Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 June 2012 to 30 June 2012

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

(2012/C 224/02)

— Issuing, maintenance or modification 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
14/6/2012	Tilmicosin	See Annex I	See Annex I	18/6/2012
18/6/2012	Milaxyn plus and associated names	See Annex II	See Annex II	20/6/2012
28/6/2012	Flutiform and associated names	See Annex III	See Annex III	3/7/2012
28/6/2012	Iffeza and associated names	See Annex IV	See Annex IV	3/7/2012

[1] OJ L 311, 28.11.01, p. 67.
[2] OJ L 311, 28.11.01, p. 1.

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORMS, ACTIVE SUBSTANCE, STRENGTHS OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
Austria	Richter Pharma AG Feldgasse 19 A-4600 Wels AUSTRIA	Pulmotil G 100 g/kg Arzneimittel-Vormischung zur Herstellung von Fütterungsarzneimitteln für Schweine und Kaninchen	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Austria	Richter Pharma AG Feldgasse 19 A-4600 Wels AUSTRIA	Pulmotil G 200 g/kg Arzneimittel-Vormischung zur Herstellung von Fütterungsarzneimitteln für Schweine und Kaninchen	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52 Stoofstraat 52 1000 Brussel BELGIUM	Pulmotil 40 VET Pre-mix	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52 Stoofstraat 52 1000 Brussel BELGIUM	Pulmotil 100 VET Pre-mix	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52 Stoofstraat 52 1000 Brussel BELGIUM	Pulmotil 100 Granules	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue de l'Etuve 52 Stoofstraat 52 1000 Brussel BELGIUM	Pulmotil 200 VET Pre-mix	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits

Member State EU/EEA	Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
Cyprus	Eli Lilly Regional Operations GmbH Elanco Animal Health Kolblgasse 8-10 1030 Wien AUSTRIA	Pulmotil pre-mix 200 g/kg ,πρόμιγμα για φαρμακούχο ζωοτροφή,για χοίρους και κονίκλους.	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Czech Republic	Eli Lilly Regional Operations GmbH Elanco Animal Health Kolblgasse 8-10 1030 Wien AUSTRIA	Pulmotil 200 mg/g pre-mix pro medikaci krmiva	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Germany	Lilly Deutschland GmbH Abt. Elanco Animal Health Werner-Reimers-Str. 2-4 D-61352 Bad Homburg GERMANY	Pulmotil G 40	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Germany	Lilly Deutschland GmbH Abt. Elanco Animal Health Werner-Reimers-Str. 2-4 D-61352 Bad Homburg GERMANY	Pulmotil G 100	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Germany	Lilly Deutschland GmbH Abt. Elanco Animal Health Werner-Reimers-Str. 2-4 D-61352 Bad Homburg GERMANY	Pulmotil G 20 % AMV	Tilmicosin (as phospate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Denmark	Elanco Animal Health Eli Lilly Danmark A/S Nybrovej 110 DK-2800 Kongens Lyngby DENMARK	Pulmotil Vet.	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Denmark	Elanco Animal Health Eli Lilly Danmark A/S Nybrovej 110 DK-2800 Kongens Lyngby DENMARK	Pulmotil Vet.	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits

Member State EU/EEA	Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
Denmark	Elanco Animal Health Eli Lilly Danmark A/S Nybrovej 110 DK-2800 Kongens Lyngby DENMARK	Pulmotil Vet.	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Greece	Eli Lilly Regional Operations GmbH Elanco Animal Health Kolblgasse 8-10 1030 Wien AUSTRIA	PULMOTIL 200	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Spain	ELANCO VALQUÍMICA, S.A. Avda. de la Industria 30 28108 Alcobendas Madrid SPAIN	PULMOTIL G 40	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Spain	ELANCO VALQUÍMICA, S.A. Avda. de la Industria 30 28108 Alcobendas Madrid SPAIN	PULMOTIL G 100	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Spain	ELANCO VALQUÍMICA, S.A. Avda. de la Industria 30 28108 Alcobendas Madrid SPAIN	PULMOTIL G 200	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
France	LILLY France 13 Rue Pages 92158 Suresnes Cedex FRANCE	PULMOTIL TILMICOSINE 40 PORC-LAPIN	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
France	QALIAN 34 Rue Jean Monnet Zi D'Etriche 49500 Serge FRANCE	SANTAMIX TILMICOSINE 40 PORCINS - LAPINS	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits

Member State EU/EEA	Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
France	SOGEVAL 200 Route de Mayenne Zi des Touches 53000 Laval France	CONCENTRAT VO 08 TILMICOSINE PORCIN-LAPIN	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Hungary	Eli Lilly Regional Operations GmbH Elanco Animal Health Kolblgasse 8-10 1030 Wien AUSTRIA	Pulmotil G 200 gyógypre-mix	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Ireland	Eli Lilly and Company Ltd Elanco Animal Health Lilly House Priestly Road Basingstoke Hampshire RG24 9NL UNITED KINGDOM	Pulmotil G40 Pre-mix for medicated feedingstuff	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Ireland	Eli Lilly and Company Ltd Elanco Animal Health Lilly House Priestly Road Basingstoke Hampshire RG24 9NL UNITED KINGDOM	Pulmotil G100 Pre-mix for medicated feedingstuff	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Ireland	Eli Lilly and Company Ltd Elanco Animal Health Lilly House Priestly Road Basingstoke Hampshire RG24 9NL UNITED KINGDOM	Pulmotil G200 Pre-mix for medicated feedingstuff	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Italy	ELI LILLY ITALIA SPA VIA GRAMSCI 731/733 - SESTO FIORENTINO – FI ITALY	PULMOTIL G 200 PRE-MIX	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits

Member State EU/EEA	Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
Italy	CEVA VETEM SpA via Colleoni 15 20041 Agrate Brianza (MB) ITALY	MICLOZAN 200 PRE-MIX	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Netherlands	Eli Lilly Nederland B.V. Elanco Animal Health Grootslag 1-5 3991 RA Houten THE NETHERLANDS	PULMOTIL® G40 pre-mix voor gemedicineerd voer voor varkens	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Netherlands	Eli Lilly Nederland B.V. Elanco Animal Health Grootslag 1-5 3991 RA Houten THE NETHERLANDS	PULMOTIL® G100 pre-mix voor gemedicineerd voer voor varkens	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Netherlands	Eli Lilly Nederland B.V. Elanco Animal Health Grootslag 1-5 3991 RA Houten THE NETHERLANDS	PULMOTIL® G200 pre-mix voor gemedicineerd voer voor varkens	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Portugal	Lilly Portugal – Produtos Farmacêuticos, Lda. Rua Cesário Verde, nº5- piso 4 Linda-a-Pastora 2790 – 326 QUEIJAS PORTUGAL	Pulmotil G40 Pré-mistura medicamentosa para alimento medicamentoso para suínos e coelhos	Tilmicosin (as phosphate)	40 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Portugal	Lilly Portugal – Produtos Farmacêuticos, Lda. Rua Cesário Verde, nº5- piso 4 Linda-a-Pastora 2790 – 326 QUEIJAS PORTUGAL	Pulmotil G100 Pré-mistura medicamentosa para alimento medicamentoso para suínos e coelhos	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits

Member State EU/EEA	Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
Portugal	Lilly Portugal – Produtos Farmacêuticos, Lda. Rua Cesário Verde, nº5- piso 4 Linda-a-Pastora 2790 – 326 QUEIJAS PORTUGAL	Pulmotil G200 Pré-mistura medicamentosa para alimento medicamentoso para suínos e coelhos	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Romania	Eli Lilly Regional Operations GmbH Elanco Animal Health Kolblgasse 8-10 1030 Wien AUSTRIA	PULMOTIL 200g/kg pre-mix	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
Slovak Republic	Elli Lilly and Company Limited. Speke Operations Fleming RoadSpeke Liverpool L24 9LN UNITED KINGDOM	Pulmotil G 200 pre-mix ad us.vet.	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
United Kingdom	Eli Lilly and Company Ltd Elanco Animal Health Lilly House Priestly Road Basingstoke Hampshire RG24 9NL UNITED KINGDOM	Pulmotil G100 Pre-mix for Medicated Feedingstuff	Tilmicosin (as phosphate)	100 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits
United Kingdom	Eli Lilly and Company Ltd Elanco Animal Health Lilly House Priestly Road Basingstoke Hampshire RG24 9NL UNITED KINGDOM	Pulmotil G200 Pre-mix for Medicated Feedingstuff	Tilmicosin (as phosphate)	200 g tilmicosin per kg pre-mix	Pre-mix for medicated feedingstuff	Pigs, Rabbits

ANNEX II

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Austria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Austria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Bulgaria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus таблетки за кучета	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Bulgaria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus таблетки за кучета	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Bulgaria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus таблетки за кучета	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Cyprus	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Δισκία Για Σκύλους	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Czech Republic	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tablety pro psy	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Czech Republic	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tablety pro psy	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Czech Republic	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tablety pro psy	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Denmark	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Denmark	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Estonia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletid koertele	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Estonia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletid koertele	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Finland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus 50 mg/144 mg/ 150 mg tablet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Finland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus 50 mg/144 mg/ 150 mg tablet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Finland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus 50 mg/144 mg/ 150 mg tablet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
France	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Milaxyn comprimé pour chiens	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
France	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Strantel comprimé pour chiens	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
France	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazical comprimé pour chiens	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
France	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Voxical comprimé pour chiens	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Strantel Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Greece	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel plus Δισκία Για Σκύλους	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Greece	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel plus Δισκία Για Σκύλους	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Greece	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel plus Δισκία Για Σκύλους	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletta kutyák részére A.U.V	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletta kutyák részére A.U.V	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletta kutyák részére A.U.V	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Iceland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus töflur fyrir hunda	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Iceland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus töflur fyrir hunda	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Milaxyn Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazical Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Strantel Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Voxical Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Italy	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Canitel Plus compresse per cani	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Italy	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus compresse per cani	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Italy	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel compresse per cani	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Latvia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel tablets Tabletes suņiem	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Latvia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel tablets Tabletes suņiem	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Latvia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel tablets Tabletes suņiem	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Lithuania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletės šunims	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Lithuania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletės šunims	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Lithuania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletės šunims	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Luxembourg	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Luxembourg	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Norway	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Vet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Norway	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Vet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Poland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletki dla psów	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Poland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletki dla psów	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Poland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletki dla psów	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus Comprimidos para cães	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Comprimidos para cães	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus Comprimidos para cães	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Romania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus Comprimate pentru câini	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Romania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Comprimate pentru câini	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Romania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus Comprimate pentru câini	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovakia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tablety pre psov	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovakia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tablety pre psov	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovakia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tablety pre psov	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovenia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tablete za pse	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovenia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tablete za pse	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Slovenia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tablete za pse	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Spain	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel comprimidos para perros	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Spain	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel comprimidos para perros	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Spain	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel comprimidos para perros	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Sweden	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel vet. 150 mg/ 144 mg/50 mg tablett för hund	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Sweden	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Strantel vet. 150 mg/ 144 mg/50 mg tablett för hund	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Easimax plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

ANNEX III

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANT IN THE MEMBER STATES

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 Mikrogramm/ 5 Mikrogramm pro Sprühstoß Druckgasinhalation	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Austria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 Mikrogramm/ 5 Mikrogramm pro Sprühstoß Druckgasinhalation	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Austria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 Mikrogramm/ 10 Mikrogramm pro Sprühstoß Druckgasinhalation	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Belgium	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 mcg/5 mcg, aërosol, suspensie	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Belgium	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 mcg/5 mcg, aërosol, suspensie	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Belgium	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 mcg/10 mcg, aërosol, suspensie	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Bulgaria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Bulgaria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Cyprus	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Cyprus	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Cyprus	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Czech Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Czech Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Czech Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Denmark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Denmark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Denmark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Finland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Finland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Finland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
France	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
France	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
France	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Germany	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Germany	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Germany	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Iceland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Iceland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Iceland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Ireland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Ireland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Ireland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Italy	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Italy	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Italy	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Luxembourg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Luxembourg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Luxembourg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Netherlands	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 microgram/ 5 microgram/dosis aërosol, suspensie	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Netherlands	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 microgram/ 5 microgram/dosis aërosol, suspensie	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Netherlands	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 microgram/ 10 microgram/dosis aërosol, suspensie	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Norway	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Norway	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Norway	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Poland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Poland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Poland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Romania	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 microgram/ 5 microgram suspensie de inhalat presurizată	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Romania	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 microgram/ 5 microgram suspensie de inhalat presurizată	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Romania	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 microgram/ 10 microgram suspensie de inhalat presurizată	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Slovak Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 50/5 µg	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 125/5 µg	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Slovak Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 250/10 µg	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Sweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Sweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Sweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
United Kingdom	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
United Kingdom	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
United Kingdom	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use

ANNEX IV

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANT IN THE MEMBER STATES

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strengths	Pharmaceutical form	Route of administration
Austria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Austria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Austria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Belgium	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 50 mcg/5 mcg, aërosol, suspensie	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Belgium	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 125 mcg/5 mcg, aërosol, suspensie	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Belgium	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 250 mcg/10 mcg, aërosol, suspensie	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Bulgaria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strengths	Pharmaceutical form	Route of administration
Bulgaria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Bulgaria	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Cyprus	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Cyprus	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Cyprus	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Czech Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Czech Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Czech Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strengths	Pharmaceutical form	Route of administration
Denmark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Denmark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Denmark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Finland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Finland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Finland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
France	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
France	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strengths	Pharmaceutical form	Route of administration
France	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Germany	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Germany	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Germany	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Iceland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Iceland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Iceland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Ireland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strengths	Pharmaceutical form	Route of administration
Ireland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Ireland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Italy	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Italy	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Italy	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Luxembourg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Luxembourg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Luxembourg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strengths	Pharmaceutical form	Route of administration
Netherlands	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 50 microgram/5 microgram/dosis aërosol, suspensie	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Netherlands	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 125 microgram/5 microgram/dosis aërosol, suspensie	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Netherlands	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 250 microgram/10 microgram/dosis aërosol, suspensie	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Norway	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffera®	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Norway	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffera®	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Norway	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffera®	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Poland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Poland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strengths	Pharmaceutical form	Route of administration
Poland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Romania	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 50 microgram/5 microgram suspensie de inhalat presurizată	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Romania	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 125 microgram/5 microgram suspensie de inhalat presurizată	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Romania	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 250 microgram/10 microgram suspensie de inhalat presurizată	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Slovak Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 50/5 µg	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strengths	Pharmaceutical form	Route of administration
Slovak Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 125/µg	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Slovak Republic	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza 250/10 µg	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
Sweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Sweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
Sweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use
United Kingdom	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	50 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
United Kingdom	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	125 mcg/5 mcg	Pressurised Inhalation Suspension	Inhalation use
United Kingdom	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Iffeza	250 mcg/10 mcg	Pressurised Inhalation Suspension	Inhalation use