

Final Belgian list:

(Last update 6/03/2020)

Marketing name	Active substance	MAH	Reason on list
ACARIZAX	STANDARDIZED ALLERGEN EXTRACT FROM HOUSE DUST MITES	ALK-ABELLO A/S	New Biological
ADCETRIS	BRENTUXIMAB VEDOTINE	TAKEDA GLOBAL R&D CENTRE (EUROPE) LTD	New AS, Conditional auth, PASS
ADYNOVI	RURIOCTOCOG ALFA PEGOL	BAXALTA INNOVATIONS GMBH	New AS, PASS, New Biological
AFSTYLA	LONOCTOCOG ALFA	CSL BEHRING GmbH	New AS, New Biological
AIMOVIG	ERENUMAB	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
AITARO	STANDARDIZED ALLERGEN EXTRACT FROM HOUSE DUST MITES	ALK-ABELLO A/S	New Biological
AJOVY	FREMANEZUMAB	TEVA GmbH	New AS, New Biological
ALECENSA	ALECTINIB	ROCHE REGISTRATION LIMITED	New AS, Conditional auth
ALOFISEL	DAVASTROCEL	TAKEDA PHARMA A/S	New AS, New biological
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, New Biological
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
AMSPARITY	ADALIMUMAB	PFIZER EUROPE MA EEIG	New Biological
ANORO ELLIPTA	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
ATRIANCE	NELARABINE 5.00 MG/ML	GLAXO GROUP LTD	Auth under excep circumstances
AXUMIN	FUCICLOVINE	BLUE EARTH DIAGNOSTICS LTD	New AS
BATREVAC TETRA	INFLUENZA VIRUS SURFACE ANTIGENS, INACTIVATED (HAEMAGGLUTININ AND NEURAMINIDASE)	MYLAN HEALTHCARE B.V.	New Biological
BAVENCIO	AVELUMAB	MERCK SERONO EUROPE LIMITED	New AS, Conditional auth, New biological
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
BEOVU	BROLUCIZUMAB	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
BESPONSA	INOTUZUMAB OZOGAMICIN	PFIZER LIMITED	New AS, New Biological
BESREMI	ROPEGINTERFERON ALFA-2B	AOP ORPHAN PHARMACEUTICALS AG	New AS, New Biological
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, Conditional 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
BRIVIACT	BRIVARACETAM	UCB Pharma S.A.	New AS
CABLIVI	CAPLACIZUMAB	ABLYNX N.V.	New AS, New Biological
CABOMETYX	CABOZANTINIB	IPSEN PHARMA	New AS
CAPRELSA	VANDETANIB	ASTRAZENECA AB	New AS, Conditional auth
CEPLENE	HISTAMINE DIHYDROCHLORIDE	MEDA AB	Auth under excep circumstances
CERDELGA	ELIGLUSTAT	GENZYME EUROPE B.V.	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, New biological
CINRYZE	C1-INHIBITOR 500.00 IU	VIROPHARMA BVBA	PASS
COAGADEX	HUMAN COAGULATION FACTOR X	BIO PRODUCTS LABRATORY LTD	New Biological
COMETRIQ	CABOZANTINIB	TMC Pharma Services Ltd	New AS, Conditional auth
CONVULEX	VALPROIC ACID	TAKEDA BELGIUM	PASS
COTELLIC	COBIMETINIB	ROCHE REGISTRATION LIMITED	New AS
CRESEMBA	ISAVUCONAZOLE	PFIZER	New AS
CRYSVITA	BUROSUMAB	KYOWA KIRIN LTD	New AS, PASS, New Biological
CUTAQUIG	HUMAN NORMAL IMMUNOGLOBULIN	OCTOPHARMA GMBH	New Biological
CUVITRU	IMMUNOGLOBULIN	BAXALTA INNOVATIONS GMBH, AUSTRIA	New Biological
DARZALEX	DARATUMUMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS, New biological
DAXAS	ROFLUMILAST	NYCOMED GMBH	PASS
DECTOVA	ZANAMIVIR	GLAXOSMITHKLINE TRADING SERVICES LTD	Authorised under exceptional circumstances
DEFITELIO	DEFIBROTIDE	Gentium	New Biological, authorised under exceptional circumstances

DELSTRIGO	DORAVIRINE/LAMIVUDINE/TENOFIVIR DISOPROXIL	Merck Sharp & Dohme Ltd	New AS
DELYBA	DELAMANID	Otsuka Novel Products GmbH	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
DENGXAXIA	DENGUE TETRAVALANT VACCINE (live, attenuated)	SANOFI PASTEUR	New AS, New Biological
DESCOVY	EMTRICITABINE, TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INTERNATIONAL LIMITED	New AS
DOPTELET	AVATROMBOPAG	DOVA PHARMACEUTICALS IRELAND LIMITED	New AS
DUAKLIR GENUAIR	ACLIDINIUM BROMIDE/ FORMOTERL FUMARATE DIHYDRATE	ASTRAZENECA AB	PASS
DUPIXENT	DUPILUMAB	SANOFI-AVENTIS GROUPE	New AS, New biological
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, New biological
EMGALITY	GALCANEZUMAB	ELI LILLY NEDERLAND BV	New AS, New Biological
EMPLICITI	ELOTUZUMAB	BRYSTOL MYERS SQUIBB PHARMA EEIG	New AS, New biological
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
EPCLUSA	SOFOSBUVIR/ VELPATASVIR	GILEAD SCIENCES INTERNATIONAL LTD	New AS
EPISALVAN	BIRCH BARK EXTRACT	Birken AG	New AS
ERELZI	ETANERCEPT	SANDOZ GMBH	New Biological
ERLEADA	APALUTAMIDE	JANSSEN-CILAG INTERNATIONAL NV	New AS
ERVEBO	EBOLA ZAIRE VACCINE (rVSVΔG-ZEBOV-GP,live)	Merck Sharp & Dohme B.v.	New AS, New Biological, Cond auth
ESPEROCT	TUROCTOCOG ALFA PEGOL	NOVO NORDISK A/S	New AS, New Biological, PASS
EVENITY	ROMOSUZUMAB	UCB Pharma S.A.	New AS, New Biological
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	PASS
FARYDAK	Panobinostat	Novartis Europharm limited	New AS
FASENRA	BENRALIZUMAB	ASTRAZENECA	New Biological, New AS
FERCAYL	IRON DEXTRAN NON NUMERICAL AMOUNT	LABORATORIA STEROP NV	PASS
FERTINORM KIT	Gonadotrophin Postmenopausal (HMG) Non Numerica	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
FOTIVDA	TIVOZANIB	EUSA PHARMA UK LTD	New AS
FULPHILA	PEGFILGRASTIM	MYLAN SAS	New Biological
GALAFOLD	MIGALASTAT	AMICUS THERAPEUTICS UK LTD	New AS
GAMMAPLEX 10%	HUMAN NORMAL IMMUNOGLOBULIN	BIO PRODUCTS GMBH, NEU-ISENBURG, DE	New Biological
GENVOYA	ELVITEGRAVIR/ COBICISTAT/ EMTRICITABINE/ TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES LTD	New AS
GIAPREZA	ANGIOTENSIN II ACETATE	LA JOLLA PHARMACEUTICAL II B.V.	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
GRASUSTEK	PEGFILGRASTIM	JUTA PHARMA GMBH	New Biological
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, New biological
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, Conditional auth, New biological
HULIO	ADALIMUMAB	MYLAN S.A.S.	New Biological

HYQVIA	IMMUNOGLOBULIN HUMAN NORMAL 100.00 MG/ML	BAXTER INNOVATIONS GMBH	New Biological
HYRIMOZ	ADALIMUMAB	SANDOZ GMBH	New Biological
IBRANCE	PALBOCICLIB	PFIZER LIMITED	New AS
ICLUSIG	PONATINIB	Incyte Biosciences Distribution B.V.	PASS
IDACIO	ADALIMUMAB	FRESENIUS KABI DEUTSCHLAND GmbH	New Biological
IDELVION	ALBUTREPENONACOG ALFA	CSL BEHRING GmbH	New AS, New Biological
ILUMETRI	TILDRAKIZUMAB	ALMIRALL S.A	New AS, New Biological
IMFINZI	DURVALUMAB	ASTRAZENECA AB	New AS, New Biological
IMLYGIC	TALIMOGENE LAHERPAREPVEC	AMGEN EUROPE BV	New AS, New biological
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
ISTURISA	OSILODROSTAT	NOVARTIS EUROPHARM LIMITED	New AS
ISOCURAL	ISOTRETINOIN	PIERRE FABRE BENELUX	PASS
ISOSUPRA LIDOSE	ISOTRETINOIN	Laboratoires Smb S.A.	PASS
ISOTRETINOIN EG	ISOTRETINOIN	EUROGENERICS N.V.	PASS
ITULAZAX	STANDARDISED ALLERGEN EXTRACT FROM BIRCH	ALK-ABELLO A/S	New Biological
JAYDESS	LEVONORGESTREL 13.50 MG	BAYER N.V.	PASS
JINARC	TOLVAPTAN	Otsuka Pharmaceutical Europe Ltd	PASS
JIVI	DAMOCTOCOG ALFA PEGOL	BAYER AG	New AS, New Biological, PASS
JULUCA	DOLUTEGRAVIR/ RILPIVIRINE	ViiV Healthcare UK Limited	New AS
KANJINTI	TRASTUZUMAB	AMGEN EUROPE BV	New Biological
KANUMA	SEBELIPASE ALFA	Synageva BioPharma Ltd	New AS, PASS, New biological
KETOCONAZOLE HRA	KETOCONAZOLE	LABORATOIRE HRA PHARMA	PASS

KEVZARA	SARILUMAB	SANOFI-AVENTIS GROUPE	New AS, New biological
KEYTRUDA	PEMBROLIZUMAB	Merck Sharp & Dohme Ltd	New AS, New biological
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
LAVENTAIR	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
LEDRAXEN	ENOXAPARIN SODIUM	VENIPHARM	New Biological
LEMTRADA	ALEMTUZUMAB	SANOFI BELGIUM	PASS
LENALIDOMIDE ACCORD	LENALIDOMIDE	ACCORD HEALTHCARE LIMITED	New AS
LENVIMA	LENVATINIB	EISAI EUROPE LIMITED	New AS
LIBTAYO	CEMIPLIMAB	REGENERON IRELAND U.C.	New AS, New Biological, Conditional auth
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
LONSURF	TRIFLURIDINE, TIPIRACIL	LES LABORATOIRES SERVIER	New AS
LORVIQUA	LORLATINIB	PFIZER EUROPE MA EEIG	New AS, Conditional auth
LUMARK	LUTETIUM, ISOTOPE OF MASS 177	IDB RADIOPHARMACY B.V.	New AS
LUSUTROMBOPAG SHIONOGI	LUSUTROMBOPAG	SHIONOGI B.V.	New AS
LUTATHERA	LUTETIUM (177Lu) OXODOTREOTIDE	Advanced Accelerator Applications	New AS
MACIMORELIN AETEMA ZENTARIS	MACIMORELIN	AETEMA ZENTARIS GmbH	New AS
MAVIRET	GLECAPREVIR/ PIBRENTASVIR	ABBVIE LTD	New AS, PASS
MAYZENT	SIPONIMOD	NOVARTIS EUROPHARM LIMITED	New AS
MEDIKINET RETARD	METHYLPHENIDATE HYDROCHLORIDE	MEDICE ARZEIMITTEL PÜTTNER GMBH CO. KG	PASS
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

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 auth
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
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
NUCEIVA	BOTULINUM TOXIN TYPE A	EVOLUS PHARMA LIMITED	New Biological
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
OGIVRI	TRASTUZUMAB	MYLAN S.A.S.	New Biological
OLUMIANT	BARICITINIB	ELI LILLY NEDERLAND BV	New AS
ONCASPAS	PEGASPERGASE	LES LABORATOIRES SERVIER	New Biological
ONDEXXYA	ANDEXANET ALFA	PORTOLA NETHERLANDS BV	New AS, New Biological, Conditinal auth
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
ORCHIDEA	CHLORMADINONE, ETHINYLESTRADIOL	Meda Pharma	Outcome Referral Art 31, PASS
ORKAMBI	LUMACAFTOR/ IVACAFTOR	VERTEX PHARMACEUTICALS LIMIT	New AS
ORPHACOL	CHOLIC ACID	LABORATOIRES CTRS	Auth under excep circumstances
OXERVATE	CENGERMIN	DOMPE FARMACEUTICI S.p.a.	New AS

OZANEX	OZENAXACIN	FERRER INTERNACIONAL SA	New AS
OZEMPIC	SEMAGLUTIDE	NOVO NORDISK A/S	New AS
PALYNZIQ	PEGVALIASE	BIOMARIN INTERNATIONAL LTD	New AS, New Biological
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
PEGFILGRASTIM MUNDIPHARMA	PEGFILGRASTIM	MUNDIPHARMA BIOLOGICS SL	New Biological
PELGRAZ	PELFILGRATIM	ACCORD HEALTHCARE LIMITED	New Biological
PELMEG	PEGFILGRASTIM	CINFA BIOTECH S.L.	New Biological
PENTHROX	MEHOXYFLURANE	MEDICAL DEVELOPMENTS UK LTD	PASS
PICATO	INGENOL MEBUTATE	LEO LABORATORIES LTD	PASS
PIFELTRO	DORAVIRINE	Merck Sharp & Dohme BV	New AS
PLASMAVOLUME REDIBAG 6%	HYDROXYETHYL STARCH	BAXTER S.A.	Outcome Referral Art 31, PASS
POLIVY	POLATUZUMAB VEDOTIN	ROCHE REGISTRATION GMBH	New AS, New Biological, Conditional auth
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
QARZIBA	DINUTUXIMAB BETA	EUSA PHARMA UK LTD	New Biological, PASS, Authorised under exceptional circumstances
QUINSAIR	LEVOFLOXACIN	Aptalis Pharma SAS	PASS
QUOFENIX	DELAFLOXACIN	A.MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE	New AS
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 PHENYL BUTYRATE	HORIZON THERAPEUTIC LIMITED	New AS, PASS
RAXONE	IDEBENONE	SANTHERA PHARMACEUTICALS (Deutschland) GmbH	Auth under excep circumstances
REAGILA	CARIPRAZINE	GEDEON RICHTER Plc	New AS
RECARBIO	IMIPENEM/CILASTATIN/RELBACTAM	MERCK SHARP & DOHME BV	New AS
REFIXIA	NONACOG BETA PEGOL	NOVO NORDISK A/S	New AS, PASS, New Biological
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
RHOKIINSA	NETARSUDIL	AEIRE PHARMACEUTICALS IRELAND LTD	New AS
RINVOQ	UPADACITINIB	ABBVIE DEUTSCHLAND GMBH & CO. KG	New AS
RITEMVIA	RITUXIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
RIXATHON	RITUXIMAB	SANDOZ GMBH	New Biological
RIXIMYO	RITUXUMAB	SANDOZ GMBH	New Biological
RIZMOIC	NALDEMEDINE	SHIONOGI B.V.	New AS
ROACCUTANE	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
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
SEMGLEE	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
SIXMO	BUPRENORPHINE	L.MOLTENI & C. dei F.lli Alitti Soc.Es.S.p.A.	New Biological, PASS
SKYRIZI	RISANKIZUMAB	ABBVIE DEUTSCHLAND GMBH & CO. KG	New AS, New Biological
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 Spezialpräparate mbh	New Biological
SPHEROX	SPHEROIDS OF HUMAN AUTOLOGOUS MATRIX-ASSOCI	CO.DON AG	New AS
SPINRAZA	NUSINERSEN	BIOGEN IDEC LTD	New AS
SPIOLTO RESPIMAT		BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS

SPRAVATO	ESKETAMINE	JANSSEN-CILAG INTERNATIONAL NV	Restrictions with regards to the safe and effective use of the medicinal product
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	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS, PASS
STRIVERDI RESPIMAT	OLODATEROL	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS, PASS
STRONTIUM RANELATE ARISTO 2G GR	STRONTIUM RANELATE	ARISTO PHARMA Limited	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
SUNOSI	SOLRIAMFETOL	JAZZ PHARMACEUTICALS IRELAND LTD	New AS
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
TAKUDEX	TRAMADOL HYDROCHLORIDE/ DEXKETOPROFEN	GUIDOTTI FARMA	PASS
TAKHZYRO	LANADELUMAB	SHIRE PHARMACEUTICALS IRELAND LTD	New AS, New Biological
TAVLESSE	FOSTAMATINIB	RIGEL PHARMACEUTICALS BV	New AS
TALZENNA	TALAZOPARIB	PFIZER EUROPE MA EEIG	New AS
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
TEMYBRIC ELIPPTA	FLUTICASONE FUROATE/ UMECLIDINIUM/ VILANTEROL	GLAXOSMITHKLINE TRADING SERVICES	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
TOOKAD	PADELIPORFIN	STEBA BIOTECH SA	New AS
TRANSLARNA	ATALUREN	PTC Therapeutics Limited	New AS, Conditional auth
TRAZIMERA	TRASTUZUMAB	PFIZER EUROPE MA EEG	New Biological
TRELEGY ELLIPTA	FLUTICASONE FUROATE/ UMECLIDINIUM/ VILANTEROL	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS
TREMFYA	GUSELKUMAB	JANSSEN-CILAG	New AS
TRIVALENT INFLUENZA VACCINE	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOFI PASTEUR	New Biological
TROGARZO	IBALIZUMAB	THERATECHNOLOGIES INTERNATIONAL LIMITED	New AS, New Biological
TRUBERZI	ELUXADOLINE	Aptalis Pharma SAS	New AS
TRUMENBA	MENINGOCOCCAL GROUP B VACCINE (RECOMBINANT, COMPONENT, ADSORBED)	PFIZER LIMITED	New AS, New Biological
TRUXIMA	RITUXIMA	MUNDIPHARMA	New Biological
TYSABRI	NATALIZUMAB	BIOGEN IDEC LTD	PASS
UDENYCA	PEGFILGRASTIM	ERA Consulting Gmbh	New Biological
ULTOMIRIS	RAVULIZUMAB	ALEXION EUROPE SAS	New AS, New Biological
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
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
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, Conditional auth
VEPACEL	INFLUENZA VIRUS (INACTIVATED) Q.S.	BAXTER INNOVATIONS GMBH	New AS
VERASEAL	HUMAN FIBRINOGEN/ HUMAN THROMBIN	INSTITUTO 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
VITRAKVI	LAROTRECTINIB	BAYER AG	Conditional auth, New AS
VIZIMPRO	DACOMITINIB	PFIZER EUROPE MA EEIG	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
WAYLIVRA	VOLANESORSEN	AKCEA THERAPEUTICS IRELAND LTD	New AS, Conditional 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	TELOTRISTAT	IPSEN PHARMA	New AS
XOFIGO	Radium Ra 223 dichloride	Bayer Pharma AG	PASS
XOSPATA	GILTERITINIB	ASTELLAS PHARMA EUROPE 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
ZAVICEFTA	CEFTAZIDIME/ AVIBACTAM	ASTRAZENECA AB	New AS
ZEJULA	NIRAPARIB	TESARO UK Ltd	New AS
ZEPATIER	ELBASVIR/GRAZOPREVIR	MERCK SHARP & DOHME LTD	New AS
ZERBAXA	CEFTOLOZANE/ TAZOBACTAM	MERCK SHARP & DOHME LTD	New AS
ZESSLY	INFLIXIMAB	SANDOZ	New Biological
ZIEXTENZO	PEGFILGRASTIM	SANDOZ GMBH	New Biological
ZINPLAVA	BEZLOTOXUMAB	MERCK SHARP & DOHME LTD	New AS
ZIRABEV	BEVACIZUMAB	PFIZER EUROPE MA EEIG	New Biological
ZOELY	NOMOGESTROL ACETATE / ESTRADIOL HEMIHYDRATE	THERAMEX S.r.l.	PASS
ZURAMPIC	LESINURAD	ASTRAZENECA AB	New AS, PASS

ZYKADIA	CERITINIB	NOVARTIS EUROPHARM LIMITED	New AS, Conditional auth
ZYNTEGLO	AUTOLOGOUS CD34 + CELLS ENCODING β A-T87Q-GLOBINGENE	BLUEBIRD BIO (NETHERLANDS) B.V.	New AS
ZYNQUISTA	SOTAGLIFOZIN	SANOFI-AVENTIS GROUPE	New AS

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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