

Final Belgian list: (Last update 08/07/2016)

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
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
CHAMPIX	VARENICLINE (TARTRATE)-	PFIZER LIMITED	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	BRYSTOL MYERS SQUIBB/ PFIZER EEIG	New AS
EMPLICITI	ELOTUZUMAB	BRYSTOL MYERS SQUIBB PHARMA EEIG	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
EPERZAN	ALBIGLUTIDE	GlaxoSmithKline Trading Services Limited	New AS
EPISALVAN	BIRCH BARK EXTRACT	Birken AG	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 Numerical	Laboratoires Génévrier 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 PAPILLOMAVIRUS 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
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.	UNIQUE 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)	SANOFI PASTEUR SA	New Biological
HEXYON	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	SANOFI 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
KRYSTEXXA	PEGLOTICASE	SAVIENT PHARMA IRELAND LIMITED	New AS, PASS
KYPROLIS	CARFILZOMIB	AMGEN EUROPE BV	New AS
LACTEST	GASILOXE	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)	AEGERION 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	CATRIDEACOG	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	LUMACAFOR/ IVACAFOR	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
QUINSAIR	LEVOFLOXACIN	Aptalis Pharma SAS	PASS
RAPIBLOC	LANDIOLOL	AOP ORPHAN PHARMACEUTICALS	New AS
RAPLIXA	HUMAN FIBRINOGEN , HUMAN THROMBIN	PROFIBRIX BV	New Biological
RAVICTI	GLYCEROL PHENYLBUTYRATE	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	JANSSEN-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	JANSSEN-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)	SANOFI 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
VICTRELIS	BOCEPREVIR	MERCK SHARP & DOHME LTD	New AS
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	SANOFI-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
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	CERITINIB	NOVARTIS EUROPHARM LIMITED	New AS, Cond Auth
ZYTIGA	ABIRATERONE ACETATE-	JANSSEN-CILAG INTERNATIONAL NV	New AS

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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