

Annex I

List of the names, pharmaceutical form, strengths of the medicinal products, route of administration, applicant in the Member States

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 20 mg/5 ml Suspension zum Einnehmen	20mg/5ml	oral suspension	oral use
Austria	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 40 mg/5 ml Suspension zum Einnehmen	40mg/5ml	oral suspension	oral use
Denmark	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
Denmark	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Finland	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale	20mg/5ml	oral suspension	oral use
Finland	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale	40mg/5ml	oral suspension	oral use
France	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
France	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Germany	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
Germany	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use
Greece	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
Greece	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Ireland	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
Ireland	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use
Italy	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatina Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
Italy	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatina Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Netherlands	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatine Vale Pharmaceuticals 20mg/5ml suspensie voor oraal gebruik	20mg/5ml	oral suspension	oral use
Netherlands	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatine Vale Pharmaceuticals 40mg/5ml suspensie voor oraal gebruik	40mg/5ml	oral suspension	oral use
Norway	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
Norway	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Portugal	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Sinvastatina Vale	20mg/5ml	oral suspension	oral use
Portugal	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Sinvastatina Vale	40mg/5ml	oral suspension	oral use
Spain	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 20 mg/5 ml suspensión oral	20mg/5ml	oral suspension	oral use
Spain	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale 40 mg/5 ml suspensión oral	40mg/5ml	oral suspension	oral use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Sweden	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
Sweden	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use
United Kingdom	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	20mg/5ml	oral suspension	oral use
United Kingdom	Vale Pharmaceuticals Limited 1b Gurtnafleur Business Park Gurtnafleur, Clonmel Co. Tipperary Ireland	Simvastatin Vale Pharmaceuticals	40mg/5ml	oral suspension	oral use