

Final Belgian list: (Last update 07/02/2019)

Marketing name	Active substance	MAH	Reason on list
ABASAGLAR (ABASRIA previous)	INSULINE GLARGINE	ELI LILLY REGIONAL OPERATIONS GMBH	New Biological
ACARIZAX	STANDARDIZED ALLERGEN EXTRACT FROM HOUSE DUST MITES	ALK-ABELLO A/S	New Biological
ACCOFIL	FILGASTRIM	ACCORD HEALTHCARE LIMITED	New Biological
ADCETRIS	BRENTUXIMAB VEDOTINE	TAKEDA GLOBAL R&D CENTRE (EUROPE) LTD	New AS, Cond Auth, PASS
ADEMPAS	RIOCIGUAT	BAYER PHARMA	New AS
ADYNOVI	RURIOCTOCOG ALFA PEGOL	BAXALTA INNOVATIONS GMBH	New AS, PASS
AIMOVIG	ERENUMAB	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
AFSTYLA	LONOCOCOG ALFA	CSL BEHRING GmbH	New AS
AITARO	STANDARDIZED ALLERGEN EXTRACT FROM HOUSE DUST MITES	ALK-ABELLO A/S	New Biological
AKYNZEO	NETUPITANT, PALONOSETRON	HELSINN BIREX PHARMACEUTICALS LTD	New AS
ALECENSA	ALECTINIB	ROCHE REGISTRATION LIMITED	New AS, Cond Auth
ALOFISEL	DAVASTROCEL	TiGenix SAU	New AS
ALPHA-RIX TETRA	INFLUENZA VACCINE INACTIVATED	GLAXOSMITHKLINE BIOLOGICALS S.A.	New Biological
ALPIVAB	PERAMIVIR	BIOCRYST UK LTD	New AS
ALPROLIX	EFTRENOCOG ALFA	BIOGEN IDEC LTD	New AS
ALUNBRIG	BRIGATINIB	TAKEDA PHARMA A/S	New AS
AMGEVITA	ADALIMUMAB	AMGEN EUROPE BV	New biological
AMITEND	STANDARDIZED ALLERGEN EXTRACT FROM HOUSE DUST MITES	ALK-ABELLO A/S	New Biological
AMITIZA	LUBIPROSTON	Sucampo Pharma Europe Ltd	New AS
ANORO	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
APLEEK	ETHINYL ESTRADIOL/GESTODENE	BAYER PHARMA AG	PASS
ATRIANCE	NELARABINE 5.00 MG/ML	GLAXO GROUP LTD	Auth under excep circumstances
ATRYN	ANTITHROMBIN ALFA	GTC BIOTHERAPEUTICS UK LIMITED	Auth under excep circumstances, PASS
AXUMIN	FUCICLOVINE	BLUE EARTH DIAGNOSTICS LTD	New AS
BAVENCIO	AVELUMAB	MERCK SERONO EUROPE LIMITED	New AS, conditional auth
BELLINA	CHLORMADINONE, ETHINYLESTRADIOL	GEDEON RICHTER Plc	Outcome Referral Art 31, PASS
BENEPALI	ETANERCEPT	SAMSUNG BIOEPSIS UK Limited	New Biological
BENLYSTA	BELIMUMAB	GLAXO GROUP LTD	New AS
BESPONSA	INOTUZUMAB OZOGAMICIN	PFIZER LIMITED	New AS

BIKTARVY	BICTEGRAVIR/ EMTRICITABINE/ TENOFOVIR/ ALAFENAMIDE	GILEAD SCIENCES INTERNATIONAL LIMITED	New AS
BIOTHRAX (also known as BaciThrax in France)	ANTHRAX ANTIGEN FILTRATE	EMERGENT SALES AND MARKETING GERMANY Gmbh	New biological
BLINCYTO	BLINATUMOMAB	AMGEN EUROPE BV	New AS, conditional auth
BLITZIMA	RITUXIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New biological
BOSULIF	BOSUTINIB (MONOHYDRATE) 100.00 MG	PFIZER LIMITED	New AS, Cond Auth, PASS
BRAFTOVI	ENCORAFENIB	PIERRE FABRE MEDICAMENT	New AS
BRETARIS GENUAIR	ACLIDINIUM BROMIDE	ALMIRALL S.A	New AS, PASS
BRIMICA GENUAIR	ACLIDINIUM BROMIDE/ FORMOTERL FUMARATE DIHYDRATE	ALMIRALL S.A	New AS, PASS
BRINEURA	CERLIPONASE ALFA	BIOMARIN INTERNATIONAL LTD	New AS, authorised under excep circumstances, PASS
BRINTELLIX	VORTIOXETINE	H. LUNDBECK A/S	New AS
BRIVIACT	BRIVARACETAM	UCB Pharma S.A.	New active substance
CABLIVI	CAPLACIZUMAB	ABLYNX N.V.	New AS
CABOMETYX	CABOZANTINIB	IPSEN PHARMA	New active substance
CAPRELSA	VANDETANIB	ASTRAZENECA AB	New AS, Cond Auth
CEPLENE	HISTAMINE DIHYDROCHLORIDE	MEDA AB	Auth under excep circumstances
CERDELGA	ELIGLUSTAT	GENZYME EUROPE B.V.	New AS, PASS
CHENODEOXYCHOLIC ACID SIGMA-TAU	CHENODEOXYCHOLIC ACID	SIGMA-TAU ARZNEIMITTEL GmbH	Authorised under exceptional circumstances, PASS
CHLOE	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	Mithra Pharmaceuticals SA	PASS
CIDOFOVIR	CIDOFOVIR	EMCURE PHARMA UK LTD	PASS
CINQAERO	RESLIZUMAB	TEVA PHARMACEUTICALS LIMITED	New AS
CINRYZE	C1-INHIBITOR 500.00 IU	VIROPHARMA BVBA	PASS
CLUVOT	HUMAN FACTOR VIII	CSL BEHRING GmbH	New Biological
COAGADEX	HUMAN COAGULATION FACTOR X	BIO PRODUCTS LABRATORY LTD	New Biological
COMETRIQ	CABOZANTINIB	TMC Pharma Services Ltd	New AS, Cond Auth
CONVULEX	VALPROIC ACID	TAKEDA BELGIUM	PASS
CORLENTOR	IVABRADINE	SERVIER, LES LABORATOIRES	PASS
COSENTYX	SECUKINUMAB	NOVARTIS EUROPHARM LIMITED	New AS
COTELLIC	COBIMETINIB	ROCHE REGISTRATION LIMITED	New AS
CRESEMBA	ISAVUCONAZOLE	BASILEA MEDICAL LTD	New AS
CRYSVITA	BUROSUMAB	KYOWA KIRIN LTD	New AS, PASS

CUVITRU	IMMUNOGLOBULIN	BAXALTA INNOVATIONS GMBH, AUSTRIA	New biological
CYLTEZO	ADALIMUMAB	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New biological
CYRAMZA	RAMUCIRUMAB	ELI LILLY NEDERLAND BV	New AS
DAKLINZA	DACLATASVIR	BRISTOL MYERS SQUIBB/PFIZER EEIG	New AS
DARZALEX	DARATUMUMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS
DAXAS	ROFLUMILAST	NYCOMED GMBH	PASS
DEFITELIO	DEFIBROTIDE	Gentium	New biological, authorised under exceptional circumstances
DELSTRIGO	DORAVIRINE/LAMIVUDINE/TENOFIVIR DISOPROXIL	Merck Sharp & Dohme Ltd	New AS
DELTYBA	DELAMANID	Otsuka Novel Products GmbH	New AS, Cond 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
DENGVAXIA	DENGUE TETRAVALANT VACCINE (live, attenuated)	SANOFI PASTEUR	New AS, New biological
DESCOVY	EMTRICITABINE, TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INTERNATIONAL LIMITED	New AS
DINUTUXIMAB BETA APEIRON	DINUTUXIMAB BETA	APEIRON BIOLOGICS AG	New biological, authorised under exceptional circumstances, PASS
DOMPERIDON MYLAN	DOMPERIDONE MALEATE	MYLAN SPRL	PASS
DOMPERIDON TEVA	DOMPERIDONE MALEATE	TEVA PHARMA BELGIUM N.V.	PASS
DOMPERIDONE EG	DOMPERIDONE MALEATE	EUROGENERICS N.V.	PASS
DOMPERIDONE INSTANT EG	DOMPERIDONE	EUROGENERICS N.V.	PASS
DOMPERIDONE MYLAN	DOMPERIDONE MALEATE	MYLAN BVBA/SPRL	PASS
DOMPERIDONE SANDOZ 10 MG	DOMPERIDON	SANDOZ NV	PASS
DOMPERITOP	DOMPERIDONE MALEATE	APOTEX NV	PASS
DUAKLIR GENUAIR	ACLIDINIUM BROMIDE/ FORMOTERL FUMARATE DIHYDRATE	ASTRAZENECA AB	PASS
DUPIXENT	DUPIUMAB	SANOFI-AVENTIS GROUPE	New AS
DUZALLO	ALLOPURINOL/ LESINURAD	GRUNENTHAL GMBH	New AS
EKLIRA GENUAIR	ACLIDINIUM (BROMURE)	ASTRAZENECA AB	New AS, PASS
ELAPRASE	IDURSULFASE	SHIRE HUMAN GENETIC THERAPIES AB	Auth under excep circumstances

ELEBRATO ELLIPTA	FLUTICASONE FUROATE/ UMECLIDINIUM/ VILANTEROL	GLAXOSMITHKLINE TRADING SERVICES LTD	New AS
ELOCTA	EFMOROCTOCOG ALFA	BIOGEN IDEC LTD	New AS
EMGALITY	GALCANEZUMAB	ELI LILLY NEDERLAND BV	New AS, New Biological
EMPLICITI	ELOTUZUMAB	BRYSTOL MYERS SQUIBB PHARMA EEIG	New AS
ENANPLUS	TRAMADOL HYDROCHLORIDE/ DEXKETOPROFEN	LABORATOIRE MENARINI	PASS
ENDOLUCINBETA	LUTETIUM(177 Lu) CHLORIDE	ITG ISOTOPE TECHNOLOGIES GARCHING GMBH	New AS
ENOXAPARIN BECAT (ALSO KNOWN IN EU COUNTRIES AS LOSIMA, ENOXAPARIN ROVI, CRUSIA AND AROVI)	ENOXAPARIN SODIUM	LABORATORIOS FARMACEUTICOS ROVI SA	New Biological
ENTRESTO	SACUBITRIL/ VALSARTAN	NOVARTIS EUROPHARM LIMITED	New AS
ENTYVIO	VEDOLIZUMAB	TAKEDA PHARMA A/S	New AS
EPCLUSA	SOFOSBUVIR/ VELPATASVIR	GILEAD SCIENCES INTERNATIONAL LTD	New AS
EPISALVAN	BIRCH BARK EXTRACT	Birken AG	New AS
ERELZI	ETANERCEPT	SANDOZ GMBH	New biological
ERIVEDGE	VISMODEGIB	ROCHE REGISTRATION LIMITED	New AS, Cond Auth
ERLEADA	APALUTAMIDE	JANSSEN-CILAG INTERNATIONAL NV	New AS
EURARTESIM	PIPERAQUINE TETRAPHOSPHATE (TETRAHYDRATE) , DIHYDROARTEMISININ (DHA)	SIGMA-TAU INDUSTRIE FARMAC. RIUNITE SPA	New AS, PASS
EVOLTRA	CLOFARABINE	GENZYME EUROPE B.V.	Auth under excep circumstances
EVOTAZ	ATAZANAVIR/COBICISTAT	Bristol-Myers Squibb Pharma Eeig	New AS
EXJADE	DEFERASIROX	NOVARTIS EUROPHARM LIMITED	PASS
EXVIERA	DASABUVIR	ABBVIE LTD	New AS
FARYDAK	Panobinostat	Novartis Europharm limited	New AS
FASENRA	BENRALIZUMAB	ASTRAZENECA	New biological
FERCAYL	IRON DEXTRAN NON NUMERICAL AMOUNT	LABORATORIA STEROP NV	PASS
FERTINORM KIT	Gonadotrophin Postmenopausal (HMG) Non Numerical	Laboratoires Génévrier SA	New Biological
FEXERIC	FERRIC CITRATE COORDINATION COMPLEX	KERYX BIOPHARMA UK LTD	New AS, PASS
FIASP	INSULIN ASPART	NOVO NORDISK A/S	New Biological
FIBCLOT	HUMAN FIBRINOGEN	LABORATOIRE FRANÇAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES	New Biological
FIBRYGA	HUMAN FIBRINOGEN	OCTAPHARMA GMBH	New biological
FIRDAPSE	AMIFAMPRIDINE (PHOSPHATE)	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS
FLIXABI	INFLIXIMAB	SAMSUNG BIOEPSIS UK Limited	New Biological

FLUCELVAX TETRA	INFLUENZA VACCINE (surface antigen, inactivated prepared in cell cultures)	SEQIRUS NETHERLANDS B.V.	New biological
FLUENZ TETRA	INFLUENZA VIRUS (LIVE, ATTENUATED Q.S., NASAL)	MEDIMMUNE LLC	New AS
FOTIVDA	TIVOZANIB	EUSA PHARMA UK LTD	New AS
FULPHILA	PEGFILGRASTIM	MYLAN SAS	New biological
GALAFOLD	MIGALASTAT	AMICUS THERAPEUTICS UK LTD	New AS
GALLIAPHARM	Germanium (68Ge) chloride / gallium (68Ga) chloride	ECKERT & ZIEGLER RADIOPHARM GMBH	New AS
GARDASIL 9	HUMAN PAPILOMAVIRUS 9-VALENT (recombinant, adsorbed)	SANOFI PASTEUR MSD	New AS
GAZYVARO	OBINUTUZUMAB	ROCHE REGISTRATION LIMITED	New AS
GENVOYA	ELVITEGRAVIR/ COBICISTAT/ EMTRICITABINE/ TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES LTD	New AS
GILENYA	FINGOLIMOD (HYDROCHLORIDE) 0.50 MG	NOVARTIS EUROPHARM LIMITED	New AS, PASS
GLIVEC	IMATINIB	NOVARTIS EUROPHARM LIMITED	PASS
GLYXAMBI	EMPAGLIFOZIN/LINAGLIPTIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
GRATIELLA 35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	3DDD PHARMA N.V.	PASS
HALIMATOZ	ADALIMUMAB	SANDOZ GMBH	New Biological
HARVONI	LEDIPASVIR, SOFOSBUVIR	GILEAD SCIENCES LTD	New AS
HEFIYA	ADALIMUMAB	SANDOZ GMBH	New Biological
HELEN	CHLORMADINONE, ETHINYLESTRADIOL	Mithra Pharmaceuticals S.A.	Outcome Referral Art 31, PASS
HEMLIBRA	EMICIZUMAB	ROCHE REGISTRATION LIMITED	New AS
HEPAXANE	ENOXAPARIN SODIUM	CHEMI SPA	New biological
HERZUMA	TRASTUZUMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New biological
HETLIOZ	TASIMELTEON	Vanda Pharmaceuticals Limited Ltd	New AS
HOLOCLAR	EX VIVO EXPENDED AUTOLOGOUS HUMAN CORNEAL EPITHELIAL CELLS CONTAINING STEM CELLS	CHIESI FARMACEUTICI SPA	New AS, Cond Auth
HULIO	ADALIMUMAB	MYLAN S.A.S.	New Biological
HYQVIA	IMMUNOGLOBULIN HUMAN NORMAL 100.00 MG/ML	BAXTER INNOVATIONS GMBH	New Biological
HYRIMOX	ADALIMUMAB	SANDOZ GMBH	New Biological
IBLIAS	OCTOCOG ALFA	BAYER PHARMA AG	New Biological
IBRANCE	PALBOCICLIB	PFIZER LIMITED	New AS

IDELVION	ALBUTREPENONACOG ALFA	CSL BEHRING GmbH	New AS
ILUMETRI	TIDRAKIZUMAB	ALMIRALL S.A	New AS, New Biological
IMBRUVICA	IBRUTINIB	JANSSEN-CILAG INTERNATIONAL NV	New AS
IMFINZI	DURVALUMAB	ASTRAZENECA AB	New AS, New Biological
IMLYGIC	TALIMOGENE LAHERPAREPVEC	AMGEN EUROPE BV	New AS
IMNOVID (POMALIDOMIDE CELGENE)	POMALIDOMIDE	CELGENE EUROPE LIMITED	New AS, PASS
IMRALDI	ADALIMUMAB	SAMSUNG BIOEPSIS UK Limited	New AS
IMVANEX	Modified Vaccinia Ankara virus - Bavarian Nordic (MVA-BN) live virus	BAVARIAN NORDIC A/S	New AS, Auth under excep circumstances
INCRELEX	MECASERMIN	IPSEN PHARMA	Auth under excep circumstances, PASS
INCRUSE	UMECLIDINIUM BROMIDE	Glaxo Group Ltd	New AS
INJECTAFER	FERRIC CARBOXYMALTOSE	VIFOR France SA	PASS
INFLUVAC TETRA	INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVED)	MYLAN IRE healthcare Ltd	New Biological
INHIXA	ENOXAPARIN SODIUM	TECHDOW EUROPE AB	New Biological
INSULIN LISPRO SANOFI	INSULIN LISPRO	SANOFI-AVENTIS GROUPE	New biological
INTRAROSA	PRASTERONE	ENDOCEUTICS Ltd	PASS
INTUNIV	Guanfacine	SHIRE PHARMACEUTICAL CONTRACTS LTD	PASS
IQYMUNE	HUMAN NORMAL IMMUNOGLOBULIN	LABORATOIRE FRANÇAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES	New Biological
ISOCURAL	ISOTRETINOIN	PIERRE FABRE BENELUX	PASS
ISOSUPRA LIDOSE	ISOTRETINOIN	Laboratoires Smb S.A.	PASS
ISOTRETINOIN EG	ISOTRETINOIN	EUROGENERICS N.V.	PASS
IVABRADINE ANPHARM	IVABRADINE	ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.-	PASS
JARDIANCE	EMPAGLIFLOZIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
JAYDESS	LEVONORGESTREL 13.50 MG	BAYER N.V.	PASS
JINARC	TOLVAPTAN	Otsuka Pharmaceutical Europe Ltd	PASS
JIVI	DAMOCTOCOG ALFA PEGOL	BAYER AG	New active substance, New biological, PASS
JULUCA	DOLUTEGRAVIR/ RILPIVIRINE	ViiV Healthcare UK Limited	New AS
KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS LIMIT	New AS, PASS
KANJINTI	TRASTUZUMAB	AMGEN EUROPE BV	New Biological
KANUMA	SEBELIPASE ALFA	Synageva BioPharma Ltd	New AS, PASS

KENGREXAL	CANGRELOR	The Medicines Company UK Ltd	New AS
KETOCONAZOLE HRA	KETOCONAZOLE	LABORATOIRE HRA PHARMA	PASS
KEVZARA	SARILUMAB	SANOFI-AVENTIS GROUPE	New active substance
KEYTRUDA	PEMBROLIZUMAB	Merck Sharp & Dohme Ltd	New AS
KISPLYX	LENVATINIB	EISAI EUROPE LIMITED	New AS
KOLBAM	CHOLIC ACID	FGK REPRESENTATIVE SERVICE GMBH	Auth under excep circumstances
KISQALI	RIBOCICLIB	NOVARTIS EUROPHARM LIMITED	New as
KOVALTRY	OCTOCOG ALFA	BAYER PHARMA AG	New AS
KYMRIAH	TISAGENLECLEUCEL	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
KYNTHEUM	BRODALUMAB	LEO PHARMA A/S	New AS
KYPROLIS	CARFILZOMIB	AMGEN EUROPE BV	New AS
LAMZEDE	VELMANASE ALFA	CHIESI FARMACEUTICI SPA	New AS, Auth under excep circumstances
LARTRUVO	OLARATUMAB	ELI LILLY NEDERLAND BV	New AS, conditional auth
LAVENTAIR	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
LENALIDOMIDE ACCORD	LENALIDOMIDE	ACCORD HEALTHCARE LIMITED	New AS
LENVIMA	LENVATINIB	EISAI EUROPE LIMITED	New AS
LIFMIOR	ETANERCEPT	PFIZER LIMITED	New Biological
LIXIANA	EDOXABAN	DAIICHI SANKYO EUROPE GmbH	New AS
LISVY	ETHINYLESTRADIOL, GESTODENE	GEDEON RICHTER	PASS
LOJUXTA	LOMITAPIDE (MESYLATE)	AEGERION PHARMACEUTICALS	New AS, Auth under excep circumstances
LOKELMA	SODIUM ZIRCONIUM CYCLOSILICATE	ASTRAZENECA AB	New AS
LONQUEX	LIPEGFILGRASTIM	TEVA PHARMA BV	New AS, PASS
LONSURF	TRIFLURIDINE, TIPIRACIL	LES LABORATOIRES SERVIER	New AS
LUMARK	LUTETIUM, ISOTOPE OF MASS 177	IDB RADIOPHARMACY B.V.	New AS
LUTATHERA	LUTETIUM (177Lu) OXODOTREOTIDE	Advanced Accelerator Applications	New AS
LYMPHOSEEK	TILMANOCEPT	NAVIDEA BIOPHARMACEUTICALS LIMITED LTD	New AS
LYNPARZA	OLAPARIB	ASTRAZENECA AB	New AS
MACIMORELIN AETEMA Z	MACIMORELIN	AETEMA ZENTARIS GmbH	New AS
MAVIRET	GLECAPREVIR/ PIBRENTASVIR	ABBVIE LTD	New AS, PASS
MEDIKINET RETARD	METHYLPHENIDATE HYDROCHLORIDE	MEDICE ARZEIMITTEL PÜTTNER GMBH CO. KG	PASS
MEKINIST	TRAMETINIB	GLAXO GROUP LTD	New AS
MEKTOVI	BINIMETINIB	PIERRE FABRE MEDICAMENT	New AS

MEPSEVII	VESTRONIDASE ALFA	ULTRAGENYX GERMANY GMBH	New AS, New Biological, Auth under exceptional circumstances
MERIOFERT	MENOTROPHIN	LABORATOIRE GENEVRIER SA	New Biological
MOTILIUM	DOMPERIDONE MALEATE	JOHNSON & JOHNSON CONSUMER N.V.	PASS
MOTILIUM	DOMPERIDONE	JOHNSON & JOHNSON CONSUMER N.V.	PASS
MOTILIUM	DOMPERIDONE	PI-PHARMA NV	PASS
MOTILIUM	DOMPERIDONE	IMPEXECO SA	PASS
MOVENTIG	NALOXEGOL	ASTRAZENECA AG	New AS
MOVYMIA	TERIPARATIDE	STADA ARZNEIMITTEL AG	New Biological
MVASI	BEVACIZUMAB	AMGEN EUROPE BV	New biological
MYALEPTA	METRELEPTIN	AEGERION PHARMACEUTICALS BV	New AS, New Biological, Auth under exceptional circumstances
MYLOTARG	GEMTUZUMAB	PFIZER LIMITED	New AS, New Biological
MYSIMBA	NALTREXONE, BUPROPION	OREXIGEN THERAPEUTICS IRELAND LIMITED	PASS
NAGLAZYME	GALSULFASE	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS
NATPAR	PARATHYROID HORMONE	SHIRE PHARMACEUTICALS IRELAND LTD	CONDITIONAL AUTORISATION
NEOPARIN	ENOXAPARINUM NATRICUM	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	New Biological
NEOTIGASON	ACITRETINE	AUROBINDO Pharma B.V.	PASS
NEPARVIS	SACUBITRIL/ VALSARTAN	NOVARTIS EUROPHARM LIMITED	New AS
NERLYNX	NERATINIB	PUMA BIOTECHNOLOGY, LTD	New AS
NEURACEQ	FLORBETABEN (18F)	Piramal Imaging GmbH	New AS
NEXOBRID	PROTEOLYTIC ENZYMES (CONCENTRATE) ENRICHED IN BROMELAIN	MEDIWOUND GERMANY	New AS, PASS
NINLARO	IXAZOMIB	TAKEDA PHARMA A/S	New AS, conditional auth
NUCALA	MEPOLIZUMAB	GLAXOSMITHKLINE TRADING SERVICES	New AS
NUWIQ	SIMOCTOCOG ALFA	OCTAPHARMA AB	New AS
OBIZUR	SUSOCTOCOG ALFA	BAXALTA INNOVATIONS GMBH	New AS, authorised under excep circumstances
OCALIVA	OBETICHOLIC ACID	INTERCEPT PHARMA LTD	New AS, conditional auth
OCREVUS	OCRELIZUMAB	ROCHE REGISTRATION LIMITED	New AS
ODEFSEY	EMTRICITABINE/RILPIVIRINE/ TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INTERNATIONAL LIMITED	New AS
ODOMZO	SONIDEGIB	NOVARTIS EUROPHARM LIMITED	New AS
OFEV	NINTEDANIB	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS

OGIVRI	TRASTUZUMAB	MYLAN S.A.S.	New biological
OLUMIANT	BARICITINIB	ELI LILLY NEDERLAND BV	New AS
ONCASPAR	PEGASPERGASE	BAXALTA INNOVATIONS GMBH	New biological
ONGENTYS	OPICAPONE	BIAL - PORTELA & C ^a , SA	New AS
ONTRUZANT	TRASTUZUMAB	SAMSUNG BIOEPSIS UK Limited	New biological
ONPATTRO	PATISIRAN	ALNYLAM NETHERLANDS BV	New AS
OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS
ORBACTIV	ORITAVANCIN	THE MEDICINES COMPANY UK LTD	New AS
ORCHIDEA	CHLORMADINONE, ETHINYLESTRADIOL	Meda Pharma	Outcome Referral Art 31, PASS
ORKAMBI	LUMACAFOR/ IVACAFTOR	VERTEX PHARMACEUTICALS LIMIT	New AS
OROPERIDYS	DOMPERIDONE	PIERRE FABRE MEDICAMENT	PASS
ORPHACOL	CHOLIC ACID	LABORATOIRES CTRS	Auth under excep circumstances
OTEZLA	APREMILAST	CELGENE EUROPE LIMITED	New AS
OXERVATE	CENEGERMIN	DOMPE FARMACEUTICI S.p.a.	New AS
OZANEX	OZENAXACIN	FERRER INTERNACIONAL SA	New active substance
OZEMPIC	SEMAGLUTIDE	NOVO NORDISK A/S	New active substance
PANDEMIC INFLUENZA VACCINE H5N1 MEDIMMUNE	PANDEMIC INFLUENZA VACCINE (H5N1)(live attenuated, nasal)	MEDIMMUNE LLC	New AS, conditional auth
PANZYGA	HUMAN NORMAL IMMUNOGLOBULIN	OCTAPHARMA GMBH	New Biological
PARSABIV	ETELCALCETIDE	AMGEN EUROPE BV	New AS
PELGRAZ	PELFILGRATIM	ACCORD HEALTHCARE LIMITED	New Biological
PELMEG	PEGFILGRASTIM	CINFA BIOTECH S.L.	New Biological
PENTHROX	MEHOXYFLURANE	MEDICAL DEVELOPMENTS UK LTD	PASS
PIFELTRO	DORAVIRINE	Merck Sharp & Dohme BV	New AS
PIXUVRI	PIXANTRONE (DIMALEATE)	CTI LIFE SCIENCES LTD	New AS, Cond Auth
PLASMAVOLUME REDIBAG 6%	HYDROXYETHYL STARCH	BAXTER S.A.	Outcome Referral Art 31, PASS
PLEGRIDY	PEGINTERFERON BETA-1A	BIOGEN IDEC LTD	New AS
PORTRAZZA	NECITUMUMAB	ELI LILLY NEDERLAND BV	New AS
POTELIGEO	MOGAMULIZUMAB	KYOWA KIRIN HOLDINGS B.V.	New AS, New biological
PRALUENT	ALIROCUMAB	SANOFI-AVENTIS GROUPE	New AS
PRAXBIND	IDARUCIZUMAB	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
PREVYMIS	LETERMOVIR	Merck Sharp & Dohme Ltd	New AS

PROCORALAN	IVABRADINE	SERVIER, LES LABORATOIRES	PASS
QUINSAIR	LEVOFLOXACIN	Aptalis Pharma SAS	PASS
RAGWIZAX	STANDARDIZED ALLERGEN EXTRACT FROM POLLEN FROM SHORT RAGWEED (AMBROSIA ARTEMISIFOLIA)	ALK-ABELLO A/S	New Biological
RAPIBLOC	LANDIOLOL	AOP ORPHAN PHARMACEUTICALS	New AS
RAVICTI	GLYCEROL PHENYLBUTYRATE	HORIZON THERAPEUTIC LIMITED	New AS, PASS
RAXONE	IDEBENONE	SANTHERA PHARMACEUTICALS (Deutschland) GmbH	Auth under excep circumstances
REAGILA	CARIPRAZINE	GEDEON RICHTER Plc	New AS
REFIXIA	NONACOG BETA PEGOL	NOVO NORDISK A/S	New AS, PASS
REKOVELLE	FOLLITROPIN ALPHA	FERRING PHARMACEUTICALS A/S	NEW BIOLOGICAL
REPATHA	EVOLOCUMAB	AMGEN EUROPE BV	New AS
RESPREEZA	HUMAN ALFA-1 PROTEINASE INHIBITOR	CSL BEHRING GmbH	New AS
REVESTIVE	TEDUGLUTIDE	NYCOMED DANMARK APS	New AS, PASS
REVLIMID	LENALIDOMIDE	CELGENE EUROPE LIMITED	PASS
REZOLSTA	DARUNAVIR/COBICISTAT	JANSSEN-CILAG INTERNATIONAL NV	New AS
RITEMVIA	RITUXIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
RIXATHON	RITUXIMAB	SANDOZ GMBH	New Biological
RISXIMYO	RITUXUMAB	SANDOZ GMBH	New Biological
RIXUBIS	NONACOG GAMMA	BAXTER INNOVATIONS GMBH	New Biological
ROAC CUTANE	ISOTRETINOIN	N.V. ROCHE S.A.	PASS
ROLUFTA	UMECLIDINIUM	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS, PASS
ROTEAS	EDOXABAN	DAIICHI SANKYO EUROPE GmbH	New AS
RUBRACA	RUCAPARIB	CLOVIS ONCOLOGY UK LIMITED	New AS, conditional auth
RXULTI	BREPIRAZOLE	NEw AS	Otsuka Pharmaceutical Europe Ltd
RYDAPT	MIDOSTAURIN	NOVARTIS EUROPHARM LIMITED	New AS
SAXENDA	LIRAGLUTIDE	NOVO NORDISK A/S	New Biological
SCENESSE	AFAMELANOTIDE	CLINUVEL UK LIMITED	New AS, Auth under excep circumstances
SEASONIQUE	LEVONORGESTREL, ETHINYLESTRADIOL	TEVA PHARMA BELGIUM N.V.	PASS
SEGLUROMET	ERTUGLIFLOZIN/ METFORMIN HYDROCHLORIDE	Merck Sharp & Dohme Ltd	New AS
SENGLEE	INSULIN GLARGINE	MYLAN SAS	New Biological
SENSHIO	OSPEMIFENE	SHIONOGI LIMITED	New as, PASS

SHINGRIX	HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)	GLAXOSMITHKLINE BIOLOGICALS S.A.	New AS
SIRTURO	BEDAQUILINE	JANSSEN-CILAG INTERNATIONAL NV	New AS, conditional auth
SIVEXTRO	TEDIZOLID PHOSPHATE	CUBIST UK LTD	New AS
SOMAKIT TOC	EDOTREOTIDE	Advanced Accelerator Applications	New AS
SONAZOID POWDER AND SOLVENT FOR SOLUTION OF FOR INJECTION 8 MICROLITER/ML	PERFLUROBUTANE	GE Healthcare AS	New AS
SOVALDI	SOFOSBUVIR	GILEAD SCIENCES INTERNATIONAL LTD	New AS
SPECTRILA	ASPARGINASE	Medac Gesellschaft für Klinische Spezialialpräparate mbh	New biological
SPHEROX	SPHEROIDS OF HUMAN AUTOLOGOUS MATRIX-ASSOCIATED	CO.DON AG	New AS
SPINRAZA	NUSINERSEN	BIOGEN IDEC LTD	New AS
SPIOLTO RESPIMAT		BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
STEGLATRO	ERTUGLIFLOZIN	Merck Sharp & Dohme Ltd	New AS
STEGLUJAN	ERTUGLIFLOZIN/ SITAGLIPTIN	Merck Sharp & Dohme Ltd	New AS
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	New AS, PASS	GLAXOSMITHKLINE TRADING SERVICES LIMITED
STRIVERDI RESPIMAT	OLODATEROL	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS, PASS
SUBLIVAC BIRKE	ALLERGEN EXTRACT OF POLLEN FROM BIRCH	HAL ALLERGIE GMBH	New Biological
SUBLIVAC BAUME	ALLERGEN EXTRACT OF POLLEN FROM BIRCH, ALDER AND HAZEL	HAL ALLERGIE GMBH	New Biological
SULIQUA	INSULINE GLARGINE/ LIXISENATIDE	SANOFI-AVENTIS GROUPE	New AS
SULOVAS	SULOXIDE	AFLOFARM FARMACJA POLSKA SP. Z o.o.	New biological
SYLVANT	SILTUXIMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS
SYMKEVI	TEZACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	New AS
SYMTUZA	DARUNAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR ALAFENAMIDE	JANSSEN-CILAG INTERNATIONAL NV	New AS

SYNJARDY	EMPAGLIFLOZIN/METFORMIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
TAGRISSO	OSIMERTINIB	ASTRAZENECA AB	New AS, conditional auth
TAKUDEK	TRAMADOL HYDROCHLORIDE/ DEXKETOPROFEN	GUIDOTTI FARMA	PASS
TAKHZYRO	LANADELUMAB	SHIRE PHARMACEUTICALS IRELAND LTD	New AS, New biological
TALTZ	IXEKIZUMAB	ELI LILLY NEDERLAND BV	New AS
TARGOCID	TEICOPLANIN	SANOFI Belgium NV	PASS
TECENTRIQ	ATEZOLIZUMAB	ROCHE REGISTRATION LIMITED	New AS
TEGSEDI	INOTERSEN	IONIS USA LIMITED	New AS
TERROSA	TERIPARATIDE	GEDEON RICHTER	New Biological
TETRASPAN 6%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
TETRASPAN 10%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
THIOSIX	TIOGUANIN	TEVA NEDERLAND B.V.	Auth under excep circumstances
THORINANE	ENOXAPARIN SODIUM	PHARMATHEN SA	New Biological
TIVICAY	DOLUTEGRAVIR	ViiV Healthcare UK Limited	New AS
TOOKAD	PADELIPORFIN	STEBA BIOTECH SA	New AS
TRANSLARNA	ATALUREN	PTC Therapeutics Limited	New AS, conditional auth
TRELEGY ELLIPTA	FLUTICASONE FUROATE/ UMECLIDINIUM/ VILANTEROL	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS
TREMFYA	GUSELKUMAB	JANSSEN-CILAG	New AS
TRIUMEQ	DOLUTEGRAVIR, ABACAVIR, LAMIVUDINE	VIIV HEALTHCARE UK Ltd	New AS
TRUBERZI	ELUXADOLINE	Aptalis Pharma SAS	New AS
TRULICITY	DULAGLUTIDE	ELI LILLY NEDERLAND BV	New AS
TRUMENBA	MENINGOCOCCAL GROUP B VACCINE (RECOMBINANT, COMPONENT, ADSORBED)	PFIZER LIMITED	New AS
TRUXIMA	RITUXIMA	MUNDIPHARMA	New Biological
TUXELLA	RITUXIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
TYSABRI	NATALIZUMAB	BIOGEN IDEC LTD	PASS
UDENYCA	PEGFILGRASTIM	ERA Consulting Gmbh	New Biological
ULTIBRO BREEZHALER	INDACATEROL (MALEATE) , GLYCOPYRRONIUM (BROMIDE)	NOVARTIS EUROPHARM LIMITED	PASS
ULUNAR BREEZHALER	INDACATEROL (MALEATE) , GLYCOPYRRONIUM (BROMIDE)	NOVARTIS EUROPHARM LIMITED	PASS
UPTRAVI	SELEXIPAG	Actelion Registration Ltd	New AS
VABOMERE	MEROPENEM/ VABORBACTAM	REMPEX LONDON LIMITED	New AS
VALPROATE MYLAN	SODIUM VALPROATE	MYLAN BVBA	PASS

VALPROATE RETARD EG	SODIUM VALPROATE, VALPROIC ACID	EG	PASS
VALPROATE RETARD MYLAN	SODIUM VALPROATE	MYLAN BVBA	PASS
VALPROATE SANDOZ	SODIUM VALPROATE, VALPROIC ACID	SANDOZ NV	PASS
VARGATEF	NINTEDANIB	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
VARUBY	ROLAPITANT	TESARO UK Ltd	New AS
VAXELIS	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	SANOFI PASTEUR MSD SNC	New Biological
VAXIGRIP TETRA	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOFI PASTEUR MSD GMBH	New Biological
VEDROP	TOCOPHEROL D-ALPHA (AS TOCOFERSOLAN)	ORPHAN EUROPE SARL	Auth under excep circumstances, PASS
VELPHORO	Mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches	Vifor Fresenius Medical Care Renal Pharma France	New AS
VELTASSA	PATIROMER	Vifor Fresenius Medical Care Renal Pharma France	New AS
VEMLIDY	TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INTERNATIONAL LTD	New AS
VENOFER	IRON SUCROSE	Vifor France	PASS
VENOHES 6%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
VENCLYXTO	VENETOCLAX	ABBVIE LTD	New AS, Cond Auth
VEPACEL	INFLUENZA VIRUS (INACTIVATED) Q.S.	BAXTER INNOVATIONS GMBH	New AS
VERASEAL	HUMAN FIBRINOGEN/ HUMAN THROMBIN	ISTITUTO GRIFOLS SA	New biological
VERZENIOS	ABEMACICLIB	ELI LILLY NEDERLAND BV	New AS
VEYVONDI	VONICOG ALFA	BAXALTA INNOVATIONS GMBH	New AS, New Biological
VIEKIRAX	OMBITASVIR, PARITAPREVIR, RITONAVIR	ABBVIE LTD	New AS
VIHUMA	SIMOCTOCOG ALFA	OCTOPHARMA AB	New AS
VIMIZIM	ELOSULFASE ALFA	BIOMARIN EUROPE LTD	New AS, PASS
VIZAMYL	FLUTEMETAMOL (18F)	GE Healthcare Ltd	New AS
VOKANAMET	CANAGLIFLOZIN / METFORMIN-HYDROCHLORIDE	JANSSEN-CILAG INTERNATIONAL NV	New AS
VOLULYTE 6%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS
VOLUVEN 6%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS
VOLUVEN 10%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS
VOSEVI	SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	GILEAD SCIENCES INTERNATIONAL LIMITED	New as, PASS
VYNDAQEL	TAFAMIDIS (MEGLUMINE)	PFIZER LIMITED	Auth under excep circumstances, New AS, PASS
WAKIX	PITOLISANT HYDROCHLORIDE	BIOPROJET PHARMA	New AS, PASS

XADAGO	SAFINAMIDE	Zambon Group SpA	New AS
XALKORI	CRIZOTINIB	PFIZER LIMITED	New AS, Cond Auth
XARELTO	RIVAROXABAN 10.00 MG	BAYER SCHERING PHARMA AG	PASS
XELJANZ	TOFACITINIB	PFIZER LIMITED	New AS
XERAVA	ERAVACYCLINE	TETRAPHASE PHARMACEUTICALS IRELAND LIMITED	New AS
XERMELO	TELOTTRISTAT	IPSEN PHARMA	New AS
XGEVA	DENOSUMAB	AMGEN EUROPE BV	New biological
XOFIGO	Radium Ra 223 dichloride	Bayer Pharma AG	PASS
XOTERNA BREEZHALER	INDACATEROL / GLYCOPYRRONIUM	TEVA PHARMA BV	PASS
XULTOPHY	INSULIN DEGLUDEC, LIRAGLUTIDE	NOVO NORDISK A/S	New Biological
XYDALBA	DALBAVANCIN	DURATA THERAPEUTICS INTERNATIONAL bv	New AS
YANIMO RESPIMAT	TIOTROPIUM BROMIDE MONOHYDRATE / OLODATEROL HYDROCHLORIDE	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
YESCARTA	AXICABTAGENE CILOLEUCEL	KITE PHARMA EU BV	New AS, New Biological, PASS
ZALMOXIS	ALLOGENEIC T CELLS GENETICALLY MODIFIED WITH A RETROVIRAL VECTOR ENCODING FOR A TRUNCATED FORM OF THE HUMAN LOW AFFINITY NERVE GROWTH FACTOR RECEPTOR (LNGFR) AND THE HERPES SIMPLEX I VIRUS THYMIDINE KINASE (HSV-TK MUT2)	MOLMED S.P.A.	New AS, conditional auth
ZAVICEFTA	CEFTAZIDIME/ AVIBACTAM	ASTRAZENECA AB	New AS
ZEJULA	NIRAPARIB	TESARO UK Ltd	New AS
ZEPATIER	ELBASVIR/GRAZOPRE VIR	MERCK SHARP & DOHME LTD	New AS
ZERBAXA	CEFTOLOZANE/ TAZOBACTAM	MERCK SHARP & DOHME LTD	New AS
ZESSLY	INFLIXIMAB	SANDOZ	New biological
ZEVTERA	CEFTOBIPROTE MEDOCARIL SODIUM	BASILEA MEDICAL LTD	New AS
ZILIUM	DOMPERIDONE MALEATE	KELA PHARMA NV	PASS
ZIEXTENZO	PEGFILGRASTIM	SANDOZ GMBH	New biological
ZINPLAVA	BEZLOTOXUMAB	MERCK SHARP & DOHME LTD	New AS
ZOELY	NOMOGESTROL ACETATE / ESTRADIOL HEMIHYDRATE	THERAMEX S.r.l.	PASS
ZURAMPIC	LESINURAD	ASTRAZENECA AB	New AS, PASS
ZYDELIG	IDELALISIB	GILEAD SCIENCES INTERNATIONAL LTD	New AS
ZYKADIA	CERITINIB	NOVARTIS EUROPHARM LIMITED	New AS, Cond Auth

NOTE	
In Red	commercialised / commercialisé / gecommercialiseerd
in Black	not commercialised / pas commercialisé / niet gecommercialiseerd
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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