

**Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 September 2008 to 30 September 2008**

*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC of the European Parliament and of the Council <sup>(1)</sup> or Article 38 of Directive 2001/82/EC of the European Parliament and of the Council <sup>(2)</sup>)*

(2008/C 276/03)

**— Issuing, maintenance or modification of a national marketing authorisation**

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
3.9.2008	Cozaar	See Annex I	See Annex I	8.9.2008
3.9.2008	Cozaar Comp	See Annex II	See Annex II	8.9.2008
9.9.2008	Arcoxia	See Annex III	See Annex III	11.9.2008
9.9.2008	Etoricoxib	See Annex IV	See Annex IV	11.9.2008
11.9.2008	Activelle	See Annex V	See Annex V	15.9.2008
11.9.2008	Rapinyl	See Annex VI	See Annex VI	15.9.2008
15.9.2008	Remeron	See Annex VII	See Annex VII	17.9.2008
23.9.2008	Gemzar	See Annex VIII	See Annex VIII	24.9.2008
26.9.2008	Sodium Salicylate	See Annex IX	See Annex IX	29.9.2008
26.9.2008	Toltrazuril	See Annex X	See Annex X	29.9.2008
26.9.2008	Aclasta	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	This Decision is addressed to the Member States	29.9.2008

**— Suspension of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
9.9.2008	Pulairmax	See Annex XI	See Annex XI	11.9.2008

**— Lift of suspension of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
5.9.2008	Suramox 15 % LA — Stabox 15 % LA	See Annex XII	See Annex XII	9.9.2008

<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(2)</sup> OJ L 311, 28.11.2001, p. 1.

## ANNEX I

**LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES**

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Austria	Merck Sharp & Dohme GmbH Donau-City-Straße 6 A-1220 Wien	Cosaar 12,5 mg — Filmtabletten	12,5 mg	Film-coated tablet	Oral use
Austria	Merck Sharp & Dohme GmbH Donau-City-Straße 6 A-1220 Wien	Cosaar 50 mg — Filmtabletten	50 mg	Film-coated tablet	Oral use
Austria	Merck Sharp & Dohme GmbH Donau-City-Straße 6 A-1220 Wien	Cosaar 100 mg — Filmtabletten	100 mg	Film-coated tablet	Oral use
Belgium	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar 100 mg	100 mg	Film-coated tablet	Oral use
Belgium	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar 50 MG	50 mg	Film-coated tablet	Oral use
Belgium	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar 12,5 mg	12,5 mg	Film-coated tablet	Oral use
Belgium	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar Cardio Start	21 X 12,5 mg + 14 X 50 mg	Film-coated tablet	Oral use
Belgium	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan 100 mg	100 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Belgium	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan 50 mg	50 mg	Film-coated tablet	Oral use
Belgium	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan 12,50 mg	12,5 mg	Film-coated tablet	Oral use
Belgium	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan Cardio Start	21 X 12,5 mg + 14 X 50 mg	Film-coated tablet	Oral use
Bulgaria	Merck Sharp & Dohme Bulgaria EOOD 55 Nikola Vapzarov blvd. EXPO 2000, east wing, sections B1 & B2, 1st fl. BG-1407 Sofia	Cozaar	50 mg	Film-coated tablet	Oral use
Cyprus	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar	50 mg	Film-coated tablet	Oral use
Cyprus	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar	100 mg	Film-coated tablet	Oral use
Denmark	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar	12,5 mg	Film-coated tablet	Oral use
Denmark	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar	50 mg	Film-coated tablet	Oral use
Denmark	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar	100 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Denmark	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar Startpakke	12,5 mg + 50 mg	Film-coated tablet	Oral use
Estonia	Merck Sharp & Dohme OÜ Peterburi tee 46 EE-11415 Tallinn	Cozaar	100 mg	Film-coated tablet	Oral use
Estonia	Merck Sharp & Dohme OÜ Peterburi tee 46 EE-11415 Tallinn	Cozaar	50 mg	Film-coated tablet	Oral use
Estonia	Merck Sharp & Dohme OÜ Peterburi tee 46 EE-11415 Tallinn	Cozaar 12,5 mg	12,5 mg	Film-coated tablet	Oral use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 Postbus 581 2003 PC Haarlem Nederland	Cozaar	12,5 mg	Film-coated tablet	Oral use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 Postbus 581 2003 PC Haarlem Nederland	Cozaar	12,5 mg and 50 mg (initiation pack)	Film-coated tablet	Oral use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 Postbus 581 2003 PC Haarlem Nederland	Cozaar	50 mg	Film-coated tablet	Oral use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 Postbus 581 2003 PC Haarlem Nederland	Cozaar	100 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
France	Merck Sharp Dohme Chibret 3, av. Hoche F-75114 Paris Cedex 08	Cozaar 100 mg film-coated tablets	100 mg	Film-coated tablet	Oral use
France	Merck Sharp Dohme Chibret 3, av. Hoche F-75114 Paris Cedex 08	Cozaar 50 mg scored coated tablets	50 mg	Scored coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Cardopal Start 12,5 mg Filmtabletten	12,5 mg	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Lorzaar 100 mg Filmtabletten	100 mg	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Lorzaar 50 mg Filmtabletten	50 mg	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Lorzaar Protect 100 mg Filmtabletten	100 mg	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Lorzaar Protect 50 mg Filmtabletten	50 mg	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Lorzaar Start 12,5 mg Filmtabletten	12,5 mg	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Pinzaar 100 mg Filmtabletten	100 mg	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Pinzaar 50 mg Filmtabletten	50 mg	Film-coated tablet	Oral use
Germany	VARIPHARM ARZNEIMITTEL GmbH Lindenplatz 1 D-85540 Haar	Lorzaar Varipharmstart 12,5 mg Film- tabletten	12,5 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Greece	VIANEX A.E. Tatoiou Street GR-14671 Nea Erythraia	Cozaar	12,5 mg	Film-coated tablet	Oral use
Greece	VIANEX A.E. Tatoiou Street GR-14671 Nea Erythraia	Cozaar	50 mg	Film-coated tablet	Oral use
Greece	VIANEX A.E. Tatoiou Street GR-14671 Nea Erythraia	Cozaar	100 mg	Film-coated tablet	Oral use
Hungary	Merck Sharp & Dohme Hungary Ltd 50, Alkotás u. H-1123 Budapest	Cozaar	12,5 mg	Film-coated tablet	Oral use
Hungary	Merck Sharp & Dohme Hungary Ltd 50, Alkotás u. H-1123 Budapest	Cozaar	50 mg	Film-coated tablet	Oral use
Hungary	Merck Sharp & Dohme Hungary Ltd 50, Alkotás u. H-1123 Budapest	Cozaar	100 mg	Film-coated tablet	Oral use
Ireland	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar 50 mg Film-coated tablets	50 mg	Film-coated tablet	Oral use
Ireland	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar 100 mg Film-coated tablets	100 mg	Film-coated tablet	Oral use
Ireland	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar 12,5 mg Film-coated tablets	12,5 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Italy	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Lortaan 50 mg compresse rivestite con film	50 mg	Film-coated tablet	Oral use
Italy	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Lortaan 12,5 mg compresse rivestite con film	12,5 mg	Film-coated tablet	Oral use
Italy	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Lortaan 100 mg compresse rivestite con film	100 mg	Film-coated tablet	Oral use
Italy	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Neo-Lotan 50 mg compresse rivestite con film	50 mg	Film-coated tablet	Oral use
Italy	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Neo-Lotan 12,5 mg compresse rivestite con film	12,5 mg	Film-coated tablet	Oral use
Italy	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Neo-Lotan 100 mg compresse rivestite con film	100 mg	Film-coated tablet	Oral use
Italy	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. Viale Shakespeare 47 I-00144 Roma	Losaprex 50 mg compresse rivestite con film	50 mg	Film-coated tablet	Oral use
Italy	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. Viale Shakespeare 47 I-00144 Roma	Losaprex 12,5 mg compresse rivestite con film	12.5 mg	Film-coated tablet	Oral use
Italy	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. Viale Shakespeare 47 I-00144 Roma	Losaprex 100 mg compresse rivestite con film	100 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Latvia	SIA Merck Sharp & Dohme Latvia Skanstes street 13 LV-1013 Riga	Cozaar 50 mg film-coated tablets	50 mg	Film-coated tablet	Oral use
Latvia	SIA Merck Sharp & Dohme Latvia Skanstes street 13 LV-1013 Riga	Cozaar 100 mg film-coated tablets	100 mg	Film-coated tablet	Oral use
Lithuania	UAB Merck Sharp & Dohme Geležinio Vilko 18A LT-01112 Vilnius	Cozaar (Losartan)	12,5 mg	Film-coated tablet	Oral use
Lithuania	UAB Merck Sharp & Dohme Geležinio Vilko 18A LT-01112 Vilnius	Cozaar (Losartan)	50 mg	Film-coated tablet	Oral use
Lithuania	UAB Merck Sharp & Dohme Geležinio Vilko 18A LT-01112 Vilnius	Cozaar (Losartan)	100 mg	Film-coated tablet	Oral use
Luxembourg	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar 100 mg	100 mg	Film-coated tablet	Oral use
Luxembourg	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar 50 MG	50 mg	Film-coated tablet	Oral use
Luxembourg	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar 12,5 mg	12,5 mg	Film-coated tablet	Oral use
Luxembourg	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar Cardio Start	21 X 12,5 mg + 14 X 50 mg	Film-coated tablet	Oral use
Luxembourg	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan 100 mg	100 mg	Film-coated tablet	Oral use



Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Luxembourg	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan 50 mg	50 mg	Film-coated tablet	Oral use
Luxembourg	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan 12,50 mg	12,5 mg	Film-coated tablet	Oral use
Luxembourg	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan Cardio Start	21 X 12,5 mg + 14 X 50 mg	Film-coated tablet	Oral use
Malta	Merck Sharp & Dohme Ltd. Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	“Cozaar 100 mg” pilloli miksija b’rita	10 mg	Film-coated tablet	Oral use
Malta	Merck Sharp & Dohme Ltd. Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	“Cozaar 50 mg” pilloli miksija b’rita	50 mg	Film-coated tablet	Oral use
The Netherlands	Merck Sharp & Dohme Postbus 581 2003 PC Haarlem Nederland	Cozaar 50	50 mg	Film-coated tablet	Oral use
The Netherlands	Merck Sharp & Dohme Postbus 581 2003 PC Haarlem Nederland	Cozaar 100	100 mg	Film-coated tablet	Oral use
Poland	MSD Polska Sp. z o.o. Chłodna 51 PL-00-867 Warszawa	Cozaar	12,5 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Poland	MSD Polska Sp. z o.o. Chłodna 51 PL-00-867 Warszawa	Cozaar	50 mg	Film-coated tablet	Oral use
Poland	MSD Polska Sp. z o.o. Chłodna 51 PL-00-867 Warszawa	Cozaar	100 mg	Film-coated tablet	Oral use
Portugal	Merck Sharp & Dohme, Lda. Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Cozaar	50 mg	Film-coated tablet	Oral use
Portugal	Merck Sharp & Dohme, Lda. Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Cozaar 100 mg	100 mg	Film-coated tablet	Oral use
Portugal	Merck Sharp & Dohme, Lda. Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Cozaar IC	12,5 mg	Film-coated tablet	Oral use
Portugal	Merck Sharp & Dohme, Lda. Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Cozaar IC — Titulação	12,5 mg + 50 mg	Film-coated tablet	Oral use
Portugal	LABORATÓRIO MEDINFAR Produtos Farmacêuticos, SA Rua Manuel Ribeiro de Pavia, 1-1 Venda Nova P-2700-547 Amadora	Lortaan IC	12,5 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Portugal	LABORATÓRIO MEDINFAR Produtos Farmacêuticos, SA Rua Manuel Ribeiro de Pavia, 1-1 Venda Nova PT-2700-547 Amadora	Lortaan IC — Titulação	12,5 mg + 50 mg	Film-coated tablet	Oral use
Portugal	LABORATÓRIO MEDINFAR Produtos Farmacêuticos, SA Rua Manuel Ribeiro de Pavia, 1-1 Venda Nova P-2700-547 Amadora	Lortaan	50 mg	Film-coated tablet	Oral use
Portugal	LABORATÓRIO MEDINFAR Produtos Farmacêuticos, SA Rua Manuel Ribeiro de Pavia, 1-1 Venda Nova P-2700-547 Amadora	Lortaan 100 mg	100 mg	Film-coated tablet	Oral use
Romania	Merck Sharp & Dohme Romania S.R.L. Bucharest Business Park Șos. București-Ploiești, Nr. 1A Clădirea C1, Etaj 3 Sector 1, București România	Cozaar, comprimate filmate, 50 mg	50 mg	Film-coated tablet	Oral use
Slovenia	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140 SLO-1000 Ljubljana	Cozaar 12,5 mg filmsko obložene tablete	12,5 mg	Film-coated tablet	Oral use
Slovenia	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140 SLO-1000 Ljubljana	Cozaar 50 mg filmsko obložene tablete	50 mg	Film-coated tablet	Oral use
Slovenia	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140 SLO-1000 Ljubljana	Cozaar 100 mg filmsko obložene tablete	100 mg	Film-coated tablet	Oral use
Spain	Merck Sharp and Dohme de España, S.A. C/ Josefa Valcárcel, 38 E-28027 Madrid	Cozaar 12,5 mg Inicio	12,5 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Spain	Merck Sharp and Dohme de España, S.A. C/ Josefa Valcárcel, 38 E-28027 Madrid	Cozaar 50 mg	50 mg	Film-coated tablet	Oral use
Spain	Merck Sharp and Dohme de España, S.A. C/ Josefa Valcárcel, 38 E-28027 Madrid	Cozaar 100 mg	100 mg	Film-coated tablet	Oral use
Sweden	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar 12,5 mg filmdragerade tabletter	12,5 mg	Film-coated tablet	Oral use
Sweden	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar 12,5 mg + 50 mg filmdragerade tabletter	12,5 + 50 mg	Film-coated tablet	Oral use
Sweden	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar 50 mg filmdragerade tabletter	50 mg	Film-coated tablet	Oral use
Sweden	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar 100 mg filmdragerade tabletter	100 mg	Film-coated tablet	Oral use
United Kingdom	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar 50 mg Film-coated tablets	50 mg	Film-coated tablet	Oral use
United Kingdom	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar 25 mg Film-coated tablets	25 mg	Film-coated tablet	Oral use
United Kingdom	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar 100 mg Film-coated tablets	100 mg	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium	Strength	Pharmaceutical Form	Route of administration
Iceland	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar	12,5 mg	Film-coated tablet	Oral use
Iceland	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar	50 mg	Film-coated tablet	Oral use
Iceland	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar	100 mg	Film-coated tablet	Oral use
Norway	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar	12,5 mg	Film-coated tablet	Oral use
Norway	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar	50 mg	Film-coated tablet	Oral use
Norway	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar	100 mg	Film-coated tablet	Oral use

## ANNEX II

## LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Austria	Merck Sharp & Dohme GmbH Donau-City-Straße 6 A-1220 Wien	Cosaar Plus — Filmtabletten	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Austria	Merck Sharp & Dohme GmbH Donau-City-Straße 6 A-1220 Wien	Fortzaar-Filmtabletten	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Belgium	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar Plus Forte 100 mg/25 mg	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Belgium	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar Plus 50 mg/12,5 mg	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Belgium	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan Plus Forte 100 mg/25 mg	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Belgium	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan Plus 50 mg/12,5 mg	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Bulgaria	Merck Sharp & Dohme Bulgaria EOOD 55 Nikola Vaptzarov blvd. EXPO 2000, east wing, sections B1 & B2, 1st fl. BG-1407 Sofia	Hyzaar	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Cyprus	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Fortzaar	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Cyprus	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Hyzaar	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Denmark	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar Comp.	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Denmark	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar Comp. Forte	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Denmark	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Cozaar Comp. 100 mg/12,5 mg	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Denmark	Merck Sharp & Dohme BV Postbus 581 2003 PC Haarlem Nederland	Fortzaar	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablets	Oral use
Estonia	Merck Sharp & Dohme OÜ Peterburi tee 46 EE-11415 Tallinn	Hyzaar	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Estonia	Merck Sharp & Dohme OÜ Peterburi tee 46 EE-11415 Tallinn	Fortzaar	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 P.O.Box 581 2031 BN Haarlem Nederland	Cozaar Comp	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 P.O.Box 581 2031 BN Haarlem Nederland	Cozaar Comp	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 P.O.Box 581 2031 BN Haarlem Nederland	Cozaar Comp Forte	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
France	Merck Sharp Dohme Chibret 3, av. Hoche F-75114 Paris Cedex 08	Fortzaar 100 mg/25 mg comprimé pelliculé	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
France	Merck Sharp Dohme Chibret 3, av. Hoche F-75114 Paris Cedex 08	Hyzaar 100 mg/25 mg comprimé pelliculé	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
France	Merck Sharp Dohme Chibret 3, av. Hoche F-75114 Paris Cedex 08	Fortzaar 50 mg/12,5 mg comprimé pelliculé	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
France	Merck Sharp Dohme Chibret 3, av. Hoche F-75114 Paris Cedex 08	Hyzaar 50 mg/12,5 mg comprimé pelliculé	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
France	Merck Sharp Dohme Chibret 3, av. Hoche F-75114 Paris Cedex 08	Fortzaar 100 mg/12,5 mg comprimé pelliculé	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Lorzaar Plus 50/12,5 mg Filmtabletten	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Cardopal Plus 50/12,5 mg Filmtabletten	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Germany	VARIPHARM ARZNEIMITTEL GmbH Lindenplatz 1 D-85540 Haar	Lorzaar Varipharm Plus 50/12,5 mg Filmtabletten	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Fortzaar 100/25 mg Filmtabletten	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use



Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Germany	VARIPHARM ARZNEIMITTEL GmbH Lindenplatz 1 D-85540 Haar	Fortzaar Varipharm 100/25 mg Filmtabletten	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Germany	MSD Chibropharm GmbH Postfach 1202 D-85530 Haar	Lorzaar Plus Forte 100/12,5 mg Filmtabletten	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Greece	VIANEX A.E. Tatoiou Street GR-14671 Nea Erythraia	Hyzaar	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Greece	VIANEX A.E. Tatoiou Street GR-14671 Nea Erythraia	Hyzaar 100/25	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Hungary	Merck Sharp & Dohme Hungary Ltd 50, Alkotás u. H-1123 Budapest	Hyzaar 50/12,5 mg	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Hungary	Merck Sharp & Dohme Hungary Ltd 50, Alkotás u. H-1123 Budapest	Hyzaar Forte 100/25 mg	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Iceland	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	Cozaar' Comp 50 mg/12,5 mg film-coated tablets	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Iceland	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	Cozaar' Comp 100 mg/25 mg film-coated tablets	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Iceland	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Hizaar 50 mg + 12,5 mg compresse rivestite con film	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Ireland	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Hizaar 100 mg + 25 mg compresse rivestite con film	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Ireland	Merck Sharp & Dohme (Italia) S.p.A. Via G. Fabbroni 6 I-00191 Roma	Forzaar 100 mg + 25 mg compresse rivestite con film	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Italy	Neopharmed S.p.A. Via G. Fabbroni, 6 I-00191 Roma	Neo-Lotan Plus 50 mg + 12,5 mg compresse rivestite con film	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Italy	Neopharmed S.p.A. Via G. Fabbroni, 6 I-00191 Roma	Neo-Lotan Plus 100 mg + 25 mg compresse rivestite con film	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Italy	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. viale Shakespeare 47 I-00144 Roma	Losazid 50 mg + 12,5 mg compresse rivestite con film	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Italy	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. viale Shakespeare 47 I-00144 Roma	Losazid 100 mg + 25 mg compresse rivestite con film	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Italy	SIA Merck Sharp & Dohme Latvia Skanstes street 13 LV-1013 Riga	Hyzaar 50 mg/12,5 mg	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Italy	SIA Merck Sharp & Dohme Latvia Skanstes street 13 LV-1013 Riga	Fortzaar 100 mg/25 mg	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Italy	UAB Merck Sharp & Dohme Geležinio Vilko 18A LT-01112 Vilnius	Fortzaar (Losartan/Hydrochlorothiazide)	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Latvia	UAB Merck Sharp & Dohme Geležinio Vilko 18A LT-01112 Vilnius	Hyzaar (Losartan/Hydrochlorothiazide)	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Latvia	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar Plus Forte 100 mg/25 mg	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Lithuania	Merck Sharp & Dohme BV Chaussée de Waterloo, 1135 B-1180 Bruxelles	Cozaar Plus 50 mg/12,5 mg	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Lithuania	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan Plus Forte 100 mg/25 mg	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Luxembourg	Therabel Pharma S.A. Rue Egide Van Ophem, 108 B-1180 Bruxelles	Loortan Plus 50 mg/12,5 mg	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Luxembourg	Merck Sharp & Dohme Ltd Hertfordshire Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	“Cozaar Comp” 50/12,5 mg pilloli miksija b'rita	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Luxembourg	Merck Sharp & Dohme Ltd Hertfordshire Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	“Cozaar Comp” 100/25 mg pilloli miksija b'rita	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Luxembourg	Merck Sharp & Dohme Ltd Hertfordshire Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	“Cozaar Comp” 100/12,5 mg pilloli miksija b'rita	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Malta	Merck Sharp & Dohme Postbus 581 2003 PC Haarlem Nederland	Cozaar Plus 100/12,5	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Malta	Merck Sharp & Dohme Postbus 581 2003 PC Haarlem Nederland	Fortzaar 100/25	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Malta	Merck Sharp & Dohme Postbus 581 2003 PC Haarlem Nederland	Hyzaar 50/12,5	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
The Netherlands	MSD Polska Sp. z o.o. ul. Chłodna 51 PL-00-867 Warszawa	Hyzaar	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
The Netherlands	MSD Polska Sp. z o.o. ul. Chłodna 51 PL-00-867 Warszawa	Hyzaar Forte	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
The Netherlands	Merck Sharp & Dohme, Lda. Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Cozaar Plus	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Norway	Merck Sharp & Dohme, Lda. Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Cozaar Plus	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Norway	Merck Sharp & Dohme, Lda. Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Fortzaar	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Norway	Heptafarma- Companhia Farmacêutica Sociedade Unipessoal, Lda Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Siaara	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Poland	Laboratório Medinfar Produtos Farmacêuticos, SA Rua Manuel Ribeiro de Pavia, 1-1 Venda Nova P-2700-547 Amadora	Lortaan Plus	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Poland	Laboratório Medinfar Produtos Farmacêuticos, SA Rua Manuel Ribeiro de Pavia, 1-1 Venda Nova P-2700-547 Amadora	Lortaan Plus	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Portugal	Frosst Portuguesa Produtos Farmacêuticos, Lda. Quinte da Fonte Edifício Vasco da Gama, 19 P.O. BOX 214 Porto Salvo P-2780-730 Paço d'Arcos	Losartan + Hidroclorotiazida Frosst	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Portugal	Merck Sharp & Dohme Romania S.R.L. Bucharest Business Park Șos. București-Ploiești, Nr. 1A Clădirea C1, Etaj 3 Sector 1, București România	Hyzaar® 50 mg/12,5 mg comprimate filmate	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Portugal	Merck Sharp & Dohme Romania S.R.L. Bucharest Business Park Șos. București-Ploiești, Nr. 1A Clădirea C1, Etaj 3 Sector 1, București România	Fortzaar® 100/25 mg comprimate filmate	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Portugal	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140 SLO-1000 Ljubljana	Hyzaar	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Portugal	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140 SLO-1000 Ljubljana	Hyzaar	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Portugal	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140 SLO-1000 Ljubljana	Fortzaar	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Portugal	Merck Sharp and Dohme de España, S. A. C/ Josefa Valcárcel, 38 E-28027 Madrid	Cozaar Plus	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Romania	Merck Sharp and Dohme de España, S. A. C/ Josefa Valcárcel, 38 E-28027 Madrid	Fortzaar	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Romania	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar Comp 50 mg/12,5 mg filmdra- gerade tableter	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Slovenia	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar Comp 100 mg/12,5 mg filmdra- gerade tableter	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Slovenia	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar Comp Forte 100 mg/25 mg film- dragerade tableter	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Slovenia	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar-Comp 50/12,5 mg film-coated tablets	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Spain	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar-Comp 100/25 mg film-coated tablets	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name Losartan potassium and hydrochlorothiazide	Strength	Pharmaceutical Form	Route of administration
Spain	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Herts EN11 9BU United Kingdom	Cozaar-Comp 100 mg/12,5 mg film-coated tablets	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Sweden	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar-Comp 50/12,5 mg	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
Sweden	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar-Comp Forte	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use
Sweden	Merck Sharp & Dohme PO Box 581 2003 PC Haarlem Nederland	Cozaar-Comp 100/12,5 mg	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
United Kingdom	MSD BV Waarderweg 39 2031 BN Haarlem Nederland	Cozaar Comp	50 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
United Kingdom	MSD BV Waarderweg 39 2031 BN Haarlem Nederland	Cozaar Comp	100 mg losartan potassium — 12,5 mg hydrochlorothiazide	Film-coated tablet	Oral use
United Kingdom	MSD BV Waarderweg 39 2031 BN Haarlem Nederland	Cozaar Comp Forte	100 mg losartan potassium — 25 mg hydrochlorothiazide	Film-coated tablet	Oral use

## ANNEX III

**LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS/MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES**

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria	Merck Sharp & Dohme GmbH Donau-City-Straße 6 A-1220 Wien	Arcoxia	90 mg	Film-coated tablets	Oral use
Belgium	Merck Sharp and Dohme Chaussée de Waterloo, 1135 B-1180 Brussels	Arcoxia	90 mg	Film-coated tablets	Oral use
Czech Republic	Merck Sharp & Dohme B.V. Waanderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Cyprus	Merck Sharp & Dohme B.V. Waanderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Denmark	Merck Sharp & Dohme B.V. Waanderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Estonia	Merck Sharp & Dohme OÜ Peterburi tee 46 EE-11415 Tallinn	Arcoxia	90 mg	Film-coated tablets	Oral use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 P.O Box 581 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
France	Merck Sharp Dohme Chibret 3, avenue Hoche F-75114 Paris Cedex 8	Arcoxia	90 mg	Film-coated tablets	Oral use
Germany	MSD Sharp & Dohme GmbH Lindenplatz 1 D-85540 Haar	Arcoxia	90 mg	Film-coated tablets	Oral use



Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Greece	VIANEX S.A. Tatoiou Street, GR-14671 Nea Erythrea	Arcoxia	90 mg	Film-coated tablets	Oral use
Hungary	Merck Sharp & Dohme Magyarország Kft. Alkotás utca 50 H-1123 Budapest	Arcoxia	90 mg	Film-coated tablets	Oral use
Iceland	Merck Sharp & Dohme Regulatory Affairs Iceland Smedeland 8 DK-2600 Glostrup	Arcoxia	90 mg	Film-coated tablets	Oral use
Ireland	Merck Sharp and Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9B4 United Kingdom	Arcoxia	90 mg	Film-coated tablets	Oral use
Italy	Merck Sharp & Dohme S.p.A. Via G. Fabbroni, 6 I-00191 Roma	Arcoxia	90 mg	Film-coated tablets	Oral use
Latvia	SIA Merck Sharp & Dohme Latvija Skanstes 13 LV-1013 Riga	Arcoxia	90 mg	Film-coated tablets	Oral use
Lithuania	UAB, Merck Sharp & Dohme Lenktoji str. 27/Kestucio str. 59 LT-08124 Vilnius	Arcoxia	90 mg	Film-coated tablets	Oral use
Luxembourg	Merck Sharp & Dohme Chaussee de Waterloo, 1135 B-1180 Bruxelles	Arcoxia	90 mg	Film-coated tablets	Oral use
Malta	Merck, Sharp & Dohme Ltd Hertfordshire Road Hoddesdon Hertfordshire EN11 9BU United Kindgdom	Arcoxia	90 mg	Film-coated tablets	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Merck Sharp & Dohme B.V. Waanderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Norway	Merck Sharp & Dohme B.V. Waanderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Poland	MSD Polska Sp. z o.o. ul. Chłodna 51 PL-00-867 Warszawa	Arcoxia	90 mg	Film-coated tablets	Oral use
Portugal	Merck Sharp & Dohme, Lda. PRT Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Arcoxia	90 mg	Film-coated tablets	Oral use
Slovakia	Merck Sharp & Dohme B.V.Waarderweg 39 P.O. Box 581 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Slovenia	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140 SLO-1000 Ljubljana	Arcoxia	90 mg	Film-coated tablets	Oral use
Spain	Merck Sharp & Dohme de España, S.A. Josefa Valcárcel, 38 E-28027 Madrid	Arcoxia	90 mg	Film-coated tablets	Oral use
Sweden	Merck Sharp & Dohme BV PO Box 581 2003 PC Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
United Kingdom	Merck Sharpe & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	Arcoxia	90 mg	Film-coated tablets	Oral use

## ANNEX IV

**LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS/MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES**

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria	Merck Sharp & Dohme GmbH Donau-City-Straße 6 A-1220 Wien	Arcoxia	90 mg	Film-coated tablets	Oral use
		Auxib	90 mg	Film-coated tablets	Oral use
Belgium	Merck Sharp and Dohme Chaussée de Waterloo, 1135 B-1180 Brussels	Arcoxia	90 mg	Film-coated tablets	Oral use
		Ranaxox	90 mg	Film-coated tablets	Oral use
Bulgaria	Merck Sharp & Dohme Bulgaria EOOD 55 Nikola Vapzarov blvd. EXPO 2000, east wing, section B1 & B2 1st fl. BG-1407 Sofia	Arcoxia	90 mg	Film-coated tablets	Oral use
Czech Republic	Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Cyprus	Merck Sharp & Dohme BV. Waarderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Denmark	Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN, Haarlem Postbox 581 Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Estonia	Merck Sharp & Dohme OÜ Peterburi tee 46 EE-11415 Tallinn	Arcoxia	90 mg	Film-coated tablets	Oral use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39 P.O Box 581 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
		Turox	90 mg	Film-coated tablets	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
France	Merck Sharp Dohme Chibret 3, avenue Hoche F-75114 Paris Cedex 8	Arcoxia	90 mg	Film-coated tablets	Oral use
Germany	MSD Sharp & Dohme GmbH Lindenplatz 1 D-85540 Haar	Arcoxia	90 mg	Film-coated tablets	Oral use
Greece	VIANEX S.A. Tatoiou Street, GR-14671 Nea Erythrea	Arcoxia	90 mg	Film-coated tablets	Oral use
Hungary	Merck Sharp & Dohme Magyarország Kft. Alkotás utca 50 H-1123 Budapest	Arcoxia	90 mg	Film-coated tablets	Oral use
Iceland	Merck Sharp & Dohme Regulatory Affairs Iceland Smedeland 8 DK-2600 Glostrup	Arcoxia	90 mg	Film-coated tablets	Oral use
Ireland	Merck Sharp and Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9B4 United Kingdom	Arcoxia	90 mg	Film-coated tablets	Oral use
Italy	Merck Sharp & Dohme S.p.A. Via G. Fabbroni 6 I-00191 Roma	Arcoxia	90 mg	Film-coated tablet	Oral use
Italy	Istituto Gentili S.p.A. Via Benedetto Croce 37 I-56125 Pisa	Algix	90 mg	Film-coated tablet	Oral use
Italy	Neopharmed S.p.A. Via G. Fabbroni 6 I-00191 Roma	Recoxib	90 mg	Film-coated tablets	Oral use
Italy	Addenda Pharma S.r.l Viale Shakespeare 47 I-00144 Roma	Tauxib	90 mg	Film-coated tablets	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Latvia	SIA Merck Sharp & Dohme Latvija Skanstes 13 LV-1013 Riga	Arcoxia	90 mg	Film-coated tablets	Oral use
Lithuania	UAB, Merck Sharp & Dohme Lenktoji str. 27/Kestucio str. 59 LT-08124 Vilnius	Arcoxia	90 mg	Film-coated tablets	Oral use
Luxembourg	Merck Sharp & Dohme Chaussee de Waterloo 1135 B-1180 Bruxelles	Arcoxia	90 mg	Film-coated tablets	Oral use
		Ranaxox	90 mg	Film-coated tablets	Oral use
Malta	Merck, Sharp & Dohme Ltd Hertfordshire Road Hoddesdon Hertsfordshire EN11 9BU United Kindgdom	Arcoxia	90 mg	Film-coated tablets	Oral use
The Netherlands	Merck Sharp & Dohme B.V. Waanderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
		Auxib	90 mg	Film-coated tablets	Oral use
Norway	Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Poland	MSD Polska Sp. z o.o. ul. Chłodna 51 PL-00-867 Warszawa	Arcoxia	90 mg	Film-coated tablets	Oral use
Portugal	Merck Sharp & Dohme, Lda. PRT Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo P.O. Box 214 P-2770-192 Paço d'Arcos	Arcoxia	90 mg	Film-coated tablets	Oral use
Portugal	Laboratórios Bial — Portela & C <sup>a</sup> , S.A. PRT Av. da Siderurgia Nacional S. Mamede do Coronado Portugal	Exxiv	90 mg	Film-coated tablets	Oral use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Portugal	Farmacox — Companhia Farmacêutica Sociedade Unipessoal, Lda. PRT Quinta da Fonte Edifício Vasco da Gama, 19 Porto Salvo Paço d'Arcos Portugal	Turox	90 mg	Film-coated tablets	Oral use
Romania	Merck Sharp & Dohme Romania S.R.L. Bucharest Business Park Soseaua Bucuresti-Ploiesti nr. 1A Corp C1, etaj 3, sector 1 RO-013681 Bucharest	Arcoxia	90 mg	Film-coated tablets	Oral use
Slovakia	Merck Sharp & Dohme B.V.Waarderweg 39 P.O. Box 581 2031 BN Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
Slovenia	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140 SLO-1000 Ljubljana	Arcoxia	90 mg	Film-coated tablets	Oral use
Spain	Merck Sharp & Dohme de España, S.A. Josefa Valcárcel, 38 E-28027 Madrid	Arcoxia	90 mg	Film-coated tablets	Oral use
Spain	Laboratorios Abello, S.A. Josefa Valcárcel, 38 E-28027 Madrid	Exxiv	90 mg	Film-coated tablets	Oral use
Sweden	Merck Sharp & Dohme BV PO Box 581 2003 PC Haarlem Nederland	Arcoxia	90 mg	Film-coated tablets	Oral use
		Turox	90 mg	Film-coated tablets	Oral use
United Kingdom	Merck Sharpe & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	Arcoxia	90 mg	Film-coated tablets	Oral use
		Auxib 90	90 mg	Film-coated tablets	Oral use
		Exxiv 90	90 mg	Film-coated tablets	Oral use
		Turox 90	90 mg	Film-coated tablets	Oral use

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS/MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES**

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria		Novo Nordisk Pharma GmbH Opernring 3-5 A-1010 Wien	Noviana 0,5 mg/0,1 mg Film-tabletten	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Belgium		Novo Nordisk Pharma N.V Boulevard International 55/6, B-1070 Brussel	Activelle minor comprimés pelliculés	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Bulgaria		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Eviana филмирани таблетки	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Czech Republic		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Noviana potahované tablety	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Denmark		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Activelle <i>low</i> filmovertrukne tabletter	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Estonia		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Activelle	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Finland		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Activelle 0,5 mg/0,1 mg tabl.	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
France		Novo Nordisk Pharmaceutique S.A.S 30, rue De Valmy F-92936 Paris La Défense Cedex	Activelle 0,5 mg/0,1 mg, comprimé pelliculé	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Germany		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Noviana	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Hungary		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Noviana filmlabletta	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Iceland		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Activelle low 0,5 mg/0,1 mg tablets filmuhúðaðar töflur	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Ireland		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Activelle Tablets	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Italy		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Activelle 0,5 mg/0,1 mg compreste film-rivestite	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Latvia		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Noviana 0,5 mg/0,1 mg apvalk- otās tabletes	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Lithuania		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Activelle	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Luxembourg		Novo Nordisk Pharma N.V Riverside Business Park Boulevard International B-1070 Brussels	Activelle comprimés pelliculés	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
The Netherlands		Novo Nordisk Farma B.V. Flemingweg 18 2408 AV Alphen a/d Rijn Nederland	Activelle filmomhulde tabletten	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Norway		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Noviana 0,5 mg/0,1 mg tablett filmbrasjert	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Portugal		Novo Nordisk, A/S DNK Novo Allé DK-2880 Bagsværd	Activelle	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use



Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Romania		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Noviana comprimate filmate	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Slovak Republic		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Noviana	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Slovenia		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Noviana filmsko obložene tablete	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Spain		Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	Activelle 0,5 mg/ 0,1 mg comprimidos recubiertos de película	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
Sweden	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd		Activelle	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use
United Kingdom		Novo Nordisk Pharma Ltd Broadfield Park Brighton Road RH11 9RT Crawley West Sussex United Kingdom	Noviana film-coated tablets	Estradiol (as hemihydrate) 0,5 mg + Norethisterone acetate 0,1 mg	Film-coated tablets	Oral use

## ANNEX VI

## LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS AND MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Belgium		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Cyprus		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl (')	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Czech Republic		ProStrakan Ltd, Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Denmark		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Estonia		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Finland		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl (¹)	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
France		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Germany		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Greece		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Hungary		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Iceland		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Ireland		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Italy		ProStrakan Ltd Galabank Business Park, Galashiels TD1 1QH United Kingdom	Rapinyl (*)	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Latvia		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Lithuania		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Luxembourg		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Norway		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Poland		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Portugal		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Slovak Republic		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Slovenia		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
Spain		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl (1)	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Sweden	ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom		Abstral	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use
United Kingdom		ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Rapinyl	50 µg 100 µg 200 µg 300 µg 400 µg 600 µg 800 µg	Sublingual tablet	Sublingual use

(<sup>1</sup>) Name approval pending.

## ANNEX VII

## LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTES OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Organon GesmbH Siebenbrunnengasse 21/D/IV A-1050 Wien	Mirtazapine	Remeron SolTab Schmelz-tabletten	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab Schmelz-tabletten	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab Schmelz-tabletten	45 mg	Orodispersible tablets	Oral use	
Belgium	Organon Europe B.V. Kloosterstraat 6 5349AB Oss Nederland  Delegation of power: Organon België n.v. Terhulpesteenweg, 166 B-1170 Brussels	Mirtazapine	Remergon	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergon	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergon	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergon SolTab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergon SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergon SolTab	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergon	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
Cyprus	C.A.Papaellinas & Co Ltd 179 Yiannos Kranidiotis Avenue 2235 Latsia, Nicosia Cyprus	Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Czech Republic	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	REMERON 15 MG	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	REMERON 30 MG	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	REMERON 45 MG	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	REMERON SOLTAB 15 MG	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	REMERON SOLTAB 30 MG	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	REMERON SOLTAB 45 MG	45 mg	Orodispersible tablets	Oral use	
Denmark	IMI Pharma A/S Literbuen 9 DK-2740 Skovlunde	Mirtazapine	Mitazon Smelt	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mitazon Smelt	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mitazon Smelt	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mitazon	30 mg	Film-coated tablets	Oral use	
	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron Smelt	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron Smelt	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron Smelt	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron Oral, opløsning	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
Estonia	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron SolTab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	45 mg	Orodispersible tablets	Oral use	



Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)	
Finland	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron Soltab	15 mg	Orodispersible tablets	Oral use		
		Mirtazapine	Remeron Soltab	30 mg	Orodispersible tablets	Oral use		
		Mirtazapine	Remeron Soltab	45 mg	Orodispersible tablets	Oral use		
		Mirtazapine	Remeron	15 mg	Film-coated tablets	Oral use		
		Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use		
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use		
		Mirtazapine	Remeron	15 mg/ml	Oral solution	Oral use	990 mg/66 ml	
	Oy Organon Ab Maistraatinportti 2 FI-00240 Helsinki	Mirtazapine	Mirtazon	30 mg	Film-coated tablets	Oral use		
		Mirtazapine	Mirtazon Smelt	15 mg	Orodispersible tablets	Oral use		
		Mirtazapine	Mirtazon Smelt	30 mg	Orodispersible tablets	Oral use		
		Mirtazapine	Mirtazon Smelt	45 mg	Orodispersible tablets	Oral use		
	France	Organon S.A. Immeuble Optima 10, rue Godefroy F-92821 PUTEAUX Cedex	Mirtazapine	Norset	15 mg	Film-coated tablets	Oral use	
			Mirtazapine	Norset	30 mg	Film-coated tablets	Oral use	
Mirtazapine			Norset	15 mg	Orodispersible tablets	Oral use		
Mirtazapine			Norset	30 mg	Orodispersible tablets	Oral use		
Mirtazapine			Norset	45 mg	Orodispersible tablets	Oral use		
Mirtazapine			Norset	15 mg/ml	Oral solution	Oral use	990 mg/66 ml	

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Germany	Organon GmbH Mittenheimer Straße 62 D-85764 Oberschleißheim	Mirtazapine	Remergil	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergil	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergil	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergil SolTab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergil SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergil SolTab	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergil	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
	STADApHarm GmbH Stadastraße 2-18 D-61118 Bad Vilbel	Mirtazapine	Mirtazapin STADA	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapin STADA	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapin STADA	45 mg	Orodispersible tablets	Oral use	
Greece	Organon Hellas S.A. 122, Vouliagmenis Av. Helliniko GR-167 77 Athens	Mirtazapine	Remeron	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron SolTab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron	15 mg/ml	Oral solution	Oral use	990 mg/66 ml

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Hungary	N.V. Organon, Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	45 mg	Orodispersible tablets	Oral use	
Iceland	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron Smelt	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron Smelt	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron Smelt	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron 15 mg/ml	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
Ireland	Organon Laboratories Ltd Cambridge Science Park Milton Road CB4 0FL United Kingdom	Mirtazapine	Zispin® film-coated tablets	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Zispin® film-coated tablets	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Zispin® film-coated tablets	45 mg	Film-coated tablets	Oral use	
	Organon (Ireland) Limited PO Box 2857 Drynam Road Swords, Co. Dublin Ireland	Mirtazapine	Zispin® Soltab® orodispersible tablets	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Zispin® Soltab® orodispersible tablets	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Zispin® Soltab® orodispersible tablets	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Zispin® oral solution	15 mg/ml	Oral solution	Oral use	990 mg/66 ml

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Italy	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	mirtazapine	Remeron	15 mg	Film-coated tablets	Oral use	
		mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
		Mirtazapine	Remeron	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapina Organon	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapina Organon	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapina Organon	45 mg	Orodispersible tablets	Oral use	
Latvia	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron SolTab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	45 mg	Orodispersible tablets	Oral use	
Lithuania	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron Sol Tab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron Sol Tab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron Sol Tab	45 mg	Orodispersible tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Luxembourg	Organon Europe B.V. Kloosterstraat 6 5349AB Oss Nederland  Delegation of power: Organon België n.v. Terhulpesteenweg, 166 B-1170 Brussels	Mirtazapine	Remergon	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergon	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergon	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remergon SolTab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergon SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergon SolTab	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remergon	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
The Netherlands	N.V. Organon Kloosterstraat 6 Postbus 20 5340 BH Oss Nederland	Mirtazapine	Remeron	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron drank	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
		Mirtazapine	Remeron SolTab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapine orodispergeerbare tabletten	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapine orodispergeerbare tabletten	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapine orodispergeerbare tabletten	45 mg	Orodispersible tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Norway	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron-S smeltetabletter	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron-S smeltetabletter	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron-S smeltetabletter	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron mikstur, oppløsning	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
Poland	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
Portugal	Organon Portuguesa Produtos Químicos e Farmacêuticos, Lda Av. José Malhoa, 16-B -2º P-1070-159 Lisboa	Mirtazapine	Mirtazapina Organon	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Mirtazapina Organon	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron SolTab	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
	Aacifar Produtos Químicos e Farmacêuticos, Lda Av. José Malhoa, 16-B -2º P-1070-159 Lisboa	Mirtazapine	Mirtazon	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazon	30 mg	Orodispersible tablets	Oral use	
Mirtazapine		Mirtazon	45 mg	Orodispersible tablets	Oral use		

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Romania	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron SolTab 15 mg	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab 30 mg	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron SolTab 45 mg	45 mg	Orodispersible tablets	Oral use	
Slovak Republic	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	REMERON 15 mg	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	REMERON 30 mg	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	REMERON 45 mg	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	REMERON Soltab 15 mg	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	REMERON Soltab 30 mg	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	REMERON Soltab 45 mg	45 mg	Orodispersible tablets	Oral use	
Spain	Organon Española, S.A. Ctra. De Hospitalet, 147-149 Cityparc Ronda de Dalt Edificio Amsterdam E-08940 Cornellá de Llobregat, Barcelona	Mirtazapine	Rexer	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Rexer	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Rexer	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Rexer Flas	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Rexer Flas	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Rexer Flas	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Rexer	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Mirtazapina Organon	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapina Organon	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapina Organon	45 mg	Orodispersible tablets	Oral use	

Member State	Marketing Authorisation Holder	INN	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Sweden	N.V. Organon Kloosterstraat 6 P.O. Box 20 5340 BH Oss Nederland	Mirtazapine	Remeron	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Remeron	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
		Mirtazapine	Remeron-S	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron-S	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Remeron-S	45 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Mirtazapin IP	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Mirtazapin IP	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Mirtazapin IP	45 mg	Film-coated tablets	Oral use	
United Kingdom	Organon Laboratories Ltd Cambridge Science Park Milton Road Cambridge CB4 0FL United Kingdom	Mirtazapine	Mirtazapine 15 mg tablets	15 mg	Film-coated tablets	Oral use	
		Mirtazapine	Mirtazapine 30 mg tablets	30 mg	Film-coated tablets	Oral use	
		Mirtazapine	Mirtazapine 45 mg tablets	45 mg	Film-coated tablets	Oral use	
		Mirtazapine	Mirtazapine 15 mg/ml oral solution	15 mg/ml	Oral solution	Oral use	990 mg/66 ml
		Mirtazapine	Zispin SolTab 15 mg orodispersible tablet	15 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Zispin SolTab 30 mg orodispersible tablet	30 mg	Orodispersible tablets	Oral use	
		Mirtazapine	Zispin SolTab 45 mg orodispersible tablet	45 mg	Orodispersible tablets	Oral use	



## ANNEX VIII

## LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria	Eli Lilly Ges.m.b.H Kölblgasse 8-10 A-1030 Wien	Gemzar 200 mg — Trockensubstanz zur Infusionsbereitung	200 mg	Powder for solution for infusion	Intravenous use
Austria	Eli Lilly Ges.m.b.H Kölblgasse 8-10 A-1030 Wien	Gemzar 1 g — Trockensubstanz zur Infusionsbereitung	1 000 mg	Powder for solution for infusion	Intravenous use
Belgium	Eli Lilly Benelux s.a. Rue de L'Etuve, 52 B-1000 Brussels	Gemzar 1000	1 000 mg	Powder for solution for infusion	Intravenous use
Belgium	Eli Lilly Benelux s.a. Rue de L'Etuve, 52 B-1000 Brussels	Gemzar 200	200 mg	Powder for solution for infusion	Intravenous use
Bulgaria	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Bulgaria	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Czech Republic	Eli Lilly ČR, s. r. o Pobřežní 1A CZ-186 00 Praha 8	Gemzar 1 g	1 g	Powder for solution for infusion	Intravenous use
Czech Republic	Eli Lilly ČR, s. r. o Pobřežní 1A CZ-186 00 Praha 8	Gemzar 200 mg	200 mg	Powder for solution for infusion	Intravenous use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Cyprus	PHADISCO LTD 185 Giannou Kranidioti Avenue CY-2234 Latsia	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Cyprus	PHADISCO LTD 185 Giannou Kranidioti Avenue CY-2234 Latsia	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Denmark	Eli Lilly Danmark A/S Nybrovej 110 DK-2800 Kongens Lyngby	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Denmark	Eli Lilly Danmark A/S Nybrovej 110 DK-2800 Kongens Lyngby	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Estonia	Eli Lilly Holdings Limited, Kingsclere Road, Basingstoke, Hampshire, RG21 6XA United Kingdom	Gemzar 200 mg powder for solution for infusion	200 mg	Powder for solution for infusion	Intravenous use
Estonia	Eli Lilly Holdings Limited Kingsclere Road Basingstoke Hampshire RG21 6XA United Kingdom	Gemzar 1 g powder for solution for infusion	1 g	Powder for solution for infusion	Intravenous use
Finland	Oy Eli Lilly Finland Ab Rajatorpantie 41 C PL 16 FI-01641 Vantaa	Gemzar 200 mg powder for solution for infusion	200 mg	Powder for solution for infusion	Intravenous use
Finland	Oy Eli Lilly Finland Ab Rajatorpantie 41 C PL 16 FI-01641 Vantaa	Gemzar 1 g powder for solution for infusion	1 g	Powder for solution for infusion	Intravenous use
France	LILLY France S.A.S. 13, rue Pagès F-92158 Suresnes Cedex	Gemzar 1 000 mg, poudre pour solution pour perfusion	1 000 mg	Powder for solution for infusion	Intravenous use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
France	LILLY France S.A.S. 13, rue Pagès F-92158 Suresnes Cedex	Gemzar 200 mg, poudre pour solution pour perfusion	200 mg	Powder for solution for infusion	Intravenous use
Germany	Lilly Deutschland GmbH Teichweg 3 D-35396 Gießen	Gemzar 200 mg Pulver zur Herstellung einer Infusionslösung	200 mg	Powder for solution for infusion	Intravenous use
Germany	Lilly Deutschland GmbH Teichweg 3 D-35396 Gießen	Gemzar 1 g Pulver zur Herstellung einer Infusionslösung	1 000 mg	Powder for solution for infusion	Intravenous use
Greece	FARMASERVE LILLY S.A.Cl 15 Km National Road Athens-Lamia GR-14564 Athens	ΓΚΕΜΖΑΡ	200 mg	Powder for solution for infusion	Intravenous use
Greece	FARMASERVE LILLY S.A.Cl 15 Km National Road Athens-Lamia GR-14564 Athens	ΓΚΕΜΖΑΡ	1 000 mg	Powder for solution for infusion	Intravenous use
Hungary	Eli Lilly Nederland BV PO Box 379 3990 GD Houten Nederland	Gemzar 1 g powder for injection	1 g	Powder for injection	Intravenous use
Hungary	Eli Lilly Nederland BV PO Box 379 3990 GD Houten Nederland	Gemzar 200 mg powder for injection	200 mg	Powder for injection	Intravenous use
Ireland	Eli Lilly and Company Limited Lilly House Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Gemzar 200 mg powder for solution for infusion	200 mg	Powder for solution for infusion	Intravenous use
Ireland	Eli Lilly and Company Limited Lilly House Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Gemzar 1 g powder for solution for infusion	1 g	Powder for solution for infusion	Intravenous use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Iceland	Eli Lilly Denmark Nybrovej 110 DK-2800 Lyngby	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Iceland	Eli Lilly Denmark Nybrovej 110 DK-2800 Lyngby	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Italy	Eli Lilly Italia S.P.A. Via Gramsci 731/733 I-50019 Sesto Fiorentino, Florence	Gemzar 200 mg powder for solution for infusion and intravesical instillation	200 mg	Powder for solution for infusion and intravesical instillation	Intravenous use and intravesical use
Italy	Eli Lilly Italia S.P.A. Via Gramsci 731/733 I-50019 Sesto Fiorentino, Florence	Gemzar 1 g powder for solution for infusion and intravesical instillation	1 g	Powder for solution for infusion and intravesical instillation	Intravenous use and intravesical use
Latvia	Eli Lilly Holdings Limited Kingsclere Road Basingstoke Hampshire RG 216XA5 United Kingdom	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Latvia	Eli Lilly Holdings Limited Kingsclere Road Basingstoke Hampshire RG 216XA5 United Kingdom	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Lithuania	Eli Lilly Holdings Limited Kingsclere Road Basingstoke Hampshire RG 216XA5 United Kingdom	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Lithuania	Eli Lilly Holdings Limited Kingsclere Road Basingstoke Hampshire RG 216XA5 United Kingdom	Gemzar	1 000 mg	Powder for solution for infusion	Intravenous use
Luxembourg	Eli Lilly Benelux s.a. Rue de l'Etuve, 52 B-1000 Bruxelles	Gemzar	200 mg	Powder for solution for infusion	Intravenous use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Luxembourg	Eli Lilly Benelux s.a. Rue de l'Etuve, 52 B-1000 Bruxelles	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Malta	Eli Lilly and Company Limited Lilly House Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Malta	Eli Lilly and Company Limited Lilly House Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Gemzar	1 g	Powder for solution for infusion	Intravenous use
The Netherlands	Eli Lilly Nederland BV Grootslag 1-5 3991 RA Houten Nederland	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
The Netherlands	Eli Lilly Netherlands BV Grootslag 1-5 3991 RA Houten Nederland	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Norway	Eli Lilly Norge AS Postboks 6090 Etterstad N-0601 Oslo	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Norway	Eli Lilly Norge AS Postboks 6090 Etterstad N-0601 Oslo	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Poland	Lilly France S.A.S. 2, rue du Colonel Lilly F-67642 Fegersheim	Gemzar	200 mg	Powder for solution for infusion	Intravenous use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Poland	Lilly France S.A.S. 2, rue du Colonel Lilly F-67642 Fegersheim	Gemzar	1 g	Powder for solution for infusion	Intravenous use
Portugal	Lilly Portugal — Produtos Farmacêuticos, Lda Rua Dr. António Loureiro Borges, 1 Piso 1 Arquiparque-Miraflores P-1499-016 Algés	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Portugal	Lilly Portugal — Produtos Farmacêuticos, Lda Rua Dr. António Loureiro Borges, 1 Piso 1 Arquiparque-Miraflores P-1499-016 Algés	Gemzar	1 000 mg	Powder for solution for infusion	Intravenous use
Romania	Lilly France S.A.S. 2, rue du Colonel Lilly F-67642 Fegersheim	Gemzar 1 g	1 000 mg	Powder for solution for infusion	Intravenous use
Romania	Lilly France S.A.S. 2, rue du Colonel Lilly F-67642 Fegersheim	Gemzar 200 mg	200 mg	Powder for solution for infusion	Intravenous use
Slovakia	Eli Lilly ČR, s. r. o. Pobřežní 1A CZ-186 00 Praha 8	Gemzar 1 g	1 g	Powder for solution for infusion	Intravenous use
Slovakia	Eli Lilly ČR, s. r. o. Pobřežní 1A CZ-186 00 Praha 8	Gemzar 200 mg	200 mg	Powder for solution for infusion	Intravenous use
Slovenia	Eli Lilly farmacevtska družba, d.o.o. Dunajska cesta 156 SLO-1000 Ljubljana	Gemzar 200 mg prašek za raztopino za infundiranje	200 mg	Powder for solution for infusion	Intravenous use
Slovenia	Eli Lilly farmacevtska družba, d.o.o. Dunajska cesta 156 SLO-1000 Ljubljana	Gemzar 1 g prašek za raztopino za infundiranje	1 g	Powder for solution for infusion	Intravenous use

Member State	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Spain	Lilly S.A. Avenida de la Industria, 30 E-28108 Alcobendas, Madrid	Gemzar 1 g powder for solution for injection	1 g	Powder for solution for injection	Intravenous use
Spain	Lilly S.A. Avenida de la Industria, 30 E-28108 Alcobendas, Madrid	Gemzar 200 mg powder for solution for injection	200 mg	Powder for solution for injection	Intravenous use
Sweden	Eli Lilly Sweden AB Box 721 S-169 27 Solna	Gemzar	200 mg	Powder for solution for infusion	Intravenous use
Sweden	Eli Lilly Sweden AB Box 721 S-169 27 Solna	Gemzar	1 g	Powder for solution for infusion	Intravenous use
United Kingdom	Eli Lilly and Company Limited Lilly House Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Gemzar 200 mg powder for solution for infusion	200 mg	Powder for solution for infusion	Intravenous use
United Kingdom	Eli Lilly and Company Limited Lilly House Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Gemzar 1g powder for solution for infusion	1 g	Powder for solution for infusion	Intravenous use

## ANNEX IX

**NAME, PHARMACEUTICAL FORMS, STRENGTH OF THE MEDICINAL PRODUCT, ANIMAL SPECIES,  
ROUTES OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDER/APPLICANT**

Member State/Marketing Authorisation Number	Marketing Authorisation Holder	Product invented name	Pharmaceutical Form	Strength/Active substance (INN)	Animal species
Austria (8-00694)	Chevita Tierarzneimittel Ges.m.b.H.	Asprimax 850 mg/g	Powder for oral solution	Sodium salicylate	Pigs
The Netherlands (REG NL 8913)	Dopharma Research B.V.	NA-SALICYLAAT, 100 %, powder for solution for oral administration	Powder for oral solution	Sodium salicylate	Calves and pigs
The Netherlands (REG NL 10411)	Dopharma Research B.V.	NA-SALICYLAAT, 80 % WSP	Powder for oral solution	Sodium salicylate	Calves and pigs
Decentralised procedure subject to an Article 33 Referral (CD 17 April 2008)	Eurovet Animal Health B.V.	SOLACYL 100 %, powder for oral solution for calves and pigs	Powder for oral solution		Calves and pigs



## ANNEX X

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTE(S) OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES**

Member State	Invented name	Marketing Authorisation Holder Company Name and Address	Animal species	Pharmaceutical Form	Strength	Indications
Austria	Baycox 25 mg/ml Lösung zum Eingeben für Hühner und Puten	Bayer Austria Ges.m.b.H Herbststraße 6-10 A-1160 Wien	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Belgium	Baycox 2,5 % orale oplossing	Bayer SA-NV Health Care Animal Health Louizalaan 143, Avenue Louise B-1050 Brussel	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Bulgaria	Baycox 2,5 % solution	Bayer HealthCare AG D-51368 Leverkusen	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Bulgaria	Cevazuril oral solution	Ceva Santé Animale La Balastrière F-33501 Libourne Cedex	Broilers, breeders, pullets and turkeys	Oral solution	25 mg/ml	Prevention and treatment of coccidiosis
Cyprus	Baycox 2,5 % oral solution	Bayer HealthCare AG D-51368 Leverkusen	Broilers and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Czech Republic	Baycox 2,5 % sol. ad us. vet.	Bayer s. r. o. Litvínovská 609/3 CZ-190 21 Praha 9	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
France	Baycox 2,5 %	BAYER SANTE 13, rue Jean Jaurès F-92807 Puteaux	Chickens: broilers, pullets and breeders	Oral solution	25 mg/ml	Prevention and treatment of coccidiosis
France	CEVAZURIL	Ceva Santé Animale La Balastrière F-33501 Libourne Cedex	Chickens: broilers, pullets and breeders	Oral solution	25 mg/ml	Prevention and treatment of coccidiosis

Member State	Invented name	Marketing Authorisation Holder Company Name and Address	Animal species	Pharmaceutical Form	Strength	Indications
Germany	Baycox 2,5 %	Bayer Vital GmbH D-51368 Leverkusen	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Greece	Baycox 2,5 % oral solution	Bayer HealthCare AG D-51368 Leverkusen	Broilers and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Hungary	Baycox 2,5 % solution A.U.V.	Bayer Hungaria Kft.Co. Ltd. Alkotás u. 50 H-1123 Budapest	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Ireland	Baycox 2,5 % Solution	Bayer Ltd Animal Health Division The Atrium Blackthorn Road Dublin 18 Ireland	Chickens	Oral solution	25 mg/ml	Treatment and control of coccidiosis
Italy	Baycox soluzione 2,5 %	Bayer S.p.A. Viale Certosa 130 I-20156 Milano	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Italy	Cevazuril (1)	CEVA VETEM S.p.A. Via Colleoni 15 Agrate Brianza Italia	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Poland	Baycox 2,5 %	Bayer HealthCare AG D-51368 Leverkusen	Broilers, breeders, turkeys and pigeons	Oral solution	25 mg/ml	Chickens and turkeys: treatment of coccidiosis Pigeons: Treatment and prevention of coccidiosis
Portugal	Baycox 2,5 % oral solution	Bayer Portugal S.A Rua Da Quinta do Pinheiro, Nº 5 P-2794-003 Carnaxide	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Romania	Cevazuril	Ceva Santé Animale La Balastrière F-33501 Libourne Cedex	Broilers, breeders, pullets and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis

Member State	Invented name	Marketing Authorisation Holder Company Name and Address	Animal species	Pharmaceutical Form	Strength	Indications
Slovakia	Baycox 2,5 % sol. a.u.v.	Bayer s. r. o. Litvínovská 609/3 CZ-190 21 Praha 9	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
Slovenia	Baycox 2,5 % w/v oral solution	Bayer d.o.o. Bravničarjeva ulica 13 SLO-1000 Ljubljana	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
The Netherlands	Baycox 2,5 %	Bayer BV HealthCare Animal Health Postbus 80 3640 AB Mijdrecht Energieweg 1 3641 RT Mijdrecht Nederland	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
The Netherlands	Baycox oplossing 2,5 %	Bayer BV HealthCare Animal Health Postbus 80 3640 AB Mijdrecht Energieweg 1 3641 RT Mijdrecht Nederland	Chickens and turkeys	Oral solution	25 mg/ml	Treatment of coccidiosis
United Kingdom	Baycox 2,5 % oral solution	Bayer Plc Animal Health Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	Broilers and broiler breeders	Oral solution	25 mg/ml	Treatment of coccidiosis

(<sup>1</sup>) The marketing authorisation is suspended on 12 June 2007.

## ANNEX XI

**LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH(S) OF THE MEDICINAL PRODUCT, ROUTE OF ADMINISTRATION, APPLICANT, MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES**

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg/Dosis Pulver zur Inhalation	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg/Dosis Pulver zur Inhalation	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg/Dosis Pulver zur Inhalation	400 µg	Inhalation powder	Inhalation use	400 micrograms
Belgium		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg inhala- tiepoeder	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg inhala- tiepoeder	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg inhala- tiepoeder	400 µg	Inhalation powder	Inhalation use	400 micrograms
Cyprus		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg Σκόνη για εισπνοή	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg Σκόνη για εισπνοή	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg Σκόνη για εισπνοή	400 µg	Inhalation powder	Inhalation use	400 micrograms
Czech Republic		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulmax 100 µg Prášek k inhalaci	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulmax 200 µg Prášek k inhalaci	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulmax 400 µg Prášek k inhalaci	400 µg	Inhalation powder	Inhalation use	400 micrograms

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Denmark	IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom		Pulairmax	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax	400 µg	Inhalation powder	Inhalation use	400 micrograms
Estonia		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax	400 µg	Inhalation powder	Inhalation use	400 micrograms
Finland		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg inha- laatiojauhe	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg inha- laatiojauhe	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg inha- laatiojauhe	400 µg	Inhalation powder	Inhalation use	400 micrograms
Germany		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 Mikro- gramm/Dosis Pulver zur Inhalation	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 Mikro- gramm/Dosis Pulver zur Inhalation	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 Mikro- gramm/Dosis Pulver zur Inhalation	400 µg	Inhalation powder	Inhalation use	400 micrograms

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Greece		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg Κόνις για εισπνοή	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg Κόνις για εισπνοή	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg Κόνις για εισπνοή	400 µg	Inhalation powder	Inhalation use	400 micrograms
Ireland		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg Inhalation Powder	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg Inhalation Powder	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg Inhalation Powder	400 µg	Inhalation powder	Inhalation use	400 micrograms
Italy		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 polvere per inalazione	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 mcg polvere per inalazione	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 mcg polvere per inalazione	400 µg	Inhalation powder	Inhalation use	400 micrograms
Latvia		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax	400 µg	Inhalation powder	Inhalation use	400 micrograms
Lithuania		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax	400 µg	Inhalation powder	Inhalation use	400 micrograms

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Luxembourg		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg poudre pour inhalation	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg poudre pour inhalation	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg poudre pour inhalation	400 µg	Inhalation powder	Inhalation use	400 micrograms
Malta		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg Trab li jittiehed bin-nifs	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg Trab li jittiehed bin-nifs	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg Trab li jittiehed bin-nifs	400 µg	Inhalation powder	Inhalation use	400 micrograms
The Netherlands		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulmax 100 mg, inhalatiepoeder	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulmax 200 mg, inhalatiepoeder	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulmax 400 mg, inhalatiepoeder	400 µg	Inhalation powder	Inhalation use	400 micrograms
Norway		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulairmax 100 µg inhalasjonspulver	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax 200 µg inhalasjonspulver	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax 400 µg inhalasjonspulver	400 µg	Inhalation powder	Inhalation use	400 micrograms

Member State	Marketing Authorisation Holder	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Poland		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulmax 100 µg proszek do inhalacji	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulmax 200 µg proszek do inhalacji	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulmax 400 µg proszek do inhalacji	400 µg	Inhalation powder	Inhalation use	400 micrograms
Portugal	Teva Pharma — Produtos Farmaceuticos, Lda. Lagoas Park Edificio 1, Piso 3 P-2740-264 Porto Salvo		Pulmax, 100 µg pó para inalação	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulmax, 200 µg pó para inalação	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulmax, 400 µg pó para inalação	400 µg	Inhalation powder	Inhalation use	400 micrograms
Slovak Republic		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Pulmax 100 mcg Inhalačný prášok	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulmax 200 mcg Inhalačný prášok	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulmax 400 mcg Inhalačný prášok	400 µg	Inhalation powder	Inhalation use	400 micrograms
Spain		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ United Kingdom	Budesonida TEVA 100 microgramos polvo para inhalación EFG	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Budesonida TEVA 200 microgramos polvo para inhalación EFG	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Budesonida TEVA 400 microgramos polvo para inhalación EFG	400 µg	Inhalation powder	Inhalation use	400 micrograms
Sweden		IVAX Pharmaceuticals UK Ltd IVAX Quays Albert Basin Royal Docks London E16 2QJ Royaume-Uni	Pulairmax	100 µg	Inhalation powder	Inhalation use	100 micrograms
			Pulairmax	200 µg	Inhalation powder	Inhalation use	200 micrograms
			Pulairmax	400 µg	Inhalation powder	Inhalation use	400 micrograms



## ANNEX XII

**LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS, ANIMAL SPECIES, FREQUENCY AND ROUTES OF ADMINISTRATION, RECOMMENDED DOSES, WITHDRAWAL PERIODS AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES CONCERNED BY THE REFERRAL**

Member State	Marketing Authorisation Holder	(Invented) Name	Pharmaceutical Form	Strength	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period (meat and milk)
Czech Republic	Virbac S.A. 1ère Avenue 2056 M Lid F-06516 Carros Cedex	Suramox 15 % LA	Suspension for injection	150 mg/ml	Cattle, pigs	Two intramuscular injections at 48 hours interval	15 mg amoxicillin/kg bw (equivalent to 1 ml/10 kg)	Meat and offal: Cattle: 58 days Pigs: 35 days Milk: 2,5 days
Spain <sup>(1)</sup>	Virbac S.A. 1ère Avenue 2056 M Lid F-06516 Carros Cedex	Stabox 15 % LA	Suspension for injection	150 mg/ml	Cattle, pigs	Two intramuscular injections at 48 hours interval	15 mg amoxicillin/kg bw (equivalent to 1 ml/10 kg)	Meat and offal: Cattle: 58 days Pigs: 35 days Milk: 2,5 days
Italy	Virbac S.A. 1ère Avenue 2056 M Lid F-06516 Carros Cedex	Stabox 15 % LA	Suspension for injection	150 mg/ml	Cattle, pigs	Two intramuscular injections at 48 hours interval	15 mg amoxicillin/kg bw (equivalent to 1 ml/10 kg)	Meat and offal: Cattle: 58 days Pigs: 35 days Milk: 2,5 days
France <sup>(2)</sup>	Virbac S.A. 1ère Avenue 2056 M Lid F-06516 Carros Cedex	Suramox 15 % LA	Suspension for injection	150 mg/ml	Cattle, pigs	Two intramuscular injections at 48 hours interval	15 mg amoxicillin/kg bw (equivalent to 1 ml/10 kg)	Meat and offal: Cattle: 58 days Pigs: 35 days Milk: 2,5 days

<sup>(1)</sup> Marketing Authorisation not granted.

<sup>(2)</sup> Reference Member State for the Mutual recognition Procedure.