Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 May 2012 to 31 May 2012

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

(2012/C 190/02)

— 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
7.5.2012	Vivaglobin and associated names	See Annex I	See Annex I	8.5.2012
22.5.2012	Femara and associated names	See Annex II	See Annex II	23.5.2012
25.5.2012	Priorix and associated names	See Annex III	See Annex III	30.5.2012
25.5.2012	Prontax 5 Mg/ml	See Annex IV	See Annex IV	30.5.2012
25.5.2012	Prontax 10 Mg/ml	See Annex V	See Annex V	29.5.2012

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

ANNEX I

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

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	CSL Behring GmbH Emil-von-Behring-Straße 76 35041 Marburg an der Lahn Germany	Vivaglobin 160 mg/ml Injektionslösung (subkutane Anwendung)	160 mg/ml	solution for injection	subcutaneous use
Belgium	CSL Behring GMBH Emil-von-Behring-Str. 76 35041 Marburg Germany	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
Denmark	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg, Germany	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
Finland	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg, Germany	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
France	CSL BEHRING SA - PARIS 44 rue Cambronne 75015 Paris, France	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
Germany	CSL Behring GmbH, Emil von Behring Strasse 76, 35041 Marburg	Vivaglobin	Solution for infusion, 160 mg/ml	solution for infusion	subcutaneous use
Greece	CSL BEHRING ΜΕΠΕ XATZHGIANNI MEKSI 5 ATHENS 11528	VIVAGLOBIN	16 % (W/V) [150-170 MG]	solution for injection	subcutaneous use
Hungary	CSL Behring GmbH Emil-von-Behring-str. 76. 35041 Marburg Germany	Vivaglobin 160 mg/ml oldatos injekció szubkután alkalmazásra	160 mg/ml solution for injection (subcutaneous use)	solution for injection	subcutaneous use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	CSL BEHRING GmbH Emil von Behring Str 76 D-35041 Marburg-Germany	VIVAGLOBIN	160 MG/ML	solution for injection	subcutaneous use
Luxembourg	CSL BEHRING GMBH 76 EMIL-VON-BEHRING-STRASSED 35041 MARBURG	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
The Netherlands	CSL Behring GmbH, Emil v. Behring Str. 76, 35041 Marburg, Germany	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
Norway	CSL Behring GmbH, Emil-von-Behring-Str. 76, 35041 Marburg, Germany	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
Poland	CSL Behring GmbH, Emil-von-Behring-Str. 76, 35041 Marburg, Germany	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
Portugal	CSL Behring GmbH Emil-von-Behring Strasse, 76 D-35041 Marburg Germany	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use
Spain	CSL BEHRING, GMBH Emil von Bhering Strasse, 76 35041 Marburg, Germany	VIVAGLOBIN 160 mg/ml para inyección (uso subcutáneo)	160 mg/ml	solution for injection	subcutaneous use
Sweden	CSL Behring GmbH, Emil-von-Behring-Strasse 76 35041 Marburg, Tyskland	Vivaglobin	160 mg/ml	solution for injection	subcutaneous use

ANNEX II

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

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Austria	Novartis Pharma GmbH Stella-Klein Loew-Weg 17 1020 Vienna Austria	Femara 2,5 mg – Filmtabletten	2,5 mg	film-coated tablet	Oral
Belgium	Novartis Pharma N.V. Medialaan, 40 bus 1, 1800 Vilvoorde Belgium	Femara	2,5 mg	film-coated tablet	Oral
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 90429 Nuernberg Germany	Femara	2,5 mg	film-coated tablet	Oral
Cyprus	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR United Kingdom	Femara	2,5 mg	film-coated tablet	Oral
Czech Republic	Novartis s.r.o., Gemini, budova B Na Pankráci 1724/129 140 00 Prague 4 Czech Republic	Femara	2,5 mg	film-coated tablet	Oral
Denmark	Novartis Healthcare A/S Lyngbyvej 172, 2100 København Ø Denmark	Femar	2,5 mg	film-coated tablet	Oral
Estonia	Novartis Finland Oy Metsänneidonkuja 10 02130 Espoo Finland	Femara	2,5 mg	film-coated tablet	Oral

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Finland	Novartis Finland Oy Metsänneidonkuja 10 02130 Espoo Finland	Femar	2,5 mg	film-coated tablet	Oral
France	Novartis Pharma S.A.S. 2 & 4, rue Lionel Terray, 92500 Rueil Malmaison Cédex France	Fémara 2,5 mg comprimé pelliculé	2,5 mg	film-coated tablet	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg Germany	Femara 2,5 mg Filmtabletten	2,5 mg	film-coated tablet	Oral
Greece	Novartis (Hellas) S.A.C.I. 12 km of National Road Athens, Lamia Nº 1, 14451 Metamorphosis, Athens Greece	FEMARA	2,5 mg	film-coated tablet	Oral
Hungary	Novartis Hungária Kft. Pharma 1114 Budapest, Bartók Béla út 43-47 Hungary	Femara 2,5 mg filmtabletta	2,5 mg	film-coated tablet	Oral
Iceland	Novartis Healthcare A/S Lyngbyvej 172, 2100 København Ø Denmark	Femar	2,5 mg	film-coated tablet	Oral
Ireland	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR United Kingdom	Femara 2,5 mg Film-coated Tablets	2,5 mg	film-coated tablet	Oral
Italy	Novartis Europharm Ltd Wimblehurst Road RH12 5 Ab - Horsham (West Sussex) United Kingdom	Femara	2,5 mg	film-coated tablet	Oral

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Latvia	Novartis Finland Oy Metsänneidonkuja 10, 02130 Espoo Finland	Femara 2,5 mg apvalkotās tabletes	2,5 mg	film-coated tablet	Oral
Lithuania	Novartis Finland Oy Metsänneidonkuja 10, 02130 Espoo Finland	Femara	2,5 mg	film-coated tablet	Oral
Luxembourg	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg, Germany	Femara	2,5 mg	film-coated tablet	Oral
Malta	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR United Kingdom	Femara	2,5 mg	film-coated tablet	Oral
Netherlands	Novartis Pharma B.V. Raapopseweg 1, 6824 DP Arnhem The Netherlands	Femara	2,5 mg	film-coated tablet	Oral
Norway	Novartis Norge AS Postboks 4284 Nydalen, 0401 Oslo Norway	Femar	2,5 mg	film-coated tablet	Oral
Poland	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg, Germany	Femara	2,5 mg	film-coated tablet	Oral
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edif. 8, Quinta da Beloura 2710-444 Sintra Portugal	Femara	2,5 mg	film-coated tablet	Oral

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Romania	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg, Germany	Femara 2,5 mg comprimate filmate	2,5 mg	film-coated tablet	Oral
Slovak Republic	Novartis, s.r.o. Gemini, budova B Na Pankráci 1724,/129 14000 Prague 4, Czech Republic	Femara	2,5 mg	film-coated tablet	Oral
Slovenia	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg, Germany	Femara 2,5 mg filmsko obložene tablete	2,5 mg	film-coated tablet	Oral
Spain	Laboratorios Padró, S.A. Gran Via de les Corts Catalanes, No 764 08013 Barcelona Spain	Loxifan 2,5 mg comprimidos recubiertos con película	2,5 mg	film-coated tablet	Oral
	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, No 764 08013 Barcelona Spain	Femara 2,5 mg comprimidos recubiertos con película	2,5 mg	film-coated tablet	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B, Box 1150, 18311 Täby, Sweden	Femar	2,5 mg	film-coated tablet	Oral
United Kingdom	Novartis Pharmaceuticals UK Limited Trading as Ciba Laboratories Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR United Kingdom	Femara 2,5 mg Tablets	2,5 mg	film-coated tablet	Oral

ANNEX III

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

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength (*)	Pharmaceutical form	Route of administration
Austria	GlaxoSmithKline Pharma GmbH Albert Schweitzer-Gasse 6 A-1140 Wien Austria	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Austria	GlaxoSmithKline Pharma GmbH Albert Schweitzer-Gasse 6 A-1140 Wien Austria	Priorix		Powder in vials and solvent in prefilled-syringes for solution for injection	Subcutaneous use Intramuscular use
Belgium	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Bulgaria	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for suspension for injection	Subcutaneous use Intramuscular use
Cyprus	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Czech Republic	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Estonia	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength (*)	Pharmaceutical form	Route of administration
Finland	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
France	Laboratoire GlaxoSmithKline 100 route de Versailles 78163 Marly-le-Roi Cedex France	Priorix powder and solvent for solution for injection in a pre-filled syringe Measles, mumps, and rubella vaccine (live)		Powder and solvent for solution for injection	Subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 D-80339 München Germany	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Greece	GlaxoSmithKline AEBE 266 Kifisias avenue 152 32 Halandri Greece	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Iceland	GlaxoSmithKline ehf. Thverholt 14 105 Reykjavik Iceland	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham Dublin 16 Ireland	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 37135 Verona Italy	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Latvia	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix pulveris un šķīdinātājs injekciju šķīduma pagatavošanai		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength (*)	Pharmaceutical form	Route of administration
Lithuania	UAB 'GlaxoSmithKline Lietuva' Goštauto 40A LT-01112, Vilnius Lithuania	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Luxembourg	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Malta	SmithKline Beecham plc Great West Road, Brentford, Middlesex TW8 9GS Trading as GlaxoSmithKline UK Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Netherlands	GlaxoSmithKline BV Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Priorix		Powder and solvent for solution for injection	Subcutaneous use
Norway	GlaxoSmithKline AS Forskningsveien 2a Postboks 180 Vinderen 0319 Oslo Norway	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Poland	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Portugal	Smith Kline & French Portuguesa, Produtos Farmacêuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque – Miraflores 1495-131 Algés Portugal	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength (*)	Pharmaceutical form	Route of administration
Romania	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Slovak Republic	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Slovenia	GSK d.o.o., Ljubljana, Knezov štradon 90, 1000 Ljubljana Slovenia	Priorix prašek in vehikel za raztopino za injiciranje		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Spain	GlaxoSmithKline, S.A. C/Severo Ochoa, 2 28760 Tres Cantos (Madrid) Spain	Priorix polvo y disolvente en jeringa precargada para solución inyectable		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Sweden	GlaxoSmithKline AB, Box 516, 169 29 Solna Sweden	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
United Kingdom	SmithKline Beecham plc 980 Great West Road, Brentford, Middlesex TW8 9GS United Kingdom Trading as GlaxoSmithKline UK Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

(*) Strength applicable for all countries
After reconstitution, 1 dose (0,5 ml) contains:

Live attenuated measles virus (Schwarz strain)	not less than $10^{3.0}$ $CCID_{50}$
Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain)	not less than $10^{3.7}$ $CCID_{50}$
Live attenuated rubella virus (Wistar RA 27/3 strain)	not less than $10^{3.0}$ $CCID_{50}$

ANNEX IV

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, WITHDRAWAL PERIODS, APPLICANT IN THE MEMBER STATES

Member State EU/EEA	Applicant	Name	Pharmaceutical form	INN/Strength	Animal species	Route of administration	Recommended dose	Withdrawal periods
Austria	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Bulgaria	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Denmark	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Spain	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Dectomax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Finland	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
France	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml solution pour pour on pour bovins	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving

Member State EU/EEA	Applicant	Name	Pharmaceutical form	INN/Strength	Animal species	Route of administration	Recommended dose	Withdrawal periods
Hungary	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Ireland	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Dectomax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Iceland	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
The Netherlands	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Norway	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Poland	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Portugal	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving

Member State EU/EEA	Applicant	Name	Pharmaceutical form	INN/Strength	Animal species	Route of administration	Recommended dose	Withdrawal periods
Romania	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Sweden	(Applicant) Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving
Slovenia	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Dectomax 5 mg/ml Pour-On Solution for Cattle	Pour-on solution	Doramectin 5 mg/ml	Cattle	topical - on the back of the animal	1 ml per 10 kg bodyweight	**CATTLE:** Meat and offal: 35 days. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving

ANNEX V

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, WITHDRAWAL PERIODS, APPLICANT IN THE MEMBER STATES

Member State EU/EEA	Applicant	Name	Pharmaceutical form	INN/Strength	Animal species	Route of administration	Recommended dose	Withdrawal periods
Austria	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Bulgaria	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Cyprus	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs – intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.

Member State EU/EEA	Applicant	Name	Pharmaceutical form	INN/Strength	Animal species	Route of administration	Recommended dose	Withdrawal periods
Czech Republic	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	DECTOMAX 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Denmark	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs – intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Estonia	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.

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Greece	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Spain	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	DECTOMAX 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Finland	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.

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France	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution injectable pour bovins, ovins et porcins	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Hungary	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Ireland	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Dectomax 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.

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Iceland	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Latvia	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Lithuania	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.

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Malta	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
The Nether-lands	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Norway	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.

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Poland	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Portugal	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Romania	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.

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Sweden	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Slovenia	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Dectomax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.
Slovakia	Pfizer Limited Veterinary Medical Research & Development Sandwich Kent CT13 9NJ United Kingdom	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Solution for injection	Doramectin 10 mg/ml	Cattle, sheep and pigs	Cattle - subcutaneous Sheep and pigs - intra-muscular	Cattle and sheep - 1 ml per 50 kg bodyweight Pigs - 1 ml per 33 kg bodyweight	**CATTLE:** Meat and offal: - withdrawal period: 54 days. Milk: - The product is not permitted for use in lactating cows used to produce milk for human consumption. Do not use in dry dairy cows including pregnant dairy heifers within 60 days prior to calving. **SHEEP:** Meat and offal: - withdrawal period: 63 days. Milk: - The product is not permitted for use in lactating sheep used to produce milk for human consumption. Do not use in dry dairy ewes including pregnant dairy ewe lambs within 70 days prior to lambing. **PIGS:** Meat and offal: - withdrawal period 56 days.