROMIDE	GLAXOSMITHKLINE (IRELAND) LIMITED	New AS
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
ISTURISA	OSILODROSTAT	NOVARTIS EUROPARM LIMITED	New AS
ITULAZAX	STANDARDISED ALLERGEN EXTRACT FROM BIRCH	ALK-ABELLO A/S	New Biological
JAYDESS	LEVONORGESTREL 13.50 MG	BAYER AB	PASS
JAYPIRCA	PIRTOBRUTINIB	ELI LILLY NEDERLAND B.V.	New AS, Conditional auth
JCOVDEN	COVID-19 vaccine (Ad26.COV2-S [recombinant])	JANSSEN-CILAG INTERNATIONAL NV	New AS, New Biological
JEMPERLI	DOSTARLIMAB	GLAXOSMITHKLINE (IRELAND) LIMITED	New AS, New Biological
JINARC	TOLVAPTAN	OTSUKA PHARMACEUTICAL EUROPE LTD	PASS
JUBBONTI	DENOSUMAB	SANDOZ GMBH	New Biological
JYSELECA	FILGOTINIB	GALAPAGOS NV	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
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

KINPEYGO	BUDESONIDE	STADA ARZNEIMITTEL AG	Conditional auth
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
LAVENTAIR ELLIPTA	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
LEDRAXEN	ENOXAPARIN SODIUM	VENIPHARM	New Biological
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, Authorised under exceptional 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)	AMRYT PHARMACEUTICALS DAC	New AS, Auth under excep circumstances
LONAPEGSSOMATROPIN ASCENDIS PHARMA	LONAPEGSSOMATROPIN	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
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
MAYZENT	SIPONIMOD	NOVARTIS EUROPHARM LIMITED	New AS
MEDIKINET RETARD	METHYLPHENIDATE HYDROCHLORIDE	MEDICE ARZEIMITTEL PÜTTNER GMBH CO. KG	PASS
MENQUADFI	MENINGOCOCCAL GROUP A, C, W and Y CONJUGATE VACCINE	SANOFI PASTEUR	New Biological
MEPSEVII	VESTRONIDASE ALFA	ULTRAGENYX GERMANY GMBH	authorized under exceptional 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
MVABEA	EBOLA VACCINE (MVA-BN-Filo [recombinant])	JANSSEN-CILAG INTERNATIONAL NV	New AS, New biological, Auth under excep circumstances
MYALEPTA	METRELEPTIN	AMRYT PHARMACEUTICALS DAC	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
NILEMDO	BEMPEDOIC ACID	DAIICHI SANKYO EUROPE GMBH	New AS
NUBEQA	DARULOTAMIDE	BAYER AG	New AS
NULIBRY	FOSDENOPTERIN	TMC PHARMA (EU) Limited	New AS, Auth under excep circumstances
NUSTENDI	BEMPEDOIC ACID/ EZETIMIBE	DAIICHI SANKYO EUROPE GMBH	New AS
NUVAXOVID	SARS-COV-2 RECOMBINANT SPIKE PROTEIN	NOVAVAX CZ, a.s.	New AS, New Biological
NYVEPRIA	PEGFILGRASTIM	PFIZER EUROPE MA EEIG	New Biological
NYXTHRACIS (previously OBILTOXAXIMAB SFL)	OBILTOXAXIMAB	SFL PHARMACEUTICALS DEUTSCHLAND GMBH	New AS, New Biological, Auth under excep circumstances
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	BLAXOSMITHKLINE 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

ORCHIDEA	CHLORMADINONE, ETHINYLESTRADIOL	MADAUS GMBH	PASS
ORGOVYX	RELUGOLIX	MYOVANT SCIENCES IRELAND LIMITED	New AS
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
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
PERCOLOZIN	ENOXAPARIN SODIUM	VENIPHARM	New Biological
PHESGO	PERTUZUMAB/ TRASTUZUMAB	ROCHE REGISTRATION GMBH	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 TETRAKETAN	NOVARTIS EUROPHARM LIMITED	New AS
POLIVY	POLATUZUMAB VEDOTIN	ROCHE REGISTRATION GMBH	New AS, New Biological
PONVORY	PONESIMOD	JANSSEN-CILAG INTERNATIONAL NV	New AS
POMBILITI	CIPAGLUCOSIDASE ALPHA	AMICUS THERAPEUTICS EUROPE LIMITED	New AS, New Biological
PREHEVBRI	HEPATITIS B VACCINE (RECOMBINANT, ADSORBED)	VBI VACCINES B.V.	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 A	DENGUE TETRAVALENT VACCINE (live, attenuated)	TAKEDA GMBH	New Biological
QINLOCK	RIPRETINIB	DECIPHERA PHARMACEUTICALS (NETHERLANDS) B.V.	New AS
QUINSAIR	LEVOFLOXACIN	CHIESI FARMACEUTICI S.P.A.	PASS
QUOFENIX	DELAFL OXACIN	A.MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	New AS

QUVIVIQ	DARIDOREXANT	IDORSIA PHARMACEUTICALS DEUTSCHLAND GMBH	New AS
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
RECARBRIO	IMIPENEM/CILASTATIN/RELEBACTAM	MERCK SHARP & DOHME B.V.	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
RHOKIINSA	NETARSUDIL	SANTEN OY	New AS
RINVOQ	UPADACITINIB	ABBVIE DEUTSCHLAND GMBH & CO. KG	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
ROLUFTA ELLIPTA	UMECLIDINIUM	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS, PASS
RONAPREVE	CASIRIVIMAB/ IMDEVIMAB	ROCHE REGISTRATION GMBH	New AS, New Biological
ROZLYTREK	ENTRECTINIB	ROCHE REGISTRATION GMBH	New AS, conditional auth
RUKOBI	FOSTEMSAVIR	VIIV HEALTHCARE BV	New AS
RUXIENCE	RITUXIMAB	PFIZER EUROPE MA EEIG	New Biological
RYBELSUS	SEMAGLUTIDE	NOVO NORDISK A/S	New biological
RYBREVANT	AMIVANTAMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS, New Biological, Conditional auth
RYEQO	RELUGOLIX/ ESTRADIOL/ NORETHISTERONE ACETATE	GEDEON RICHTER Plc	New AS
RYSTIGGO	BOZANOLIXIZUMAB	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
SIRTURO	BEDAQUILINE	JANSSEN-CILAG INTERNATIONAL NV	New AS, Conditional auth
SIXMO	BUPRENORPHINE	L.MOLTENI & C. dei F.lli Alitti Soc.Es.S.p.A.	PASS
SKYCLARYS	OMAVELOXOLONE	REATA IRELAND LIMITED	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, Cond 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
SPRAVATO	ESKETAMINE	JANSSEN-CILAG INTERNATIONAL NV	Restrictions with regards to the safe and effective use of the medicinal product
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
SULOVAS	SULOXIDE	AFLOFARM FARMACJA POLSKA SP. Z o.o.	New Biological
SUNLENCA	LENACAPAVIR	GILEAD SCIENCES IRELAND UC	New AS
SUNOSI	SOLRIAMFETOL	ATNAHS PHARMA NETHERLANDS B. V.	New AS
SUPEMTEK	QUADRIVALENT INFLUENZA VACCINE (RECOMBINANT, PREPARED IN CELL CULTURE)	SANOFI PASTEUR	New Biological
SYLVANT	SILTUXIMAB	EUSA PHARMA NETHERLANDS B.V.	New AS
TABRECTA	CAPMATINIB	NOVARTIS EUROPHARM LIMITED	New AS
TALVEY	TALQUETAMAB	JANSSEN-CILAG INTERNATIONAL NV	New active substance, new biological and Conditional marketing authorisation
TAVLESSE	FOSTAMATINIB	TAKEDA PHARMACEUTICALS INTERNATIONAL AG IRELAND BRANCH	New AS
TAVNEOS	AVACOPAN	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	New AS
TECARTUS	autologous anti-CD19-transduced CD3+ cells	Gilead Sciences	New AS, New Biological, Cond auth, PASS
TECOVIRIMAT SIGA	TECOVIRIMAT MONOHYDRATE	SIGA TECHNOLOGIES NETHERLANDS B.V.	New AS, Authorised under exceptional circumstances
TECVAYLI	TECLISTAMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS, New Biological, Cond auth
TEMYBRIC ELIPPTA	FLUTICASONE FUROATE/ UMECLIDINIUM/ VILANTEROL	GLAXOSMITHKLINE TRADING SERVICES	New AS
TEPKINLY	EPCORITAMAB	ABBVIE DEUTSCHLAND GMBH & CO. KG	New AS, New biological and conditional marketing autorisation

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	TEZEPelumAB	ASTRAZENECA AB	New AS, New Biological
THIOSIX	TIoGUANIN	TEVA NEDERLAND B.V.	Auth under excep circumstances
TIBSOVO	IVOSIDENIB	LES LABORATOIRES SERVIER	New AS
TIZVENI	TISLELIZUMAB	BEIGENE IRELAND LIMITED	New Biological
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	SEAGEN B.V.	New AS
TYENNE	TOCILIZUMAB	RESENIUS KABI DEUTSCHLAND GMBH	New Biological
TYRUKO	NATALIZUMAB	SANDoZ GMBH	New Biological
ULTOMIRIS	RAVULIZUMAB	ALEXION EUROPE SAS	New AS, 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	FIZER 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
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
WEGOYV	SEMAGLUTIDE	NOVO NORDISK A/S	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
XOSPATA	GILTERITINIB	ASTELLAS PHARMA EUROPE BV	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
YSELT	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
ZERCEPAC	TRASTUZUMAB	ACCORD HEALTHCARE S.L.U.	New AS, New Biological
ZEPOSIA	OZANIMOD	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS
ZOKINVY	LONAFARNIB	EIGERBIO EUROPE LTD	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, Cond 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

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