

Final Belgian list: (Last update 01/08/2016)

marketing name	Active substance	MAH	Reason on list	Monthly modifications: +/-
ABASGLAR (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	
AITARO	STANDARDIZED ALLERGEN EXTRACT FROM HOUSE DUST MITES	ALK-ABELLO A/S	New Biological	
AKYNZEO	NETUPITANT, PALONOSETRON	HELSINN BIREX PHARMACEUTICALS LTD	New AS	
ALBUMEON	HUMAN ALBUMIN	?	New biological	
ALPHA-RIX TETRA	INFLUENZA VACCINE INACTIVATED	GLAXOSMITHKLINE BIOLOGICALS S.A.	New Biological	
ALPROLIX	EFTRENOCOG ALFA	BIOGEN IDEC LTD	New AS	
AMITEND	STANDARDIZED ALLERGEN EXTRACT FROM HOUSE DUST MITES	ALK-ABELLO A/S	New Biological	
AMITIZA	LUBIPROSTON	Sucampo Pharma Europe Ltd	New AS	
AMYVID	FORBETAPIR (F-18) Q.S.	ELI LILLY NEDERLAND BV	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	
AUBAGIO	TERIFLUNOMIDE	SANOFI-AVENTIS GROUPE	New AS	
BELLINA	CHLORMADINONE, ETHINYLESTRADIOL	GEDEON RICHTER Plc	Outcome Referral Art 31, PASS	
BEMFOLA	Follitropin alfa	FINOX Biotech AG	New biological	
BENEPALI	ETANERCEPT	SAMSUNG BIOEPSIS UK Limited	New Biological	
BENLYSTA	BELIMUMAB	GLAXO GROUP LTD	New AS	
BETMIGA	MIRABEGRON	ASTELLAS PHARMA EUROPE B.V.	New AS	
BEXSERO	NEISSERIA MENINGITIDES B, RECOMBINANT, COMPONENT, ADSORBED Q.S.	NOVARTIS VACCINES & DIAGNOSTICS S.R.L.	New AS	
BLINCYTO	BLINATUMOMAB	AMGEN EUROPE BV	New AS, conditional auth	
BOSULIF	BOSUTINIB (MONOHYDRATE) 100.00 MG	PFIZER LIMITED	New AS, Cond Auth, PASS	
BRETARIS GENUAIR	ACLIDINIUM BROMIDE	ALMIRALL S.A	New AS, PASS	
BRIMICA GENUAIR	ACLIDINIUM BROMIDE/ FORMOTERL FUMARATE DIHYDRATE	ALMIRALL S.A	New AS, PASS	
BRINTELLIX	VORTIOXETINE	H. LUNDBECK A/S	New AS	
BRIVIACT	BRIVARACETAM	UCB Pharma S.A.	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	
CINRYZE	C1-INHIBITOR 500.00 IU	VIROPHARMA BVBA	PASS	

CICLOVIR 75 MG/ML CONCENTRATE FOR SOLUTION FOR INJECTION	CIDOFOVIR	EMCURE PHARMA UK LTD	PASS	
CLAUDIA - 35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	SANDOZ N.V.	PASS	
CLEVIPREX	CLEVIDIPINE BUTYRATE	THE MEDICINES COMPANY UK LTD	New AS	
CLUVOT	HUMAN FACTOR VIII	CSL BEHRING GmbH	New Biological	
COMETRIQ	CABOZANTINIB	TMC Pharma Services Ltd	New AS, Cond Auth	
CONSTELLA	LINACLOTIDE	ALMIRALL S.A	New AS	
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	
COAGADEX	HUMAN COAGULATION FACTOR X	BIO PRODUCTS LABRATORY LTD	New Biological	
CRESEMBA	ISAVUCONAZOLE	BASILEA MEDICAL LTD	New AS	
CUPRYMINA	COPPER (64-CU) CHLORIDE Q.S.	SPARKLE S.R.L	New AS	
CYRAMZA	RAMUCIRUMAB	ELI LILLY NEDERLAND BV	New AS	
DACOGEN	DECITABINE	JANSSEN-CILAG INTERNATIONAL NV	New AS	
DAKLINZA	DACLATASVIR	BRISTOL MYERS SQUIBB/PFIZER EEIG	New AS	
DALIRESP	ROFLUMILAST 500.00 MCG	NYCOMED GMBH	PASS	
DAPHNE	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	MITHRA PHARMACEUTICALS S.A.	PASS	
DARZALEX	DARATUMUMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS	
DAXAS	ROFLUMILAST	NYCOMED GMBH	PASS	
DEFITELIO	DEFIBROTIDE	Gentium	New biological, authorised under exceptional circumstances	
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	
DESCOVY	EMTRICITABINE, TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INTERNATIONAL LIMITED	New AS	
DIANE-35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	BAYER N.V.	PASS	
DIFICLIR	FIDAXOMICIN	ASTELLAS PHARMA EUROPE B.V.	New AS	
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	
DOMPERITOP	DOMPERIDONE MALEATE	APOTEX NV	PASS	
DUAKLIR GENUAIR	ACLIDINIUM BROMIDE/ FORMOTERL FUMARATE DIHYDRATE	ALMIRALL S.A	PASS	
EBYMECT	DAPAGLIFLOZIN/METFORMIN	ASTRAZENECA AB	New AS	
EDARBI	AZILSARTAN MEDOXOMIL (POTASSIUM)	TAKEDA GLOBAL R&D CENTRE (EUROPE) LTD	New AS	
EDISTRIDE	DAPAGLIFLOZIN	ASTRAZENECA AB	New AS	
EDURANT	RILPIVIRINE (HYDROCHLORIDE)	JANSSEN-CILAG INTERNATIONAL NV	New AS	
EKLIRA GENUAIR	ACLIDINIUM (BROMURE)	ALMIRALL S.A.	New AS, PASS	
ELAPRASE	IDURSULFASE	SHIRE HUMAN GENETIC THERAPIES AB	Auth under excep circumstances	
ELISAMYLAN 35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	MYLAN BVBA/SPRL	PASS	
ELOCTA	EFMOROCTOCOG ALFA	BIOGEN IDEC LTD	New AS	
ELVANSE / TYVENSE	LISDEXAMPHETAMINE	BRISTOL MYERS SQUIBB/ PFIZER EEIG	New AS	
EMPLICITI	ELOTUZUMAB	BRISTOL MYERS SQUIBB PHARMA EEIG	New AS	
ENDOLUCINBETA	LUTETIUM(177 Lu) CHLORIDE	ITG ISOTOPE TECHNOLOGIES GARCHING GMBH	New AS	+
ENTRESTO	SACUBITRIL/ VALSARTAN	NOVARTIS EUROPHARM LIMITED	New AS	
ENTYVIO	VEDOLIZUMAB	TAKEDA PHARMA A/S	New AS	
ENUREV BREEZHALER	GLYCOPYRRONIUM (BROMIDE)	NOVARTIS EUROPHARM LIMITED	New AS, PASS	
ENZEPI	PANCREAS POWDER	Aptalis PHARMA SAS	New Biological	+
EPERZAN	ALBIGLUTIDE	GlaxoSmithKline Trading Services Limited	New AS	
EPISALVAN	BIRCH BARK EXTRACT	Birken AG	New AS	
EPCLUSA	SOFOSBUVIR/ VELPATASVIR	GILEAD SCIENCES INTERNATIONAL LTD	New AS	+
ERIVEDGE	VISMODEGIB	ROCHE REGISTRATION LIMITED	New AS, Cond Auth	
ESBRIET	PIRFENIDONE	INTERMUNE EUROPE LTD	New AS, PASS	
EURARTESIM	PIPERAQUINE TETRAPHOSPHATE (TETRAHYDRATE) , DIHYDROARTEMISININ (DHA)	SIGMA-TAU INDUSTRIE FARMAC. RIUNITE SPA	New AS, PASS	
EVARREST	FIBRINOGEN, HUMAN Q.S., THROMBIN, HUMAN Q.S.	OMRIX BIOPHARMACEUTICALS N.V.	New Biological	
EVIPLERA	ENOFOVIR DISOPROXIL (FUMARATE) , EMTRICITABINE , RILPIVIRINE (HYDROCHLORIDE)	GILEAD SCIENCES LTD	New AS	
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	
EYLEA	AFLIBERCEPT	BAYER AG	New AS	
EZICLEN	SULPHATE ANHYDROUS, MAGNESIUM SULFATE HEPTAHYDRATE, POTASSIUM SULPHATE	IPSEN PHARMA	PASS	
FAMPYRA	FAMPRIDINE	BIOGEN IDEC LTD	New AS, Cond Auth	
FARYDAK	Panobinostat	Novartis Europharm limited	New AS	
FERCAYL	IRON DEXTRAN NON NUMERICAL AMOUNT	LABORATORIA STEROP NV	PASS	
FERTINORM KIT	Gonadotrophin Postmenopausal (HMG) Non Numerica	Laboratoires Genévrier SA	New Biological	

FEXERIC	FERRIC CITRATE COORDINATION COMPLEX	KERYX BIOPHARMA UK LTD	New AS, PASS	
FLIXABI	INFLIXIMAB	SAMSUNG BIOEPSIS UK Limited	New Biological	
FIBCLOT	HUMAN FIBRINOGEN	LABORATOIRE FRANÇAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES	New Biological	
FIRDAPSE	AMIFAMPRIDINE (PHOSPHATE)	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS	
FLUENZ TETRA	INFLUENZA VIRUS (LIVE, ATTENUATED Q.S., NASAL)	MEDIMMUNE LLC	New AS	
FORXIGA	DAPAGLIFLOZIN (PROPANEDIOL MONOHYDRATE)	BRISTOL MYERS SQUIBB/ASTRAZENECA EEIG	New AS	
FYCOMPA	PERAMPANEL	EISAI EUROPE LTD	New AS	
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)	SANOPI PASTEUR MSD	New AS	
GAZYVARO	OBINUTUZUMAB	ROCHE REGISTRATION LIMITED	New AS	
GENVOYA	ELVITEGRAVIR/ COBICISTAT/ EMTRICITABINE/ TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES LTD	New AS	
GEONISTIN	OXYTETRACYCLIN, NYSTATIN	Pliva Hrvatska d.o.o.	PASS	
GILENYA	FINGOLIMOD (HYDROCHLORIDE) 0.50 MG	NOVARTIS EUROPHARM LIMITED	New AS, PASS	
GIOTRIF	AFATINIB	Boehringer Ingelheim International	New AS	
GLIVEC	IMATINIB	NOVARTIS EUROPHARM LIMITED	PASS	
GLYBERA	ALIPOGENE TIPARVOVEC Q.S.	UNIQUIRE BIOPHARMA B.V	New AS, Auth under excep circumstances, PASS	
GRASTOFIL	FILGASTRIM	Apotex Europe	New Biological	
GRATIELLA 35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	3DDD PHARMA N.V.	PASS	
HAES-STERIL 6%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS	
HAES-STERIL 10%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS	
HARVONI	LEDIPASVIR, SOFOSBUVIR	GILEAD SCIENCES LTD	New AS	
HELEN	CHLORMADINONE, ETHINYLESTRADIOL	Mithra Pharmaceuticals S.A.	Outcome Referral Art 31, PASS	
HETLIOZ	TASIMELTEON	Vanda Pharmaceuticals Limited Ltd	New AS	
HEXACIMA	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	SANOPI PASTEUR SA	New Biological	
HEXYON	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	SANOPI PASTEUR MSD	New Biological	
HOLOCLAR	EX VIVO EXPENDED AUTOLOGOUS HUMAN CORNEAL EPITHELIAL CELLS CONTAINING STEM CELLS	CHIESI FARMACEUTICI SPA	New AS, Cond Auth	

HYQVIA	IMMUNOGLOBULIN HUMAN NORMAL 100.00 MG/ML	BAXTER INNOVATIONS GMBH	New Biological	
IBLIAS	OCTOCOG ALFA	BAYER PHARMA AG	New Biological	
ICLUSIG	PONATINIB (HYDROCHLORIDE)	ARIAD PHARMA LTD	New AS	
IDELVION	ALBUTREPENONACOG ALFA	CSL BEHRING GmbH	New AS	
ILARIS	CANAKINUMAB	NOVARTIS EUROPHARM LIMITED	Auth under excep circumstances, PASS	
IMBRUVICA	IBRUTINIB	JANSSEN-CILAG INTERNATIONAL NV	New AS	
IMLYGIC	TALIMOGENE LAHERPAREPVEC	AMGEN EUROPE BV	New AS	
IMNOVID (POMALIDOMIDE CELGENE)	POMALIDOMIDE	CELGENE EUROPE LIMITED	New AS, PASS	
IMVANEX	Modified Vaccinia Ankara virus - Bavarian Nordic (MVA-BN) live virus	BAVARIAN NORDIC A/S	New AS, Auth under excep circumstances	
INCIVO	TELAPREVIR	JANSSEN-CILAG INTERNATIONAL NV	New AS	
INCRELEX	MECASERMIN	IPSEN PHARMA	Auth under excep circumstances, PASS	
INCRESYNC	ALOGLIPTIN/PIOGLITAZONE	TAKEDA PHARMA A/S	New AS	
INCRUSE	UMECLIDINIUM BROMIDE	Glaxo Group Ltd	New AS	
INFLECTRA	INFLIXIMAB	HOSPIRA UK LTD	New Biological	
INFLUSPLIT/ FLUARIX TETRA	Influenza virus inactivated split virion	GLAXO GROUP LTD	New Biological	
INJECTAFER	FERRIC CARBOXYMALTOSE	VIFOR France SA	PASS	
INLYTA	AXITINIB	PFIZER LIMITED	New AS	
INTUNIV	Guanfacine	SHIRE PHARMACEUTICAL CONTRACTS LTD	PASS	
INVOKANA	CANAGLIFLOZIN	JANSSEN-CILAG INTERNATIONAL NV	New AS	
IVABRADINE ANPHARM	IVABRADINE	ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.	PASS	
JAKAVI	RUXOLITINIB (PHOSPHATE)	NOVARTIS EUROPHARM LIMITED	New AS, PASS	
JARDIANCE	EMPAGLIFLOZIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS	
JAYDESS	LEVONORGESTREL 13.50 MG	BAYER N.V.	PASS	
JENTADUETO	METFORMIN HYDROCHLORIDE , LINAGLIPTIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS	
JETREA	OCRIPLASMIN	THROMBOGENICS NV	New AS	
JINARC	TOLVAPTAN	Otsuka Pharmaceutical Europe Ltd	PASS	
KADCYLA	TRASTUZUMAB EMTANSINE	ROCHE REGISTRATION LIMITED	New AS	
KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS LIMIT	New AS, PASS	
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	
KEYTRUDA	PEMBROLIZUMAB	Merck Sharp & Dohme Ltd	New AS	
KOLBAM	CHOLIC ACID	FGK REPRESENTATIVE SERVICE GMBH	Auth under excep circumstances	
KOVALTRY	OCTOCOG ALFA	BAYER PHARMA AG	New Biological	
KYPROLIS	CARFILZOMIB	AMGEN EUROPE BV	New AS	

LACTEST	GASIOXE	Lactest S.L. / Venter Pharma S.L.	New AS
LATUDA	LURASIDONE	TAKEDA PHARMA A/S	New AS
LAVENTAIR	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
LEMTRADA	ALEMTUZUMAB	GENZYME THERAPEUTICS LTD	New Biological
LENVIMA	LENVATINIB	EISAI EUROPE LIMITED	New AS
LIBERTEK	ROFLUMILAST	NYCOMED GMBH	PASS
LIXIANA	ADOXABAN	DAIICHI SANKYO EUROPE GmbH	New AS
LISVY	ETHINYLESTRADIOL, GESTODENE	GEDEON RICHTER	PASS
LOJUXTA	LOMITAPIDE (MESYLATE)	AGERION PHARMACEUTICALS	New AS, Auth under excep circumstances
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
LYMPHOSEEK	TILMANOCEPT	NAVIDEA BIOPHARMACEUTICALS LIMITED LTD	New AS
LYNPARZA	OLAPARIB	ASTRAZENECA AB	New AS
LYXUMIA	LIXISENATIDE	SANOFI-AVENTIS GROUPE	New AS
MACI	CHONDROCYTES, AUTOLOGOUS CULTURED Q.S.	GENZYME EUROPE B.V.	New AS
MEKINIST	TRAMETINIB	GLAXO GROUP LTD	New AS
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	IMPEXCO SA	PASS
MOVENTIG	NALOXEGOL	ASTRAZENECA AG	New AS
MYSIMBA	NALTREXONE, BUPROPION	OREXIGEN THERAPEUTICS IRELAND LIMITED	PASS
NAGLAZYME	GALSULFASE	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS
NEURACEQ	FLORBETABEN (18F)	Piramal Imaging GmbH	New AS
NEOPARIN	ENOXAPARINUM NATRICUM	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	New Biological
NEPARVIS	SACUBITRIL/ VALSARTAN	NOVARTIS EUROPHARM LIMITED	New AS
NEXOBRID	PROTEOLYTIC ENZYMES (CONCENTRATE) ENRICHED IN BROMELAIN	MEDIWOUND GERMANY	New AS, PASS
NIMENRIX	NEISSERIA MENINGITIDES A+C+W+Y, POLYSACCHARIDE CONJ. TO TETANUS TOXOID Q.S.	GLAXOSMITHKLINE BIOLOGICALS S.A.	New AS, PASS
NOVOEIGHT	Turoctocog alfa	NOVO NORDISK A/S	New AS
NOVOTHIRTEEN	CATRIDECACOG	NOVO NORDISK A/S	New AS
NUCALA	MEPOLIZUMAB	GLAXOSMITHKLINE TRADING SERVICES	New AS

NUMETZAH G16%E	alanine, arginine, aspartic acid, calcium chloride, cysteine, glucose monohydrate, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, magnesium acetate, methionine, olive oil, ornithine hydrochloride, henylalanine, potassium acetate, proline, serine, sodium chloride, sodium glycerophosphate, soybean oil, taurine, threonine, tryptophan, tyrosine, valine	BAXTER S.A.	Outcome Referral Art 31, PASS	
NUWIQ	SIMOCTOCOG ALFA	OCTAPHARMA AB	New AS	
OBIZUR	SUSOCTOCOG ALFA	BAXALTA INNOVATIONS GMBH	New AS, authorised under excep circumstances	
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	
OLYSIO	SIMEPREVIR	JANSSEN-CILAG INTERNATIONAL NV	New AS	
ONCASPAR	PEGASPERGASE	BAXALTA INNOVATIONS GMBH	New biological	
ONGENTYS	OPICAPONE	BIAL - PORTELA & C ^a , SA	New AS	
OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS	
OPGENRA	EPTOTERMIN ALFA	OLYMPUS BIOTECH LTD	PASS	
OPSUMIT	MACITENTAN	Actelion Registration Ltd	New AS	
OPTIMARK	GADOVERSETAMIDE	MALLINCKRODT MEDICAL GMBH	PASS	
ORBACTIV	ORITAVANCIN	THE MEDICINES COMPANY UK LTD	New AS	
ORKAMBI	LUMACAFTOR/ IVACAFTOR	VERTEX PHARMACEUTICALS LIMIT	New AS	
OROPERIDYS	DOMPERIDONE	PIERRE FABRE MEDICAMENT	PASS	
ORPHACOL	CHOLIC ACID	LABORATOIRES CTRS	Auth under excep circumstances	
OSSEOR	STRONTIUM RANELATE	SERVIER, LES LABORATOIRES	PASS	
OTEZLA	APREMILAST	CELGENE EUROPE LIMITED	New AS	
OVALEAP	FOLLITROPIN ALPHA	TEVA PHARMA GMBH	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	
PENTHROX	MEHOXYFLURANE	MEDICAL DEVELOPMENTS UK LTD	PASS	
PERJETA	PERTUZUMAB	ROCHE REGISTRATION LIMITED	New AS	
PICATO	INGENOL MEBUTATE	LEO PHARMA A/S	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	

PRALUENT	ALIROCUMAB	SANOFI-AVENTIS GROUPE	New AS	
PRAXBIND	IDARUCIZUMAB	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS	
PROCORALAN	IVABRADINE	SERVIER, LES LABORATOIRES	PASS	
PROTELOS	STRONTIUM RANELATE	SERVIER, LES LABORATOIRES	PASS	
QTERN	SAXAGLIPTIN/ DAPAGLIFOZIN	ASTRAZENECA AB	New AS	+
QUINSAIR	LEVOFLOXACIN	Aptalis Pharma SAS	PASS	
RAPIBLOC	LANDIOLOL	AOP ORPHAN PHARMACEUTICALS	New AS	
RAPLIXA	HUMAN FIBRINOGEN , HUMAN THROMBIN	PROFIBRIX BV	New Biological	
RAVICTI	GLYCEROL PHENYL BUTYRATE	HORIZON THERAPEUTIC LIMITED	New AS, PASS	
RAXONE	IDEBENONE	SANTHERA PHARMACEUTICALS (Deutschland) GmbH	Auth under excep circumstances	
RELVAR ELLIPTA	FLUTICASONE FUROATE: VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS	
REMSIMA	INFLIXIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	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	
REVINTY ELLIPTA	FLUTICASONE FUROATE/ VILANTEROL TRIFENATATE	GLAXO GROUP LTD	PASS	
REVLIMID	LENALIDOMIDE	CELGENE EUROPE LIMITED	PASS	
REZOLSTA	DARUNAVIR/COBICISTAT	JANSSSEN-CILAG INTERNATIONAL NV	New AS	
RISTEMPA	PEGFILGRASTIM	AMGEN EUROPE BV	New Biological	
RIXUBIS	NONACOG GAMMA	BAXTER INNOVATIONS GMBH	New Biological	
RYZODEG	INSULIN ASPART 30.00 UML, INSULIN DEGLUDEC 70.00 UML	NOVO NORDISK A/S	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	
SEEBRI BREEZHALER	GLYCOPYRRONIUM (BROMIDE)	NOVARTIS EUROPHARM LIMITED	New AS, PASS	
SELINCRO	NALMEFENE (HYDROCHLORIDE DIHYDRATE)	LUNDBECK A/S	New AS	
SENSHIO	OSPEMIFENE	SHIONOGI LIMITED	New as, PASS	
SIGNIFOR	PASIREOTIDE (DIASPARTATE)	NOVARTIS EUROPHARM LIMITED	New AS	
SIRTURO	BEDAQUILINE	JANSSSEN-CILAG INTERNATIONAL NV	New AS, conditional auth	
SIVEXTRO	TEDIZOLID PHOSPHATE	CUBIST UK LTD	New AS	
SOMATROPIN BIOPARTNERS	SOMATROPIN	BIOPARTNERS	New Biological	
SOVALDI	SOFOSBUVIR	GILEAD SCIENCES INTERNATIONAL LTD	New AS	
SPECTRILA	ASPARGINASE	Medac Gesellschaft für Klinische Spezialialpräparate mbh	New biological	
SPEDRA	AVANAFIL	VIVUS BV	New AS	

STIVARGA	REGORAFENIB	BAYER AG	New AS	
STRENSIQ	ASFOTASE ALFA	ALEXION EUROPE SAS	New AS, Aut under excep circumstances	
STRIBILD	TENOFOVIR DISOPROXIL (FUMARATE) , EMTRICITABINE , ELVITEGRAVIR , COBICISTAT	GILEAD SCIENCES LTD	New AS	
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	
SYLVANT	SILTUXIMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS	
SYNJARDY	EMPAGLIFLOZIN/METFORMIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS	
TAFINLAR	DABRAFENIB	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS	
TAGRESSO	OSIMERTINIB	ASTRAZENECA AB	New AS, conditional auth	
TALTZ	IXEKIZUMAB	ELI LILLY NEDERLAND BV	New AS	
TARGOCID	ACIPIMOX	PFIZER	PASS	
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	
TIVICAY	DOLUTEGRAVIR	ViiV Healthcare UK Limited	New AS	
TOVANOR BREEZHALER	GLYCOPYRRONIUM (BROMIDE)	NOVARTIS EUROPHARM LIMITED	New AS, PASS	
TRANSLARNA	ATALUREN	PTC Therapeutics Limited	New AS, conditional auth	
TRESIBA	INSULIN DEGLUDEC	NOVO NORDISK A/S	New AS	
TRIUMEQ	DOLUTEGRAVIR, ABACAVIR, LAMIVUDINE	VIIV HEALTHCARE UK Ltd	New AS	
TRULICITY	DULAGLUTIDE	ELI LILLY NEDERLAND BV	New AS	
TYBOST	COBICISTAT	Gilead Sciences	New AS	
TYSABRI	NATALIZUMAB	BIOGEN IDEC LTD	PASS	
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	
UNITUXUN	DINUTUXIMAB	UNITED THERAPEUTICS EUROPE LTD	New AS, PASS	
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	

VAXELIS	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	SANOI PASTEUR MSD SNC	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	
VENOFER	IRON SUCROSE	Vifor France	PASS	
VENOHES 6%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS	
VEPACEL	INFLUENZA VIRUS (INACTIVATED) Q.S.	BAXTER INNOVATIONS GMBH	New AS	
VIBATIV	TELAVANCIN	Clinigen Healthcare Limited	PASS	
VIEKIRAX	OMBITASVIR, PARITAPREVIR, RITONAVIR	ABBVIE LTD	New AS	
VIMIZIM	ELOSULFASE ALFA	BIOMARIN EUROPE LTD	New AS, PASS	
VIPDOMET	ALOGLYPTIN / METFORMIN	TAKEDA PHARMA A/S	New AS	
VIPIDIA	ALOGLYPTIN	TAKEDA PHARMA A/S	New AS	
VITEKTA	ELVITEGRAVIR	Gilead Sciences International Ltd	New AS	
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	
VONCENTO	FACTOR VIII HUMAN 1000.00 IU, FACTOR VON WILLEBRAND 2400.00 IU	TEVA PHARMA BV	New Biological	
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	
XAGRID	XAGRID	SHIRE PHARMACEUTICAL CONTRACTS LTD	Auth under excep circumstances	
XALKORI	CRIZOTINIB	PFIZER LIMITED	New AS, Cond Auth	
XARELTO	RIVAROXABAN 10.00 MG	BAYER SCHERING PHARMA AG	PASS	
XGEVA	DENOSUMAB	AMGEN EUROPE BV	New biological	
XIGDUO	DAPAGLIFLOZIN/METFORMIN	BRISTOL MYERS SQUIBB/PFIZER EEIG	New AS	
XOFIGO	Radium Ra 223 dichloride	Bayer Pharma AG	New AS	
XOTERNA BREEZHALER	INDACATEROL / GLYCOPYRRONIUM	TEVA PHARMA BV	PASS	
XTANDI	ENZALUTAMIDE	ASTELLAS PHARMA EUROPE B.V.	New AS	
XULTOPHY	INSULIN DEGLUDEC, LIRAGLUTIDE	NOVO NORDISK A/S	New Biological	
XYDALBA	DALBAVANCIN	DURATA THERAPEUTICS INTERNATIONAL bv	New AS	
YERVOY	IPILIMUMAB	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS, PASS	
ZALTRAP	AFLIBERCEPT	SANOI-AVENTIS GROUPE	New AS	
ZAVICEFTA	CEFTAZIDIME/ AVIBACTAM	ASTRAZENECA AB	New AS	

ZEVTERA 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	CEFTOBIPROTE MEDOCARIL SODIUM	BASILEA MEDICAL LTD	New AS	
ZELBORAF	VEMURAFENIB	ROCHE REGISTRATION LIMITED	New AS	
ZERBAXA	CEFTOLOZANE/ TAZOBACTAM	MERCK SHARP & DOHME LTD	New AS	
ZILIUM	DOMPERIDONE MALEATE	KELA PHARMA NV	PASS	
ZINBRYTA	DACLIZUMAB	BIOGEN IDEC LTD	New biological	+
ZINFORO	CEFTAROLINE FOSAMIL (ACETIC ACID SOLVATE MONOHYDRATE)	ASTRAZENECA AB	New AS	
ZOELY	NOMOGESTROL ACETATE / ESTRADIOL HEMIHYDRATE	THERAMEX S.r.l.	PASS	
ZONTIVITY	VORAPAXAR	MERCK SHARP & DOHME LTD	New AS	
ZURAMPIC	LESINURAD	ASTRAZENECA AB	New AS, PASS	
ZYDELIG	IDELALISIB	GILEAD SCIENCES INTERNATIONAL LTD	New AS	
ZYKADIA	CERTINIB	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 non disponible / info 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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