

ANNEX I

**LIST OF THE NAMES, STRENGTHS OF THE VETERINARY MEDICINAL
PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION,
RECOMMENDED DOSE AND MARKETING AUTHORISATION HOLDERS IN
THE MEMBER STATES**

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Austria	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec injection Injektionslösung für Rinder und Schweine	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Austria	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Austria	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Austria	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Austria	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 10 mg/ml Injektionssuspension für Rinder, Schafe und Schweine	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Austria	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin – Injektionslösung für Tiere	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Austria	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Austria	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Injektionslösung Für Tiere: Rinder, Schafe, Schweine	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Austria	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Injektionslösung für Rinder	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Belgium	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	BOVIMEC B	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Belgium	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN 10MG/ML	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Belgium	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN CATTLE	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Belgium	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	IVOMECE F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Belgium	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Belgium	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC 1 % Solution injectable	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Belgium	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC F solution injectable	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Belgium	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	Ivomec	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Belgium	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	QUALIMEC 10MG/ML	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Belgium	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Oplossing voor Injectie voor rundvee	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Bulgaria	Intervet International B.V. Wim de Korvrstraat 35, 5831 AA, Boxmeer, The Netherlands	Ivotan LA	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1% injectable solution	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Bulgaria	Alfasan International B.V., P.O. Box 78, 3440 AB Woerden, The Netherlands	Alfamec 1 %	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	BIOVET JSC 39 Petar Rakov Str. 4550 Pesthera Bulgaria	Pandex 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	Centrovvet Ltd. Av.Los Cerrillos 602 Santiago, Chile	Microdes Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Bulgaria	Interchemie werken “de Adelaar” BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	Promectine	Ivermectin 10 mg/ml	Cattle, pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Bulgaria	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Cyprus	Panchris Feeds Ltd. P.O.Box 40261, 6302 Larnaca Cyprus	Bimectin Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Cyprus	Vetagrica Ltd 3 Othellou Street, 2540 Dhali Industrial Estate Nicosia Cyprus	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Cyprus	Spyros Stavrinides Chemicals Ltd 28 Stasinou Avenue, 1060 Nicosia, Cyprus	Noromectin injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	Vétoquinol s.r.o., Zámečnická 411, 288 02 Nymburk, Czech Republic	Biomectin 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	CEVA Animal Health Slovakia, spol. s r.o. Račianska 77 83 102 BRATISLAVA Slovak Republic	Cevamec 1 % inj. ad us. vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Czech Republic	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1 %	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1% inj. ad. us. vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Super inj. a.u.v.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle, sheep	Subcutaneous	200 µg ivermectin/kg bw
Czech Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Inj ad us vet	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec inj. ad us. vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Czech Republic	Bioveta a.s., Komenského 212 683 23 Ivanovice na Hané Czech Republic	Biomec 10 mg/ml Injekční roztok	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Czech Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin injekční roztok pro skot	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Denmark	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec Vet	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimec Vet	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Denmark	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomec vet.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Ivermectin "Virbac" Vet., injektionsvæske, opløsning	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Coopermec Vet	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Denmark	Merial Norden A/S Mileparken 20 E 2740 Skovlunde Denmark	Ivomec vet., injektionsvæske 10 mg/ml	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1% injection, süstelahus	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Estonia	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Bimectin injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1% injectable solution	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Estonia	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Finland	Scanvet Eläinlääkkeet Oy PL 27 13721 PAROLA Finland	Animec vet	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Finland	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimectin vet	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Finland	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 10 mg/ml vet injektioneste, liuos	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Finland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec injection 10 mg/ml solution for injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Finland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet 10mg/ml Solution for Injection	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Finland	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC VET 10 mg/ml injektioneste, liuos	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
France	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMECD	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
France	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC SOLUTION INJECTABLE POUR BOVINS	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
France	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC D SOLUTION INJECTABLE	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
France	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Solution Injectable pour Bovins Porçins Ovins	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	IVERMECTINE ECO 10 MG/ML SOLUTION I NJECTABLE	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	QUALIMEC 10 MG/ML SOLUTION INJECTABLE	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN BOVIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
France	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	CEVAMEC BOVINS OVINS SOLUTION INJECTABLE	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
France	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Magamectine iInjectable, solution injectable	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Medimec Injectable, Solution Injectable	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% Solution Injectable Bovine, Porcins	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
France	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectine Solution Injectable pour bovins	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
France	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Germany	MERIAL GmbH Am Söldnermoos 6 D-85399 Hallbergmoos Germany	Ivomec	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injektion	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Diapec R	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Wedemec R	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumex Injektion für Rinder	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Germany	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1% Injektion	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Germany	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Inektionslösung	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Greece	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% 1% Ενέσιμο Διάλυμα	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1% 1% Ενέσιμο Διάλυμα	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Greece	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Inj. Sol.	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	VETERIN ABEE Aspropyrgos Attikis 19300 Greece	VETERMEC	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs:300 µg ivermectin/kg bw
Greece	PNG Gerolymatos S.A. 13, Asklipiou 145 68 KRYONERI, ATTICA Greece	VALANEQ	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Greece	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	MAXIMEC	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Greece	SCHERING PLOUGH SA 65,Ag Dimitriou 17455, Athens Greece	TIZOVAL	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Bayer Hungária Ltd. H-1123 Budapest Alkotás u. 50. Hungary	Baymec Trio 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdynskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Ceva-Phylaxia Oltóanyagtermelő Zrt. Szállás u. 5 1107 Budapest Hungary	Cevamec 1% injekció A.U.V	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Divasa Farmavic Hungaria Ltd. H-6070 Izsák, Kossuth L. u. 60. Hungary	ECOMECTIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Bremer Pharma GmbH. Werkstrasse 42 34414 Warburg-Scherfede Germany	FROMMECTIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Hungary	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	IVERGEN PREMIUM LA	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Veterina Polska Sp. Zo.o. Ul. Mogilska 80, 31546 Krakow Poland	Iverktin Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	VMD Animal Health Ltd. Közraktár u. 22/b. II. 3., 1093 Budapest Hungary	IVERVETo 1 %	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec injekció A.U.V.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec super injekció A.U.V.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Hungary	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Hungary	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Vetimec 10 mg/ml solution for injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Kilo-mec 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Mastermectin 1 Per Cent	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	C-Corp, 78 Coombe Road, New Malden, Surrey KT3 4QS, United Kingdom	Coopermec 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Injectable Solution	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec for Cattle Swine and Sheep 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Super Solution for Injection	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Ireland	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Panomec 1% Solution for Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Classic Injection for Cattle and Sheep 1% w/v	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Ireland	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Fatromectin 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanimec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec 1% solution Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumex Injection for Cattle, 1%, Solution for injection for cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Anisec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Aninject Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chaniject Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Sumiject Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Medimec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Topimec Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin 1.0 %w/v Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Mectaject 1.0 % Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bovimectin 1% solution for injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injection for Cattle & Sheep	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Trimectin Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bovimec 1.0% w/v Solution for Injection for Cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Primectin 1% w/v Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Solution for Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Enovex Injection 1% w/v	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Ireland	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closiver Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Iceland	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec vet.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Italy	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Baymec 1% Soluzione	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Italy	INTERVET PRODUCTIONS SRL Via Nettunense km 20, 300 04011 Aprilia Italy	Ivogell	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Merial Italia S.p.A. a Socio Unico, Via Vittor Pisani, 16 Milano Italy	Ivomec	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Merial Italia S.p.A. a Socio Unico, Via Vittor Pisani, 16 Milano Italy	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Italy	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec iniettable	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	Fatro Via Emilia, 285 40064 Ozzano Emilia (Bologna) Italy	Tolomec	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Italy	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC Soluzione iniettabile	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Italy	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC F soluzione iniettabile	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Italy	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Soluzione iniettabile per bovini	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Italy	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Divamectin 1% Solution for Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Latvia	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland	Animec Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	Bimectin Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Latvia	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1%	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Latvia	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 10 mg/ml	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs 300 µg ivermectin/kg bw
Latvia	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEK 1% Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs:300 µg ivermectin/kg bw
Latvia	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Latvia	Pharmaceutical Company PFO "VETOS-FARMA" sp. z.o.o., Dzierzoniwska street 21 58-260 Bielawa Poland	Iwermektyna 1% Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Latvia	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEK PLUS, injekcinis tirpalas	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Lithuania	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMEK 1%, injekcinis tirpalas	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%, injekcinis tirpalas	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1%, injekcinis tirpalas	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Lithuania	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injekcinis tirpalas	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Invesa International S.A. Esmeralda 19 08950 Esplugues de Llobregat Barcelona Spain	PROMECTINE	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	Bimeda Chemical Export Ltd. (a division of Cross Vetpharm Group Limited), Broomhill Road Tallaght Dublin 24 Ireland	BIMECTIN	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Lithuania	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN 10 mg/ml	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Luxembourg	MERIAL Belgium S.A. Bld Sylvain Dupuis 243 1070 Bruxelles Belgium	Ivomec solution pour injection	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Luxembourg	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1%	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Luxembourg	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% inj.sol. bovine and porcine	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs 300 µg ivermectin/kg bw
Luxembourg	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin 1% solution for injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Luxembourg	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 1% solution for injection	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Luxembourg	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec solution pour injection bovine	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Malta	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Malta	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	Iveripra-I	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Malta	Interchemie werken “de Adelaar” BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Malta	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Malta	INDUSTRIAL VETERINARIA, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat Barcelona Spain	Promectine	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
The Netherlands	Merial B.V. Kleermakerstraat 10 1991 JL Velsbroek The Netherlands	Ivomec	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
The Netherlands	Merial B.V. Kleermakerstraat 10 1991 JL Velsbroek The Netherlands	Ivomec Plus	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
The Netherlands	Merial B.V. Kleermakerstraat 10 1991 JL Velsbroek The Netherlands	Panomec Injectievloeistof	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Euromece Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
The Netherlands	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin Cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
The Netherlands	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin Injectie	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
The Netherlands	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ges-o-mec 10mg/ml oplossing voor injectie	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10mg/g solution for injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
The Netherlands	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands	Iverveto 1%	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Norway	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec vet, injeksjonsvæske, oppløsning 10 mg/ml	Ivermectin 10 mg/ml	Cattle, Sheep, Reindeer, Pigs	Subcutaneous	Cattle, Sheep, Reindeer: 200 µg ivermectin/kg bw Pigs:300 µg ivermectin/kg bw
Norway	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Vet Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Norway	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC VET	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Vetoquinol Biowet Sp. z o.o., ul. Kosynierów Gdyńskich 13-14, 66-400 Gorzów Wlkp., Poland	Biomectin 1%	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Ceva Sante Animale La Ballastiere B.P. 126 33501 Libourne Cedex France	Cevamec 1%	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. ul. Grójecka 6 05-651 Drwalew Poland	Ivermina 1% Inj	Ivermectin 10 mg/ml	Cattle, pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Pharmaceutical Company PFO "VETOS-FARMA" sp. z o.o., Dzierzoniwska street 21 58-260 Bielawa Poland	Iwermektyna 1% Iniekcja	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Poland	Agri- Biovet Sp. z o.o. ul. Smocza 27 01-048 Warsaw Poland	Pandex 1%	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Scan Vet Poland Sp. z o.o. Skiereszewo, ul. Kiszowska 9 62-200 Gniezno Poland	Paramectin 1%	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Poland	Przedsiębiorstwo Wielobranżowe Vet Agro Sp. z o.o. ul. Gliniana 32 20-616 Lublin Poland	Vetamectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Tizoval Bovinos 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Portugal	Calier Portugal S.A Centro Empresarial Sintra-Estoril II, Ed. C, R. Pé de Mouro Estrada de Albarraque 2710 - 335 Sintra Portugal	Ivertin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Portugal	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Chanectin Injectável	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Portugal	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Maximec Injectável para bovinos e ovinos 1%	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Portugal	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1% Sol Injectável	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Vectimax 10 mg/MI Sol. Inj. Este é	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	Merial Portuguesa - Saúde Animal, Lda AV Maria Lamas, Lote 19 - BL - A Piso 2 Parque Industrial Comercial Serra das Minas 2635-432 Rio de Mouro Portugal	Ivomec F	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Portugal	Merial Portuguesa - Saúde Animal, Lda AV Maria Lamas, Lote 19 - BL - A Piso 2 Parque Industrial Comercial Serra das Minas 2635-432 Rio de Mouro Portugal	Ivomec 1% Bovinos, Solução Injectável	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Portugal	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injectável 1%	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injectável 1%	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec F, Solução Injectável 1mg/ml	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Portugal	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC, Solução injectável	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Portugal	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin FF, solução injectável para bovinos	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Romania	ANTIBIOTICE IASI S.A. Str. Valea Lupului, nr. 1, Iași, jud. Iași Romania	Ivermectina 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	BIOWET GORZOW PHARMACEUTICALS COMPANY- Kosynierów Gdyńskich 13/14 ST., Gorzow WLPK Poland	Biomectin 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	BIOVET JSC 39 Petar Rakov Str. 4550 Pesthera Bulgaria	Pandex 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	Bioveta a.s., Komenského 212 683 23 Ivanovice na Hané Czech Republic	Biomec inj.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Romania	Bremer Pharma GmbH Cherbourger Str. 25 27540 Bremerhaven Germany	Bremamectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	CEVA SANTE ANIMALE Str. Chindiei, nr. 5 Sector 4 040185 Bucureşti Romania	Cevamec 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	DAR AL DAWA VETERINARY & AGRICULTURAL INDUSTRIAL Co. LTD. Jordan NA UR 11710 PO BOX 285 Jordania	Ivodad 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	DUTCH FARM VETERINARY PHARMACEUTICALS B.V. Veemweg 1-3771 MT BARNEVELEND The Netherlands	Dufamec 1% inj.	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 1% injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	FARMAVET S.A. Str. Petricani 198, Chişinău Republica Moldova	Ivermectina 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Romania	HEMOFARM – HEMOVET Beogradski Put BB Vrsac Serbia	Ivermektin S	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	Iveripra I	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	Interchemie werken “de Adelaar” BV Horsterweg 26A 5811 AC Castenray The Netherlands	Intermectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	INTERVET PRODUCTIONS SRL Via Nettunense km 20, 300 04011 Aprilia Italy	Ivogell	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	INTERVET ROMANIA S.R.L. Şoseaua de Centură, nr. 27-28, 077040 Chiajna, Ilfov Romania	Ivotan LA	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	PANTEX Ganzestaartsedijk 8 – 5525 KC Duizel The Netherlands	Panmectin 10	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Romania	PASTEUR – Filiala Filipești Str. Principală, nr. 944, Filipeștii de Pădure, Jud. Prahova Romania	Evomec	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7, Voluntari Romania	Romivermectin B ₁ 1%	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	SYVA Av. Párroco Pablo Diez, 49 – 57 24010 – Leon Spain	Zoomectin	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Romania	VMD Animal Health Ltd. Közraktár u. 22/b. II. 3., 1093 Budapest Hungary	Iverveto 1% Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Slovak Republic	Vétoquinol s.r.o., Zámečnická 411, 288 02 Nymburk, Czech Republic	Biomectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	CEVA Animal Health Slovakia, spol. s r.o. Račianska 77 83 102 BRATISLAVA Slovak Republic	Cevamec 1 % inj. ad us. vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Goats, Pigs	Subcutaneous	Cattle, Sheep, Goats: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Slovak Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Injection ad us vet	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec 1% inj. ad us.vet.	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec Super inj. ad us.vet.	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
Slovak Republic	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovak Republic	Pharmagal spol.s.r.o. Murgašova 5 949 01 Nitra Slovak Republic	Galmectin	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Slovak Republic	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin injekčný roztok pre hovädzi dobytok	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Slovenia	VET4VET d.o.o. Gerbičeva 50, 1000 Ljubljana Slovenia	Animec Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovenia	VETERINA Plus d.o.o., Dunajska 51, 1000 Ljubljana, Slovenia	IVERKTIN 1% solution for injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Slovenia	MERIAL 29 avenue Tony Garnier 69007 LYON France	IVOMECC solution for injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Spain	DIVASA FARMATIC, S.A. Ctra. Sant Hipolit, km 71 08503 – Gurb-Vic Barcelona Spain	DIVAMECTIN 1% SOLUCION	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Spain	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin 1% Solution Inyectable para Bovino y Porcino	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Spain	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	VIRBAMEC SOLUCIÓN INYECTABLE PARA BOVINOS	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	TIZOVAL VACUNO INYECTABLE	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	CHANECTIN INYECTABLE	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Inyectable	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Spain	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	IVERTIN BOVINO	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	INDUSTRIAL VETERINARIA, S.A. C/ Esmeralda, 19 08950 Esplugues de Llobregat Barcelona Spain	PROMECTINE	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	SUMEX INYECTABLE BOVINO	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	Laboratorios HIPRA S.A. Avda. La Selva, 135 17170 Amer, Girona Spain	IVERIPRA-I	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	ECOMECTIN 10 MG/ML SOLUCION INYECTABLE	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Spain	Chemo Iberica Gran Vía Carlos III, 98 – 7 th floor. 08028 Barcelona, Spain	BOVECTIN	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Spain	MERIAL LABORATORIOS S.A Tarragona, 161-Locales D/E 08014 Barcelona Spain	Ivomec Inyectable Para Vacuno	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
Spain	MERIAL LABORATORIOS S.A Tarragona, 161-Locales D/E 08014 Barcelona Spain	Ivomec F Inyectable Para Vacuno	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
Spain	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Solucion inyectable para bovino	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
Sweden	MERIAL 29 avenue Tony Garnier 69007 LYON France	Ivomec® vet.	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Sweden	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2 2080-104 Almeirim Portugal	Virbamec vet. 10 mg/ml injektionsvätska, lösning	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
Sweden	Bimeda (a division of Cross Vetpharm Group Limited) Broomhill Road Tallaght Dublin 24 Ireland	Bimectin® vet.	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Sweden	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin vet Solution for Injection 10mg/ml	Ivermectin 10 mg/ml	Cattle, Reindeer, Pigs	Subcutaneous	Cattle, Reindeer: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Sweden	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin, 10 mg/ml, Injektionsvätska, lösning	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
Sweden	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec, 10 mg/ml, Injektionsvätska, lösning	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Laboratorios Calier SA Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Valles Barcelona Spain	Ivertin Cattle	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
United Kingdom	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Classic Injection for Cattle and Sheep	Ivermectin 10 mg/ml	Cattle, Sheep	Subcutaneous	200 µg ivermectin/kg bw
United Kingdom	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Ivomec Super Injection for Cattle	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
United Kingdom	Merial Animal Health Limited Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom	Panomec Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Chanelle Animal Health Ltd 7 Rodney Street Liverpool L1 9HZ United Kingdom	Animec Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Injectable Solution For Cattle and Swine	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
United Kingdom	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala, 22080-104 Almeirim Portugal	Virbamec Injectable Solution for Cattle, Swine and Sheep	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	VIRBAC DE PORTUGAL Laboratorios Lda Rua Dionísio Saraiva, Lote 1, 1º Andar, Sala 2, 2080-104 Almeirim Portugal	Virbamec Super	Ivermectin 10 mg/ml, Clorsulon 100 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 2 mg clorsulon/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Enovex Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Noromectin Multi Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Injection	Ivermectin 10 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Bimectin 1% w/v Solution for Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Cross Vetpharm Group Ltd, Broomhill Road Tallaght Dublin 24 Ireland	Ecomec 1% Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Cross Vetpharm Group Ltd, Broomhill RoadTallaghtDublin 24Ireland	Qualimintic 1% Injection	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Alstoe Ltd Sheriff Hutton Industrial Park Sheriff Hutton York YO60 6RZ United Kingdom	Alstomec	Ivermectin 10 mg/ml	Cattle, Pigs	Subcutaneous	Cattle: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw

Member State	Marketing Authorisation Holder and address	Invented name	Strengths	Animal species	Route of administration	Recommended dose
United Kingdom	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Qualimec 10 mg/ml Solution for Injection	Ivermectin 10 mg/ml	Cattle, Sheep, Pigs	Subcutaneous	Cattle, Sheep: 200 µg ivermectin/kg bw Pigs: 300 µg ivermectin/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closamectin Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Closiver Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw
United Kingdom	Norbrook Laboratories Limited Station Works Camlough Road Newry BT35 6JP Country Down Northern Ireland	Norofas Solution for Injection	Ivermectin 5 mg/ml, Closantel 125 mg/ml	Cattle	Subcutaneous	200 µg ivermectin/kg bw, 5 mg closantel/kg bw

ANNEX II

**SCIENTIFIC CONCLUSIONS AND GROUNDS FOR AMENDMENT OF THE
SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE
LEAFLET**

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF INJECTABLE VETERINARY MEDICINAL PRODUCTS CONTAINING IVERMECTIN

1. Introduction

Ivermectin is a broad spectrum endectocide of the avermectin family. In cattle injectable veterinary medicinal products containing ivermectin, either as a single active ingredient or in combination with a second active substance, are used against infestations with endoparasites and ectoparasites by administering 200 µg ivermectin/kg bw subcutaneously.

Ivermectin was previously evaluated by the CVMP in order to establish maximum residue limits (MRLs). A toxicological Acceptable Daily Intake (ADI) of 10 µg/kg bw/day (600 µg/person per day) was established based on the NOEL of 0.5 mg/kg bw/day retained from a 14-week dog study, applying a safety factor of 50.

Ivermectin is currently included in Annex I of Council Regulation (EEC) No 2377/90 with MRLs for all food producing species as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissue	Other provisions
Ivermectin	22,23-Dihydro-avermectin B1a	All mammalian food producing species	100 µg/kg 100 µg/kg 30 µg/kg	Fat Liver Kidney	Not for use in animals producing milk for human consumption.

Based on these MRLs, the daily intake of total residues will represent about 15% of the ADI.

Marketing Authorisations for injectable veterinary medicinal products containing ivermectin for use in cattle have been granted in all Member States of the European Union via different authorisation procedures (mutual recognition procedures and national procedures) and under various legal bases (full, generic, bibliographic, informed consent).

The United Kingdom expressed concerns that the difference in withdrawal periods established across the European Union for the relevant products may present a potential serious risk to human health, and requested the Committee for Medicinal Products for Veterinary Use (CVMP) to give its opinion on the matter.

The procedure involved 293 authorised injectable veterinary medicinal products containing ivermectin (see Annex I).

2. Discussion of specific issues raised in the referral notification

From the overall data submitted by the MAHs and the National Competent Authorities of the Member States only 11 ivermectin residue depletion studies were considered of adequate quality for the purpose of calculating withdrawal periods, as only in these studies the relevant tissues including the injection sites were sampled and analysed. It was noted that some of the studies were identical but were submitted by different MAHs.

Wherever possible the CVMP used the statistical method for calculating the individual withdrawal periods based on single studies, but in line with the CVMP Note for Guidance: approach towards harmonisation of withdrawal periods (EMEA/CVMP/036/95)¹, where the necessary parameters were not shown to be valid for the statistical analysis, the alternative approach was used for calculating withdrawal periods.

Since there is no muscle MRL for ivermectin, the ADI-based approach was used for evaluating the total daily intake of residues that may arise from the consumption of tissues of each animal (EMEA/CVMP/542/03-Final)².

When the alternative approach was used for individual residue study data the withdrawal period was derived from the first time point at which all calculated intakes were below the ADI, with the addition of a safety span. A safety span of 30% was used in view of the large variation in the intake figures, which was primarily caused by the variation of residues found in injection sites.

Based on the 11 ivermectin residue depletion studies of adequate quality provided, the CVMP calculated the withdrawal periods for 12 products. The individual withdrawal periods calculated by the CVMP ranged from 21 days to 78 days. Additionally, for a further 11 products for which residue depletion data were provided, it was concluded that no individual withdrawal period could be calculated due to the inadequacy of the submitted product-specific data.

A key question raised by this referral asks whether there is a formulation effect on residue depletion from tissues and particularly from the injection site. To address this question quality experts examined the qualitative and quantitative composition of all the 293 ivermectin containing products that are the subject of this referral, grouping products that can be considered to be the same or essentially the same. In this way, 13 formulation groups were established. Each group contained products considered to be essentially the same, in formulation terms.

¹ CVMP Note for guidance: Approach towards harmonisation of withdrawal periods
<http://www.emea.europa.eu/pdfs/vet/swp/003695en.pdf>

² CVMP Guideline on Injection Site Residues. EMEA website publication,
<http://www.emea.europa.eu/pdfs/vet/swp/054203en.pdf>

The table below lists the 13 formulation groups along with the number of products in each group, the number of available studies for each group, and the individual withdrawal periods calculated for the various products for which adequate data were made available. The numbering of the formulation groups is arbitrary.

Table 1. Formulation groups allocated for the 293 products that are the subject of this referral.

Formulation Group	Number of products	Number of acceptable residue depletion studies	Individual withdrawal periods (days) derived from the ivermectin residue studies
1	108	5	21, 23, 37, 47, >49
2	45	1	46
3	18	1	42
4	58	1	29
5	3	No suitable data	–
6	22	1	78
7	1	No suitable data	–
8	1	No suitable data	–
9	2	No suitable data	–
10	19	1	55
11	13	1	29
12	2	No suitable data	–
13	1	No suitable data	–

From table 1 above, it is clear that for group 1, for which a number of studies was available, the range of calculated withdrawal periods varied considerably (from 21 to >49 days). The variability in calculated withdrawal periods reflects the variability in the depletion profiles and particularly the variability in depletion of residues from the injection site. It should be noted that for many of the studies the scatter of the data was such that the harmonised statistical method for the establishment of withdrawal periods could not be used, and the withdrawal period that results from use of the alternative method is always highly dependent on the choice of time points.

An attempt was made to find a correlation between the slopes or intercepts of the depletion curves and any of the following parameters: formulation group, bodyweight, breed, sex, age, and injection volume, using ANOVA or Pearson's methodology. From the data available no correlations were found that could explain the difference in depletion profiles or estimated withdrawal periods, and none of the parameters recorded could be identified as a large single source of variation.

While the precise sources of variation remain unidentified, it is quite likely that the sampling procedure is one important factor; it is difficult to be sure that the area with the highest residue concentration is accurately sampled, in particular for subcutaneous injections. The high level of variation in residue concentrations and depletion profiles seen both within and between formulation groups could easily have masked a formulation effect. Overall, from the data examined, the presence of a formulation effect can neither be confirmed nor refuted. Other sources of variation connected to the subcutaneous use of ivermectin were therefore considered to be of more importance than formulation with regard to residue depletion and withdrawal periods.

However, literature data indicate that the formulation can have an impact on the absorption rate of avermectins from the injection sites. Such an effect has been shown in experimental studies performed by a number of different groups (Lo *et al.*, 1985³; Wicks *et al.*, 1993⁴; Lifschitz *et al.* 1999⁵, Lifschitz *et al.*, 2004⁶). In these studies, different formulations showed different absorption patterns of avermectins (including ivermectin), while all other parameters were the same (such as species, breed, weight, and place of injection). These observations support the view that in the studies provided to the CVMP, sources of variation were present that were more important than formulation effects.

As a matter of principle with regards to products that have been shown to be bioequivalent, it should be noted that the definition of bioequivalence does not guarantee equal levels of residues at the injection site far beyond the time points where plasma samples were taken. In fact, a small and pharmacologically insignificant difference in absorbed fraction (e.g. 99.5% versus 99.9%) at a certain time point may imply a significant difference in the amount remaining in the injection site (a factor of 5 in this example).

Because the equivalence of local residue levels at the injection site cannot be predicted based on plasma bioequivalence, and because published data indicate that formulation can have an impact on residue depletion profiles for ivermectin, the CVMP considered that, in general, there is no basis for automatically extrapolating a withdrawal period established for one formulation to a second formulation, even if plasma bioequivalence has been shown.

On the other hand, there is no scientific rationale to explain why withdrawal periods for formulations that are the same or essentially the same, should be different. While the data examined by the CVMP did lead to the calculation of different withdrawal periods for products that are essentially the same, this variability is not considered to reflect product specific effects but is rather a feature of the way the products were used (i.e. the variation results from differences such as animal bodyweight, breed, sex, age, injection volume and sampling procedure).

The CVMP considers that products that are essentially the same (in formulation terms) should have identical withdrawal periods. For the purposes of this referral, that means that the withdrawal periods for all products in a single formulation group should be the same. Moreover, because of the fact that the variation in the residue profile due to sources of variation connected to the subcutaneous use of ivermectin is much greater than the formulation effect, the Committee concluded that it would be appropriate to consider the totality of ivermectin residue data from all formulation groups to derive a single harmonised withdrawal period.

³ Lo, P-K.A., Fink, D.W., Williams, J.B., Blondinger, J. (1985) Pharmacokinetic studies of ivermectin: effects of formulation. *Vet. Res. Comm.* **9**: 251-268

⁴ Wicks, S.R., Kaye, B., Weatherley, A.J., Lewis, D., Davison, E., Gibson, S.P., Smith, D.G. (1993) Effect of formulation on the pharmacokinetics and efficacy of doramectin. *Vet. Parasitol.* **49**: 17-26

⁵ Lifschitz, A., Virkel, G. Pis, A., Imperiale, F., Sanchez, S., Alvarez, L., Kujanek, R, Lanusse, C. (1999) Ivermectin disposition kinetics after subcutaneous and intramuscular administration of an oil-based formulation to cattle. *Vet. Parasitol.* **86**: 203-215

⁶ Lifschitz, A., Sallovitz, J., Imperiale, F., Pis, A., Jauregui Lorda, J., Lanusse, C. (2004) Pharmacokinetic evaluation of four ivermectin generic formulations in calves. *Vet. Parasitol.* **119**: 247-257

2.1 Calculation of a harmonised withdrawal period for ivermectin containing injectable products for use in cattle

In the figure below, all available data for the total intake of ivermectin residues is plotted and compared to the ADI.

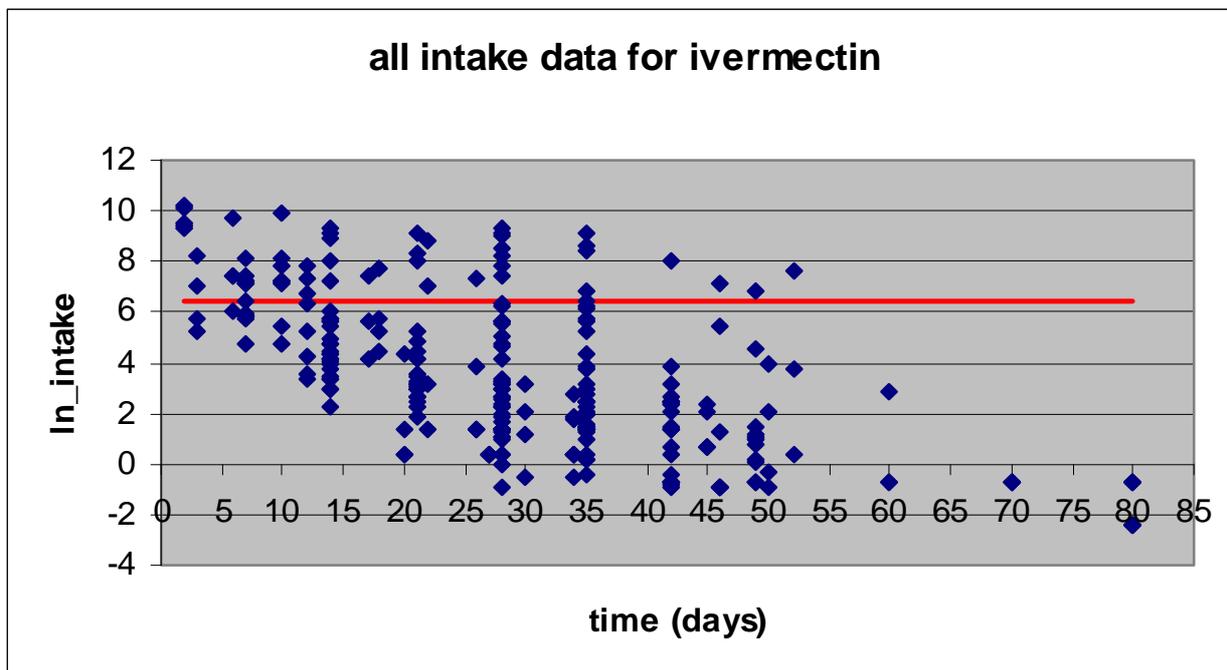


Figure 1. On a log-scale, the total ivermectin residue intake (μg) for a consumer, calculated from data of each animal (data points), compared with the ADI ($\mu\text{g}/\text{person}$, horizontal line).

It was not possible to use the statistical method for the analysis of these pooled data because a number of relevant statistical assumptions were not met. However, the Committee considered that the use of the alternative approach (first time point below the ADI plus safety span) would insufficiently take account of the substantial amount of data (280 data points) available in this particular case. The Committee considered that based on the totality of the data, and based on the fact that at and beyond day 49 the intake calculation remains above the ADI for only two animals, a withdrawal period of 49 days would provide a degree of safety comparable to that provided using the statistical approach (and a withdrawal period based on the 95% tolerance limit). Therefore, the Committee concluded that a harmonised withdrawal period of 49 days could be established for the ivermectin component of all injectable products containing ivermectin, for use in cattle.

2.2 Derivation of the withdrawal period for injectable veterinary medicinal products contains ivermectin as well as a second active substance (combination products)

The harmonised withdrawal period of 49 days is relevant only to the ivermectin component of injectable products containing ivermectin. For injectable veterinary medicinal products containing ivermectin in combination with another active substance residue depletion of the second active substance must also be considered, and a withdrawal period for the second active substance derived. The withdrawal period for the product will be the longer of the withdrawal periods derived for the individual components. If the withdrawal period determined on the basis of residue depletion data for the second active substance is less than 49 days, then a withdrawal period of 49 days is recommended for the product. If, on the other hand, the withdrawal period determined on the basis of residue depletion data for the second active substance is greater than 49 days, then the recommended withdrawal period for the product should be based on depletion of residues of the second active substance. Therefore, a withdrawal period of at least 49 days will apply for the combination products in all cases.

Of the formulation groups to which products were allocated in this procedure, two contained combination products; one with products containing the active substances ivermectin and clorsulon, and the second with products containing the active substances ivermectin and closantel.

All products containing ivermectin and clorsulon had similar formulations and a number of residue depletion studies were submitted for the clorsulon component of products in this group. The studies were well-conducted and comprised a considerable number of slaughter time points. Considering the totality of the data on clorsulon residue depletion, the statistical method could not be used for calculating the withdrawal periods as the relevant statistical assumptions were not met. Taking residue data from the studies into consideration, the first time point at which no values exceeded the MRL for clorsulon was 60 days. Using the alternative approach and applying safety span of 10% a withdrawal period of 66 days was derived. A safety span of 10% was considered appropriate as the studies were large and robust.

Since the withdrawal period calculated based on the clorsulon component for these product exceeds the 49 days derived for the ivermectin component, 66 days is recommended as the withdrawal period for the combination products containing ivermectin and clorsulon.

Residue depletion data submitted for the formulation group containing ivermectin and closantel led to a withdrawal period of 36 days for closantel, calculated using the alternative approach and applying a safety span of 30%. Since this is below the 49 days limit applied for the ivermectin component, a withdrawal period of 49 days is recommended for the combination products containing ivermectin and closantel.

GROUND S FOR AMENDMENT OF THE SUMMARY OF PRODUCT CHARACTERISTICS

Whereas:

- the CVMP assessed the original data provided during this referral and concluded that, based on these data, an impact of formulation on residue depletion could not be demonstrated and that the variability in the data was such that an effect of formulation on residue depletion could have been masked;
- the CVMP considered that sources of variation linked to the subcutaneous use of ivermectin in cattle are present that lead to different depletion profiles in residue studies, and this variation is of much more importance than any variation that may be caused by formulation differences. These differences are also expected to occur in practice;
- the CVMP considered that, taking into account the high variation observed, a single harmonised withdrawal period based on all available residue intake data should be established for all products concerned that contain ivermectin as the only active substance;
- the CVMP considered that for combination products containing ivermectin as well as a second active substance, residue depletion of the second active substance must also be considered when setting the withdrawal period and the withdrawal period for the product shall be the longest established for the individual components.

the CVMP has recommended the amendment of the Marketing Authorisations for all injectable veterinary medicinal products containing ivermectin for use in cattle as referred in Annex I for which the Summary of Product Characteristics, labelling and package leaflet are set out in Annex III.

ANNEX III

**AMENDMENT TO THE SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET**

**AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE
SUMMARY OF PRODUCT CHARACTERISTICS**

A. For products listed in Annex I containing ivermectin and clorsulon as active ingredients:

4.11 Withdrawal period(s)

Cattle: Meat and offal - 66 days.

B. For products listed in Annex I containing ivermectin as sole active ingredient or in combination with closantel:

4.11 Withdrawal period(s)

Cattle: Meat and offal - 49 days.

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE LABELLING

A. For products listed in Annex I containing ivermectin and clorsulon as active ingredients:

8. WITHDRAWAL PERIOD

Cattle: Meat and offal - 66 days.

B. For products listed in Annex I containing ivermectin as sole active ingredient or in combination with closantel:

8. WITHDRAWAL PERIOD

Cattle: Meat and offal - 49 days.

**AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE
PACKAGE LEAFLET**

A. For products listed in Annex I containing ivermectin and clorsulon as active ingredients:

10. WITHDRAWAL PERIOD

Cattle: Meat and offal - 66 days.

B. For products listed in Annex I containing ivermectin as sole active ingredient or in combination with closantel:

10. WITHDRAWAL PERIOD

Cattle: Meat and offal - 49 days