

Annex I

List of nationally authorised medicinal products and marketing authorisation applications

Annex IA. Medicinal products for which the marketing authorisations are recommended for maintenance and marketing authorisation applications for which bioequivalence vis-à-vis the EU reference medicinal product has been established or may continue to be assessed by the relevant national competent authorities

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Austria	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	5 mg	Tablet	Oral use
Austria	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	10 mg	Tablet	Oral use
Belgium	Eurogenerics N.V./S.A.		Tramadol/Paracetamol EG 37,5/325 mg filmomhulde tabletten	Tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Croatia	Pliva Hrvatska d.o.o.		Diuver 5 mg tablets	Torasemide	5 mg	tablet	Oral use
Croatia	Pliva Hrvatska d.o.o.		Diuver 10 mg tablets	Torasemide	10 mg	tablet	Oral use
Cyprus	Accord Healthcare S.L.U		Amlodipin Accord tablet 5mg	Amlodipine	5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Accord Healthcare S.L.U		Amlodipin Accord tablet 10mg	Amlodipine	10 mg	Tablet	Oral use
Cyprus	Delorbis Pharmaceutica LS LTD		Zormid Eye Drops, Solution 20Mg/MI	Dorzolamide	20 mg/ml	Eye drops, solution	Ocular use
Czech Republic	Accord Healthcare Polska Sp. z o.o.		Amlodipin Accord	Amlodipine	5 mg	Tablet	Oral use
Czech Republic	Accord Healthcare Polska Sp. z o.o.		Amlodipin Accord	Amlodipine	10 mg	Tablet	Oral use
Czech Republic	Mylan Ireland Limited		TRAMYLPA	Tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Denmark	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Denmark	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	5 mg	Tablet	Oral use
Denmark	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	10 mg	Tablet	Oral use
Denmark	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	10 mg	Tablet	Oral use
Estonia	Teva Pharma B.V.		Torasemide Teva	Torasemide	5 mg	Tablet	Oral use
Estonia	Teva Pharma B.V.		Torasemide Teva	Torasemide	10 mg	Tablet	Oral use
Finland	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Finland	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	10 mg	Tablet	Oral use
France	Mylan SAS		TIANEPTINE MYLAN PHARMA 12,5 mg, comprimé enrobé	Tianeptine	12,5 mg	Coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG		Azithromycin Heumann	Azithromycin	250 mg	Film-coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG		Azithromycin Heumann	Azithromycin	500 mg	Film-coated tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG		Dorzolamid Heumann 20 mg/ml Augentropfen	Dorzolamide	20 mg/ml	Eye drops, solution	Ocular use
Germany		Hormosan Pharma	Tianesan 12,5 mg Filmtabletten	Tianeptine	12,5 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Aliud Pharma GmbH		Torasemid AL 5 mg Tabletten	Torasemide	5 mg	Tablet	Oral use
Germany	Aliud Pharma GmbH		Torasemid AL 10 mg Tabletten	Torasemide	10 mg	Tablet	Oral use
Germany	ratiopharm GmbH		Torasemid-ratiopharm 5 mg Tabletten	Torasemide	5 mg	Tablet	Oral use
Germany	ratiopharm GmbH		Torasemid-ratiopharm 10 mg Tabletten	Torasemide	10 mg	Tablet	Oral use
Germany	STADAPHARM GmbH		Torasemid STADA 5 mg Tabletten	Torasemide	5 mg	Tablet	Oral use
Germany	STADAPHARM GmbH		Torasemid STADA 10 mg Tabletten	Torasemide	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Abz-Pharma Gmbh		Torasemid AbZ 5 mg Tabletten	Torasemide	5 mg	Tablet	Oral use
Germany	Abz-Pharma Gmbh		Torasemid AbZ 10 mg Tabletten	Torasemide	10 mg	Tablet	Oral use
Germany	STADAPHARM		Tramadolhydrochlorid/Paracetamol STADA 37,5 mg/325 mg Filmtabletten	Tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Greece	Rafarm A.E.B.E		Rexazon	Dexamethasone	2 mg	Soluble tablet	Oral use
Greece	Rafarm A.E.B.E		Rexazon	Dexamethasone	4 mg	Soluble tablet	Oral use
Greece	Rafarm A.E.B.E		Rexazon	Dexamethasone	8 mg	Soluble tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Ireland	Accord Healthcare Ireland Ltd		Amlodipine 5mg tablets	Amlodipine	5 mg	Tablet	Oral use
Ireland	Accord Healthcare Ireland Ltd		Amlodipine 10mg tablets	Amlodipine	10 mg	Tablet	Oral use
Ireland	Clonmel Healthcare Ltd,		Xymel Comp 37.5mg/325mg Film-Coated Tablets	Tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Italy	Accord Healthcare S.L.U		Amlodipina Accord	Amlodipine	5 mg	Tablet	Oral use
Italy	Accord Healthcare S.L.U		Amlodipina Accord	Amlodipine	10 mg	Tablet	Oral use
Italy	Epionpharma S.r.l.		Varcodes	Dexamethasone	2 mg	Effervescent tablet	Oral use
Italy	Epionpharma S.r.l.		Varcodes	Dexamethasone	4 mg	Effervescent tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Epionpharma S.r.l.		Varcodes	Dexamethasone	8 mg	Effervescent tablet	Oral use
Italy	Aurora Biofarma Srl.		AUROZEB	Rosuvastatin/eze timibe	5 mg/10 mg	Film-coated tablet	Oral use
Italy	Aurora Biofarma Srl.		AUROZEB	Rosuvastatin/eze timibe	10 mg/10 mg	Film-coated tablet	Oral use
Italy	Aurora Biofarma Srl.		AUROZEB	Rosuvastatin/eze timibe	20 mg/10 mg	Film-coated tablet	Oral use
Italy	Aurora Biofarma Srl.		AUROZEB	Rosuvastatin/eze timibe	40 mg/10 mg	Film-coated tablet	Oral use
Italy	Teva Italia S.r.l.		Torasemide Teva Italia 10 mg compresse	Torasemide	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Latvia	Teva Pharma B.V.		Torasemide Teva 5 mg tabletēs	Torasemide	5 mg	Tablet	Oral use
Latvia	Teva Pharma B.V.		Torasemide Teva 10 mg tabletēs	Torasemide	10 mg	Tablet	Oral use
Lithuania	Teva Pharma B.V.		Torasemide Teva 5 mg tabletēs	Torasemide	5 mg	Tablet	Oral use
Lithuania	Teva Pharma B.V.		Torasemide Teva 10 mg tabletēs	Torasemide	10 mg	Tablet	Oral use
Luxembourg	Eurogenerics N.V./S.A.		Tramadol/Paracetamol EG 37,5/ 325mg comprimés pelliculés	Tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Norway	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Norway	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	10 mg	Tablet	Oral use
Poland	Accord Healthcare Polska Sp. z o.o.		Almiden	Amlodipine	5 mg	Tablet	Oral use
Poland	Accord Healthcare Polska Sp. z o.o.		Almiden	Amlodipine	10 mg	Tablet	Oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o.		Diuver	Torasemide	5 mg	Tablet	Oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o.		Diuver	Torasemide	10 mg	Tablet	Oral use
Portugal	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	10 mg	Tablet	Oral use
Portugal	Mylan, Lda.		Tianeptina Mylan	Tianeptine	12,5 mg	Film-coated tablet	Oral use
Portugal	Lupin Europe GmbH		Neluptin	Tianeptine	12,5 mg	Film-coated tablet	Oral use
Portugal	Mylan, Lda.		Tramadol + Paracetamol Mylan	Tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Romania	Antibiotice S.A		NOBIXAL 12,5 mg	Tianeptine	12,5 mg	Film-coated tablet	Oral use
Slovakia	Mylan Ireland Limited		Tianeptin Mylan 12,5 mg	Tianeptine	12,5 mg	Film-coated tablet	Oral use
Slovakia	Mylan Ireland Limited		Tramylpa 37,5 mg/325 mg	Tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Slovenia	Pliva Ljubljana d.o.o.		Diuver	Torsemide	5 mg	Tablet	Oral use
Slovenia	Pliva Ljubljana d.o.o.		Diuver	Torsemide	10 mg	Tablet	Oral use
Spain	Accord Healthcare S.L.U		AMLODIPINO ACCORD 5 mg comprimidos EFG	Amlodipine	5 mg	Tablet	Oral use
Spain	Accord Healthcare S.L.U		AMLODIPINO ACCORD 10 mg comprimidos EFG	Amlodipine	10 mg	Tablet	Oral use
Spain		Laboratorios Alter, S.A.	ARROX PLUS 10 mg/10 mg comprimidos recubiertos con película	Rosuvastatin/eze timibe	10 mg/10 mg	Film-coated tablet	Oral use
Spain		Laboratorios Alter, S.A.	ARROX PLUS 20 mg/10 mg comprimidos recubiertos con película	Rosuvastatin/eze timibe	20 mg/10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Spain		Laboratorios Alter, S.A.	ARROX PLUS 40 mg/10 mg comprimidos recubiertos con película	Rosuvastatin/ezetimibe	40 mg/10 mg	Film-coated tablet	Oral use
Spain		Laboratorios Alter, S.A.	ROSUVASTATINA/EZETIMIBA ALTER 10 mg/10mg comprimidos recubiertos con película	Rosuvastatin/ezetimibe	10 mg/10 mg	Film-coated tablet	Oral use
Spain		Laboratorios Alter, S.A.	ROSUVASTATINA/EZETIMIBA ALTER 20 mg/10mg comprimidos recubiertos con película	Rosuvastatin/ezetimibe	20 mg/10 mg	Film-coated tablet	Oral use
Spain	Laboratorio STADA, S.L.		Torasemida STADA 5 mg	Torasemide	5 mg	Tablet	Oral use
Spain	Laboratorio STADA, S.L.		Torasemida STADA 10 mg	Torasemide	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Laboratorio Stada, S.L.		TRAMADOL/PARACE TAMOL STADA 37,5 mg/325 mg comprimidos recubiertos con película EFG	Tramadol/parace tamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		TRAMADOL/PARACE TAMOL MYLAN PHARMACEUTICALS 37,5 mg/325 mg comprimidos recubiertos con película EFG	Tramadol/parace tamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Spain	Laboratorios Alter, S.A.		TRAMADOL/PARACE TAMOL ALTER 37,5 mg/325 mg comprimidos recubiertos con película EFG	Tramadol/parace tamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Sweden	Jubilant Pharmaceuticals N.V.		Amlodipin Jubilant	Amlodipine	5 mg	Tablet	Oral use
Sweden	Jubilant Pharmaceuticals N.V.		Amlodipin Jubilant	Amlodipine	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	5 mg	Tablet	Oral use
Sweden	Accord Healthcare B.V.		Amlodipin Accord	Amlodipine	10 mg	Tablet	Oral use
Sweden	Orifarm Generics A/S		Hydrokortison Orifarm	Hydrocortisone	10 mg	Tablet	Oral use
Sweden	Orifarm Generics A/S		Hydrokortison Orifarm	Hydrocortisone	20 mg	Tablet	Oral use
The Netherlands	Jubilant Pharmaceuticals N.V.		Amlodipine (als besilaat) Jubilant 5 mg, tabletten	Amlodipine	5 mg	Tablet	Oral use
The Netherlands	Jubilant Pharmaceuticals N.V.		Amlodipine (als besilaat) Jubilant 10 mg, tabletten	Amlodipine	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Accord Healthcare B.V.		Amlodipine (als besilaat) Accord 5 mg, tabletten	Amlodipine	5 mg	Tablet	Oral use
The Netherlands	Accord Healthcare B.V.		Amlodipine (als besilaat) Accord 10 mg, tabletten	Amlodipine	10 mg	Tablet	Oral use
The Netherlands	Aurora Biofarma Srl.		Rozemib 5 mg/10 mg, filmomhulde tabletten	Rosuvastatin/eze timibe	5 mg/10 mg	Film-coated tablet	Oral use
The Netherlands	Aurora Biofarma Srl.		Rozemib 10 mg/10 mg, filmomhulde tabletten	Rosuvastatin/eze timibe	10 mg/10 mg	Film-coated tablet	Oral use
The Netherlands	Aurora Biofarma Srl.		Rozemib 20 mg/10 mg, filmomhulde tabletten	Rosuvastatin/eze timibe	20 mg/10 mg	Film-coated tablet	Oral use
The Netherlands	Aurora Biofarma Srl.		Rozemib 40 mg/10 mg, filmomhulde tabletten	Rosuvastatin/eze timibe	40 mg/10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Accord Healthcare Limited		Amlodipine 5 mg Tablets	Amlodipine	5 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Accord Healthcare Limited		Amlodipine 10 mg Tablets	Amlodipine	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Teva UK Limited		Torasemide 5 mg Tablets	Torasemide	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Teva UK Limited		Torasemide 10 mg Tablets	Torasemide	10 mg	Tablet	Oral use

Annex IB. Medicinal products for which the marketing authorisations are recommended for suspension and marketing authorisation applications which do not satisfy the criteria for authorisation

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Austria		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 200 mg Filmtabletten	Ibuprofen	200 mg	Film-coated tablet	Oral use
Austria		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 400 mg	Ibuprofen	400 mg	Film-coated tablet	Oral use
Austria		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 600 mg	Ibuprofen	600 mg	Film-coated tablet	Oral use
Austria		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 800 mg	Ibuprofen	800 mg	Film-coated tablet	Oral use
Austria		Fair-med Healthcare GmbH	Ibuprofen FMH 200 mg Filmtabletten	Ibuprofen	200 mg	Film-coated tablet	Oral use
Austria		Fair-med Healthcare GmbH	Ibuprofen FMH 400 mg Filmtabletten	Ibuprofen	400 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Austria		Fair-med Healthcare GmbH	Ibuprofen FMH 600 mg Filmtabletten	Ibuprofen	600 mg	Film-coated tablet	Oral use
Austria		Fair-med Healthcare GmbH	Ibuprofen FMH 800 mg Filmtabletten	Ibuprofen	800 mg	Film-coated tablet	Oral use
Austria	Aziende Chimiche Riunite Angelini Francesco S.p.A		BoxaGrippal 200 mg/30 mg Weichkapseln	Ibuprofen/pseudo ephedrine	200 mg/30 mg	Capsule, soft	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		Atorvastatine Mylan 10 mg filmomhulde tabletten	Atorvastatin	10 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		Atorvastatine Mylan 20 mg filmomhulde tabletten	Atorvastatin	20 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		Atorvastatine Mylan 40 mg filmomhulde tabletten	Atorvastatin	40 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Belgium	Mylan S.P.R.L.- B.V.B.A.		Atorvastatine Mylan 80 mg filmomhulde tabletten	Atorvastatin	80 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		AtorvastaMylan 10 mg filmomhulde tabletten	Atorvastatin	10 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		AtorvastaMylan 20 mg filmomhulde tabletten	Atorvastatin	20 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		AtorvastaMylan 40 mg filmomhulde tabletten	Atorvastatin	40 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		AtorvastaMylan 80 mg filmomhulde tabletten	Atorvastatin	80 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		Mylanatorvastigen 10 mg [Film-coated tablet]	Atorvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Belgium	Mylan S.P.R.L.- B.V.B.A.		Mylanatorvastigen 20 mg [Film-coated tablet]	Atorvastatin	20 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		Mylanatorvastigen 40 mg [Film-coated tablet]	Atorvastatin	40 mg	Film-coated tablet	Oral use
Belgium	Mylan S.P.R.L.- B.V.B.A.		Mylanatorvastigen 80 mg [Film-coated tablet]	Atorvastatin	80 mg	Film-coated tablet	Oral use
Belgium	JOHNSON & JOHNSON CONSUMER N.V./S.A.		Bronchosedal Dextromethorphan Unidose 15 mg oral solution in sachet	Dextromethorpha n	15 mg/5 ml	Oral solution in sachet	Oral use
Belgium	Mylan bvba/sprl		Efavirenz Mylan	Efavirenz	600 mg	Film-coated tablet	Oral use
Belgium		Tillomed Pharma GmbH	Paliperidon Tillomed 3 mg, tabletten met verlengde afgifte	Paliperidone	3 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Belgium		Tillomed Pharma GmbH	Paliperidon Tillomed 6 mg, tabletten met verlengde afgifte	Paliperidone	6 mg	Prolonged-release tablet	Oral use
Belgium		Tillomed Pharma GmbH	Paliperidon Tillomed 9 mg, tabletten met verlengde afgifte	Paliperidone	9 mg	Prolonged-release tablet	Oral use
Belgium		Theramex Ireland Limited	Ovalute 100 mg, zachte capsule	Progesterone	100 mg	Capsule, soft	Oral use
Belgium		Theramex Ireland Limited	Ovalute 200 mg, zachte capsule	Progesterone	200 mg	Capsule, soft	Oral use
Belgium	Mylan bvba/sprl		Zolmitriptan ODIS Mylan	Zolmitriptan	2,5 mg	Orodispersible tablet	Oral use
Belgium	Mylan bvba/sprl		Zolmitriptan ODIS Mylan	Zolmitriptan	5 mg	Orodispersible tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Bulgaria	Mylan Ireland Limited		Atorgen 10 mg film - coated tablets	Atorvastatin	10 mg	Film-coated tablet	Oral use
Bulgaria	Mylan Ireland Limited		Atorgen 20 mg film - coated tablets	Atorvastatin	20 mg	Film-coated tablet	Oral use
Bulgaria		STADA Arzneimittel AG	Parabol	Ibuprofen/paracetamol	200 mg/500 mg	Capsule, soft	Oral use
Bulgaria	STADA Arzneimittel AG		Grippostad StopCold	Ibuprofen/pseudoephedrine	200 mg/30 mg	Capsule, soft	Oral use
Croatia		STADA Arzneimittel AG	Combodolor 200 mg/500 mg meke kapsule	Ibuprofen/paracetamol	200 mg/500 mg	Capsule, soft	Oral use
Cyprus	Generics Pharma Hellas Ltd		Atorvastatin Generics 10 mg film-coated tablets	Atorvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Generics Pharma Hellas Ltd		Atorvastatin Generics 20 mg film-coated tablets	Atorvastatin	20 mg	Film-coated tablet	Oral use
Cyprus	Generics Pharma Hellas Ltd		Atorvastatin Generics 40 mg film-coated tablets	Atorvastatin	40 mg	Film-coated tablet	Oral use
Cyprus	Hellas Ltd		Cencipral Tablet, Film Coated 30Mg	Cinacalcet	30 mg	Film-coated tablet	Oral use
Cyprus	Remedica LTD		Cencipral Tablet, Film Coated 60Mg	Cinacalcet	60 mg	Film-coated tablet	Oral use
Cyprus	Remedica LTD		Cencipral Tablet, Film Coated 90Mg	Cinacalcet	90 mg	Film-coated tablet	Oral use
Cyprus	Nassington LTD		Zircos Tablet, Film Coated 5Mg	Rosuvastatin	5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Nassington LTD		Zircos Tablet, Film Coated 10Mg	Rosuvastatin	10 mg	Film-coated tablet	Oral use
Cyprus	Nassington LTD		Zircos Tablet, Film Coated 20Mg	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Czech Republic	Mylan Ireland Limited		Atorvastatin Mylan 10 mg potahované tablety	Atorvastatin	10 mg	Film-coated tablet	Oral use
Czech Republic	Mylan Ireland Limited		Atorvastatin Mylan 20 mg potahované tablety	Atorvastatin	20 mg	Film-coated tablet	Oral use
Czech Republic	Mylan Ireland Limited		Atorvastatin Mylan 40 mg potahované tablety	Atorvastatin	40 mg	Film-coated tablet	Oral use
Czech Republic		Strides Pharma (Cyprus) Limited	IBUPROFEN STRIDES	Ibuprofen	200 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic		Strides Pharma (Cyprus) Limited	IBUPROFEN STRIDES	Ibuprofen	400 mg	Film-coated tablet	Oral use
Czech Republic		Strides Pharma (Cyprus) Limited	IBUPROFEN STRIDES	Ibuprofen	600 mg	Film-coated tablet	Oral use
Czech Republic		Strides Pharma (Cyprus) Limited	IBUPROFEN STRIDES	Ibuprofen	800 mg	Film-coated tablet	Oral use
Czech Republic		PharmConsul s.r.o.	Brumet (previously Ibuber)	Ibuprofen	400 mg	Capsule, soft	Oral use
Czech Republic		PharmConsul s.r.o.	Ibamed (previously Ibuprofen Pharmconsul)	Ibuprofen	400 mg	Capsule, soft	Oral use
Czech Republic		PharmConsul s.r.o.	Ibivil (previously Ibunex)	Ibuprofen	400 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic		STADA Arzneimittel AG	STADALGEN	Paracetamol/ibuprofen	200 mg/500 mg	Capsule, soft	Oral use
Czech Republic	Actavis Group PTC ehf.		FOXIS	Tramadol/paracetamol	37,5 mg/325 mg	film-coated tablet	oral use
Czech republic	Mylan Ireland Limited		PIOGLITAZON MYLAN	Pioglitazone	15 mg	Tablet	Oral use
Czech republic	Mylan Ireland Limited		PIOGLITAZON MYLAN	Pioglitazone	30 mg	Tablet	Oral use
Denmark	Orifarm Generics A/S		Alfacalcidol "Orifarm"	Alfacalcidol	0,25 mcg	Capsule, soft	Oral use
Denmark	Orifarm Generics A/S		Alfacalcidol "Orifarm"	Alfacalcidol	0,5 mcg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Denmark	Orifarm Generics A/S		Alfacalcidol "Orifarm"	Alfacalcidol	1 mcg	Capsule, soft	Oral use
Denmark	Mylan AB		Atorvastatin "Mylan"	Atorvastatin	10 mg	Film-coated tablet	Oral use
Denmark	Mylan AB		Atorvastatin "Mylan"	Atorvastatin	20 mg	Film-coated tablet	Oral use
Denmark	Mylan AB		Atorvastatin "Mylan"	Atorvastatin	40 mg	Film-coated tablet	Oral use
Denmark	Mylan AB		Atorvastatin "Mylan"	Atorvastatin	80 mg	Film-coated tablet	Oral use
Denmark		Amarox Pharma B.V.	Atorvastatin "Amarox"	Atorvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Denmark		Amarox Pharma B.V.	Atorvastatin "Amarox"	Atorvastatin	20 mg	Film-coated tablet	Oral use
Denmark		Amarox Pharma B.V.	Atorvastatin "Amarox"	Atorvastatin	40 mg	Film-coated tablet	Oral use
Denmark		Amarox Pharma B.V.	Atorvastatin "Amarox"	Atorvastatin	80 mg	Film-coated tablet	Oral use
Denmark	2care4 Generics Aps		Carexarit	Clonidine	25 mcg	Coated tablet	Oral use
Denmark		Strides Pharma (Cyprus) Limited	Ibuprofen "Strides"	Ibuprofen	200 mg	Film-coated tablet	Oral use
Denmark		Strides Pharma (Cyprus) Limited	Ibuprofen "Strides"	Ibuprofen	400 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Denmark		Strides Pharma (Cyprus) Limited	Ibuprofen "Strides"	Ibuprofen	600 mg	Film-coated tablet	Oral use
Denmark		Strides Pharma (Cyprus) Limited	Ibuprofen "Strides"	Ibuprofen	800 mg	Film-coated tablet	Oral use
Denmark	Bristol Laboratories Ltd.		Ibuprofen "Bril"	Ibuprofen	200 mg	Film-coated tablet	Oral use
Denmark	Bristol Laboratories Ltd.		Ibuprofen "Bril"	Ibuprofen	400 mg	Film-coated tablet	Oral use
Denmark	Bristol Laboratories Ltd.		Ibuprofen "Bril"	Ibuprofen	600 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Denmark	Orifarm Generics A/S		Farmidur	Isosorbide mononitrate	30 mg	Prolonged-release tablet	Oral use
Denmark	Aristo Pharma GmbH		Kagitz	Quetiapine	50 mg	Prolonged-release tablet	Oral use
Denmark	Aristo Pharma GmbH		Kagitz	Quetiapine	300 mg	Prolonged-release tablet	Oral use
Denmark	Aristo Pharma GmbH		Kagitz	Quetiapine	400 mg	Prolonged-release tablet	Oral use
Finland	Orifarm Generics A/S		Alfacalcidol Orifarm	Alfacalcidol	0,25 mcg	Capsule, soft	Oral use
Finland	Orifarm Generics A/S		Alfacalcidol Orifarm	Alfacalcidol	0,5 mcg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Finland	Orifarm Generics A/S		Alfacalcidol Orifarm	Alfacalcidol	1 mcg	Capsule, soft	Oral use
Finland		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	200 mg	Film-coated tablet	Oral use
Finland		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	400 mg	Film-coated tablet	Oral use
Finland		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	600 mg	Film-coated tablet	Oral use
Finland		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	800 mg	Film-coated tablet	Oral use
Finland		Fair-med Healthcare GmbH	Ibuprofen Fmh	Ibuprofen	200 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Finland		Fair-med Healthcare GmbH	Ibuprofen Fmh	Ibuprofen	400 mg	Film-coated tablet	Oral use
Finland		Fair-med Healthcare GmbH	Ibuprofen Fmh	Ibuprofen	600 mg	Film-coated tablet	Oral use
Finland		Fair-med Healthcare GmbH	Ibuprofen Fmh	Ibuprofen	800 mg	Film-coated tablet	Oral use
France	Viartis Santé		Atorvastatine Viartis 10mg, comprimé pelliculé	Atorvastatin	10 mg	Film-coated tablet	Oral use
France	Viartis Santé		Atorvastatine Viartis 20mg, comprimé pelliculé	Atorvastatin	20 mg	Film-coated tablet	Oral use
France	Viartis Santé		Atorvastatine Viartis 40mg, comprimé pelliculé	Atorvastatin	40 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
France	Viartis Santé		Atorvastatine Viartis 80mg, comprimé pelliculé	Atorvastatin	80 mg	Film-coated tablet	Oral use
France	Mylan SAS		EFAVIRENZ MYLAN 600 mg, comprimé pelliculé	Efavirenz	600 mg	Film-coated tablet	Oral use
France		Fair-Med Healthcare GmbH	IBUPROFÈNE FMH 200 mg, comprimé pelliculé	Ibuprofen	200 mg	Film-coated tablet	Oral use
France		Fair-Med Healthcare GmbH	IBUPROFÈNE FMH 400 mg, comprimé pelliculé	Ibuprofen	400 mg	Film-coated tablet	Oral use
France		Fair-Med Healthcare GmbH	IBUPROFÈNE FMH 600 mg, comprimé pelliculé	Ibuprofen	600 mg	Film-coated tablet	Oral use
France		Fair-Med Healthcare GmbH	IBUPROFÈNE FMH 800 mg, comprimé pelliculé	Ibuprofen	800 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
France		Theramex Ireland Limited	OVALUTE 100 mg, capsule molle	Progesterone	100 mg	Capsule, soft	Oral use
France		Theramex Ireland Limited	OVALUTE 200 mg, capsule molle	Progesterone	200 mg	Capsule, soft	Oral use
France	Mylan SAS		ZOLMITRIPTAN MYLAN 2,5 mg, comprimé pelliculé	Zolmitriptan	2,5 mg	Film-coated tablet	Oral use
France	Mylan SAS		ZOLMITRIPTAN MYLAN 2,5 mg, comprimé orodispersible	Zolmitriptan	2,5 mg	Orodispersible tablet	Oral use
Germany	1 A Pharma GmbH		Alfacalcidol - 1 A Pharma 0,25 mcg Weichkapseln	Alfacalcidol	0,25 mcg	Capsule, soft	Oral use
Germany	1 A Pharma GmbH		Alfacalcidol - 1 A Pharma 0,5 mcg Weichkapseln	Alfacalcidol	0,5 mcg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany	1 A Pharma GmbH		Alfacalcidol - 1 A Pharma 1 mcg Weichkapseln	Alfacalcidol	1 mcg	Capsule, soft	Oral use
Germany	Hexal AG		Alfacalcidol HEXAL 0.25 mcg Weichkapseln	Alfacalcidol	0,25 mcg	Capsule, soft	Oral use
Germany	Hexal AG		Alfacalcidol HEXAL 0.5 mcg Weichkapseln	Alfacalcidol	0,5 mcg	Capsule, soft	Oral use
Germany	Hexal AG		Alfacalcidol HEXAL 1 mcg Weichkapseln	Alfacalcidol	1 mcg	Capsule, soft	Oral use
Germany		Amarox Pharma B.V.	Atorvastatin AmaroX 10 mg Filmtabletten	Atorvastatin	10 mg	Film-coated tablet	Oral use
Germany		Amarox Pharma B.V.	Atorvastatin AmaroX 20 mg Filmtabletten	Atorvastatin	20 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Amarox Pharma B.V.	Atorvastatin Amarox 40 mg Filmtabletten	Atorvastatin	40 mg	Film-coated tablet	Oral use
Germany		Amarox Pharma B.V.	Atorvastatin Amarox 80 mg Filmtabletten	Atorvastatin	80 mg	Film-coated tablet	Oral use
Germany	Tillomed Pharma GmbH		Ezetimib/Simvastatin Tillomed 10 mg/10 mg Tabletten	Ezetimibe/simvastatin	10 mg/10 mg	Tablet	Oral use
Germany	Tillomed Pharma GmbH		Ezetimib/Simvastatin Tillomed 10 mg/20 mg Tabletten	Ezetimibe/simvastatin	10 mg/20 mg	Tablet	Oral use
Germany	Tillomed Pharma GmbH		Ezetimib/Simvastatin Tillomed 10 mg/40 mg Tabletten	Ezetimibe/simvastatin	10 mg/40 mg	Tablet	Oral use
Germany	Tillomed Pharma GmbH		Ezetimib/Simvastatin Tillomed 10 mg/80 mg Tabletten	Ezetimibe/simvastatin	10 mg/80 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 200 mg Filmtabletten	Ibuprofen	200 mg	Film-coated tablet	Oral use
Germany		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 400 mg Filmtabletten	Ibuprofen	400 mg	Film-coated tablet	Oral use
Germany		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 600 mg Filmtabletten	Ibuprofen	600 mg	Film-coated tablet	Oral use
Germany		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 800 mg Filmtabletten	Ibuprofen	800 mg	Film-coated tablet	Oral use
Germany		Fair-Med Healthcare GmbH	Ibuprofen FMH 200 mg Filmtabletten	Ibuprofen	200 mg	Film-coated tablet	Oral use
Germany		Fair-Med Healthcare GmbH	Ibuprofen FMH 400 mg Filmtabletten	Ibuprofen	400 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Fair-Med Healthcare GmbH	Ibuprofen FMH 600 mg Filmtabletten	Ibuprofen	600 mg	Film-coated tablet	Oral use
Germany		Fair-Med Healthcare GmbH	Ibuprofen FMH 800 mg Filmtabletten	Ibuprofen	800 mg	Film-coated tablet	Oral use
Germany	Brillpharma (Ireland) Limited		Ibuprofen Bril	Ibuprofen	200 mg	Film-coated tablet	Oral use
Germany	Brillpharma (Ireland) Limited		Ibuprofen Bril	Ibuprofen	400 mg	Film-coated tablet	Oral use
Germany	Brillpharma (Ireland) Limited		Ibuprofen Bril	Ibuprofen	600 mg	Film-coated tablet	Oral use
Germany	Angelini Pharma Italia Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.		BoxaGrippal 200 mg/30 mg Weichkapseln	Ibuprofen/pseudo ephedrine	200 mg/30 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany		PharmaMatch B.V.	Ibuprofen 200 mg/ Pseudoephedrine 30 mg Kapsel	Ibuprofen/pseudo ephedrine	200 mg/30 mg	Capsule, soft	Oral use
Germany	Infectopharm Arzneimittel und Consilium GmbH		MetfoLiquid Geriasan 1000 mg/5 ml, Lösung zum Einnehmen	Metformin	1000 mg/5 ml	Oral solution	Oral use
Germany	Tillomed Pharma GmbH		Oxybutyninhydrochlorid Creative 2,5 mg Tabletten	Oxybutynin	2,5 mg	Tablet	Oral use
Germany	Tillomed Pharma GmbH		Oxybutyninhydrochlorid Creative 5 mg Tabletten	Oxybutynin	5 mg	Tablet	Oral use
Germany		PharmaMatch B.V.	Progesteron PharmaMatch 100 mg Weichkapseln	Progesterone	100 mg	Capsule, soft	Oral use
Germany		PharmaMatch B.V.	Progesteron PharmaMatch 200 mg Weichkapseln	Progesterone	200 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany		Theramex Ireland Limited	Ovalute 100 mg Weichkapseln	Progesterone	100 mg	Capsule, soft	Oral use
Germany		Theramex Ireland Limited	Ovalute 200 mg Weichkapseln	Progesterone	200 mg	Capsule, soft	Oral use
Germany		Micro Labs GmbH	Rosuvastatin Micro Labs 10 mg Filmtabletten	Rosuvastatin	10 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Rosuvastatin Micro Labs 20 mg Filmtabletten	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Germany		Micro Labs GmbH	Rosuvastatin Micro Labs 40 mg Filmtabletten	Rosuvastatin	40 mg	Film-coated tablet	Oral use
Germany	Mylan Germany GmbH		Zolmitriptan dura Filmtabletten	Zolmitriptan	2,5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Mylan Germany GmbH		Zolmitriptan dura Filmtabletten	Zolmitriptan	5 mg	Film-coated tablet	Oral use
Germany	Mylan Germany GmbH		Zolmitriptan dura Schmelztabletten	Zolmitriptan	2,5 mg	Orodispersible tablet	Oral use
Germany	Mylan Germany GmbH		Zolmitriptan dura Schmelztabletten	Zolmitriptan	5 mg	Orodispersible tablet	Oral use
Greece	Mylan Ireland Limited		Atorvastatin/Mylan Film-coated Tablets	Atorvastatin	10 mg	Film-coated tablet	Oral use
Greece	Mylan Ireland Limited		Atorvastatin/Mylan Film-coated Tablets	Atorvastatin	20 mg	Film-coated tablet	Oral use
Greece	Mylan Ireland Limited		Atorvastatin/Mylan Film-coated Tablets	Atorvastatin	40 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Bennet Pharmaceutica L A.E.		Memaben	Memantine	5 mg + 10 mg + 15 mg + 20 mg	Soluble tablet	Oral use
Greece	Bennet Pharmaceutica L A.E.		Memaben	Memantine	10 mg	Soluble tablet	Oral use
Greece	Bennet Pharmaceutica L A.E.		Memaben	Memantine	20 mg	Soluble tablet	Oral use
Greece	Vita Longa I.K.E. (Vita Longa P.C.)		Lycis	Metformin	1000 mg/5 ml	Oral solution	Oral use
Greece		Tillomed Pharma GmbH	Paliperidone Tillomed	Paliperidone	3 mg	Prolonged-release tablet	Oral use
Greece		Tillomed Pharma GmbH	Paliperidone Tillomed	Paliperidone	6 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Greece		Tillomed Pharma GmbH	Paliperidone Tillomed	Paliperidone	9 mg	Prolonged-release tablet	Oral use
Greece	Nassington LTD		Rosupose	Rosuvastatin	5 mg	Film-coated tablet	Oral use
Greece	Nassington LTD		Rosupose	Rosuvastatin	10 mg	Film-coated tablet	Oral use
Greece	Nassington LTD		Rosupose	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Greece	Medicair Bioscience Laboratories CY LTD		Rosuvanox	Rosuvastatin	5 mg	Film-coated tablet	Oral use
Greece	Medicair Bioscience Laboratories CY LTD		Rosuvanox	Rosuvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Medicair Bioscience Laboratories CY LTD		Rosuvanox	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Greece	VELKA Hellas A.E.B.E.		Rosuvastatin/Velka	Rosuvastatin	5 mg	Film-coated tablet	Oral use
Greece	VELKA Hellas A.E.B.E.		Rosuvastatin/Velka	Rosuvastatin	10 mg	Film-coated tablet	Oral use
Greece	VELKA Hellas A.E.B.E.		Rosuvastatin/Velka	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Greece	Lavipharm AE		Rovastine	Rosuvastatin	5 mg	Film-coated tablet	Oral use
Greece	Lavipharm AE		Rovastine	Rosuvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Lavipharm AE		Rovastine	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Greece	Rafarm A.E.B.E		Zircos	Rosuvastatin	5 mg	Film-coated tablet	Oral use
Greece	Rafarm A.E.B.E		Zircos	Rosuvastatin	10 mg	Film-coated tablet	Oral use
Greece	Rafarm A.E.B.E		Zircos	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Greece	Nassington LTD		Zolvara	Rosuvastatin	5 mg	Film-coated tablet	Oral use
Greece	Nassington LTD		Zolvara	Rosuvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Nassington LTD		Zolvara	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Greece		Nassington LTD	Mesi-2	Sitagliptin/metformin	50 mg/850 mg	Film-coated tablet	Oral use
Greece		Nassington LTD	Mesi-2	Sitagliptin/metformin	50 mg/1000 mg	Film-coated tablet	Oral use
Greece		Nassington LTD	Metogline	Vildagliptin/metformin	50 mg/850 mg	Film-coated tablet	Oral use
Greece		Nassington LTD	Metogline	Vildagliptin/metformin	50 mg/1000 mg	Film-coated tablet	Oral use
Greece		Nassington LTD	PERIVALE	Sitagliptin/metformin	50 mg/850 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Greece		Nassington LTD	PERIVALE	Sitagliptin/metformin	50 mg/1000 mg	Film-coated tablet	Oral use
Greece		Verisfield AE	Toogluc	Sitagliptin/metformin	50 mg/850 mg	Film-coated tablet	Oral use
Greece		Verisfield AE	Toogluc	Sitagliptin/metformin	50 mg/1000 mg	Film-coated tablet	Oral use
Hungary		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	200 mg	Film-coated tablet	Oral use
Hungary		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	400 mg	Film-coated tablet	Oral use
Hungary		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	600 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Hungary		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	800 mg	Film-coated tablet	Oral use
Hungary		STADA Arzneimittel AG	Dolostad 200 mg/500 mg lágy kapszula	Ibuprofen/paracetamol	200 mg/500 mg	Capsule, soft	Oral use
Hungary		STADA Arzneimittel AG	Dolostad 200 mg/500 mg lágy kapszula	Ibuprofen/paracetamol	200 mg/500 mg	Capsule, soft	Oral use
Iceland	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	200 mg	Film-coated tablet	Oral use
Iceland	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	400 mg	Film-coated tablet	Oral use
Iceland	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	600 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Ireland	Bluefish Pharmaceuticals AB		Co-amoxiclav Bluefish 500 mg/125 mg film-coated tablets	Amoxicillin/clavulanic acid	500 mg/125 mg	Film-coated tablet	Oral use
Ireland	McDermott Laboratories Ltd		Atorvastatin Mylan 10 mg film-coated tablets	Atorvastatin	10 mg	Film-coated tablet	Oral use
Ireland	McDermott Laboratories Ltd		Atorvastatin Mylan 20 mg film-coated tablets	Atorvastatin	20 mg	Film-coated tablet	Oral use
Ireland	McDermott Laboratories Ltd		Atorvastatin Mylan 40 mg film-coated tablets	Atorvastatin	40 mg	Film-coated tablet	Oral use
Ireland	McDermott Laboratories Ltd		Atorvastatin Mylan 80 mg film-coated tablets	Atorvastatin	80 mg	Film-coated tablet	Oral use
Ireland	Pinewood Laboratories Limited		Atorvastatin 10 mg Film-Coated Tablets	Atorvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Ireland	Pinewood Laboratories Limited		Atorvastatin 20 mg Film-Coated Tablets	Atorvastatin	20 mg	Film-coated tablet	Oral use
Ireland	Pinewood Laboratories Limited		Atorvastatin 40 mg Film-Coated Tablets	Atorvastatin	40 mg	Film-coated tablet	Oral use
Ireland	Pinewood Laboratories Limited		Atorvastatin 80 mg Film-Coated Tablets	Atorvastatin	80 mg	Film-coated tablet	Oral use
Ireland	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	200 mg	Film-coated tablet	Oral use
Ireland	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	400 mg	Film-coated tablet	Oral use
Ireland	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	600 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Ireland		Clonmel Healthcare Ltd	Easofen Cold & Flu	Ibuprofen/pseudo ephedrine	200 mg /20 mg	Capsule, soft	Oral use
Ireland	Clonmel Healthcare Ltd,		Paralief 500 mg soft capsules	Paracetamol	500 mg	Capsule, soft	Oral use
Ireland		Theramex Ireland Limited	Ovalute	Progesterone	100 mg	Capsule, soft	Oral use
Ireland		Theramex Ireland Limited	Ovalute	Progesterone	200 mg	Capsule, soft	Oral use
Italy	Stewart Italia S.r.l.		Stemox	Amoxicillin/ clavulanic acid	400 mg/5 ml + 57 mg/5 ml	Powder for oral suspension	Oral use
Italy	Mylan S.p.A.		Atorvastatina Mylan Generics Italia	Atorvastatin	10 mg	Film-coated tablet	Oral use
Italy	Mylan S.p.A.		Atorvastatina Mylan Generics Italia	Atorvastatin	20 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Mylan S.p.A.		Atorvastatina Mylan Generics Italia	Atorvastatin	40 mg	Film-coated tablet	Oral use
Italy	Mylan S.p.A.		Atorvastatina Mylan Generics Italia	Atorvastatin	80 mg	Film-coated tablet	Oral use
Italy	Mylan S.p.A.		Efavirenz Mylan	Efavirenz	600 mg	Film-coated tablet	Oral use
Italy		Tillomed Pharma Gmbh	Paliperidone Tillomed	Paliperidone	3 mg	Prolonged-release tablet	Oral use
Italy		Tillomed Pharma Gmbh	Paliperidone Tillomed	Paliperidone	6 mg	Prolonged-release tablet	Oral use
Italy		Tillomed Pharma Gmbh	Paliperidone Tillomed	Paliperidone	9 mg	Prolonged-release tablet	Oral use
Italy	Mylan S.p.A.		Pioglitazone Mylan	Pioglitazone	15 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Mylan S.p.A.		Pioglitazone Mylan	Pioglitazone	30 mg	Tablet	Oral use
Italy	Mylan S.p.A.		Zolmitriptan Mylan Generics	Zolmitriptan	2,5 mg	Film-coated tablet	Oral use
Italy	Mylan S.p.A.		Zolmitriptan Mylan Generics	Zolmitriptan	5 mg	Film-coated tablet	Oral use
Luxembourg	JOHNSON & JOHNSON CONSUMER N.V./S.A.		Bronchosedal Dextromethorphan Unidose 15 mg oral solution en sachet	Dextromethorphan	15 mg/5 ml	Oral solution in sachet	Oral use
Luxembourg		PharmaMatch B.V.	Progesteron PharmaMatch 100 mg Weichkapseln	Progesterone	100 mg	Capsule, soft	Oral use
Luxembourg		PharmaMatch B.V.	Progesteron PharmaMatch 200 mg Weichkapseln	Progesterone	200 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Luxembourg	Micro Labs GmbH		Rosuvastatin Micro Labs 10 mg Filmtabletten	Rosuvastatin	10 mg	Film-coated tablet	Oral use
Luxembourg	Micro Labs GmbH		Rosuvastatin Micro Labs 20 mg Filmtabletten	Rosuvastatin	20 mg	Film-coated tablet	Oral use
Luxembourg	Micro Labs GmbH		Rosuvastatin Micro Labs 40 mg Filmtabletten	Rosuvastatin	40 mg	Film-coated tablet	Oral use
Luxembourg	Mylan bvba/sprl		Zolmitriptan ODIS Mylan 2,5 mg comprimé orodispersible	Zolmitriptan	2,5 mg	Orodispersible tablet	Oral use
Malta	RIA Generics Ireland Limited		Nefopam Hydrochloride 30 mg film-coated tablets	Nefopam	30 mg	Film-coated tablet	Oral use
Norway	Orifarm Generics A/S		Alfacalcidol "Orifarm"	Alfacalcidol	0,25 mcg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Norway	Orifarm Generics A/S		Alfacalcidol "Orifarm"	Alfacalcidol	0,5 mcg	Capsule, soft	Oral use
Norway	Orifarm Generics A/S		Alfacalcidol "Orifarm"	Alfacalcidol	1 mcg	Capsule, soft	Oral use
Norway	Pensa Pharma AB		Atorvastatin Pensa	Atorvastatin	10 mg	Film-coated tablet	Oral use
Norway	Pensa Pharma AB		Atorvastatin Pensa	Atorvastatin	20 mg	Film-coated tablet	Oral use
Norway	Pensa Pharma AB		Atorvastatin Pensa	Atorvastatin	40 mg	Film-coated tablet	Oral use
Norway	Pensa Pharma AB		Atorvastatin Pensa	Atorvastatin	80 mg	Film-coated tablet	Oral use
Norway	2care4 Generics Aps		Carexarit	Clonidine	25 mcg	Coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Norway	Aristo Pharma GmbH		Kagitz	Quetiapine	50 mg	Prolonged-release tablet	Oral use
Norway	Aristo Pharma GmbH		Kagitz	Quetiapine	300 mg	Prolonged-release tablet	Oral use
Norway	Aristo Pharma GmbH		Kagitz	Quetiapine	400 mg	Prolonged-release tablet	Oral use
Poland	Bluefish Pharmaceuticals AB		Co-amoxiclav Bluefish 500 mg/125 mg film- coated tablets	Amoxicillin/ clavulanic acid	500 mg/125 mg	Film-coated tablet	Oral use
Poland	Mylan Ireland Limited		Atorvagen	Atorvastatin	10 mg	Film-coated tablet	Oral use
Poland	Mylan Ireland Limited		Atorvagen	Atorvastatin	20 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Poland	Mylan Ireland Limited		Atorvagen	Atorvastatin	40 mg	Film-coated tablet	Oral use
Poland	Artespharm Sp. z o.o.		Atostat	Atorvastatin	10 mg	Film-coated tablet	Oral use
Poland	Artespharm Sp. z o.o.		Atostat	Atorvastatin	20 mg	Film-coated tablet	Oral use
Poland	Artespharm Sp. z o.o.		Atostat	Atorvastatin	40 mg	Film-coated tablet	Oral use
Poland	Artespharm Sp. z o.o.		Atostat	Atorvastatin	80 mg	Film-coated tablet	Oral use
Poland		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	200 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Poland		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	400 mg	Film-coated tablet	Oral use
Poland		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	600 mg	Film-coated tablet	Oral use
Poland		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	800 mg	Film-coated tablet	Oral use
Poland	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	200 mg	Film-coated tablet	Oral use
Poland	US Pharmacia Sp. z o.o.		Ibuprom Ultramax Sprint	Ibuprofen	600 mg	Capsule, soft	Oral use
Poland	US Pharmacia Sp. z o.o.		Ibuprom Zatoki Sprint	Ibuprofen/pseudo ephedrine	200 mg/30 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Poland		Synoptis Pharma Sp. z o.o.	Ifedrin ZATOKI APTEO MED	Ibuprofen/pseudo ephedrine	200 mg/30 mg	Capsule, soft	Oral use
Portugal	Laboratórios Basi - Indústria Farmacêutica, S.A		Amoxicilina + Ácido Clavulânico Basi	Amoxicillin/ clavulanic acid	250 mg/5 ml + 62,5 mg/5 ml	Powder for oral suspension	Oral use
Portugal	Laboratórios Basi - Indústria Farmacêutica, S.A		Amoxicilina + Ácido Clavulânico Basi	Amoxicillin/ clavulanic acid	400 mg/5 ml + 57 mg/5 ml	Powder for oral suspension	Oral use
Portugal	Mylan Lda		Atorvastatine Mylan	Atorvastatin	10 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Atorvastatine Mylan	Atorvastatin	20 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Atorvastatine Mylan	Atorvastatin	40 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Mylan Lda		Atorvastatine Mylan	Atorvastatin	80 mg	Film-coated tablet	Oral use
Portugal	Mylan Lda		Efavirenz Mylan	Efavirenz	600 mg	Film-coated tablet	Oral use
Portugal	Abdi Farma Unipessoal Limitada		Etolyn	Etodolac	600 mg	Prolonged-release tablet	Oral use
Portugal	STADA Lda.		Pramolix 500 mg cápsula mole	Paracetamol	500 mg	Capsule, soft	Oral use
Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A.		Algik Gripe	Paracetamol/pseudoephedrine	500 mg/30 mg	Capsule, soft	Oral use
Portugal	Mylan, Lda.		Pioglitazona Mylan	Pioglitazone	15 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Mylan, Lda.		Pioglitazona Mylan	Pioglitazone	30 mg	Tablet	Oral use
Portugal	Mylan, Lda.		Pioglitazona Mylan	Pioglitazone	45 mg	Tablet	Oral use
Portugal	Alter, S.A.		Rosuvastatina + Ezetimiba Alter	Rosuvastatin/eze timibe	5 mg/10 mg	Film-coated tablet	Oral use
Portugal	Alter, S.A.		Rosuvastatina + Ezetimiba Alter	Rosuvastatin/eze timibe	10 mg/10 mg	Film-coated tablet	Oral use
Portugal	Alter, S.A.		Rosuvastatina + Ezetimiba Alter	Rosuvastatin/eze timibe	20 mg/10 mg	Film-coated tablet	Oral use
Portugal	Alter, S.A.		Rosuvastatina + Ezetimiba Alter	Rosuvastatin/eze timibe	40 mg/10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Portugal	Farmalter - Produtos Farmacêuticos e Dietéticos, Lda.		Rosuvastatina + Ezetimiba Bistenibe	Rosuvastatin/eze timibe	5 mg/10 mg	Film-coated tablet	Oral use
Portugal	Farmalter - Produtos Farmacêuticos e Dietéticos, Lda.		Rosuvastatina + Ezetimiba Bistenibe	Rosuvastatin/eze timibe	10 mg/10 mg	Film-coated tablet	Oral use
Portugal	Farmalter - Produtos Farmacêuticos e Dietéticos, Lda.		Rosuvastatina + Ezetimiba Bistenibe	Rosuvastatin/eze timibe	20 mg/10 mg	Film-coated tablet	Oral use
Portugal	Farmalter - Produtos Farmacêuticos e Dietéticos, Lda.		Rosuvastatina + Ezetimiba Bistenibe	Rosuvastatin/eze timibe	40 mg/10 mg	Film-coated tablet	Oral use
Romania	S.C. Sandoz SRL		ALFACALCIDOL SANDOZ 0,25 µg	Alfacalcidol	0,25 mg	Capsule, soft	Oral use
Romania	S.C. Sandoz SRL		ALFACALCIDOL SANDOZ 0,5 µg	Alfacalcidol	0,5 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Romania		Strides Pharma (Cyprus) Limited	Ibuprofen STRIDES	Ibuprofen	200 mg	Film-coated tablet	Oral use
Romania		Strides Pharma (Cyprus) Limited	Ibuprofen STRIDES	Ibuprofen	400 mg	Film-coated tablet	Oral use
Romania		Strides Pharma (Cyprus) Limited	Ibuprofen STRIDES	Ibuprofen	600 mg	Film-coated tablet	Oral use
Romania		Strides Pharma (Cyprus) Limited	Ibuprofen STRIDES	Ibuprofen	800 mg	Film-coated tablet	Oral use
Romania		STADA Arzneimittel AG	IBUPROFEN/ PARACETAMOL 200 mg/500 mg	Ibuprofen/paracetamol	200 mg/500 mg	Capsule, soft	Oral use
Romania		PharmaMatch B.V.	Buprofess raceala si Gripa	Ibuprofen/pseudoephedrine	200 mg/30 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Slovakia	Sandoz Pharmaceuticals d.d.		Alfacalcidol SANDOZ 1 mikrogram mäkké kapsuly	Alfacalcidol	1 mcg	Capsule, soft	Oral use
Slovakia	Mylan Ireland Limited		Atorvastatine Mylan	Atorvastatin	20 mg	Film-coated tablet	Oral use
Slovakia	Mylan Ireland Limited		Atorvastatine Mylan	Atorvastatin	40 mg	Film-coated tablet	Oral use
Slovakia		STADA Arzneimittel AG	Ibumol	Ibuprofen/paracetamol	200 mg/500 mg	Capsule, soft	Oral use
Slovakia	STADA Arzneimittel AG		Parastad mäkké kapsuly	Paracetamol	500 mg	Capsule, soft	Oral use
Slovenia	Mylan Ireland Limited		Atorvastatin Mylan	Atorvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Slovenia	Mylan Ireland Limited		Atorvastatin Mylan	Atorvastatin	20 mg	Film-coated tablet	Oral use
Slovenia	Mylan Ireland Limited		Atorvastatin Mylan	Atorvastatin	40 mg	Film-coated tablet	Oral use
Slovenia		STADA Arzneimittel AG	Ibumol	Ibuprofen/paracetamol	200 mg/500 mg	Capsule, soft	Oral use
Spain	Mylan Pharmaceuticals, S.L.		ATORVASTATINA MYLAN 10 mg comprimidos recubiertos con película EFG	Atorvastatin	10 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		ATORVASTATINA MYLAN 20 mg comprimidos recubiertos con película EFG	Atorvastatin	20 mg	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals, S.L.		ATORVASTATINA MYLAN 40 mg comprimidos recubiertos con película EFG	Atorvastatin	40 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Mylan Pharmaceuticals, S.L.		ATORVASTATINA MYLAN 80 mg comprimidos recubiertos con película EFG	Atorvastatin	80 mg	Film-coated tablet	Oral use
Spain	Tarbis Farma, S.L.		ATORVASTATINA TARBIS FARMA 10 mg comprimidos recubiertos con película EFG	Atorvastatin	10 mg	Film-coated tablet	Oral use
Spain	Tarbis Farma, S.L.		ATORVASTATINA TARBIS FARMA 20 mg comprimidos recubiertos con película EFG	Atorvastatin	20 mg	Film-coated tablet	Oral use
Spain	Tarbis Farma, S.L.		ATORVASTATINA TARBIS FARMA 40 mg comprimidos recubiertos con película EFG	Atorvastatin	40 mg	Film-coated tablet	Oral use
Spain	Tarbis Farma, S.L.		ATORVASTATINA TARBIS FARMA 80 mg comprimidos recubiertos con película EFG	Atorvastatin	80 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Spain	Johnson and Johnson, S.A.		INISTON TUSIV 15 mg solución oral en sobre	Dextromethorphan	15 mg/5 ml	Oral solution in sachet	Oral use
Spain	Mylan Pharmaceutica LS, S.L.		EFAVIRENZ MYLAN 600 mg comprimidos recubiertos con película EFG	Efavirenz	600 mg	Film-coated tablet	Oral use
Spain		Fair-med Healthcare GmbH	IBUPROFEN FMH 200 mg comprimidos recubiertos con película EFG	Ibuprofen	200 mg	Film-coated tablet	Oral use
Spain		Fair-med Healthcare GmbH	IBUPROFEN FMH 400 mg comprimidos recubiertos con película EFG	Ibuprofen	400 mg	Film-coated tablet	Oral use
Spain		Fair-med Healthcare GmbH	IBUPROFEN FMH 600 mg comprimidos recubiertos con película EFG	Ibuprofen	600 mg	Film-coated tablet	Oral use
Spain		Fair-med Healthcare GmbH	IBUPROFEN FMH 800 mg comprimidos recubiertos con película EFG	Ibuprofen	800 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Spain		Laboratorios Tillomed Spain S.L.U.	PALIPERIDONA TILLOMED 3 mg comprimidos de liberación controlada	Paliperidone	3 mg	Prolonged-release tablet	Oral use
Spain		Laboratorios Tillomed Spain S.L.U.	PALIPERIDONA TILLOMED 6 mg comprimidos de liberación controlada	Paliperidone	6 mg	Prolonged-release tablet	Oral use
Spain		Laboratorios Tillomed Spain S.L.U.	PALIPERIDONA TILLOMED 9 mg comprimidos de liberación controlada	Paliperidone	9 mg	Prolonged-release tablet	Oral use
Spain		Theramex Ireland Limited	OVALUTE 100 mg cápsulas blandas	Progesterone	100 mg	Capsule, soft	Oral use
Spain	Aurovitas Spain, S.A.U.		TRAMADOL/PARACE TAMOL AUROVITAS SPAIN 37,5 mg/325 mg comprimidos recubiertos con película EFG	Tramadol/paracetamol	37,5 mg/325 mg	Film-coated tablet	Oral use
Sweden	Orifarm Generics A/S		Alfacalcidol Orifarm	Alfacalcidol	0,25 mcg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Orifarm Generics A/S		Alfacalcidol Orifarm	Alfacalcidol	0,5 mcg	Capsule, soft	Oral use
Sweden	Orifarm Generics A/S		Alfacalcidol Orifarm	Alfacalcidol	1 mcg	Capsule, soft	Oral use
Sweden	Mylan AB		Atorvastatin Mylan	Atorvastatin	10 mg	Film-coated tablet	Oral use
Sweden	Mylan AB		Atorvastatin Mylan	Atorvastatin	20 mg	Film-coated tablet	Oral use
Sweden	Mylan AB		Atorvastatin Mylan	Atorvastatin	40 mg	Film-coated tablet	Oral use
Sweden	Mylan AB		Atorvastatin Mylan	Atorvastatin	80 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Amarox Pharma B.V.		Atorvastatin Amarox	Atorvastatin	10 mg	Film-coated tablet	Oral use
Sweden	Amarox Pharma B.V.		Atorvastatin Amarox	Atorvastatin	20 mg	Film-coated tablet	Oral use
Sweden	Amarox Pharma B.V.		Atorvastatin Amarox	Atorvastatin	40 mg	Film-coated tablet	Oral use
Sweden	Amarox Pharma B.V.		Atorvastatin Amarox	Atorvastatin	80 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Flucloxacillin Sandoz	Flucloxacillin	500 mg	Film-coated tablet	Oral use
Sweden	Sandoz A/S		Flucloxacillin Sandoz	Flucloxacillin	750 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Sweden		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	200 mg	Film-coated tablet	Oral use
Sweden		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	400 mg	Film-coated tablet	Oral use
Sweden		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	600 mg	Film-coated tablet	Oral use
Sweden		Strides Pharma (Cyprus) Limited	Ibuprofen Strides	Ibuprofen	800 mg	Film-coated tablet	Oral use
Sweden	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	200 mg	Film-coated tablet	Oral use
Sweden	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	400 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Brillpharma (Ireland) Limited		Ibuprofen Brill	Ibuprofen	600 mg	Film-coated tablet	Oral use
Sweden	Brillpharma (Ireland) Limited		Ibuprofen BrillPharma	Ibuprofen	200 mg	Film-coated tablet	Oral use
Sweden	Brillpharma (Ireland) Limited		Ibuprofen BrillPharma	Ibuprofen	400 mg	Film-coated tablet	Oral use
Sweden	Brillpharma (Ireland) Limited		Ibuprofen BrillPharma	Ibuprofen	600 mg	Film-coated tablet	Oral use
Sweden	Orifarm Generics A/S		Isonova	Isosorbide mononitrate	30 mg	Prolonged-release tablet	Oral use
Sweden	Orifarm Generics A/S		Isonova	Isosorbide mononitrate	60 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Aristo Pharma GmbH		Kagitz	Quetiapine	50 mg	Prolonged-release tablet	Oral use
Sweden	Aristo Pharma GmbH		Kagitz	Quetiapine	300 mg	Prolonged-release tablet	Oral use
Sweden	Aristo Pharma GmbH		Kagitz	Quetiapine	400 mg	Prolonged-release tablet	Oral use
The Netherlands	Mylan B.V.		Atorvastatine Mylan 10 mg, filmomhulde tabletten	Atorvastatin	10 mg	Film-coated tablet	Oral use
The Netherlands	Mylan B.V.		Atorvastatine Mylan 20 mg, filmomhulde tabletten	Atorvastatin	20 mg	Film-coated tablet	Oral use
The Netherlands	Mylan B.V.		Atorvastatine Mylan 40 mg, filmomhulde tabletten	Atorvastatin	40 mg	Film-coated tablet	Oral use
The Netherlands	Mylan B.V.		Atorvastatine Mylan 80 mg, filmomhulde tabletten	Atorvastatin	80 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Amarox Pharma B.V.		Atorvastatine Amarox 10 mg filmomhulde tabletten	Atorvastatin	10 mg	Film-coated tablet	Oral use
The Netherlands	Amarox Pharma B.V.		Atorvastatine Amarox 20 mg filmomhulde tabletten	Atorvastatin	20 mg	Film-coated tablet	Oral use
The Netherlands	Amarox Pharma B.V.		Atorvastatine Amarox 40 mg filmomhulde tabletten	Atorvastatin	40 mg	Film-coated tablet	Oral use
The Netherlands	Amarox Pharma B.V.		Atorvastatine Amarox 80 mg filmomhulde tabletten	Atorvastatin	80 mg	Film-coated tablet	Oral use
The Netherlands	Sandoz B.V.		Clobazam Sandoz 10 mg, tabletten	Clobazam	10 mg	Tablet	Oral use
The Netherlands	TioFarma B.V.		Clobazam Tiofarma 10 mg, tabletten	Clobazam	10 mg	Tablet	Oral use
The Netherlands	TioFarma B.V.		Clobazam Tiofarma 20 mg, tabletten	Clobazam	20 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Sandoz B.V.		Clonazepam Sandoz 0,5 mg, tabletten	Clonazepam	0,5 mg	Tablet	Oral use
The Netherlands	Sandoz B.V.		Clonazepam Sandoz 2 mg, tabletten	Clonazepam	2 mg	Tablet	Oral use
The Netherlands	TioFarma B.V.		Clonazepam Tiofarma 0,5 mg, tabletten	Clonazepam	0,5 mg	Tablet	Oral use
The Netherlands	TioFarma B.V.		Clonazepam Tiofarma 2 mg, tabletten	Clonazepam	2 mg	Tablet	Oral use
The Netherlands	Mylan B.V.		Efavirenz Mylan 600 mg, filmomhulde tabletten	Efavirenz	600 mg	Film-coated tablet	Oral use
The Netherlands	Tillomed Pharma GmbH		Ezetimibe/Simvastatine Tillomed 10 mg/10 mg, tabletten	Ezetimibe/simvastatin	10 mg/10 mg	Tablet	Oral use
The Netherlands	Tillomed Pharma GmbH		Ezetimibe/Simvastatine Tillomed 10 mg/20 mg, tabletten	Ezetimibe/simvastatin	10 mg/20 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Tillomed Pharma GmbH		Ezetimibe/Simvastatine Tillomed 10 mg/40 mg, tabletten	Ezetimibe/simvastatin	10 mg/40 mg	Tablet	Oral use
The Netherlands	Tillomed Pharma GmbH		Ezetimibe/Simvastatine Tillomed 10 mg/80 mg, tabletten	Ezetimibe/simvastatin	10 mg/80 mg	Tablet	Oral use
The Netherlands		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 200 mg, filmomhulde tabletten	Ibuprofen	200 mg	Film-coated tablet	Oral use
The Netherlands		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 200 mg, filmomhulde tabletten	Ibuprofen	400 mg	Film-coated tablet	Oral use
The Netherlands		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 200 mg, filmomhulde tabletten	Ibuprofen	600 mg	Film-coated tablet	Oral use
The Netherlands		Strides Pharma (Cyprus) Limited	Ibuprofen Strides 200 mg, filmomhulde tabletten	Ibuprofen	800 mg	Film-coated tablet	Oral use
The Netherlands	RIA Generics Limited		Nortriptyline RIA 10 mg tabletten	Nortriptyline	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	RIA Generics Limited		Nortriptyline RIA 25 mg tabletten	Nortriptyline	25 mg	Tablet	Oral use
The Netherlands		Tillomed Pharma GmbH	Paliperidon Tillomed 3 mg, tabletten met verlengde afgifte	Paliperidone	3 mg	Prolonged-release tablet	Oral use
The Netherlands		Tillomed Pharma GmbH	Paliperidon Tillomed 6 mg, tabletten met verlengde afgifte	Paliperidone	6 mg	Prolonged-release tablet	Oral use
The Netherlands		Tillomed Pharma GmbH	Paliperidon Tillomed 9 mg, tabletten met verlengde afgifte	Paliperidone	9 mg	Prolonged-release tablet	Oral use
The Netherlands	Healthypharm B.V.		Paracetamol liquid caps HTP 500 mg, zachte capsules	Paracetamol	500 mg	Capsule, soft	Oral use
The Netherlands	MAE Holding B.V.		Paracetamol Linn 500 mg liquid caps, zachte capsules	Paracetamol	500 mg	Capsule, soft	Oral use
The Netherlands		Socium Pharma B.V.	Paracetamol/Ibuprofen Socium 500/200 mg zachte capsules	Paracetamol/ibuprofen	500 mg / 200 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands		Theramex Ireland Limited	Ovalute 100 mg, zachte capsule	Progesterone	100 mg	Capsule, soft	Oral use
The Netherlands		Theramex Ireland Limited	Ovalute 200 mg, zachte capsule	Progesterone	200 mg	Capsule, soft	Oral use
The Netherlands	RIA Generics Limited		Sertraline RIA 50 mg, filmomhulde tabletten	Sertraline	50 mg	Film-coated tablet	Oral use
The Netherlands	RIA Generics Limited		Sertraline RIA 100 mg, filmomhulde tabletten	Sertraline	100 mg	Film-coated tablet	Oral use
The Netherlands	Mylan B.V.		Zolmitriptan Mylan 2,5 mg, orodispergeerbare tabletten	Zolmitriptan	2,5 mg	Orodispersible tablet	Oral use
The Netherlands	Mylan B.V.		Zolmitriptan Mylan 5 mg, orodispergeerbare tabletten	Zolmitriptan	5 mg	Orodispersible tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Strandhaven Limited		Amlodipine 5 mg Tablets	Amlodipine	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Strandhaven Limited		Amlodipine 10 mg Tablets	Amlodipine	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Wockhardt UK Limited		Amlodipine 5 mg Tablets	Amlodipine	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Wockhardt UK Limited		Amlodipine 10 mg Tablets	Amlodipine	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Accord Healthcare Limited		Amoxicillin 250 mg Capsules	Amoxicillin	250 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Accord Healthcare Limited		Amoxicillin 500 mg Capsules	Amoxicillin	500 mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Medreich PLC		Amoxicillin 250 mg Capsules	Amoxicillin	250 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Medreich PLC		Amoxicillin 500 mg Capsules	Amoxicillin	500 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Medreich PLC		Co-Amoxiclav 250/62.5 mg Powder for Oral Suspension	Amoxicillin/ clavulanic acid	250 mg/62,5 mg	Powder for oral suspension	Oral use
United Kingdom (Northern Ireland)	Medreich PLC		Co-Amoxiclav 457/5 ml Suspension	Amoxicillin/ clavulanic acid	457 mg/5 ml	Powder for oral suspension	Oral use
United Kingdom (Northern Ireland)	Medreich PLC		Co-Amoxiclav 500/125 mg Tablets	Amoxicillin/ clavulanic acid	500 mg/125 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Generics Ltd		Atorvastatine Mylan	Atorvastatin	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Generics Ltd		Atorvastatine Mylan	Atorvastatin	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Generics Ltd		Atorvastatine Mylan	Atorvastatin	40 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Generics Ltd		Atorvastatine Mylan	Atorvastatin	80 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Wockhardt UK Limited		Atorvastatin 80 mg film-coated Tablets	Atorvastatin	80 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Wockhardt UK Limited		Atorvastatin 10 mg film-coated Tablets	Atorvastatin	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Wockhardt UK Limited		Atorvastatin 20 mg film-coated Tablets	Atorvastatin	20 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Wockhardt UK Limited		Atorvastatin 40 mg film-coated Tablets	Atorvastatin	40 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Amarox Limited		Atorvastatin 10 mg film-coated Tablets	Atorvastatin	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Amarox Limited		Atorvastatin 20 mg film-coated Tablets	Atorvastatin	20 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Amarox Limited		Atorvastatin 40 mg film-coated Tablets	Atorvastatin	40 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Amarox Limited		Atorvastatin 80 mg film-coated Tablets	Atorvastatin	80 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Morningside Healthcare Limited		Clonidine hydrochloride 25 microgram Tablets	Clonidine	25 mcg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Generics Limited		Efavirenz 600 mg film-coated Tablets	Efavirenz	600 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Ethambutol 100 mg film-coated Tablets	Ethambutol	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Ethambutol 400 mg film-coated Tablets	Ethambutol	400 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Abdi Farma Unipessoal Limitada		Etolyn 600 mg Prolonged-Release Tablets	Etodolac	600 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Medreich PLC		Flucloxacillin 250 mg Capsules	Flucloxacillin	250 mg	Capsule, hard	Oral use
United Kingdom (Northern Ireland)	Medreich PLC		Flucloxacillin 500 mg Capsules	Flucloxacillin	500 mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Gliclazide 30 mg Prolonged-Release Tablets	Gliclazide	30 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Gliclazide 40 mg Prolonged-Release Tablets	Gliclazide	40 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Gliclazide 60 mg Prolonged-Release Tablets	Gliclazide	60 mg	Prolonged-release tablet	Oral use
United Kingdom (Northern Ireland)		Blackrock Pharmaceuticals Limited	Hydrocortisone 10 mg Tablets	Hydrocortisone	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Blackrock Pharmaceuticals Limited	Hydrocortisone 20 mg Tablets	Hydrocortisone	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Silicon Pharma Limited		Hydrocortisone 10 mg Tablets	Hydrocortisone	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Silicon Pharma Limited		Hydrocortisone 20 mg Tablets	Hydrocortisone	20 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Strides Pharma UK Limited	Ibuprofen 200 mg film-coated Tablets	Ibuprofen	200 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Strides Pharma UK Limited	Ibuprofen 400 mg film-coated Tablets	Ibuprofen	400 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Strides Pharma UK Limited	Ibuprofen 600 mg film-coated Tablets	Ibuprofen	600 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)		Socium Pharma B.V.	Ibuprofen/Pseudoephedrine HCl 200/30 mg Capsules, soft	Ibuprofen/pseudoephedrine	200 mg/30 mg	Capsule, soft	Oral use
United Kingdom (Northern Ireland)		Strides Pharma UK Limited	Liothyronine sodium 5 microgram Tablets	Liothyronine	5 mcg	Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Strides Pharma UK Limited	Liothyronine sodium 20 microgram Tablets	Liothyronine	20 mcg	Tablet	Oral use
United Kingdom (Northern Ireland)	Zentiva Pharma UK Limited		Memantine hydrochloride 5 mg + 10 mg + 15 mg + 20 mg Soluble Tablets	Memantine	5 mg + 10 mg + 15 mg + 20 mg	Soluble tablet	Oral use
United Kingdom (Northern Ireland)	Zentiva Pharma UK Limited		Memantine hydrochloride 10 mg Soluble Tablets	Memantine	10 mg	Soluble tablet	Oral use
United Kingdom (Northern Ireland)	Zentiva Pharma UK Limited		Memantine hydrochloride 20 mg Soluble Tablets	Memantine	20 mg	Soluble tablet	Oral use
United Kingdom (Northern Ireland)	Colonis Pharma Limited		Metformin Colonis 500mg/5ml Oral Solution	Metformin	500 mg	Oral solution	Oral use
United Kingdom (Northern Ireland)	Colonis Pharma Limited		Metformin Colonis 850mg/5ml Oral Solution	Metformin	850 mg	Oral solution	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Colonis Pharma Limited		Metformin Colonis 1000mg/5ml Oral Solution	Metformin	1000 mg/5 ml	Oral solution	Oral use
United Kingdom (Northern Ireland)	Mercury Pharmaceuticals Limited		Nebivolol 2.5 mg Tablets	Nebivolol	2,5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Mercury Pharmaceuticals Limited		Nebivolol 5 mg Tablets	Nebivolol	5 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	RIA Generics Limited		Nefopam hydrochloride 30 mg film-coated Tablets	Nefopam	30 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	RIA Generics Limited		Nefopam hydrochloride 30 mg film-coated Tablets	Nefopam	30 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Zentiva Pharma UK Limited		Nevirapine Amneal 400 mg Prolonged-Release Tablets	Nevirapine	400 mg	Prolonged-Release Tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	RIA Generics Limited		Nortriptyline 10 mg Tablets	Nortriptyline	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	RIA Generics Limited		Nortriptyline 25 mg Tablets	Nortriptyline	25 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	RIA Generics Limited		Nortriptyline 10 mg Tablets	Nortriptyline	10 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	RIA Generics Limited		Nortriptyline 25 mg Tablets	Nortriptyline	25 mg	Tablet	Oral use
United Kingdom (Northern Ireland)		Pharmamatch B.V.	Paracetamol 500 mg Capsules, soft	Paracetamol	500 mg	Capsule, soft	Oral use
United Kingdom (Northern Ireland)		Interdos Pharma B.V.	Paracetamol/Ibuprofen interdos 500/200 mg Capsules, soft	Paracetamol/Ibuprofen	500 mg / 200 mg	Capsule, soft	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)		Pharmamatch B.V.	Paracetamol/Ibuprofen 500/200 mg Capsules, soft	Paracetamol/Ibuprofen	500 mg / 200 mg	Capsule, soft	Oral use
United Kingdom (Northern Ireland)	Generics Limited		Pioglitazone 15 mg Tablets	Pioglitazone	15 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Generics Limited		Pioglitazone 30 mg Tablets	Pioglitazone	30 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Generics Limited		Pioglitazone 45 mg Tablets	Pioglitazone	45 mg	Tablet	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Rosuvastatin 10 mg film-coated Tablets	Rosuvastatin	10 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Rosuvastatin 20 mg film-coated Tablets	Rosuvastatin	20 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Applicant	Invented name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	Brown & Burk UK Limited		Rosuvastatin 40 mg film-coated Tablets	Rosuvastatin	40 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	RIA Generics Limited		Sertraline 50 mg film-coated Tablets	Sertraline	50 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	RIA Generics Limited		Sertraline 100 mg film-coated Tablets	Sertraline	100 mg	Film-coated tablet	Oral use
United Kingdom (Northern Ireland)	Generics Limited		Zolmitriptan 2.5 mg Orodispersible Tablets	Zolmitriptan	2,5 mg	Orodispersible tablet	Oral use
United Kingdom (Northern Ireland)	Generics Limited		Zolmitriptan 5 mg Orodispersible Tablets	Zolmitriptan	5 mg	Orodispersible tablet	Oral use
United Kingdom (Northern Ireland)	Athlone Pharmaceuticals Limited		Zopiclone 7.5 mg Tablets	Zopiclone	7,5 mg	Tablet	Oral use