

Annex I

List of the names, pharmaceutical forms, strengths of the veterinary medicinal products, animal species, applicants/marketing authorisation holders in the Member States

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Austria	Alvetra & Werfft GmbH Boltzmanngasse 11, 1090 Wien, Austria	Bioplex Colistin 25 mg/g - Pulver zum Eingeben für Rinder, Schweine, Hühner	Colistin (as sulphate)	25 mg/g	Powder for use in food, drinking water or milk	Calves, pigs, chickens
Austria	Animed Service AG Liebochstrasse 9, 8143 Dobl, Austria	Colistin-Enteromix - Pulver zum Eingeben für Tiere	Colistin (as sulphate)	25 mg/g	Powder for use in food, drinking water or milk	Calves, pigs, chickens
Austria	Animed Service AG Liebochstrasse 9, 8143 Dobl, Austria	Colistinsulfat PUR "AniMed Service" 1 g/g - Pulver zum Eingeben für Tiere	Colistin (as sulphate)	1 g/g	Powder for use in drinking water	Calves, pigs, chickens
Austria	Animed Service AG Liebochstrasse 9, 8143 Dobl, Austria	Colixid 25 mg/g - Pulver zum Eingeben für Schweine	Colistin (as sulphate)	25 mg/g	Powder for use in feed	Pigs (piglets and pigs <40 kg)
Austria	aniMedica GmbH Im Südfeld 9, 48308 Senden-Bösensell, Germany	Colistinsulfat 1000 mg/g "aniMedica" - Pulver zum Eingeben für Rinder, Schweine und Hühner	Colistin (as sulphate)	1000 mg/g	Powder for use in drinking water	Calves, pigs, chickens
Austria	Ceva Sante Animale La Ballastière, 33501 Libourne, France	COLIVET 2 000 000 IU/ml Konzentrat für eine orale Lösung für Schweine und Geflügel	Colistin (as sulphate)	2 000 000 IU	Concentrate for oral solution	Pigs, poultry
Austria	Chevita Tierarzneimittel GmbH Kaplanstraße 10, 4600 Wels, Austria	Sabaco Colistin 120 mg/g - Pulver zum Eingeben für Tiere	Colistin (as sulphate)	120 mg/g	Powder for use in food, drinking water or milk	Calves, pigs, chickens

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Austria	OGRIS Pharma Vertriebs-GmbH Hinderhoferstraße 3, 4600 Wels, Austria	Colistinsulfat 120 mg/g "Ogris" - Pulver zum Eingeben für Tiere	Colistin (as sulphate)	120 mg/g	Powder for use in food, drinking water or milk	Calves, pigs, chickens
Austria	OGRIS Pharma Vertriebs-GmbH Hinderhoferstraße 3, 4600 Wels, Austria	Enteroxid "Ogris" 25 mg/g, Pulver zum Eingeben für Schweine	Colistin (as sulphate)	25 mg/g	Powder for use in feed	Pigs (piglets and pigs <40 kg)
Belgium	Divasa-Farmavic, S.A. Ctra. Sant Hipòlit, km 71 PO Box 79 08503 GURB-VIC Spain	Coliplus 2 000 000 UI/ml	Colistin	2 000 000 IU/ml	Concentrate for oral solution for use in drinking water	Cattle (calves), sheep (lambs), pigs and chickens
Belgium	EMDOKA bvba John Lijssenstraat 16 B-2321 Hoogstraten Belgium	Emdocolin 10%	Colistin	100 mg/g	Powder for oral solution	Calves and pigs
Belgium	EMDOKA bvba John Lijssenstraat 16 B-2321 Hoogstraten Belgium	Emdocolin 50%	Colistin	500 mg/g	Powder for oral solution	Calves and pigs
Belgium	EMDOKA bvba John Lijssenstraat 16 B-2321 Hoogstraten Belgium	Emdocolin Tabs	Colistin	121.56 mg (equivalent to 3 000 000 IU)	Tablet	Non-ruminating calves

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Belgium	Eurovet N.V. Poorthoevestraat 4 3550 Heusden-Zolder Belgium	Colistine Eurovet 400 000 IU/ml	Colistin	400 000 IU/ml	Concentrate for oral solution for use in drinking water or milkreplacer	Non-ruminating calves, pigs
Belgium	Eurovet N.V. Poorthoevestraat 4 3550 Heusden-Zolder Belgium	Colistinemix 1 200 000 IU/g	Colistin	1 200 000 IU/g	Powder for oral solution	Non-ruminating calves, pigs
Belgium	KELA LABORATORIA NV Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Colistimax 1200	Colistin	1 200 000 IU/g	Powder for oral solution	Non-ruminating calves, piglets
Belgium	Prodivet pharmaceuticals sa/nv Hagbenden 39c B-4731 Eynatten Belgium	Colivet Bolus	Colistin	150 mg	Tablet for oral administration	Non-ruminating calves
Belgium	Prodivet pharmaceuticals sa/nv Hagbenden 39c B-4731 Eynatten Belgium	Colivet Quick Pump	Colistin	8 mg/ml	Oral suspension	Piglets
Belgium	VMD N.V. Hoge Mauw 900 2370 Arendonk Belgium	Promycine 200 IU/mg	Colistin	200 000 IU/g	Premix for medicated feedingstuff	Chicken, pigs

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Belgium	VMD N.V. Hoge Mauw 900 2370 Arendonk Belgium	Promycine 400 IU/mg	Colistin	400 000 IU/g	Premix for medicated feedingstuff	Pigs
Belgium	VMD N.V. Hoge Mauw 900 2370 Arendonk Belgium	Promycine Bolus 3 MIO IE	Colistin	3 000 000 IU	Tablet	Non-ruminating calves
Belgium	VMD N.V. Hoge Mauw 900 2370 Arendonk Belgium	Promycine Pulvis 1000 IE/mg	Colistin	1 000 000 IU/g	Powder for oral solution	Non-ruminating calves, pigs, poultry
Belgium	VMD N.V. Hoge Mauw 900 2370 Arendonk Belgium	Promycine Pulvis 4800 IE/mg	Colistin	4 800 000 IU/g	Powder for oral solution	Non ruminating calves, pigs, poultry
Belgium	aniMedica Espana S.L.U. Esmeralda 19 08950 Esplugues de Liobregat (Barcelona) Spain	Pluscolan	Colistin sulphate	5 000 000 IU/ml	Concentrate for oral solution	Cattle (calves), pigs, sheep (lambs) and poultry
Belgium	Sogeval 200 Avenue de Mayenne Zone Industrielle des Touches 53000 Laval France	Sogecoli 2 000 000 IU/ml Colistin 2 MIU/ml	Colistin	2 000 000 IU/ml	Concentrate for oral solution	Calves, lambs, pigs, poultry

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Bulgaria	Andersen S.A. Avda. La Llana 123 Poligono Industrial "La Llana" 08191 RUBI Barcelona Spain	НИПОКСИМ 40 премикс	Colistin sulphate	1 200 000 IU/g	Premix for medicated feedingstuff	Pigs, poultry, rabbits
Bulgaria	Andersen S.A. Avda. La Llana 123 Poligono Industrial "La Llana" 08191 RUBI Barcelona Spain	НИПОКСИМ 100	Colistin sulphate	3 000 000 IU	Watersoluble oral powder	Pigs, poultry, suckling calves
Bulgaria	Andersen S.A. Avda. La Llana 123 Poligono Industrial "La Llana" 08191 RUBI Barcelona Spain	НИРОХУМЕ 200 mg/g ОРАЛНА СУСПЕНЗИЯ	Colistin sulphate	200 mg/g	Oral suspension	Pigs (after weaning, also for fattening pigs)
Bulgaria	Andersen S.A. Avda. La Llana 123 Poligono Industrial "La Llana" 08191 RUBI Barcelona Spain	НИРОХУМЕ 1000 mg/g перорален прах	Colistin sulphate	1000 mg/g	Oral powder	Pigs
Bulgaria	Ceva Sante Animale 10 avenue de La Ballastiere 33500 Libourne Cedex France	КОЛИВЕТ ПЕРОРАЛЕН РАЗТВОР	Colistin sulphate	2 M IU/ml	Oral solution	Pigs, poultry (broilers and laying hens)
Bulgaria	Ceva Sante Animale 10 avenue de La Ballastiere 33500 Libourne Cedex France	КОЛИВЕТ ПРЕМИКС	Colistin sulphate	12 g	Premix for medicated feedingstuff	Pigs, poultry (chicken-broilers, laying hens and breeders, turkeys), rabbits

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Bulgaria	Ceva Sante Animale 10 avenue de La Ballastiere 33500 Libourne Cedex France	КОЛИВЕТ прах за перорална употреба	Colistin sulphate	1.2 M IU/g	Oral powder	Pigs, calves, poultry
Bulgaria	Farma SIS OOD 4 San Stefano str. Dobrich Bulgaria	ХИДРО КОЛИСТИН	Colistin sulphate	2 000 000 IU/ml	Oral solution	Poultry, pigs
Bulgaria	Farma SIS OOD 4 San Stefano str. Dobrich Bulgaria	КОЛИСИС ПРЕМИКС	Colistin sulphate	10 g/100 g	Premix	Pigs
Bulgaria	Gabropharm OOD 16 Alei Vazrajidane str., app. 42 Russe 7200 Bulgaria	КОЛИКРИД-БГ	Colistin sulphate	2 000 000 IU/ml	Oral solution	Pigs, poultry
Bulgaria	V.M.D. n.v. Hoge Mauw 900 B-2370 Arendonk Belgium	ПРОМИЦИН-4800	Colistin sulphate	4 800 000 IU/g	Oral powder	Pigs, calves
Bulgaria	BIOSFERA FARM Ltd. 50 Yurii Gagarin str., Kostinbrod Bulgaria	COLIDEM-BIO 50	Colistin sulphate	500 mg/ g	Powder for oral use	Poultry, pigs

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Bulgaria	DIVASA - FARMAVIC, S.A. Ctra. Sant Hipolit, km 71, 08503 GURB - VIC, Barcelona Spain	Coliplus 2 000 000 IU/ml концентрат за перорален разтвор за прилагане в питейна вода за говеда, овце, свине и пилета	Colistin sulphate	2 M IU/ml	Concentrate for oral solution	Calves, lambs, pigs and chickens
Bulgaria	Zavet Kiril and Metodiy str. 5 Zavet 7330 Bulgaria	Колистин 48 водоразтворим прах	Colistin sulphate	4 800 000 IU/g	Oral powder	Calves, pigs
Croatia	ARNIKA VETERINA d.o.o., Vidikovac 20, 1000 Zagreb, Croatia	DRINKMIX COLISTIN	Colistin sulphate	5 million IU/g	Powder for oral solution	Calves, pigs, poultry
Croatia	Krka - Farma d.o.o., Radnička cesta 48, 10000 Zagreb, Croatia	GIRAXA	Colistin sulphate	50 mg/g (1.2 million IU/g)	Powder for oral solution	Calves, pigs, poultry
Croatia	VET CONSULTING d.o.o. , Matije Gupca 42, 43500 Daruvar, Croatia	COLIVETo-4800S	Colistin sulphate	4.8 million IU/g	Powder for oral solution	Calves, pigs, poultry
Cyprus	CEVA SANTE ANIMALE, Z.I. La Ballastiere 33500 Libourne France	COLIVET 2.000.000 IU/ml	Colistin (as sulphate)	2 000 000 IU/ml	Oral solution	Pigs, poultry

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Czech Republic	Andrés Pintaluba, S.A. Polígono Industrial Agro-Reus C/Prudenci Bertrana n 5, 43206 REUS (Tarragona) Spain	APSAMIX COLISTINA 40 mg/g premix pro medikaci krmiva pro prasata	Colistin (as sulphate)	40 mg/g (1 200 000 IU/g)	Pre-mix for medicated feedingstuffs	Pigs (piglets and fattening pigs)
Czech Republic	Bioveta, a. s. Komenského 212 683 23 Ivanovice na Hané Czech Republic	BIOVETA COLISTIN 1 200 000 IU/mg prášek pro přípravu perorálního roztoku	Colistin sulphate	1 200 000 IU/g	Powder for oral solution	Piglets, calves, chicken (broilers)
Czech Republic	Ceva Animal Health Slovakia spol. s r.o. Račianska 77, 81 02 Bratislava, Slovak Republic	COLIVET prášek pro přípravu perorálního roztoku	Colistin (as colistin sulphate)	1 200 000 IU/g	Powder for oral solution	Calves, piglets, chicken (broilers)
Czech Republic	Ceva Animal Health Slovakia spol. s r.o. Račianska 77, 81 02 Bratislava, Slovak Republic	COLIVET perorální roztok	Colistin (as colistin sulphate)	2 000 000 IU/ml	Oral solution	Fattening pigs, chicken
Czech Republic	Chemifarma SpA Via Don E.Servadei 16 4710 Forlì Italy	COLISTINA SOLFATO 12% sol.	Colistin sulphate	120 g/1 liter	Oral solution	Calves, pigs, chicken – broilers, laying hens, turkeys, rabbits
Czech Republic	KELA N.V. St. Lenaartseweg 48, 2320 Hoogstraten, Belgium	COLISTIMAX 1200 prášek pro přípravu perorálního roztoku	Colistin sulphate	1 200 000 IU (equivalent to 50 mg) in 1 g	Powder for oral solution	Calves (non ruminating), piglets

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Czech Republic	KRKA, d.d. Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	Giraxa 50 mg/g prášek pro perorální roztok pro telata, selata a brojlerů kura domácího	Colistin (as colistin sulphate)	50 mg/g	Powder for oral solution	Cattle (calves), pigs (piglets), chicken (broilers)
Czech Republic	Lavet Pharmaceuticals Ltd. Ottó u.14, 1161 Budapest Hungary	COLICIN 2400 plv.sol.	Colistin (as sulphate)	240 10 ⁶ IU in 100 g	Soluble powder for oral use in drinking water or for individual administration in feed	Pigs, piglets, chicken (broilers), turkey
Czech Republic	Tekro, spol. s r.o. Višňová 2/484 140 00 Praha 4 Czech Republic	MEDITEK COLIS plv. sol.	Colistin sulphate	1200 x 10 ⁶ IU/kg	Powder for oral solution	Pigs, broilers
Denmark	Alpharma BVBA Laarstraat 26, BE-B2610 Antwerp, Belgium	Dumocol Vet.	Colistin	25 mg/g	Powder for oral solution	Pigs, cattle
Denmark	Ceva Animal Health A/S Ladegårdsvej 2, DK-7100 Vejle, Denmark	Colivet	Colistin	2 M IU/ml	Oral solution	Pigs
Denmark	Divasa-Farmavic S.A. PO Box 79, Ctra. Sant Hipolit, Km 71, ES-08503 Gurb-Vic, Barcelona, Spain	Coliplus	Colistin	2 M IU/ml	Concentrate for oral solution for use in drinking water	Pigs, cattle, poultry, sheep

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Denmark	ScanVet Animal Health A/S Kongevejen 66, DK-3480 Fredensborg, Denmark	Colicol	Colistin	240 mg/ml	Solution for use in drinking water	Pigs
Denmark	ScanVet Animal Health A/S Kongevejen 66, DK-3480 Fredensborg, Denmark	Colicol	Colistin	1000 mg/ml	Granules for use in drinking water	Pigs
Denmark	Sogeval 200 Avenue de Mayenne - Zone Industrielle des Touches 53000 - Laval France	Sogecoli 2 000 000 IU/ml Colistin 2 MIU/ml	Colistin	2 000 000 IU/ml	Concentrate for oral solution	Calves, lambs, pigs, poultry
Estonia	Ceva Santé Animale 10, av. de la Ballasti�re 33500 Libourne, France	Colivet oral powder	Colistin	1 200 000 IU/g	Oral powder	Pigs, chicken, cattle (calves)
Estonia	Ceva Santé Animale 10, av. de la Ballasti�re 33500 Libourne, France	Colivet	Colistin	2 000 000 IU/ml	Concetrate for oral solution	Pigs, chicken
Estonia	V.M.D. n.v. Industrieterrein "Hoge Mauw" 900 B-2370 Arendonk, Belgium	Promycine	Colistin	160 mg/g	Powder for oral solution	Pig, cattle

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Estonia	Bela-Pharm GmbH & Co KG Lohner Str. 19, 49377 Vechta, Germany	Belacol 24% Liquid	Colistin	240 mg/ml	Oral solution	Pigs, chickens, cattle (calves)
France	CEVA SANTE ANIMALE 10 avenue de la Ballastiere, 33500 Libourne, France	COLIVET	Colistin (as sulphate)	1.2 M IU/g	Powder for oral solution	Pigs, calves, poultry
France	CEVA SANTE ANIMALE 10 avenue de la Ballastiere, 33500 Libourne, France	COLIVET SOLUTION	Colistin (as sulphate)	2 000 000 IU/ml	Oral solution	Lambs, pigs, calves, poultry
France	CEVA SANTE ANIMALE 10 avenue de la Ballastiere, 33500 Libourne, France	COLISTINE CEVA 2 MUI/ML CONCENTRE POUR SOLUTION BUVABLE POUR PORCINS ET VOLAILLES	Colistin (as sulphate)	2 M IU/ml	Oral solution	Pigs, poultry
France	Coophavet 23 rue du Prieuré Saint Herblon, 44150 Ancenis France	COFALAC	Colistin (as sulphate)	25 500 IU/g	Powder for oral suspension	Calves
France	Coophavet 23 rue du Prieuré Saint Herblon, 44150 Ancenis France	COFACOLI POUDRE	Colistin (as sulphate)	750 000 IU/g	Powder for oral solution	Lambs, rabbits, pig, calves, poultry

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France	Coophavet 23 rue du Prieuré Saint Herblon, 44150 Ancenis France	COFACOLI SOLUTION	Colistin (as sulphate)	2 000 000 IU/ml	Oral solution	Lambs, pigs, calves, poultry
France	Deltavit Zone d'activites du bois de teillay 35150 Janze France	PO 11 COLISTINE 100 LAPIN - VOLAILLE - PORC - VEAU	Colistin (as sulphate)	1 M IU/g	Powder for oral solution	Rabbits, pigs, calves, poultry
France	Deltavit Zone d'activites du bois de teillay 35150 Janze France	PM 11-B COLISTINE 400 PORC-AGNEAU ET CHEVREAU SEVRES	Colistin (as sulphate)	400 000 IU/g	Premix	Lambs, kid (goat), pigs
France	Laboratoires Biove 3 Rue De Lorraine 62510 Arques France	BIOREPAS	Colistin (as colistin sulphate)	25 000 IU/g	Oral powder	Calves
France	Laboratoires Biove 3 Rue De Lorraine 62510 Arques France	ACTI COLI B	Colistin (as sulphate)	1 M IU/g	Powder for oral solution	Rabbits, pigs, calves, poultry
France	Laboratoires Biove 3 Rue De Lorraine 62510 Arques France	ACTI COLI 2 MUI/ML	Colistin (as sulphate)	2 000 000 IU/mg	Oral solution	Lambs, pigs, calves, poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	Ucamix v colistine 200 lapin-volaille-porc et veau-agneau-chevreau sevres	Colistin (as sulphate)	25 500 IU/g	Premix	Calves, lambs, kid (goat), pigs, rabbits, poultry, turkeys, ducks, guinea hens, pheasants, partridges, geese, quails
France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	Colistine 200-cb lapin-volaille-porc et agneau-chevreau sevres franvet	Colistin (as sulphate)	200 000 IU/g	Premix	Lambs, quails, ducks, kid (goat), turkeys, rabbits, geese, guinea hens, pigs, poultry
France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	Synamix Colistine 200 Lapin-Volaille-Porc	Colistin (as sulphate)	200 000 IU/g	Premix	Ducks, turkeys, pheasants, rabbits, partidges, guinea hens, pigs, poultry
France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	COMPOMIX V COLI 1.000	Colistin (as sulphate)	1 M IU/g	Powder for oral solution	Calves
France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	UCAMIX V COLISTINE 400 PORC	Colistin (as sulphate)	400 000 UI/g	Premix	Pigs
France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	Colistine 400-Cb Porc Et Agneau-Chevreau Sevres Franvet	Colistin (as sulphate)	400 000 IU/g	Premix	Lambs, kid (goat), pigs

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France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	Colistine 400-F Porc Et Agneau-Chevreau Sevres Franvet	Colistin (as sulphate)	400 000 IU/g	Premix	Lambs, kid (goat), pigs
France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	MILICOLI	Colistin (as sulphate)	2 000 000 IU/ml	Oral solution	Lambs, pigs, calves, poultry
France	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	COLISTINE BUVABLE NOE 6,7	Colistin (as sulphate)	66.67 mg/ml	Oral solution	Lambs, pigs, calves, poultry
France	SOGEVAL 200 Avenue De Mayenne Zone Industrielle Des Touches 53000 Laval France	CONCENTRAT VO 49-2 COLISTINE 200 lapin-volaille-porc et agneau-chevreau sevres	Colistin (as sulphate)	200 000 IU/g	Premix	Lambs, quails, ducks, kid (goat), turkeys, pheasants, rabbits, geese, partidges, guinea hens, pigs, poultry
France	SOGEVAL 200 Avenue De Mayenne Zone Industrielle Des Touches 53000 Laval France	CONCENTRAT VO 49-1 COLISTINE 400 porc et agneau-chevreau sevres	Colistin (as sulphate)	400 000 IU/g	Premix	Lambs, kid (goat), pigs
France	SOGEVAL 200 Avenue De Mayenne Zone Industrielle Des Touches 53000 Laval France	SOGECOLI 2 millions UI/ml solution buvable	Colistin (as sulphate)	2 000 000 IU/ml	Oral solution	Lambs, pig, calves, poultry

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France	VIRBAC 1ere Avenue 2065 M L I D 06516 Carros Cedex France	COLIPATE	Colistin (as sulphate)	225 000 IU/ml	Oral paste	Lambs, kid (goat), piglets
France	VIRBAC 1ere Avenue 2065 M L I D 06516 Carros Cedex France	COLISTINE LACTO	Colistin (as sulphate)	10 M IU/g	Oral powder	Lambs, kid (goat), pigs, calves, poultry
France	VIRBAC 1ere Avenue 2065 M L I D 06516 Carros Cedex France	COLISTINE SULFATE 2 000 000 UI/ML BUVABLE VIRBAC	Colistin (as sulphate)	2 000 000 IU/ml	Oral solution	Lambs, pigs, calves, poultry
France	VIRBAC 1ere Avenue 2065 M L I D 06516 Carros Cedex France	ENTEROGRAM	Colistin (as sulphate)	0,45 M IU/ml	Oral paste	Calves
France	ANIMEDICA ESPANA C/ Esmeralda, 19 Esplugues De Llobregat 08950 Barcelona Spain	COLFIVE	Colistin (as sulphate)	5 000 000 IU/ml	Oral solution	Lambs, pigs, calves, poultry
France	SOGEVAL 200 Avenue De Mayenne Zone Industrielle Des Touches 53000 Laval France	COLISTINE 2 MUI/ML SOLUTION BUVABLE POUR VEAUX AGNEAUX PORCINS ET VOLAILLES	Colistin (as sulphate)	2 000 000 IU/ml	Oral solution	Lambs, pigs, calves, poultry

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Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	Animedistin 12% N	Colistin sulphate	120 mg/g	Powder	Cattle, calves, pigs, chicken
Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	animedica Enteroxid N	Colistin sulphate	25 mg/g	Powder	Pigs (up to 40 kg bw)
Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	Animedistin 2% AMV	Colistin sulphate	20 mg/g	Medicated premix	Pigs
Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	Klato Col	Colistin sulphate	120 mg/g	Powder	Cattle, calves, pigs, chicken
Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	Colistinsulfat 40	Colistin sulphate	40 mg/g	Powder	Cattle, calves, pigs, chicken
Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	Animedistin	Colistin sulphate	20 mg/g	Powder	Cattle, calves, pigs, chicken
Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	Enteroxid N AMV aniMedica	Colistin sulphate	25 mg/g	Medicated premix	Pigs (up to 40 kg bw)

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Germany	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell Germany	Colistinsulfat 100 % aniMedica	Colistin sulphate	1000 mg/g	Powder	Cattle, pigs, chicken
Germany	Bela-Pharm GmbH & Co. KG Lohner Str. 19 D-49377 Vechta Germany	Belacol 24% Liquid	Colistin sulphate	240 mg/ml	Solution	Cattle, calves, pigs, chicken
Germany	Bela-Pharm GmbH & Co. KG Lohner Str. 19 D-49377 Vechta Germany	Belacol Doser	Colistin sulphate	7.5 mg/ml	Suspension	Piglets
Germany	Bela-Pharm GmbH & Co. KG Lohner Str. 19 D-49377 Vechta Germany	Belacol soluble	Colistin sulphate	25 mg/g	Powder	Cattle, calves, pigs
Germany	Bela-Pharm GmbH & Co. KG Lohner Str. 19 D-49377 Vechta Germany	Belacol 6% Pulver	Colistin sulphate	60 mg/g	Powder	Cattle, calves, pigs, chicken
Germany	Bela-Pharm GmbH & Co. KG Lohner Str. 19 D-49377 Vechta Germany	Belacol 12% Pulver	Colistin sulphate	120 mg/g	Powder	Cattle, calves, pigs, chicken
Germany	Bela-Pharm GmbH & Co. KG Lohner Str. 19 D-49377 Vechta Germany	Belacol 100% Kompaktat	Colistin sulphate	1000 mg/g	Granules	Cattle, pigs, ducks, chicken, turkeys

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Germany	Chevita Tierarzneimittel GmbH Raiffeisenstr. 2 D-85276 Pfaffenhofen Germany	Colistin C 12 GS	Colistin sulphate	120 mg/g	Powder	Pigs, chicken
Germany	Chevita Tierarzneimittel GmbH Raiffeisenstr. 2 D-85276 Pfaffenhofen Germany	Colistin C 12 KRS	Colistin sulphate	120 mg/g	Powder	Cattle, calves, pigs
Germany	Divasa-Farmavic S.A. Ctra. Sant Hipolit, km 71 E-08503 Gurb-Vic (Barcelona) Spain	Coliplus	Colistin sulphate	2 million IU	Solution	Calves, lambs, pigs, chicken
Germany	KLAT-Chemie GmbH Visbeker Str. 12 D-26197 Ahlhorn Germany	Colistinsulfat 100	Colistin sulphate	1000 mg/g	Powder	Calves, pigs, chicken
Germany	KLAT-Chemie GmbH Visbeker Str. 12 D-26197 Ahlhorn Germany	Colistinsulfat-Klat 100	Colistin sulphate	1000 mg/g	Powder	Calves, pigs, chicken
Germany	KLAT-Chemie GmbH Visbeker Str. 12 D-26197 Ahlhorn Germany	Colistinsulfat 1 Mio. I.E./g	Colistin sulphate	1 million IU/g	Powder	Calves, pigs, chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Germany	Kon-Pharma GmbH Alter Flugplatz 38 D-49377 Vechta Germany	Colipur	Colistin sulphate	1,0 g/g	Powder	Pigs, chicken
Germany	Laboratorios Calier S. A. Barcelonas 26 E-08520 Les Franqueses del Valles, Barcelona Spain	Aquacoli 2 000 000 IU/ml, concentrate for oral solution for use in drinking water	Colistin sulphate	2 million IU/ml	Oral solution	Cattle (calves), pigs, sheep (lambs), chicken
Germany	Pharmawerk Weinböhla GmbH Poststr. 58 D-01689 Weinböhla Germany	Carbophen	Colistin sulphate	10 mg/g	Powder	Cattle, calves, pigs
Germany	Prodivet pharmaceuticals n.v./s.a. Veterinarian Products & Instruments Hagbenden 39c B-4731 Eynatten Belgium	Colivet Doser	Colistin sulphate	7.5 mg/ml	Suspension	Piglets
Germany	Prodivet pharmaceuticals n.v./s.a. Veterinarian Products & Instruments Hagbenden 39c B-4731 Eynatten Belgium	Colivet Tab	Colistin sulphate	150 mg/tablet	Tablet	Calves

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Germany	Animedica Espana S. L. U. Esmeralda 19 E-08950 Esplugues de Llobregat, Barcelona Spain	COLFIVE	Colistin sulphate	5 mg/ml	Oral solution	Cattle (calves), pigs, sheep (lambs), poultry
Germany	Bela-Pharm GmbH & Co. KG Lohner Str. 19 D-49377 Vechta Germany	Belacol 100% Kompaktat	Colistin sulphate	1000 mg/g	Granules	Cattle, calves, pigs
Germany	KLAT-Chemie GmbH Visbeker Str. 12 D-26197 Ahlhorn Germany	Coli-Klat	Colistin sulphate	1000 mg/g	Powder	Cattle (calves), pigs, chickens
Germany	Sogeval 200, Av. De Mayenne, ZI de Touches F-53000 Laval France	Colistin 2M IU/ml oral solution for calves, pigs and poultry	Colistin sulphate	2 000 000 IU/ml	Oral solution	Cattle (calves), pigs, sheep (lambs), poultry
Greece	Andres Pintulaba S.A. Edificio Grupo Pintaluba Polígono Industrial Agro-Reus Prudenci Bertrana, 5 E-43206 Reus Spain	APSAMIX COLISTINA 4%	Colistin	40 mg/g	Premix for medicated feeding stuff	Pigs
Greece	CEVA SANTE ANIMALE Z.I. La Ballastiere 33500 Libourne France	COLIVET 2.000.000 IU/ml	Colistin (as sulphate)	2 000 000 IU	Oral solution	Pigs, poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Greece	CEVA SANTE ANIMALE Z.I. La Ballastiere 33500 Libourne France	COLISTIN/CEVA	Colistin (as sulphate)	6 000 000 IU/g	Power for oral solution	Calves, pigs, chickens, turkeys
Greece	CEVA SANTE ANIMALE Z.I. La Ballastiere 33500 Libourne France	COLISTIN/CEVA	Colistin (as sulphate)	1 200 000 IU/g	Premix for medicated feeding stuff	Calves, pigs, poultry
Greece	Divasa-Farmavic S.A. Ctra. Sant Hipolit, Km 71, ES-08503 Gurb-Vic, Barcelona Spain	COLISTIN/DIVASA FARMAVIC	Colistin	2 000 000 IU/ml	Concentrate for solution	Calves, pigs, chicken, lambs
Greece	NUTRI BIOMED HELLAS EPE V.Hugo 1 & Chlois 98 Metamorfofi Attikis14452 Greece	COLIVETO VMD	Colistin	350 000 000 IU/100 g	Soluble powder	Calves, pigs, chicken, turkeys
Greece	Αφοι Τετώρου ΑΒΕ Κτηνιατρική Φαρμακοβιομηχανία 10ο χλμ Αθηνών-Λαμίας 144 51, Μεταμόρφωση, Αθήνα Greece	COLISTIN 350/ANAFASIS	Colistin	3 500 000 IU/g	Power for oral solution	Calves, lambs, pigs, chickens
Hungary	Andersen, S.A. Avda. de la Llana, 123 08191 Rubí Spain	Nipoxyme 1000 mg/g belsőleges por A.U.V.	Colistin sulphate	1000 mg/g	Powder for oral solution	Pigs

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Hungary	Andersen, S.A. Avda. de la Llana, 123 08191 Rubí Spain	NIPOXYME 200 mg/g belsőleges szuszpenzió A.U.V.	Colistin sulphate	200 mg/g	Oral suspension	Pigs (after weaning, fattening pigs)
Hungary	Andersen, S.A. Avda. de la Llana, 123 08191 Rubí Spain	Nipoxyme 40 gyógypremix A.U.V.	Colistin sulphate	40 mg/g	Premix for medicated feeding stuff	Pigs, chicken
Hungary	Andersen, S.A. Avda. de la Llana, 123 08191 Rubí Spain	Nipoxime vízdékony pulvis 100 A.U.V.	Colistin sulphate	150 mg/g	Powder for oral solution	Pigs, chicken
Hungary	Andersen, S.A. Avda. de la Llana, 123 08191 Rubí Spain	Nipoxyme 100 gyógypremix A.U.V.	Colistin sulphate	100 mg/g	Premix for medicated feeding stuff	Pigs and chicken
Hungary	Andrés Pinaluba S.A. Pol.Ind.Agro-Reus C/ Prudenci Bertrana n°5 43206 REUS (Tarragona), Spain	Apsamix colistina 40 mg/g gyógypremix sertések részére A.U.V.	Colistin	40 mg/g	Premix for medicated feeding stuff	Pigs (piglets and fattening pigs)
Hungary	Biopol Fejlesztő és Kereskedelmi Kft. 8200 Veszprém, József A. utca 34., Hungary	Coliphyl gyógypremix sertések részére A.U.V.	Colistin sulphate	120 g/kg	Premix for medicated feeding stuff	Pigs
Hungary	Ceva-Phylaxia Zrt. 1107 Budapest, Szállás u. 5., Hungary	Colivet gyógypremix koncentrátum A.U.V.	Colistin sulphate	1 200 000 000 IU/kg	Premix for medicated feeding stuff	Pigs, chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Hungary	Ceva-Phylaxia Zrt. 1107 Budapest, Szállás u. 5., Hungary	Colivet oldat A.U.V.	Colistin sulphate	2 000 000 IU/ml	Oral solution	Pigs, chicken
Hungary	Ceva-Phylaxia Zrt. 1107 Budapest, Szállás u. 5., Hungary	Colivet por belsőleges oldathoz A.U.V.	Colistin sulphate	120 000 000 IU/100 g	Powder for oral solution	Pigs, chicken
Hungary	Chemifarma S.p.a, 47122 Forli, Via Don Eugenio Sevandei 16, Italy	Colichem 12% belsőleges oldat	Colistin sulphate	120 g/l	Oral solution	Calves, chicken, pigs
Hungary	Coophavet 23 rue du Prieuré Saint Herblon, 44150 Ancenis, France	Cofacoli oldat A.U.V.	Colistin sulphate	200 000 000 IU/100 ml	Oral solution	Cattle (calves), pigs (piglets), chickens (broiler chicken, laying hens)
Hungary	Coophavet 23 rue du Prieuré Saint Herblon, 44150 Ancenis, France	Cofacoli vízoldékony porA.U.V.	Colistin sulphate	75 000 000 IU/100 g	Powder for oral solution	Calves
Hungary	Divasa - Farmavic, S.A. Ctra. Sant Hipolit, km 71 08503 GURB VIC Barcelona, Spain	Coliplus 2.000.000 NE/ml koncentrátum belsőleges oldathoz szarvasmarhák, juhok, sertések és házityúkok számára A.U.V.	Colistin sulphate	2 000 000 IU/ml	Concentrate for oral solution for use in drinking water	Cattle (calves), sheep (lambs), pigs and chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Hungary	Lavet Gyógyszergyártó Kft. 1161 Budapest, Ottó u. 14. Hungary	Colicin 2400 gyógypremix A.U.V.	Colistin sulphate	100 mg/g	Premix for medicated feeding stuff	Pigs
Hungary	Lavet Gyógyszergyártó Kft. 1161 Budapest, Ottó u. 14. Hungary	Colicin 2400 por belsőleges oldathoz A.U.V.	Colistin sulphate	100 mg/g	Powder for oral solution	Pigs, chickens
Hungary	Vim Spectrum Hungary Kft. 1029 Budapest, Adyliget, Pipitér u. 5., Hungary	Colanin 1200 por belsőleges oldathoz A.U.V.	Colistin sulphate	1 200 000 IU/g	Powder for oral solution	Pigs, chickens
Hungary	VMD. nv/sa Hoge Mauw 900, B-2370 Arendonk, Belgium	Promycine 4800 NE/mg por belsőleges oldathoz A.U.V.	Colistin sulphate	4 800 000 IU/g	Powder for oral solution	Calves, pigs
Ireland	Ceva Sante Animale, 10, Avenue de la Ballastiere, 33500 Libourne, France	COLISCOUR 2 000 000 IU/ml, concentrate for oral solution, pigs, poultry.	Colistin (as sulphate)	2 000 000 IU	Concentrate for oral solution	Pigs and poultry
Ireland	aniMedica España S.L.U. Esmeralda, 19, Esplugues de Llobregat, E-08950, Barcelona, Spain	Colfive, 5,000,000 IU/ml concentrate for oral solution	Colistin (as sulphate)	5 000 000 IU/ml	Concentrate for oral solution. Clear orange-brown solution	Cattle (calves), pigs, sheep (lambs) and poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Ireland	Sogeval 200 Avenue de Mayenne, Zone Industrielle des Touches, 53000 Laval, France	COLISTIN 2 MIU/ML oral solution for calves lambs pigs and poultry	Colistin (as sulphate)	2 000 000 IU	Oral solution	Calves, lambs, pigs, poultry
Italy	Andersen S.A. Avda. De la Llana, 123 08191 – Rubí Barcelona Spain	Nipoxyme 1000 mg/g polvere orale	Colistin sulphate	1000 mg/g	Oral powder, white to almost white powder	Pigs
Italy	Andres Pintulaba S.A. Edificio Grupo Pintaluba Polígono Industrial Agro-Reus Prudenci Bertrana, 5 E-43206 Reus Spain	Apsamix Colistina 4%	Colistin sulphate	40 mg/g	Premix for medicated feeding stuff	Pigs
Italy	Ceva Salute Animale S.p.A. Viale Colleoni, 15 20864 - Agrate Brianza (MB) Italy	Enteristin	Colistin sulphate	120 mg/g	Premix for medicated feeding Granular powder to be mixed with solid feed.	Pigs (up to 35 kg), broilers, laying hens, turkeys and rabbits
Italy	Ceva Salute Animale S.p.A. Viale Colleoni, 15 20864 - Agrate Brianza (MB) Italy	Enteristin 12% liquido	Colistin sulphate	120 mg/ml	Oral solution to be mixed exclusively to the drinking water or liquid feed	Pigs (up to 35 kg), broilers, laying hens, turkeys and rabbits
Italy	Ceva Salute Animale S.p.A. Viale Colleoni, 15 20864 - Agrate Brianza (MB) Italy	Enteristin 12% solubile	Colistin sulphate	120 g/1000 g	Oral powder for use in drinking water or liquid feed	Calves, pigs (up to 35 kg), broilers, laying hens, turkeys and rabbits

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Italy	Chemifarma S.P.A. Via Don Eugenio Servadei, 16 47122 Forli -Cesena Italy	Colisid ex colistina solfato 12% liquido	Colistin sulphate	120 mg/ml	Solution for use in drinking water or liquid food	Calves, pigs, broilers, turkeys, laying hens, rabbits
Italy	Chemifarma S.P.A. Via Don Eugenio Servadei, 16 47122 Forli -Cesena Italy	Medistin 120	Colistin sulphate	120 g/kg	Premix for medicated feeding stuff	Pigs, broilers, turkeys, laying hens
Italy	Chemifarma S.p.a. Via Don Eugenio Servadei, 16 47122 Forli Italy	Colistina solfato 12% chemifarma	Colistin sulphate	120 mg/g	Soluble powder to be administered dissolved in drinking water	Calves, pigs, broilers, turkeys, laying hens
Italy	Divasa Farmavic S.A. Ctra. Sant Hipòlit, km 71 box 79 08503 GURB-VIC, Barcelona Spain	Coliplus	Colistin sulphate	2 000 000 IU/ml	Concentrate for oral solution for use in drinking water. Clear yellow-brown solution	Cattle (calves), sheep (lambs), pigs and chicken
Italy	Doxal Italia S.p.a. largo Donegani 2 20121 - Milano Italy	Raldon	Colistin sulphate	120 mg/g	Solution for use in drinking water	Calves, piglets up to 35 kg of weight, broilers, turkeys and laying hens and rabbits
Italy	Doxal Italia S.p.a. largo Donegani 2 20121 - Milano Italy	Doxamicina	Colistin sulphate	120 mg/g	Premix for medicated feeding stuff	Piglets up to 35 kg of weight, broilers, turkeys, laying hens and rabbits

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Italy	Filozoo Srl V. del Commercio 28/30 41012 - Carpi (MO) Italy	Filostin Sol	Colistin sulphate	120 mg/g	Powder for oral solution. To be administered dissolved in drinking water	Calves, pigs (up to 35 kg), broilers, turkeys, laying hens, rabbits
Italy	Filozoo Srl V. del Commercio 28/30 41012 - Carpi (MO) Italy	Filostin 120 liquido	Colistin sulphate	120 mg/g	Oral solution for use in drinking water	Calves, pigs (up to 35 kg), broilers, turkeys, laying hens, rabbits
Italy	Filozoo Srl V. del Commercio 28/30 41012 - Carpi (MO) Italy	Filostin 120 S	Colistin sulphate	120 mg/g	Premix for medicated feeding. Powder may be administered mixed with the solid feed	Pigs (up to 35 kg), broilers, turkeys, laying hens, rabbits
Italy	Industria Italiana Integratori Trei S.P.A. Via Affarosa, 4 42010 - Rio Saliceto (RE) Italy	Enterocol	Colistin sulphate	120 mg/g	Premix for medicated feed to be administered mixed in the feed	Broilers, turkeys, laying hens, rabbits and pigs
Italy	Industria Italiana Integratori Trei S.P.A. Via Affarosa, 4 42010 - Rio Saliceto (RE) Italy	Stimixin	Colistin sulphate	120 g/kg	Powder for use in drinking water or liquid food	Calves, pigs, broilers, turkeys, laying hens and rabbits
Italy	Industria Italiana Integratori Trei S.P.A. Via Affarosa, 4 42010 - Rio Saliceto (RE) Italy	Stimixin liquido	Colistin sulphate	120 mg/g	Oral solution for use in drinking water or liquid food	Calves, pigs, broilers, turkeys, laying hens and rabbits

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Italy	Izo S.r.l. Via San Zeno, 99/A 25124 Brescia Italy	Izocolimicina	Colistin sulphate, Retinol palmitate	2 000 000 IU	Powder for oral solution	Cattle, pigs, dogs
Italy	Sintofarm Via P. Togliatti, 5 42016 - Guastalla (RE) Italy	Colmix 120	Colistin sulphate	120 mg/g	Premix for medicated feeding stuff. Powder for oral use may be administered mixed in the feed.	Broilers, turkeys, hens, rabbits, piglets up to 35 kg live weight
Italy	Sintofarm Via P. Togliatti, 5 42016 - Guastalla (RE) Italy	Colistina solfato 10%	Colistin sulphate	100 mg/g	Powder for use in drinking water or liquid feed	Calves, broilers, turkeys, laying hens, rabbits, piglets up to 35 kg live weight
Italy	Ternova S.r.l. via della libertà, 1 40064 - Ozzano dell'Emilia (BO) Italy	Enterocide ex Aticol	Colistin sulphate	4 000 000 IU/g	Powder for oral solution	Calves, buffalo calves, lambs, goats, foal, pigs, chickens, turkeys, rabbits
Italy	Vetoquinol Italia S.r.l.Via Piana, 265 47032 Bertinoro (FC) Italy	Solbac	Colistin sulphate	120 mg/g	Powder for oral solution. To be administered dissolved in drinking water or liquid food	Calves, pigs (up to 35 kg), broilers, turkeys, hens and rabbits
Italy	Vetoquinol Italia S.r.l.Via Piana, 265 47032 Bertinoro (FC) Italy	Bac Mp	Colistin sulphate	120 mg/g	Not soluble granules for oral use - premix for medicated feeding stuff	Pigs (up to 35 kg), broilers, turkeys, laying hens and rabbits

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Italy	Vetoquinol Italia S.r.l.Via Piana, 265 47032 Bertinoro (FC) Italy	Colistina solfato 12% vetoquinol Italia	Colistin sulphate	120 mg/g	Oral powder, to be dissolved only in the drinking water or liquid feed	Calves, pigs (up to 35 kg), broilers, turkeys, hens and rabbits
Italy	Vetoquinol Italia S.r.l.Via Piana, 265 47032 Bertinoro (FC) Italy	Liquibac	Colistin sulphate	120 mg/ml	Solution for use in drinking water. Liquid color from yellow to brown	Calves, pigs (up to 35 kg), broilers, turkeys, guinea fowl, ducks, hens and rabbits
Italy	Animedica Espana S.L.U. C/ Esmeralda, 19 Esplugues de Llobregat Barcelona Spain	Colfive	Colistin sulphate	5 000 000 IU/ml	Concentrate for oral solution	Cattle (calves), pigs, sheep (lambs) and poultry
Italy	Laboratorios Calier S.A. C/Barcelonés, 26 (Pla del Ramassar) 08520 Les Franqueses del Vallés (Barcelona) Spain	Aquacoli soluzione orale	Colistin sulphate	2 000 000 IU/ml	Concentrate for oral solution for use in drinking water	Cattle (calves), sheep (lambs), pigs and chickens
Italy	Sogeval S.A. 200 Avenue Mayenne Zone Industrielle des Touches 53000 - Laval France	Colistin	Colistin sulphate	2 000 000 IU	Oral solution	Calves, lambs, pigs, poultry
Latvia	CEVA SANTE ANIMALE Zone Industrielle, La Ballastiere, 33500 Libourne, France	Colivet oral solution	Colistin sulphate	2 million IU/ml	Solution for oral use	Pigs, poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Latvia	CEVA SANTE ANIMALE Zone Industrielle, La Ballastiere, 33500 Libourne, France	Colivet	Colistin sulphate	1200 million IU/kg	Powder for oral solution	Pigs, calves, poultry
Latvia	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia	Giraxa	Colistin sulphate	50 mg/g	Powder for oral solution	Calves, pigs, chicken
Latvia	LAVET Pharmaceuticals Ltd. 1161 Budapest, Otto u. 14, Hungary	Coliprim 2400	Colistin sulphate	2.4 million IU/g	Powder for oral use	Pigs, turkeys, chickens
Latvia	Sintofarm S.P.A. Via Togliatti 5, 42016 Guastalla (RE), Italy	Colistin Sulphate 10%	Colistin sulphate	100 mg/g	Powder for oral use	Broilers, layers, turkeys, pigs, calves, rabbits
Latvia	Bela-pharm GmbH & Co.KG Lohner Str. 19, 49377 Vechta, Germany	Belacol 24 % Liquid	Colistin sulphate	240 mg/ml	Solution for oral use	Calves, pigs, chickens
Lithuania	ANDERSEN S.A. Avda. de la Llana 123 Polígono Industrial „La Llana“ 08191 Rubí Spain	NIPOXYME 1000 mg/g geriamieji milteliai	Colistin sulphate	1000 mg/g (corresponds to 860 mg colistin)	Oral powder	Pigs

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Lithuania	Bela-pharm GmbH & Co.KG Lohner Str.19, D-49377 Vechta, Germany	BELACOL DOSER, 7,5 mg/ml, geriamoji suspensija kiaulėms	Colistin sulphate	7.5 mg/ml	Oral suspension	Pigs (piglets)
Lithuania	Bela-Pharm GmbH & Co.KG Lohner Strase 19, D-49377 Vechta, Germany	BELACOL 12 %, geriamieji milteliai	Colistin sulphate	120 mg/g	Oral powder	Cattle, pigs, chicken
Lithuania	Ceva Sante Animale Zone Industrielle La Ballastiere, 33500 Libourne, France	COLIVET, geriamasis tirpalas	Colistin sulphate	2 000 000 IU/ml	Oral solution	Calves, lambs, pigs and chicken
Lithuania	Ceva Sante Animale Zone Industrielle La Ballastiere, 33500 Libourne, France	COLIVET, geriamieji milteliai	Colistin sulphate	120 000 000 IU/100 g	Oral powder	Chicken, pigs, cattle (non-ruminating calves)
Lithuania	Chemifarma S.p.A Via Don E. Servadei, 16-47100 Forlì, Italy	COLISTINA SOLFATO 12 % CHEMIFARMA, geriamasis tirpalas	Colistin sulphate	120 mg/ml	Oral solution	Calves, pigs (up to 35kg), broilers, turkeys, laying hens and rabbits
Lithuania	Divasa - Farmavic, S.A. Ctra. Sant Hipòlit, km 71, 08503 GURB – VIC Barcelona, Spain	COLIPLUS, 2 000 000 TV/ml, koncentratas geriamajam tirpalui galvijams, avims, kiaulėms ir vištoms ruošti, skirtas naudoti su geriamu vandeniu	Colistin sulphate	2 000 000 IU (83,33 mg)/ml	Concentrate for oral solution	Cattle (calves), sheep (lambs), pigs and chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Lithuania	Divasa-Farmavic, S.A. Ctra. Sant Hipòlit, km 71, 08503 GURB – VIC, Barcelona, Spain	COLISTOP, geriamasis tirpalas	Colistin sulphate	2 000 000 IU/ml	Water soluble oral solution	Calves, lambs, pigs and poultry (chicken broilers)
Lithuania	Dopharma B.V. Zalmweg 24, 4941 VX Raamsdonksveer, Netherlands	COLISTIN 4800, geriamieji milteliai	Colistin sulphate	4 800 000 IU/g	Oral powder	Calves, pigs, poultry
Lithuania	Franvet 3 Zone Industrielle d'Etriché, 49500 Segré, France	MILICOLI 2000000 TV/ml geriamasis tirpalas galvijams, avims, kiaulėms, paukščiams	Colistin sulphate	2 000 000 IU/ml	Oral solution	Cattle (calves), sheep (lambs), pigs and poultry.
Lithuania	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia	GIRAXA 50 mg/g, milteliai geriamajam tirpalui ruošti veršeliams, paršeliams ir viščiukams	Colistin sulphate	50 mg/g (corresponds to 1 200 000 IU/g)	Powder for oral solution	Cattle (calves), pig (piglets), chicken
Lithuania	Sintofarm S. p. A. Via Togliatti 5-42016, Guastalla (RE), Italy	COLISTINA SOLFATO 10 % SINTOFARM, milteliai geriamajam tirpalui ruošti	Colistin sulphate	100 mg/g	Powder for oral solution	Calves, chicken broilers, laying hens, turkeys, rabbits and piglets up to 35kg
Lithuania	Bela-Pharm GmbH & Co KG Lohner Str. 19, 49377 Vechta, Germany	Belacol 24 % Liquid	Colistin sulphate	240 mg/ml	Oral solution	Calves, pigs, chickens

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Netherlands	A.A.-Vet Diergeneesmiddelen N.V., Loofklapper 6-8, 8256 SL Biddinghuizen, Netherlands	A.A. COLISTINE 1200 W.O.	Colistin sulphate	1 200 000 IU/g	Powder for oral use	Calves, pigs
Netherlands	A.A.-Vet Diergeneesmiddelen N.V., Loofklapper 6-8, 8256 SL Biddinghuizen, Netherlands	COLI 1200 W.O.	Colistin sulphate	1 200 000 IU/g	Powder for oral use	Calves, pigs
Netherlands	Aesculaap B.V. Mijlstraat 35, 5281 LJ Boxtel, Netherlands	COLISOLUTION 400	Colistin sulphate	400 000 IU/ml	Oral solution	Pigs, chicken
Netherlands	Divasa Farmavic S.A. Ctra. Sant Hipòlit km 71, 08503, Gurb-Vic, Barcelona, Spain	COLIPLUS 2.000.000 IE/ml	Colistin sulphate	2 000 000 IU/ml (equivalent to 83.33 mg/ml)	Oral solution	Calves, lambs, pigs, poultry
Netherlands	Dopharma Research B.V. Zalmweg 24, 4941 VX Raamsdonkveer, Netherlands	COLISOL	Colistin sulphate	250 000 IU/ml	Oral solution	Pigs, poultry
Netherlands	Dopharma Research B.V. Zalmweg 24, 4941 VX Raamsdonkveer, Netherlands	COLISTIN	Colistin sulphate	1 g/g (equivalent to 20 000 000 IU/mg)	Powder for oral use	Calves, pigs, chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Netherlands	Dopharma Research B.V. Zalmweg 24, 4941 VX Raamsdonkveer, Netherlands	COLISTINE 1200 TOPDRESSING	Colistin sulphate	1 200 000 IU/g	Powder for oral use	Calves, pigs, chicken
Netherlands	Dopharma Research B.V. Zalmweg 24, 4941 VX Raamsdonkveer, Netherlands	COLISTINE 4800 WSP	Colistin sulphate	4 800 000 IU/g	Powder for oral use	Calves, pigs
Netherlands	Dopharma Research B.V. Zalmweg 24, 4941 VX Raamsdonkveer, Netherlands	COLISTINE-SULFAAT 4%	Colistin sulphate	1 200 000 IU/g	Powder for oral use	Calves, pigs
Netherlands	Dopharma Research B.V. Zalmweg 24, 4941 VX Raamsdonkveer, Netherlands	DRINKMIX COLISTINE	Colistin sulphate	5 000 000 IU/g	Powder for oral use	Piglets, poultry
Netherlands	Eurovet Animal Health BV Postbus 179, 5530 AD Bladel, Netherlands	BELCOMIX 200 W.O.	Colistin sulphate	10 mg/g (equivalent to 200 000 IU/g)	Powder for oral use	Calves, pigs
Netherlands	Eurovet Animal Health BV Postbus 179, 5530 AD Bladel, Netherlands	COLISOL 400	Colistin sulphate	400 000 IU/ml	Oral solution	Pigs, calves, chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Netherlands	Eurovet Animal Health BV Postbus 179, 5530 AD Bladel, Netherlands	COLISTINE 1200 W.O.	Colistin sulphate	1 200 000 IU/g	Powder for oral use	Calves, pigs
Netherlands	Eurovet Animal Health BV Postbus 179, 5530 AD Bladel, Netherlands	COLISTINE 200 TOPDRESSING	Colistin sulphate	200 000 IU/g	Powder for oral use	Calves, pigs
Netherlands	Virbac Laboratories 1ere Avenue, 2065 m L.I.D., F-06516 Carros, France	ENTEROGEL PIG PUMP	Colistin sulphate	225 000 IU/ml	Emulsion for oral use	Piglets
Netherlands	Virbac Laboratories 1ere Avenue, 2065 m L.I.D., F-06516 Carros, France	ENTEROGEL VOOR KALVEREN	Colistin sulphate	450 000 IU/ml	Emulsion for oral use	Calves
Netherlands	Bela-pharm GmbH & Co.KG. Lohnerstrasse 19, 49377 Vechta, Germany	Belacol 24% drank	Colistin sulphate	240 mg/ml	Oral solution	Calves, pigs, chickens
Netherlands	Laboratoires Sogeval 200 Avenue de Mayenne, Zone Industrielle des Touches, 53000 Laval, France	Colistin 2 MIU/ml drank voor kalveren, lammeren, varkens en pluimvee	Colistin sulphate	2 000 000 IU/ml	Oral solution	Calves, lambs, pigs, poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Poland	ANDERSEN S.A. Avda. La Llana 123 Polígono Industrial "La Llana" 08191 RUBÍ Spain	Nipoxyme 1000 mg/g	Colistin sulphate	1000 mg/g	Oral powder	Pigs
Poland	ANDERSEN S.A. Avda. La Llana 123 Polígono Industrial "La Llana" 08191 RUBÍ Spain	NIPOXYME 200 mg/g	Colistin sulphate	200 mg/g	Oral suspension	Pigs (after weaning, fattening pigs)
Poland	ANDRÉS PINTALUBA S.A. C/Prudenci Bertrana, 5 Pol. Ind. Agro-Reus 43206 REUS (Tarragona) Spain	Apsamix Colistina 40 mg/g	Colistin sulphate	40 mg/g	Premix for medicated feeding stuff	Pigs (piglets and fattening pigs)
Poland	Ceva Sante Animale Zone Industrielle La Ballastiere 33500 Libourne, France	Colivet	Colistin sulphate	120 000 000 IU/100 g	Powder for administration in drinking water	Cattle, pigs, chicken
Poland	Ceva Sante Animale Zone Industrielle La Ballastiere 33500 Libourne, France	Colivet Solution	Colistin sulphate	2 million IU/ml	Oral solution	Chicken, pigs, turkeys
Poland	Divasa - Farmavic S.A. Ctra. Sant Hipolit, Km 71, PO Box 79, 08503 Gurb-Vic, Barcelona, Spain	Coliplus 2,000,000 IU/ml Concentrate for Oral Solution for use in drinking water for Cattle, Sheep, Swine and Chickens	Colistin sulphate	2 000 000 IU/ml	Concentrate for oral solution for use in drinking water	Cattle (calves), sheep (lambs), pigs and chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Poland	KRKA, d.d. Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto Slovenia	Giraxa 50 mg/g	Colistin sulphate	50 mg/g	Powder for oral solution	Cattle (calves), pigs, chicken
Poland	Laboratorios Calier S.A. C/Barcelones, 26 (Pla del Ramassa); Les Franqueses del Valles 08520 Barcelona, Spain	Colistina Kern	Colistin sulphate	40 mg/g	Premix for medicated feed	Pigs, chicken (hens, broilers), rabbits
Poland	MEDIVET S.A. ul. Szkolna 17 63-100 Śrem Poland	COLISTIMED 4800	Colistin sulphate	4 800 000 IU/g	Oral powder	Cattle (calves), pigs and chickens
Poland	ScanVet Poland Sp. z o.o. Skiereszewo, ul. Kiszkowska 9 62-200 Gniezno Poland	Colisol 2400	Colistin sulphate	2 400 000 IU/g	Powder for administration in drinking water	Pigs, chicken, turkey
Poland	V.M.D. n.v./s.a. Hoge Mauw 900 2370 Arendonk Belgium	PROMYCINE PULVIS 4800	Colistin sulphate	4 800 000 IU/g	Powder for administration in drinking water	Cattle (calves), pigs (piglets)
Poland	V.M.D. n.v./s.a. Hoge Mauw 900 2370 Arendonk Belgium	Promycine 200 I.U./mg	Colistin	200 IU/mg	Premix for medicated feed	Pigs and chickens

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Poland	V.M.D. n.v./s.a. Hoge Mauw 900 2370 Arendonk Belgium	Promycine 400 I.U./mg	Colistin	400 IU/mg	Premix for medicated feed	Pigs
Poland	AniMedica España, S.L.U. Esmeralda, 19 Esplugues de Llobregat Barcelona Spain	Colfive 5 000 000 IU/ ml concentrate for oral solution	Colistin sulphate	5 000 000 IU/ml	Concentrate for oral solution	Cattle (calves), pigs, sheep (lambs) and poultry
Poland	Bela-Pharm GmbH & Co.KG Lohner Straße 19, D-49377 Vechta Germany	Belacol 24% liquid	Colistin sulphate	240 mg/ml	Oral solution	Calves, pigs, chickens
Poland	Biofaktor Sp. z o.o. ul. Czysa 4 96-100 Skierniewice Poland	Colimed 1200 WSP	Colistin sulphate	1 200 000 IU/g	Powder for administration in drinking water	Cattle, pigs, chickens, turkey
Poland	Laboratorios Calier S.A. Barcelonès, 26 (Pla del Ramassà) Les Franqueses del Vallès Barcelona, Spain	Aquacoli 2000000 i.m./ ml, concentrate for oral solution for use in drinking water	Colistin sulphate	2 000 000 IU/ml	Solution for use in drinking water	Cattle (calves), sheep (lambs), pigs and chickens
Poland	PFO „Vetos-Farma“ Sp. z o.o. ul. Dzierżoniowska 21 58-260 Bielawa Poland	KOLISITN 100	Colistin sulphate	100 g/100 g	Powder for administration in drinking water	Calves, pigs, chickens

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Poland	PFO „Vetos-Farma” Sp. z o.o. ul. Dzierżoniowska 21 58-260 Bielawa Poland	KOLISITN 50	Colistin sulphate	50 g/100 g	Powder for administration in drinking water	Calves, pigs, chickens
Poland	PFO „Vetos-Farma” Sp. z o.o. ul. Dzierżoniowska 21 58-260 Bielawa Poland	KOLISITN 10	Colistin sulphate	10 g/100 g	Powder for administration in drinking water	Calves, pigs, chickens
Poland	SOGEVAL 200 Avenue De Mayenne Zi Des Touches 53000 – Laval France	Colistin 2MIU/mL oral solution for calves, lambs, pigs and poultry	Colistin sulphate	2 000 000 IU	Concentrate for oral solution	Calves, lambs, pigs, poultry
Portugal	ANDERSEN, S.A. Avda. La Llana 123 Polígono Industrial “La Llana” 08191 RUBÍ Barcelona (Espanha) Spain	Nipoxyme 200 mg/g suspensão oral	Colistin	200 mg/g	Oral suspension	Pigs (after weaning, fattening pigs)
Portugal	ANDERSEN, S.A. Avda. La Llana 123 Polígono Industrial “La Llana” 08191 RUBÍ Barcelona (Espanha) Spain	Nipoxyme1000 mg/g pó oral	Colistin sulphate	1 000 mg (equivalent to 860 mg of colistin base)	Oral powder	Pigs

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Portugal	CALIER PORTUGAL S.A Centro Empresarial Sintra-Estoril II, Ed. C, R. Pé do Mouro, Estrada de Albarraque 2710-335 Sintra Portugal	AQUACOLI 2 000 000 UI/ml, Solução oral para administração na água de bebida ou leite	Colistin sulphate	2 M IU	Oral solution	Cattle (calves), sheep (lambs), pigs and poultry
Portugal	CALIER PORTUGAL S.A Centro Empresarial Sintra-Estoril II, Ed. C, R. Pé do Mouro, Estrada de Albarraque 2710-335 Sintra Portugal	COLIKERN 500 mg/g pré-mistura medicamentosa para alimento medicamentoso para suínos	Colistin sulphate	500 mg (equivalent to 15 million IU)	Premix for medicated feed	Pigs
Portugal	CALIER PORTUGAL S.A Centro Empresarial Sintra-Estoril II, Ed. C, R. Pé do Mouro, Estrada de Albarraque 2710-335 Sintra Portugal	COLIKERN 4% pré-mistura medicamentosa para alimento medicamentoso	Colistin	40 mg	Medicated premix	Pigs, poultry and rabbits
Portugal	CEVA Saúde Animal - Produtos Farmacêuticos e Imunológicos, Lda Rua Doutor António Loureiro Borges, 9/9A- 9ªA Miraflores, 1495-131 ALGÉS Portugal	COLIVET 2 000 000 UI /ml, concentrado para solução oral para suínos e aves	Colistin	2 000 000 IU	Concentrate for oral solution	Pigs and poultry
Portugal	DIVASA - FARMAVIC, S.A. Ctra. Sant Hipòlit, km 71 08503 GURB - VIC Barcelona (Espanha) Spain	Coliplus 2.000.000 UI/ml Concentrado para Solução Oral para uso na água da bebida em Bovinos, Ovinos, Suínos, Aves (Galinhas Poedeiras, Galinhas Reprodutoras e Frangos)	Colistin	2 M IU (equivalent to 83.33 mg)	Concentrate for oral solution for use in drinking water	Cattle (calves), sheep (lambs), pigs and chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Portugal	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	COLISTINA 40 pré-mistura medicamentosa para alimento medicamentoso	Colistin	40 mg	Medicated premix	Pigs
Portugal	QALIAN 34 Rue Jean Monnet Zi D'etriche 49500 Segre France	DRYMIX ESPECIAL N°9 pré-mistura medicamentosa para alimento medicamentoso	Colistin	30 g	Medicated premix	Swine, poultry, bovine
Portugal	Tecadi Lda. Rua Cidade de santarém Zona Industrial Várzea, 2005-002 Santarém Portugal	NIPOXYME 40 pré-mistura medicamentosa para alimento medicamentoso	Colistin	40 mg	Medicated premix	Pigs, poultry and rabbits
Portugal	ZOOPAN Produtos Pecuários S.A. Rua da Liberdade, n° 77 2050-023 Aveiras de Baixo Portugal	Coliscid pré-mistura medicamentosa para alimento medicamentoso	Colistin	720 M IU/g	Medicated premix	Pigs and poultry
Romania	CEVA SANTE ANIMALE 10 avenue de la Ballastiere, 33500 Libourne, France	Colivet	Colistin sulphate	1 200 000 IU/g	Oral powder	Cattle, rabbits, poultry (laying hens, turkeys), pigs
Romania	DELOS IMPEX' 96 SRL Str. Horia, Cloşca şi Crişan, nr. 81, Otopeni, Jud. Ilfov, Romania	Colidem	Colistin sulphate	200 mg/ml	Oral solution	Pigs, poultry

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Romania	KRKA, d. d. Novo mesto Smarjeska Cesta 6 8501 Novo Mesto Slovenia	Giraxa 50 mg/ml	Colistin sulphate	50 mg/g	Powder for oral solution	Calves, pigs, chickens
Romania	LAVET PHARMACEUTICALS LTD. H-1161 Budapest, Otto u.14 Hungary	Coliprim 2400 pulvis	Colistin sulphate	120 mg/g (2 400 000 IU/g)	Water soluble powder	Pigs, poultry (hens, turkeys)
Romania	PASTEUR - Filiala Filipesti SRL Str. Principala nr. 944, Filipestii de Padure , Jud. Prahova, Romania	Avicovit	Colistin sulphate, Vitamin A, D3, E, B1, B6	2 500 000 IU/100 ml	Oral solution	Poultry (hens, turkey)
Romania	PASTEUR - Filiala Filipesti SRL Str. Principala nr. 944, Filipestii de Padure , Jud. Prahova, Romania	Colistin sulfat 50%	Colistin sulphate, Vitamin A, D3, E, B1, B6	0,5 g colistin sulphate (10 000 000 IU/g)	Water soluble powder	Calves, lambs, kids, rabbits, poultry, piglets
Romania	Prodivet Pharmaceuticals SA Hagbenden 39c B-4731 Eynatten Belgium	Colivet pig pump	Colistin sulphate	8 mg/ml	Oral suspension	Piglets
Romania	S.C. CRIDA PHARM S.R.L. 2 Intrarea Vagonetului, Bl. 101,Ap. 47, sector 6, Bucharest, Romania	Colicrid 10%	Colistin sulphate	100 mg/ml	Oral solution	Pigs, broilers

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Romania	S.C. CRIDA PHARM S.R.L. 2 Intrarea Vagonetului, Bl. 101,Ap. 47, sector 6, Bucharest, Romania	Colicrid 50% pulv.	Colistin sulphate	50 g/100 g	Powder	Pigs, broilers
Romania	VMD N.V. Hoge Mauw 900, B-2370 Arendonk, Belgium	Promycine 4.800IU/mg	Colistin sulphate	4 800 IU/mg	Oral powder	Calves, piglets
Romania	CEVA SANTE ANIMALE ROMANIA SRL 5 Chindiei , sector 4, Bucharest Romania	Colivet premix	Colistin sulphate	12 g/100 g	Premix for medicated feedingstuff	Poultry (chicken, laying hens, turkeys), pigs
Romania	DELOS IMPEX' 96 SRL Str. Horia, Cloșca și Crișan, nr. 81, Otopeni, Jud. Ilfov, Romania	Colistin 10% premix	Colistin sulphate	10 g/100 g	Powder	Pigs, poultry
Romania	DOPHARMA B.V. Zalmweg 24,P.O. BOX 205, 4940 AE Raamsdonksveer The Netherlands	Drinkmix colistin	Colistin sulphate	5 000 000 IU/g	Soluble powder	Calves, pigs, poultry
Romania	S.C. ROMVAC COMPANY S.A. Șos. Centurii, nr. 7, Voluntari, Romania	Colistirom	Colistin sulphate	150 000 000 IU/100 g	Water soluble powder	Calves, piglets, lambs, rabbits, poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Romania	ANDERSEN S.A. Avda. de la Llana 123 08191 Rubi Spain	Nipoxyme 200 mg/g	Colistin sulphate	200 mg/g	Oral suspension	Pigs
Romania	ANDERSEN S.A. Avda. de la Llana 123 08191 Rubi Spain	Nipoxyme 1000 mg/g	Colistin sulphate	1000 mg/g	Oral powder	Pigs
Romania	ANDERSEN S.A. Avda. de la Llana 123 08191 Rubi Spain	Nipoxyme soluble 100	Colistin sulphate	3 000 000 IU/g (100 mg)	Water soluble powder	Calves, pigs, poultry (chicken and laying hens)
Slovakia	Ceva Animal Health Slovakia, spol. s r.o. Račianska 77, 831 02 Bratislava, Slovak Republic	COLIVET perorálny roztok	Colistin (as colistin sulphate)	2 000 000 IU/ml	Oral solution	Pigs, domestic fowl
Slovakia	Ceva Animal Health Slovakia, spol. s r.o. Račianska 77, 831 02 Bratislava, Slovak Republic	COLIVET vodorozpustný prášok	Colistin (as colistin sulphate)	1 200 000 IU/g	Powder for oral solution	Calves, piglets and weaners, domestic fowl - broilers
Slovakia	Divasa - Farmavic S.A. Ctra. Sant Hipolit, km 71, 08503 GURB VIC, Barcelona, Spain	COLIPLUS 2 000 000 IU/ml koncentrát na perorálny roztok na použitie v pitnej vode pre hovädzí dobytok, ovce, ošípané a kurčatá	Colistin (as sulphate)	2 000 000 IU/ml (equivalent to 83.33 mg)	Oral solution (Concentrate for oral solution for use in drinking water)	Cattle (calves), sheep (lambs), pigs and chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Slovakia	Pharmagal s.r.o. Murgašova 5, 949 01 Nitra, Slovak Republic	KOLIFARM 1,2 mil. IU/g prášok na perorálny roztok	Colistin sulphate	1 200 000 IU/g	Powder for oral solution	Pigs, calves, poultry (domestic fowl, turkeys)
Slovakia	Pharmagal s.r.o. Murgašova 5, 949 01 Nitra, Slovak Republic	KOLIFARM 1,2 mil IU/g premix na medikáciu krmiva	Colistin sulphate	1 200 000 IU/g	Premix for medicated feeding stuff	Pigs, domestic fowl, turkeys
Slovakia	Tekro spol. s.r.o. Višňová 2/484, 140 00 Prague, Czech Republic	MEDITEK COLIS plv.sol. ad us.vet.	Colistin sulphate	1 200 000 IU/g	Oral powder	Pigs, broilers
Slovenia	Krka, d. d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia	Giraxa 50 mg/g prašek za peroralno raztopino za teleta, pujske in piščance	Colistin	50 mg/g	Powder for oral solution	Calves, piglets, chicken
Slovenia	aniMedica España, S.L.U. Esmeralda, 19 E-08950 Esplugues de Llobregat (Barcelona) Spain	Colfive koncentrat za peroralno raztopino	Colistin (as sulphate)	5 000 000 IU/ml	Concentrate for oral solution	Cattle (calves), pigs, sheep (lambs) and poultry
Spain	ANDERSEN, S.A. Avda. de la Llana 123 P. I. La Llana 08191 Rubi Spain	NIPOXYME 40	Colistin sulphate	40 mg/g	Premix for medicated feedingstuff	Pigs, rabbits

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	ANDERSEN, S.A. Avda. de la Llana 123 P. I. La Llana 08191 Rubi Spain	NIPOXYME 100	Colistin sulphate	100 g/kg	Premix for medicated feedingstuff	Pigs, rabbits
Spain	ANDERSEN, S.A. Avda. de la Llana 123 P. I. La Llana 08191 Rubi Spain	NIPOXYME SOLUBLE 100	Colistin sulphate	3 000 000 IU/g	Oral powder for administration in drinking water	Calves, pigs, poultry
Spain	ANDERSEN, S.A. Avda. de la Llana 123 P. I. La Llana 08191 Rubi Spain	NIPOXYME POLVO ORAL 1000 MG/G	Colistin sulphate	1000 mg/g	Oral powder for administration in drinking water	Pigs
Spain	ANDERSEN, S.A. Avda. de la Llana 123 P. I. La Llana 08191 Rubi Spain	NIPOXYME ORAL SUSPENSION 200 mg/g	Colistin sulphate	200 mg/g	Oral suspension for administration in drinking water	Pigs
Spain	ANDRES PINTALUBA, S.A. Pol.Industrial Agro-Reus C/ Prudenci Bertrana 5 43206 Reus Spain	COLIPREMIX 40	Colistin sulphate	40 mg/g (1.2*10 ⁶ IU/g)	Premix for medicated feedingstuff	Pigs, poultry
Spain	ANDRES PINTALUBA, S.A. Pol.Industrial Agro-Reus C/ Prudenci Bertrana 5 43206 Reus Spain	APSAMIX COLISTINA 40 MG/G	Colistin sulphate	40 mg/g (1.2*10 ⁶ IU/g)	Premix for medicated feedingstuff	Pigs

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	ANDRES PINTALUBA, S.A. Pol.Industrial Agro-Reus C/ Prudenci Bertrana 5 43206 Reus Spain	COLIMIX 40 mg/g	Colistin sulphate	40 mg/g (equivalent to 1 200 000 IU)	Premix for medicated feedingstuff	Pigs, rabbits
Spain	ANDRES PINTALUBA, S.A. Pol.Industrial Agro-Reus C/ Prudenci Bertrana 5 43206 Reus Spain	APASOLCOLISTINA 100 mg/g	Colistin sulphate	100 mg/g (equivalent to 3 000 000 IU)	Oral powder for administration in drinking water	Pigs
Spain	ANDRES PINTALUBA, S.A. Pol.Industrial Agro-Reus C/ Prudenci Bertrana 5 43206 Reus Spain	APASOL COLISTINA 1000 mg/g	Colistin sulphate	1000 mg/g	Oral powder for administration in drinking water	Pigs
Spain	ANDRES PINTALUBA, S.A. Pol.Industrial Agro-Reus C/ Prudenci Bertrana 5 43206 Reus Spain	COLIMIX 100 mg/g	Colistin sulphate	100 mg/g (equivalent to 3 000 000 IU)	Premix for medicated feedingstuff	Pigs, rabbits
Spain	CEVA SALUD ANIMAL, S.A. Carabela La Niña nº 12 5 ^a planta 08017 Barcelona, Spain	COLIVET 2,000,000 UI/ML	Colistin sulphate	2 000 000 UI/ml	Concentrate for oral solution	Pigs, poultry
Spain	CEVA SALUD ANIMAL, S.A. Carabela La Niña nº 12 5 ^a planta 08017 Barcelona Spain	COLIVET 5,000,000 UI/G POLVO PARA ADMINISTRACIÓN EN AGUA DE BEBIDA PARA CERDOS, AVES Y TERNEROS	Colistin sulphate	5 000 000 IU/g	Oral powder for administration in drinking water	Calves, pigs, broilers and layer hens

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	Divasa-Farmavic, S.A. Ctra. Sant Hipolit, km. 71 08503 Gurb – Vic Spain	COLIPLUS SOLUCION	Colistin sulphate	2 000 000 IU/ml	Oral solution for administration in drinking water	Pigs, broilers
Spain	Divasa-Farmavic, S.A. Ctra. Sant Hipolit, km. 71 08503 Gurb – Vic Spain	COLISTINA DIVASA 2,000,000 UI/ml	Colistin sulphate	2 M IU/ml (equivalent to 83.33 mg)	Oral solution (directly into animal mouth, drinking water)	Calves, lambs, pigs, poultry
Spain	INDUSTRIAL VETERINARIA S.A. Esmeralda, 19 - 4º 08950 Esplugues De Llobregat Spain	ACOLAN	Colistin sulphate	39 mg/g	Oral powder for administration in drinking water	Pigs
Spain	JAER, S.A. C/ Barcelona 411 Sant Vicents dels Horts 08620 Barcelona Spain	COTRISUL COLISTINA	Colistin sulphate	2 M IU/ml	Oral solution for administration in drinking water	Calves, lambs, pigs, poultry (except broilers)
Spain	LABORATORIO MAYMO, S.A. Via Augusta, 302 08017 Barcelona Spain	COLIMAY	Colistin sulphate	400 000 IU/g (19.13 mg/g)	Oral powder for administration in drinking water or feed	Calves, pigs
Spain	LABORATORIO MAYMO, S.A. Via Augusta, 302 08017 Barcelona Spain	COLISOL	Colistin sulphate	2 000 000 IU/g (95.65 mg/g)	Oral powder for administration in drinking water or feed	Calves, pigs, poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	LABORATORIOS CALIER, S.A. Barcelonés, 26 08520 Les Franqueses del Valles Spain	GANAMIX COLISTINA 4 % PREMEZCLA	Colistin sulphate	40 g/kg (119 480 000 IU/kg)	Premix for medicated feedingstuff	Pigs, poultry, rabbits
Spain	LABORATORIOS CALIER, S.A. Barcelonés, 26 08520 Les Franqueses del Valles Spain	AQUACOLI 2M UI SOLUTION FOR USE IN DRINKING WATER	Colistin sulphate	2 M IU/ml	Oral solution for administration in drinking water	Calves, lambs, pigs, poultry
Spain	LAMONS, S.A. P.I. MECANOVA Naves 27-28 25190 Lerida Spain	COLIONE LAMONS	Colistin sulphate	100 mg/ml	Oral solution for administration in drinking water	Pigs
Spain	NUTRAL, S.A. Cobalto, 261/263 28770 Colmenar Viejo Spain	COLITRAX 4 %	Colistin sulphate	40 mg/g (1.2*10 ⁶ IU/g)	Premix for medicated feedingstuff	Pigs
Spain	POLICHEM SLU Pol. Industrial Agro-Reus C/ Prudenci Bertrana 5 43206 Reus Spain	COLISTINA POLICHEM 100 mg/g	Colistin sulphate	100 mg/g (equivalent to 3 000 000 IU)	Oral powder for administration in drinking water	Pigs
Spain	S.P. VETERINARIA, S.A. Ctra. Reus-Vinyols, Km.4,1 43330 Riudoms Spain	COLIMCINA	Colistin sulphate	205 M IU/100 g	Oral powder for administration in drinking water or feed	Calves, pigs, poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	SUPER S DIANA, S.L Ctra. Barcelona - Ripoll, Km 17 08150 Parets del Valles Spain	COLISTOP POLVO	Colistin sulphate	50 M IU/100 g	Oral powder for administration in drinking water	Calves, pigs
Spain	ANDRES PINTALUBA, S.A. Pol. Industrial Agro-Reus Prudenci Bertrana 5 43206 Reus Spain	APSASOL COLISTINA 3.000.000 UI/ml	Colistin sulphate	100 mg/ml (equivalent to 3 000 000 IU/ml)	Oral solution for administration in drinking water	Pigs
Spain	aniMedica España, S.L.U.Esmeralda, 19 Esplugues de Llobregat (Barcelona) E-08950 Spain	Colfive, 5,000,000 IU/ml concentrate for oral solution	Colistin sulphate	5 000 000 IU/ml	Concentrate for oral solution	Cattle (calves), pigs, sheep (lambs) and poultry
Spain	BELA-PHARM GmbH and Co. Kg Lohner Strasse 19, D-49377 Vechta Germany	BELACOL 24 % Liquid	Colistin sulphate	240 mg/ml	Oral solution for administration in drinking water or milk	Calves, pigs, poultry
Spain	LABORATORIOS CALIER, S.A. Barcelonés, 26 Spain	GANAMIX COLISTINA 15.000.000 UI/ml PREMEZCLA MEDICAMENTOSA	Colistin sulphate	15 M IU/ml	Premix for medicated feedingstuff	Pigs
Spain	MEVET S.A.U. Pol. Industrial El Segre P. 410 25191 Lérida Spain	COLIVALL 2.000.000 UI/ml SOLUCIÓN ORAL	Colistin sulphate	2 M IU/ml	Oral solution for administration in drinking water	Calves, lambs, pigs, poultry

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
Spain	SOGEVAL 200 Avenue de Mayenne zone industrielle des touches 53000 - Laval France	Sogecoli 2 000 000 IU/ml concentrate for oral solution for calves, lambs, pigs and poultry	Colistin sulphate	2 M IU/ml	Oral solution	Cattle (calves), sheep (lambs), pigs, poultry (chickens, geese, turkeys, ducks, pheasants, partridges, quails and guinea fowl)
Sweden	Bio Vet Aps, Kongevejen 66 3480 Fredensborg, Denmark	Colicol vet.	Colistin	1 g/g	Granules for oral solution	Pigs
Sweden	Bio Vet Aps, Kongevejen 66 3480 Fredensborg, Denmark	Colicol vet.	Colistin	240 mg/ml	Solution used in drinking water	Pigs
United Kingdom	Ceva Animal Health Ltd Unit 3, Anglo Office Park White Lion Road, Amersham Buckinghamshire, HP7 9FB United Kingdom	Colibird Poultry, 2 MIU/ml Solution for Use in Drinking Water	Colistin	2 M IU/ml	Oral solution	Poultry
United Kingdom	Ceva Animal Health Ltd Unit 3, Anglo Office Park White Lion Road, Amersham Buckinghamshire, HP7 9FB United Kingdom	Coliscour Oral Solution of Colistin Sulphate 2 MIU/ml	Colistin	2 M IU/ml	Oral solution	Pigs: in particular suckling and post weaning
United Kingdom	Divasa - Farmavic S.A Ctra, Sant Hipolit Km71 PO Box 79 08503 Gurb-Vic Barcelona, Spain	Coliplus 2,000,000 IU/ml Concentrate for Oral Solution for Use in Drinking Water for Cattle, Sheep, Swine and Chickens	Colistin	2 M IU/ml	Concentrate for oral solution	Cattle (calves), sheep (lambs), pigs, chicken

Member State EU/EEA	Applicant/Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Animal species
United Kingdom	aniMedica Espana, S.L.U, Esmeralda, 19, Esplugues de Llobregat, Barcelona, E-08950, Spain	Colfive 5,000,000 IU/ml concentrate for oral solution	Colistin sulphate	5 000 000 IU/ml	Concentrate for oral solution	Cattle (calves), pigs, sheep (lambs) and poultry
United Kingdom	Sogeval 200 Avenue de Mayenne Zone Industrielle des Touches 53000 Laval, France	Colistin 2 MIU/ml Oral Solution for Calves, Lambs, Pigs and Poultry	Colistin	2 M IU/ml	Oral solution	Calves, lambs, pigs, poultry

Annex II

Scientific conclusions and grounds for amendment of the summaries of product characteristics, labelling and package leaflets

Overall summary of the scientific evaluation of veterinary medicinal products containing colistin to be administered orally (see Annex I)

1. Introduction

Colistin sulfate is a polypeptide antibiotic belonging to the polymyxin group of antibiotics. This group of antibiotics has a polypeptide structure, with mainly bactericidal activity and a medium antibacterial spectrum, which covers Gram-negative microorganisms only.

Veterinary medicinal products containing colistin as a sole active substance for oral administration in food producing animals are widely used in almost all EU Member States. Oral colistin formulations including powder, solution, premix, tablets and paste have been authorised, mainly for group and flock treatment for the treatment and prevention of different specified gastrointestinal diseases caused by sensitive Enterobacteriaceae species (e.g. *Salmonella* and *Escherichia coli*), but marketing authorisations without more specific indications do also exist. The most common target species is pigs followed by chicken and cattle next to other poultry species (e.g. turkeys), horses, rabbits, sheep and goats.

Following a request from the European Commission (EC), in July 2013 the CVMP and CHMP adopted scientific advice and detailed considerations on colistin¹. This advice critically reviews recent information on the use of colistin in food-producing animals in the EU, its effect on the development of resistance to this category of antimicrobial agents in bacterial species that are of importance for human and animal health, and the possible impact on human and animal health.

The advice states:

“Colistin is of therapeutic importance in veterinary medicine for the treatment of enteric diseases in certain food-producing species for which there are few effective alternatives available for certain indications. Currently, there is no evidence of spread of colistin resistance from food-producing animals to human patients, or vice versa.”

“Transfer of resistance either on mobile genetic elements (such as plasmids) between bacteria or from animals to humans has not been reported.”

*“However, severe nosocomial infections due to multidrug-resistant (MDR) Gram-negative bacteria now account for high morbidity and mortality in man. Colistin is therefore nowadays a last resort drug in human medicine in the context of treatment of infections caused by MDR *Pseudomonas aeruginosa*, *Acinetobacter baumannii* and *Enterobacteriaceae* (*Escherichia coli*, *Klebsiella pneumoniae*), for which mortality can be extremely high.”*

And concludes that: *“Based on current evidence it is considered appropriate to maintain the use of colistin in veterinary medicine but to restrict indications to therapy or metaphylaxis and to remove all indications for prophylactic use in order to minimise any potential risk associated with a broader use.”* and that *“The SPCs of veterinary products containing colistin should be revised to take fully into account responsible use considerations.”*

¹ Request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals, answer to the first request from the European Commission (EMA/363834/2013)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/07/WC500146812.pdf

Use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health (EMA/755938/2012)
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/07/WC500146813.pdf

Data from the last report of the EMA European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)² shows that polymyxins (colistin) are used mostly in oral forms.

The advice also indicates for combinations of colistin with other antimicrobials that *“The marketing authorisations for these products should be reviewed and unless sound justification can be provided that the combination is in line with responsible use principles, combination products should be withdrawn.”*

Therefore, on 12 May 2014, the European Commission presented to the European Medicines Agency ('the Agency') a referral notification under Article 35 of Directive 2001/82/EC for all veterinary medicinal products containing colistin as a sole active substance to be administered orally. The Committee for Medicinal Products for Veterinary Use (CVMP) was requested to give its opinion on the measures that need to be taken in order to ensure the prudent use of colistin in food-producing animals across the EU and to minimise potential risks with the use of the identified products; *inter alia* whether there is a need to include adequate indications and warnings on prudent use in the product information and/or restrict indications for the identified products taking into account the CVMP revised guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005)³.

The combinations of colistin with another antimicrobial substance and the non-oral administration of products containing colistin may be addressed as a next step following the completion of this referral procedure. It should be noted that three of the products in Annex I contain colistin in combination with vitamins. While in these cases colistin is not the only active substance, it is the sole antimicrobial in the product and therefore these products are included in the scope of this referral.

2. Discussion of the data available

Indications

About 54% of the products concerned by this procedure contain general indications, whilst the remaining 46% contain specific indications, mainly gastrointestinal infections caused by colistin sensitive Enterobacteriaceae (e.g. *E. coli* and *Salmonella*). In the previous CVMP assessment (EMA/CVMP, 2010)⁴ the Committee concluded that the benefit-risk balance regarding the use of colistin for treatment of gastrointestinal infections caused by *Salmonella* spp. was considered negative while it remained positive for the use of colistin for treatment of enteric infections caused by non-invasive *E. coli* susceptible to colistin.

The deletion of *Salmonella* spp. was recommended since none, very limited or non-conclusive clinical data was presented to support this indication. In addition, due to the poor absorption in the gut, colistin would only be effective against non-invasive *Salmonella* which questions the appropriateness of using this substance for treating *Salmonella* infections. Next to that, treatment of subclinical *Salmonella* infections with the objective to reduce the number of bacteria might interfere with control programmes (e.g. Regulation 1177/2006; EFSA, 2010⁵) for this disease.

According to the CVMP revised guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005)³ indications should be for the treatment of named pathogens and

² ESVAC, 2014. 'Sales of veterinary antimicrobial agents in 26 EU/EEA countries in 2012. (EMA/333921/2014) http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500175671.pdf

³ CVMP revised guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005) http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/02/WC500070670.pdf

⁴ EMA/CVMP. 2010. Opinion following an Article 35 referral for veterinary medicinal formulations containing colistin at 2 000 000 IU per ml and intended for administration in drinking water to food producing species. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Colistin/vet_referral_000038.jsp&mid=WCOB01ac05805c5170

⁵ EFSA. 2010. EFSA Panel on Biological Hazards; Scientific Opinion on a Quantitative Microbiological Risk Assessment of Salmonella in slaughter and breeder pigs In EFSA Journal. <http://www.efsa.europa.eu/en/efsajournal/doc/1547.pdf>

general indications should be avoided. Therefore, any general indication referring to infectious or non-infectious diseases should be deleted. In addition, orally administered colistin would not be appropriate for systemic therapy due to poor absorption from the gastrointestinal tract. Thus, any pathogens other than non-invasive *E. coli* that are typically not associated with non-invasive gastrointestinal infections, and/or associated with general infections should be taken out of the SPC.

Most of the colistin formulations concerned (approximately 90%) are for administration in feed or water for group or flock treatment and, consequently, most of the indications are for “treatment and prevention”, meaning a situation where clinically diseased animals and in-contact animals presumably in the incubation phase but not yet showing clinical signs are treated at the same time. In order to address these treatment conditions more accurately and to exclude routine preventive use in healthy animals where the bacterial disease has not been established in the group or flock at the time of treatment, the indication for group or flock treatment should be changed to “treatment and metaphylaxis”⁶. In addition, advice should be included in the SPC that the presence of the disease should be established in the group or herd before metaphylactic treatment. This is in line with the previous assessment of the CVMP and the scientific advice to the European Commission.

The use of colistin for prophylaxis does not comply with responsible use principles. Therefore, any indication for prophylaxis or production enhancement (e.g. increase of feed efficiency or growth promotion) should be taken out of the SPC, and advice should be included in the SPC that colistin should not be used for prophylaxis.

Some of the products included in the scope of this referral procedure are indicated for use in horses and, although not stated explicitly in the product literature, it is assumed that these products are used predominantly in foals. The indication salmonellosis is no longer maintained and gastrointestinal infection caused by *E. coli* (colibacillosis) is not a recognised clinical disease in foals or adult horses. The current scientific literature does not support the use of colistin in foals as its use could disrupt the gastrointestinal microflora balance, leading to a well-recognised fatal antimicrobial associated colitis, typically associated with *Clostridium difficile*. Thus, the use of colistin in horses is considered to present a serious risk in relation to target animal safety and is no longer supported. The target species “horse” and any indication for horses should be taken out of the SPC and information should be added in the SPC that the use of colistin in horses, particularly in foals, is contraindicated due to the shift in gastrointestinal microflora balance and the development of antimicrobial associated colitis, typically associated with *Clostridium difficile*, which may be fatal.

Duration of treatment

In many cases the dose is recommended as 100 000 IU/kg for mammals (non-poultry species), (range approximately 18 000 IU/kg to 250 000 IU/kg body weight), and of 75 000 IU/kg for poultry species (range approximately 19 200 IU/kg to 270 000 IU/kg body weight). The recommended treatment period is similar for poultry and non-poultry species, 3-5 days or 5-7 days for most products, but for some products the treatment period is up to 10-15 days.

There is no current scientifically well founded justification for the different treatment periods available. In line with responsible use principles the duration of treatment should be limited to the time needed for cure of the disease to avoid any unnecessary exposure.

The CVMP agreed that the treatment period should not exceed 7 days based on the following grounds: The most commonly recommended treatment duration for the products concerned is 3 to 7 days for both mammals and poultry species, indicating that this has been concluded in many cases to be a

⁶ As defined in Question and answer on the CVMP guideline on the SPC for antimicrobial products (EMA/CVMP/414812/2011-Rev.1).
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/07/WC500109155.pdf

sufficient treatment period. For enteric diseases caused by non-invasive *E. coli* the treatment effect can easily be monitored and, hence, the treatment duration can be adjusted according to the clinical course of the disease. From a pharmacological point of view, colistin exerts concentration-dependent activity and high concentrations of colistin are achieved in the gut following oral administration due to the poor absorption of the substance. Hence a maximum treatment period of 7 days would ensure sufficient efficacy in the treatment and metaphylaxis of enteric diseases associated with non-invasive *E. coli* and would also satisfy the requirement to avoid unnecessary exposure and thus reduce the risk of resistance development. In conclusion the CVMP recommended to add advice in the SPC that the duration of treatment should be limited to the minimum time necessary for the treatment of the disease, and that treatment duration should not exceed 7 days. In order to strengthen the importance of an adequate treatment period, the Committee considered it useful for the veterinarian to add relevant information on the pharmacological properties of colistin in the SPC ("Colistin exerts concentration-dependent activity against Gram-negative bacteria. Following oral administration high concentrations are achieved in the gastrointestinal tract, i.e. the target site, due to the poor absorption of the substance. These factors indicate that a longer duration of treatment than the one indicated, leading to unnecessary exposure is not recommended".)

Responsible use principles

In addition to the measures described above the CVMP recommended to include the following special precautions for use in animals in order to ensure responsible use of colistin in animals:

"Do not use colistin as a substitute for good management practices.

Colistin is a last resort drug in human medicine for treatment of infections caused by certain multidrug-resistant bacteria. In order to minimise any potential risk associated with widespread use of colistin, its use should be limited to treatment or treatment and metaphylaxis of diseases, and should not be used for prophylaxis.

Whenever possible, colistin should only be used based on susceptibility testing.

Use of the product deviating from the instructions given in the SPC may lead to treatment failures and increase the prevalence of bacteria resistant to colistin."

3. Benefit-risk assessment

Benefit assessment

The oral colistin products within the scope of this referral are effective medicines for the treatment and metaphylaxis of enteric diseases caused by non-invasive *E. coli* susceptible to colistin in certain food-producing animal species for which there are few effective alternatives available due to increasing resistance development.

Risk assessment

Colistin is a last resort antimicrobial for the treatment of infections due to highly resistant bacteria in humans, for which mortality can be very high. There is no evidence at present that the use of colistin in food-producing species resulted in widespread colistin resistance and its transfer to humans. Nevertheless, it is recognised that repeated or frequent use of an antimicrobial of the same class increases the risk of resistance development and transmission of such resistances to humans cannot be excluded. Therefore, it is prudent to minimise the possibility of resistance to colistin developing as a result of its use in animals and thereby also reduce the possibility that any resistance that does develop will be transferred to humans.

Quality, target animal safety, user safety, environmental risk and residues were not assessed in this referral procedure.

Risk management or mitigation measures

To limit the use of colistin to the treatment and metaphylaxis of enteric diseases and not to allow its use for prophylaxis would decrease the overall use of colistin products and, thus, reduce the selection pressure for resistance and would be in line with prudent use principles for antimicrobials. Any unnecessary exposure should be avoided. To limit the duration of treatment in food-producing animals to a maximum of 7 days would reduce the selection pressure for resistance without hampering the effective use of the products against justifiable indications. In addition, further information in line with prudent use principles for antimicrobials should be added in the product literature.

Evaluation of the benefit-risk balance

Oral colistin products are regarded as effective medicines against enteric infectious diseases caused by non-invasive *E. coli* susceptible to colistin in certain food-producing species. Colistin is also a last resort antimicrobial for the treatment of infections due to highly resistant bacteria in humans, therefore its overall use in veterinary medicine needs to be decreased, to reduce the risk of resistance development and transmission to humans. Colistin should not be used for the control of salmonellosis since it is not in line with control programmes for this disease and may present a risk to public and animal health. The prophylactic use of colistin and any extended use that is not in line with good veterinary practice present a risk from resistance perspective and is not justifiable from a scientific point of view.

Conclusion on the benefit-risk balance

Provided the prophylactic use of oral colistin products in food-producing species is excluded from the indications, the salmonellosis claim is deleted, and the maximum treatment period is restricted to 7 days, the benefit-risk balance of these products could continue to be regarded as positive.

Grounds for amendment of the summaries of product characteristics, labelling and package leaflets

Whereas:

- on the basis of the available data, the CVMP considered that the indication as provided in Annex III was justified;
- on the basis of the available data, the CVMP considered that the duration of treatment should be amended as described in Annex III;
- on the basis of the available data, the CVMP considered that all other indications and durations of treatment should be deleted from the product information;
- on the basis of the available data, the CVMP considered warning sentences in line with responsible use principles as provided in Annex III should be included in the product information;
- the CVMP considered that the overall benefit-risk balance is positive for the veterinary medicinal products (see Annex I), subject to amendments in the product information;

the CVMP recommended variations of the marketing authorisations for veterinary medicinal products containing colistin to be administered orally, in order to amend the summaries of product characteristics, labelling and package leaflets as set out in Annex III.

Annex III

Amendments in the relevant sections of the summary of product characteristics, labelling and package leaflet

Summary of product characteristics

4.1 Target species

Delete, where applicable, "horses".

4.2 Indications for use, specifying the target species

Delete, where applicable, any indication for prophylactic use or production enhancement.

For products to be administered in feed or water (for group/herd treatment), it should be stated "treatment and metaphylaxis", and the following advice should be added:

The presence of the disease in the herd should be established before metaphylactic treatment.

...

The indication is restricted to enteric infections caused by non-invasive *E. coli* susceptible to colistin.

Delete, where applicable, any general indication or indication for any other pathogen.

Delete, where applicable, any indication for horses.

4.3 Contraindications

Add, to all products:

Do not use in horses, particularly in foals, since colistin, due to a shift in the gastrointestinal microflora balance could lead to the development of antimicrobial associated colitis (Colitis X), typically associated with *Clostridium difficile*, which may be fatal.

...

4.4 Special warnings for each target species

Add, to all products:

Colistin exerts concentration-dependent activity against Gram-negative bacteria. Following oral administration high concentrations are achieved in the gastrointestinal tract, i.e. the target site, due to the poor absorption of the substance. These factors indicate that a longer duration of treatment than the one indicated in section 4.9, leading to unnecessary exposure, is not recommended.

...

4.5 Special precautions for use

Special precautions for use in animals

Add, to all products:

Do not use colistin as a substitute for good management practices.

Colistin is a last resort drug in human medicine for treatment of infections caused by certain multi-drug resistant bacteria. In order to minimise any potential risk associated with widespread use of colistin, its use should be limited to treatment or treatment and metaphylaxis of diseases, and should not be used for prophylaxis.

Whenever possible, colistin should only be used based on susceptibility testing.

Use of the product deviating from the instructions given in the SPC may lead to treatment failures and increase the prevalence of bacteria resistant to colistin.

...

4.9 Amounts to be administered and administration route

Delete, where applicable, any specific dosing recommendation related to pathogens other than *E. coli*.

Delete, where applicable, any specific dosing recommendation related to target species horses.

Add, to all products, the following advice:

Duration of treatment should be limited to the minimum time necessary for the treatment of the disease.

...

Replace, where applicable, treatment recommendations which are extended beyond 7 days, or where no treatment duration recommendation is given, with the following statement:

Treatment duration should not exceed 7 days.

...

Specific treatment recommendations shorter than 7 days should be maintained.

4.11 Withdrawal period(s)

Delete, where applicable, any references to horses.

Add, to all products and amend where applicable:

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Intestinal antiinfectives, antibiotics

ATCvet code: QA07AA10

5.1 Pharmacodynamic properties

Colistin exerts concentration-dependent activity against Gram-negative bacteria. Following oral administration high concentrations are achieved in the gastrointestinal tract, i.e. the target site, due to the poor absorption of the substance.

...

Labelling:

5. TARGET SPECIES

Delete, where applicable, "horses".

8. WITHDRAWAL PERIOD

Delete, where applicable, any references to horses.

Package leaflet:

4. INDICATIONS

Delete, where applicable, any indication for prophylactic use or production enhancement.

For products to be administered in feed or water (for group/herd treatment), it should be stated "treatment and metaphylaxis", and the following advice should be added:

The presence of the disease in the herd should be established before metaphylactic treatment.

...

The indication is restricted to enteric infections caused by non-invasive *E. coli* susceptible to colistin.

Delete, where applicable, any general indication or indication for any other pathogen.

Delete, where applicable, any indication for horses.

5. CONTRAINDICATIONS

Add, to all products:

Do not use in horses, particularly in foals, since colistin, due to a shift in the gastrointestinal microflora balance could lead to the development of antimicrobial associated colitis (Colitis X), typically associated with *Clostridium difficile*, which may be fatal.

...

7. TARGET SPECIES

Delete, where applicable, "horses".

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Delete, where applicable, any specific dosing recommendation related to pathogens other than *E. coli*.

Delete, where applicable, any specific dosing recommendation related to target species horses.

Replace, where applicable, treatment recommendations which are extended beyond 7 days, or where no treatment duration recommendation is given, with the following statement:

Duration of treatment should be limited to the minimum time necessary for the treatment of the disease. Treatment duration should not exceed 7 days.

...

Specific treatment recommendations shorter than 7 days should be maintained.

10. WITHDRAWAL PERIOD

Delete, where applicable, any references to horses.

12. SPECIAL WARNINGS

Add, to all products:

Special precautions for use in animals:

Do not use colistin as a substitute for good management practices.

Colistin is a last resort drug in human medicine for treatment of infections caused by certain multi-drug resistant bacteria. In order to minimise any potential risk associated with widespread use of colistin, its

use should be limited to treatment or treatment and metaphylaxis of diseases, and should not be used for prophylaxis.

Whenever possible, colistin should only be used based on susceptibility testing.

Use of the product deviating from the instructions given in the SPC may lead to treatment failures and increase the prevalence of bacteria resistant to colistin.

...