

**Summary of Community decisions on marketing authorizations in respect of medicinal products
from 1.7.2006 to 31.7.2006**

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC ⁽¹⁾ or Article 38 of Directive
2001/82/EC ⁽²⁾)

(2006/C 217/04)

— 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
4.7.2006	STAMARIL	See Annex I	See Annex I	6.7.2006
4.7.2006	Viani Evohaler	See Annex II	See Annex II	5.7.2006
4.7.2006	Seretide Diskus	See Annex III	See Annex III	5.7.2006
4.7.2006	Viani Diskus	See Annex IV	See Annex IV	5.7.2006
4.7.2006	Seretide Evohaler	See Annex V	See Annex V	5.7.2006

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

**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	Name	Strength	Pharmaceutical Form	Route of administration
Austria	Sanofi Pasteur MSD SNC 8, rue Jonas Salk F-69007 Lyon Tel: (33) 437 28 40 00 Fax: (33) 437 28 44 00	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Belgium	Sanofi Pasteur MSD SA Avenue Jules Bordet 13 B-1140 Bruxelles Tel: (32-2) 726 95 84 Fax: (32-2) 726 85 84	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Czech Republic	Aventis Pasteur SA 2, avenue Pont Pasteur F-69007 Lyon Tel: (33) 437 37 01 00 Fax: (33) 437 37 77 37	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Denmark	Sanofi Pasteur MSD SA Avenue Jules Bordet 13 B-1140 Bruxelles Tel: (32-2) 72 69 584 Fax: (32-2) 72 68 584	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Estonia	Aventis Pasteur SA 2, avenue Pont Pasteur F-69007 Lyon Tel: (33) 437 37 01 00 Fax: (33) 437 37 77 37	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Finland	Sanofi Pasteur MSD SA Avenue Jules Bordet 13 B-1140 Bruxelles Tel: (32-2) 726 95 84 Fax: (32-2) 726 85 84	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use

Member State	Marketing Authorisation Holder	Name	Strength	Pharmaceutical Form	Route of administration
France	Sanofi Pasteur MSD SNC 8, rue Jonas Salk F-69007 Lyon Tel: (33) 437 28 40 00 Fax: (33) 437 28 44 00	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Germany	Sanofi Pasteur MSD GmbH Paul-Ehrlich-Str. 1 D-69181 Leimen Tel: (49) 62 24 59 40 Fax: (49) 622 45 94 33	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Hungary	Aventis Pasteur SA 2, avenue Pont Pasteur F-69007 Lyon Tel: (33) 437 37 01 00 Fax: (33) 437 37 77 37	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Ireland	Sanofi Pasteur MSD Ltd Belgard Road Tallaght Dublin 24 Ireland Tel: (35) 314 04 16 88 Fax: (35) 314 04 16 87	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Italy	Sanofi Pasteur MSD SNC 8, rue Jonas Salk F-69007 Lyon Tel: (33) 437 28 40 00 Fax: (33) 437 28 44 00	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Latvia	Aventis Pasteur SA 2, avenue Pont Pasteur F-69007 Lyon Tel: (33) 437 37 01 00 Fax: (33) 437 37 77 37	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Lithuania	Aventis Pasteur SA 2, avenue Pont Pasteur F-69007 Lyon Tel: (33) 437 37 01 00 Fax: (33) 437 37 77 37	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use

Member State	Marketing Authorisation Holder	Name	Strength	Pharmaceutical Form	Route of administration
Luxemburg	Sanofi Pasteur MSD SA Avenue Jules Bordet 13 B-1140 Bruxelles Tel: (32-2) 726 95 84 Fax: (32-2) 726 85 84	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Poland	Aventis Pasteur SA 2, avenue Pont Pasteur F-69007 Lyon Tel: (33) 437 37 01 00 Fax: (33) 437 37 77 37	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Portugal	Sanofi Pasteur MSD SNC 8, rue Jonas Salk F-69007 Lyon Tel: (33) 437 28 40 00 Fax: (33) 437 28 44 00	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Slovakia	Aventis Pasteur SA 2, avenue Pont Pasteur F-69007 Lyon Tel: (33) 437 37 01 00 Fax: (33) 437 37 77 37	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Spain	Sanofi Pasteur MSD SA Edificio Cuzco IV Paseo de la Castellana, 141 E-28046 Madrid Tel: (34) 913 71 78 00 Fax: (34) 913 71 78 88	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Sweden	Sanofi Pasteur MSD SA Avenue Jules Bordet 13 B-1140 Bruxelles Tel: (32-2) 726 95 84 Fax: (32-2) 726 85 84	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
The Netherlands	Sanofi-Pasteur MSD SA Avenue Jules Bordet 13 B-1140 Bruxelles Tel: (32-2) 726 85 84 Fax: (32-2) 726 85 84	STAMARIL Pasteur	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use

Member State	Marketing Authorisation Holder	Name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Sanofi Pasteur MSD Limited Mallards Reach, Bridge Road Maidenhead Berkshire SL6 1QP United Kingdom Tel: (44) 16 28 78 52 91 Fax: (44) 16 28 58 81 66	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Iceland	Sanofi Pasteur MSD SA Avenue Jules Bordet 13 B-1140 Bruxelles Tel: (32-2) 726 85 84 Fax: (32-2) 726 85 84	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use
Norway	Sanofi Pasteur MSD SA Avenue Jules Bordet 13 B-1140 Bruxelles Tel: (32-2) 726 85 84 Fax: (32-2) 726 85 84	STAMARIL	Not less than 1 000 LD50 units	Powder and solvent for suspension for injection	Subcutaneous use (preferred) or intramuscular use

ANNEX II

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

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Austria	Allen Pharmazeutika Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Viani forte Dosieraerosol	25/250	Pressurised inhalation, suspension	Inhalation use
Austria	Allen Pharmazeutika Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Viani standard Dosieraerosol	25/125	Pressurised inhalation, suspension	Inhalation use
Austria	Allen Pharmazeutika Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Viani junior Dosieraerosol	25/50	Pressurised inhalation, suspension	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 25/125	25/125	Pressurised inhalation, suspension	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 25/250	25/250	Pressurised inhalation, suspension	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 25/50	25/50	Pressurised inhalation, suspension	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Viani Evohaler	25/125	Pressurised inhalation, suspension	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Viani Evohaler	25/250	Pressurised inhalation, suspension	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Viani Evohaler	25/50	Pressurised inhalation, suspension	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Viani	25/50	Pressurised inhalation, suspension	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Viani	25/125	Pressurised inhalation, suspension	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Viani	25/250	Pressurised inhalation, suspension	Inhalation use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 D-80339 München	Viani mite Dossier-Aerosol FCKW-frei 25 mg/50 mg Druckgasinhalation, Suspension	25/50	Pressurised inhalation, suspension	Inhalation use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 D-80339 München	Viani Dossier-Aerosol FCKW-frei 25 mg/125 mg Druckgasinhalation, Suspension	25/125	Pressurised inhalation, suspension	Inhalation use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 D-80339 München	Viani forte Dossier-Aerosol FCKW-frei 25 mg/250 mg Druckgasinhalation, Suspension	25/250	Pressurised inhalation, suspension	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanburys) Stonemasons Way Rathfarnham Dublin 16 Irlande	Viani Evohaler	25/50	Pressurised inhalation, suspension	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanburys) Stonemasons Way Rathfarnham Dublin 16 Irlande	Viani Evohaler	25/125	Pressurised inhalation, suspension	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanburys) Stonemasons Way Rathfarnham Dublin 16 Irlande	Viani Evohaler	25/250	Pressurised inhalation, suspension	Inhalation use
Italy	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg	Aliflus	25/50	Pressurised inhalation, suspension	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Italy	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg	Aliflus	25/125	Pressurised inhalation, suspension	Inhalation use
Italy	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg	Aliflus	25/250	Pressurised inhalation, suspension	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 25/50	25/50	Pressurised inhalation, suspension	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 25/125	25/125	Pressurised inhalation, suspension	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 25/250	25/250	Pressurised inhalation, suspension	Inhalation use
Portugal	Alodial Farmacêutica, Lda. Estrada Marco do Grilo Zemouto P-2830 Coia	Veraspir Inalador	25/50	Pressurised inhalation, suspension	Inhalation use
Portugal	Alodial Farmacêutica, Lda. Estrada Marco do Grilo Zemouto P-2830 Coia	Veraspir Inalador	25/125	Pressurised inhalation, suspension	Inhalation use
Portugal	Alodial Farmacêutica, Lda. Estrada Marco do Grilo Zemouto P-2830 Coia	Veraspir Inalador	25/250	Pressurised inhalation, suspension	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Brisair 25/125	25/125	Pressurised inhalation suspension	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Brisair 25/250	25/250	Pressurised inhalation suspension	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Spain	GlaxoSmithKline SA Parque Tecnologico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Brisair 25/50	25/50	Pressurised inhalation suspension	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Viani Evohaler mite	25/50	Pressurised inhalation, suspension	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Viani Evohaler	25/125	Pressurised inhalation, suspension	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Viani Evohaler forte	25/250	Pressurised inhalation, suspension	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Viani 50 Evohaler	25/50	Pressurised inhalation suspension	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Viani 125 Evohaler	25/125	Pressurised inhalation suspension	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Viani 250 Evohaler	50/250	Pressurised inhalation suspension	Inhalation use

ANNEX III

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

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Austria	Glaxo SmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Seretide Diskus forte	50/500	Inhalation powder, predispensed	Inhalation use
Austria	Glaxo SmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Seretide Diskus standard	50/250	Inhalation powder, predispensed	Inhalation use
Austria	Glaxo SmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Seretide Diskus junior	50/100	Inhalation powder, predispensed	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 50/100 Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 50/250 Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 50/500 Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby	Seretide	50/100	Inhalation powder, predispensed	Inhalation use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby	Seretide	50/250	Inhalation powder, predispensed	Inhalation use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby	Seretide	50/500	Inhalation powder, predispensed	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Seretide Diskus	50/100	Inhalation powder, predispensed	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Seretide Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Seretide Diskus	50/500	Inhalation powder, predispensed	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Seretide Diskus	50/100	Inhalation powder, predispensed	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Seretide Diskus	50/250	Inhalation powder, predispensed	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Seretide Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Germany	Schwarz Pharma Deutschland GmbH Alfred-Nobel-Str. 10 D-40789 Monheim	atmadisc mite 50mg/100mg Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Germany	Schwarz Pharma Deutschland GmbH Alfred-Nobel-Str. 10 D-40789 Monheim	atmadisc 50mg/250mg Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Germany	Schwarz Pharma Deutschland GmbH Alfred-Nobel-Str. 10 D-40789 Monheim	atmadisc forte 50mg/500mg Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Greece	GlaxoSmithKline A.E.B.E Leof. Kifisias 266 GR-15232 Halandri, Athens	Seretide Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Greece	GlaxoSmithKline A.E.B.E Leof. Kifisias 266 GR-15232 Halandri, Athens	Seretide Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Greece	GlaxoSmithKline A.E.B.E Leof. Kifisias 266 GR-15232 Halandri, Athens	Seretide Diskus	50/500	Inhalation powder, predispensed	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanbury) Stonemasons Way Rathfarnham Dublin 16 Ireland	Seretide Diskus 100	50/100	Inhalation powder, predispensed.	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanbury) Stonemasons Way Rathfarnham Dublin 16 Ireland	Seretide Diskus 250	50/250	Inhalation powder, predispensed.	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanbury) Stonemasons Way Rathfarnham Dublin 16 Ireland	Seretide Diskus 500	50/500	Inhalation powder, predispensed.	Inhalation use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 I-37135 Verona	Seretide Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 I-37135 Verona	Seretide Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 I-37135 Verona	Seretide Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 50/100 Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 50/250 Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 50/500 Diskus	50/500	Inhalation powder, predispensed	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque Miraflores P-1495-131 Algés	Seretaide Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque Miraflores P-1495-131 Algés	Seretaide Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque Miraflores P-1495-131 Algés	Seretaide Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Seretide Accuhaler	50/100	Inhalation powder, predispensed	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Seretide Accuhaler	50/250	Inhalation powder, predispensed	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Seretide Accuhaler	50/500	inhalation powder, predispensed	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Seretide Diskus mite	50/100	Inhalation powder, predispensed	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Seretide Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Seretide Diskus forte	50/500	inhalation powder, predispensed	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist Nederland	Seretide 50/100 Diskus	50/100	Inhalation powder, predispensed	Inhalation use
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist Nederland	Seretide 50/250 Diskus	50/250	Inhalation powder, predispensed	Inhalation use
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist Nederland	Seretide 50/500 Diskus	50/500	Inhalation powder, predispensed	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Seretide 100 Accuhaler	50/100	Inhalation powder, predispensed	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Seretide 250 Accuhaler	50/250	Inhalation powder, predispensed	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Seretide 500 Accuhaler	50/500	Inhalation powder, predispensed	Inhalation use

ANNEX IV

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

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Austria	Allen Pharmazeutika Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Viani Diskus forte	50/500	Inhalation powder, predispensed	Inhalation use
Austria	Allen Pharmazeutika Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Viani Diskus standard	50/250	Inhalation powder, predispensed	Inhalation use
Austria	Allen Pharmazeutika Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Viani Diskus junior	50/100	Inhalation powder, predispensed	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 50/100 Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 50/250 Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Viani 50/500 Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Viani Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Viani Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Viani Diskus	50/500	Inhalation powder, predispensed	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Viani Diskus	50/100	Inhalation powder, predispensed	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Viani Diskus	50/250	Inhalation powder, predispensed	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Viani Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Germany	GlaxoSmithKline GmbH & Co KG Theresienhöhe 11 D-80339 München	Viani mite 50 mg/100 mg Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Germany	GlaxoSmithKline GmbH & Co KG Theresienhöhe 11 D-80339 München	Viani 50 mg/250 mg Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Germany	GlaxoSmithKline GmbH & Co KG Theresienhöhe 11 D-80339 München	Viani forte 50 mg/500 mg Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanburys) Stonemasons Way Rathfarnham Dublin 16 Ireland	Viani Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanburys) Stonemasons Way Rathfarnham Dublin 16 Ireland	Viani Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanburys) Stonemasons Way Rathfarnham Dublin 16 Ireland	Viani Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Italy	Menarini International Operations Luxem- bourg S.A. 1, Avenue de la Gare L-1611 Luxembourg	Aliflus Diskus	50/100	Inhalation powder, predispensed	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Italy	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg	Aliflus Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Italy	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg	Aliflus Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v., Rue du Tilleul 13, B-1332 Genval	Viani 50/100 Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v., Rue du Tilleul 13, B-1332 Genval	Viani 50/250 Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v., Rue du Tilleul 13, B-1332 Genval	Viani 50/500 Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Portugal	Alodial Farmacêutica, Lda. Estrada Marco do Grilo Zemouto P-2830 Coina	Veraspir Diskus	50/100	Inhalation powder, predispensed	Inhalation use
Portugal	Alodial Farmacêutica, Lda. Estrada Marco do Grilo Zemouto P-2830 Coina	Veraspir Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Portugal	Alodial Farmacêutica, Lda. Estrada Marco do Grilo Zemouto P-2830 Coina	Veraspir Diskus	50/500	Inhalation powder, predispensed	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Brisair Accuhaler	50/100	Inhalation powder, predispensed	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Brisair Accuhaler	50/250	Inhalation powder, predispensed	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Brisair Accuhaler 50	50/500	Inhalation powder, predispensed	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Viani Diskus mite	50/100	Inhalation powder, predispensed	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Viani Diskus	50/250	Inhalation powder, predispensed	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Viani Diskus forte	50/500	Inhalation powder, predispensed	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Viani 100 Accuhaler	50/100	Inhalation powder, predispensed	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Viani 250 Accuhaler	50/250	Inhalation powder, predispensed	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Viani 500 Accuhaler	50/500	Inhalation powder, predispensed	Inhalation use

ANNEX V

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

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Austria	Glaxo SmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Seretide forte Dosieraerosol	25/250	Pressurised inhalation, suspension	Inhalation use
Austria	Glaxo SmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Seretide standard Dosieraerosol	25/125	Pressurised inhalation, suspension	Inhalation use
Austria	Glaxo SmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 A-1140 Wien	Seretide junior Dosieraerosol	25/50	Pressurised inhalation, suspension	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 25/125	25/125	Pressurised inhalation, suspension	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 25/250	25/250	Pressurised inhalation, suspension	Inhalation use
Belgium	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 25/50	25/50	Pressurised inhalation, suspension	Inhalation use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby	Seretide	25/50	Pressurised inhalation, suspension	Inhalation use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby	Seretide	25/125	Pressurised inhalation, suspension	Inhalation use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby	Seretide	25/250	Pressurised inhalation, suspension	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Seretide Evohaler	25/125	Pressurised inhalation, suspension	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Seretide Evohaler	25/250	Pressurised inhalation, suspension	Inhalation use
Finland	GlaxoSmithKline Oy Piispansilta 9A P.O. Box 24 FIN-02231 Espoo	Seretide Evohaler	25/50	Pressurised inhalation, suspension	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Seretide	25/50	Pressurised inhalation suspension	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Seretide	25/125	Pressurised inhalation suspension	Inhalation use
France	Laboratoire GlaxoSmithKline 100, route de Versailles F-78163 Marly-le-roi Cedex	Seretide	25/250	Pressurised inhalation suspension	Inhalation use
Germany	Schwarz Pharma Deutschland GmbH Alfred-Nobel-Str. 10 D-40789 Monheim	atmadisc mite Dosier-Aerosol FCKW-frei 25 mg/50 mg Druckgasinhalation, Suspension	25/50	Pressurised inhalation suspension	Inhalation use
Germany	Schwarz Pharma Deutschland GmbH Alfred-Nobel-Str. 10 D-40789 Monheim	atmadisc Dosier-Aerosol FCKW-frei 25 mg/125 mg Druckgasinhalation, Suspension	25/125	Pressurised inhalation suspension	Inhalation use
Germany	Schwarz Pharma Deutschland GmbH Alfred-Nobel-Str. 10 D-40789 Monheim	atmadisc forte Dosier-Aerosol FCKW-frei 25 mg/250 mg Druckgasinhalation, Suspension	25/250	Pressurised inhalation suspension	Inhalation use
Greece	GlaxoSmithKline A.E.B.E Leof. Kifisias 266 GR-15232 Halandri, Athens	Seretide Inhaler	25/250	Pressurised inhalation suspension	Inhalation use
Greece	GlaxoSmithKline A.E.B.E Leof. Kifisias 266 GR-15232 Halandri, Athens	Seretide Inhaler	25/50	Pressurised inhalation suspension	Inhalation use
Greece	GlaxoSmithKline A.E.B.E Leof. Kifisias 266 GR-15232 Halandri, Athens	Seretide Inhaler	25/125	Pressurised inhalation suspension	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Iceland	GlaxoSmithKline ehf Thverholt 14 IS-105 Reykjavik	Seretide	25/50	Pressurised inhalation suspension	Inhalation use
Iceland	GlaxoSmithKline ehf Thverholt 14 IS-105 Reykjavik	Seretide	25/125	Pressurised inhalation suspension	Inhalation use
Iceland	GlaxoSmithKline ehf Thverholt 14 IS-105 Reykjavik	Seretide	25/250	Pressurised inhalation suspension	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanbury) Stonemasons Way Rathfarnham Dublin 16 Irlande	Seretide 50 Evohaler	25/50	Pressurised inhalation, suspension	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanbury) Stonemasons Way Rathfarnham Dublin 16 Irlande	Seretide 125 Evohaler	25/125	Pressurised inhalation, suspension	Inhalation use
Ireland	GlaxoSmithKline (Ireland) Limited (trading as: Allen & Hanbury) Stonemasons Way Rathfarnham Dublin 16 Irlande	Seretide 250 Evohaler	25/250	Pressurised inhalation, suspension	Inhalation use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 I-37135 Verona	Seretide	25/50	Pressurised inhalation, suspension	Inhalation use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 I-37135 Verona	Seretide	25/125	Pressurised inhalation, suspension	Inhalation use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 I-37135 Verona	Seretide	25/250	Pressurised inhalation, suspension	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 25/50	25/50	Pressurised inhalation, suspension	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 25/125	25/125	Pressurised inhalation, suspension	Inhalation use
Luxembourg	GlaxoSmithKline s.a./n.v. Rue du Tilleul 13 B-1332 Genval	Seretide 25/250	25/250	Pressurised inhalation, suspension	Inhalation use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque Miraflores P-1495-131 Algés	Seretaide Inalador	25/50	Pressurised inhalation, suspension	Inhalation use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque Miraflores P-1495-131 Algés	Seretaide Inalador	25/125	Pressurised inhalation, suspension	Inhalation use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque Miraflores P-1495-131 Algés	Seretaide Inalador	25/250	Pressurised inhalation, suspension	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Seretide 25/50	25/50	Pressurised inhalation suspension	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Seretide 25/125	25/125	Pressurised inhalation suspension	Inhalation use
Spain	GlaxoSmithKline SA Parque Tecnológico de Madrid Calle Severo Ochoa 2 E-28760, Tres Cantos, Madrid	Seretide 25/250	25/250	Pressurised inhalation suspension	Inhalation use

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Seretide Evohaler mite	25/50	Pressurised inhalation, suspension	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Seretide Evohaler	25/125	Pressurised inhalation, suspension	Inhalation use
Sweden	GlaxoSmithKline AB Box 516 S-169 29 Solna	Seretide Evohaler forte	25/250	Pressurised inhalation, suspension	Inhalation use
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist Nederland	Seretide 25/50	25/50	Pressurised inhalation, suspension	Inhalation use
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist Nederland	Seretide 25/125	25/125	Pressurised inhalation, suspension	Inhalation use
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ Zeist Nederland	Seretide 25/250	25/250	Pressurised inhalation, suspension	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Seretide 50 Evohaler	25/50	Pressurised inhalation, suspension	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Seretide 125 Evohaler	25/125	Pressurised inhalation, suspension	Inhalation use
United Kingdom	Glaxo Wellcome UK Limited, trading as Allen & Hanburys Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Seretide 250 Evohaler	50/250	Pressurised inhalation, suspension	Inhalation use