

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 July 2016 to 31 July 2016**

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

(2016/C 312/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
8.8.2016	Saizen (and associated names) and Humatrope (and associated names)	somatropin	Not applicable	Not applicable	9.8.2016

— Revocation of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
14.7.2016	Colistin combinations	colistin	See Annex I	See Annex I	15.7.2016

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

ANNEX

List of the names, pharmaceutical forms, strengths of the veterinary medicinal products, animal species, route of administration, and marketing authorisation holders in the Member States

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Farma vet Ltd 40 Otec Paisii str. Shumen Bulgaria	Колитеравил/COLI — TET-RAVIT	Oxytetracycline hydrochloride Colistin sulphate	5,0 g 3 500 000 UI	Oral solution	Chickens and pigs	Oral administration
Bulgaria	COOPHAVET S.A.S. B.P. 7 Saint Herblon 44153 ANCENIS Cedex France	Колисултрикс/COLISULTRIX	Trimethoprim Colistin sulphate	3,75 g 50 MIU	Oral powder	Chickens, rabbits, pigs, calves and lambs	Oral administration
Croatia	Armika Veterina d.o.o. Vodovodna 20a 10000 Zagreb Croatia	COLISULTRIX	Trimethoprim Colistin sulphate	3,75 g 50 MIU	Oral powder	Calves, lambs, kids, piglets, poultry and rabbits	Oral
Croatia	Ceva Santé Animale 10 Avenue de la Ballastière 33500 Libourne France	QUINOCOL	Enrofloxacin Colistin sulphate	100 g 41,67 g	Oral solution	Chicken, turkey	Oral
Cyprus	FATRO S.p.A. Via Emilia, 285 40064 Ozzano Emilia (Bologna) Italy	BACOLAM powder for oral solution for calves, sheep, goats, pigs, foals, chickens, turkeys (excluding layers)	Amoxicillin trihydrate Colistin sulphate	100 mg 500 000 I.U.	Powder for oral solution	Calves, sheep, goats, pigs, foals, chickens, turkeys (excluding layers)	Administer the dose subdivided into two administrations each day, dissolved in drinking water or in milk.

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Cyprus	Vetequinol Italia S.R.L. Via Piana, 265 47032 Bertinoro Italy	ZEMAMIX premix for medicated feedingstuff for pigs	Amoxicillin trihydrate Colistin sulphate	11,48 g 4,00 g	Premix for medicated feedingstuff	Pigs	Premix for medicated feedingstuff in insoluble powder, to be administered orally properly mixed in solid feed.
Czech Republic	LAVET Pharmaceuticals Ltd Otró u.14 1161 Budapest Hungary	AMOXYCOL plv.sol.	Amoxicillin trihydrate Colistin sulphate	640 mg/g 3 200 000 IU/g	Powder for oral solution for use in drinking water or in feed	Pigs, chicken (broilers)	Oral
Czech Republic	COOPHAVET S.A.S. B.P. 7 Saint Herblon 44153 ANCENIS Cedex France	BELCOSPIRA ORAL prášek pro přípravu perorálního roztoku	Colistin sulphate Spiramycin adipate	500 000 IU 650 000 IU	Powder for oral solution	Calves, piglets, foals, chicken	Oral
Czech Republic	COOPHAVET S.A.S. B.P. 7 Saint Herblon 44153 ANCENIS Cedex France	COLISULTRIX plv. sol.	Trimethoprim Colistin sulphate	37,5 mg 500 000 IU/g	Powder for oral solution	Chicken	Oral
Czech Republic	Industria Italiana Integratori Trei S.p.A. Via Corassori, 62 41100 Modena Italy	MICROAMOX COLI premix pro medikaci krmiva	Amoxicillin trihydrate Colistin sulphate	100 mg/g 600 000 IU/g	Premix for medicated feed	Pigs	Oral

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	MERIAL 29 avenue Tony Garnier 69007 LYON France	BELCOSPIRA ORAL	Colistin sulphate Spiramycin adipate	500 000 IU/g 650 000 IU/g	Powder for oral use	Cattle, pigs, poultry	Oral use
France	LABORATOIRES BIOVE 3 Rue de Lorraine 62510 Arques France	COLAMPI B	Ampicillin trihydrate Colistin sulphate	25 mg/g 0,075 MIU/g	Powder for oral use	Pigs, calves	Oral use
France	LABORATOIRES BIOVE 3 Rue de Lorraine 62510 Arques France	COLAMPI O	Ampicillin trihydrate Colistin sulphate	1 g/tablet 1 MIU/tablet	Tablet	Calves	Oral use
France	VETOQUINOL Magny Verinois 70200 Lure France	COLIDIARYL	Colistin sulphate Erythromycin estolate	83 400 IU/g 16 600 IU/g	Powder for oral use	Lamb, goat, piglets, foals, calves	Oral use
France	MERIAL 29 avenue Tony Garnier 69007 LYON France	COLISULTRIX POWDRE	Colistin sulphate Trimethoprim	500 000 IU/g 37,5 mg/g	Powder for oral use	Lamb, goat, rabbits, pigs, calves, poultry	Oral use
France	VIRBAC 1ere Avenue 2065m L.I.D. 06516 Carros Cedex France	ENTEROGEL 30	Colistin sulphate Scopolamine Sulfaguanidine	10,5 MIU/syringe 0,216 g/syringe 4,2 g/syringe	Oral paste	Foals, calves	Oral use

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France	VIRBAC 1ere Avenue 2065m L.I.D. 06516 Carros Cedex France	INTESTIVO	Colistin sulphate Sulfaguandine	2,5 MIU/tablet 1 g/tablet	Tablet	Lamb, goat, calve	Oral use
France	MERIAL 29 avenue Tony Garnier 69007 LYON France	N.P. 8	Colistin sulphate Neomycin sulfate	300 000 IU/g 60 000 IU/g	Powder for oral use	Lamb, goat, rabbits, pigs, calves, poultry	Oral use
France	QALLIAN 34 rue Jean Monnet ZI D'Etiché BP20341 49503 Segré Cedex France	OXYCOLI	Colistin sulphate Oxytetracycline hydrochloride	200 000 IU/g 0,07 g/g	Premix for medicated feed	Pigs, calves	Oral use
France	Ceva Santé Animale 10 Avenue de la Ballastière 33500 Libourne France	PHADILACT	Ampicillin trihydrate Colistin sulphate	5,00 mg/g 1 000 000 IU/g	Powder for oral use	Lamb, goat, calves, poultry	Oral use
France	QALLIAN 34 rue Jean Monnet ZI D'Etiché BP20341 49503 Segré Cedex France	PRÉMELANGE MÉDICAMENTS TEUX CS FRANVET	Colistin sulphate Sulfadiméthoxine	700 000 IU/g 210 mg/g	Premix	Lamb, calves	Oral use
France	VETOQUINOL Magny Vermois 70200 Lure France	SEPTOTRYL-COLISTINE	Colistin sulphate Sulfaméthoxyypyridazine	2 MIU/tablet 1 g/tablet	Tablet	Lamb, dogs, foals, calves	Oral use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	Lavet Gyógyszergyártó Kft. Ottó u. 14 1161 Budapest Hungary	Amoxycol por belsőleges oldathoz A.U.V.	Amoxicillin trihydrate Colistin sulphate	640,0 mg/g 133,3 mg/g	Powder for oral solution	Pigs, chickens	In drinking water use
Hungary	Industria Italiana Integratori Trei S.p.A. Viale Corassori, 62 41100 Modena Italy	BETAMICYN győgypremix sertések részére A.U.V.	Amoxicillin trihydrate Colistin sulphate	100 g/kg 600 MIU/kg	Premix for medicated feeding stuff	Pigs	In feed use
Hungary	Rhone Vet Kft. Petőfi u. 9. 2053 Herceghalom Hungary	Colisutrix belsőleges por	Trimethoprim Colistin sulphate	3,75 g/100 g 50 MIU/100 g	Powder for oral solution	Cattle (calves), sheep (lambs), pigs and chickens, rabbit, goat	In drinking water use
Italy	Fatro S.p.a. Via Emilia, 285 40064 Ozzano Emilia Italy	COMBOMIX	Amoxicillin trihydrate Colistin sulphate	115 mg/g 40 mg/g	Premix for medicated feeding stuff	Pigs, chickens (other than laying hens in lay)	Oral
Italy	Industria Italiana Integratori Trei S.P.A. Via Affarosa, 4 42010 — Rio Saliceto Italy	BETAMICYN	Amoxicillin trihydrate Colistin sulphate	100 g/kg 600 MIU/kg	Premix for medicated feeding stuff	Pigs	Oral
Italy	Doxal Italia S.p.a. largo Donegani 2 20121 — Milano Italy	CLOVER BMP	Amoxicillin trihydrate Colistin sulphate	115 g/kg 40 g/kg	Premix for medicated feeding stuff	Pigs	Oral

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Industria Italiana Integratori Trei S.p.A. Via Affarosa, 4 42010 — Rio Saliceto Italy	DUOBAN	Doxycycline hyclate Colistin sulphate	60 mg/g 1 200 000 IU/g	Premix for medicated feeding stuff	Pigs, rabbits	Oral
Italy	Virbac S.r.l. Via Caldera 21 20153 Milano Italy	DUALMIX	Amoxicillin trihydrate Colistin sulphate	115 mg/g 4 mg/g (20 000 UI/mg)	Premix for medicated feeding stuff	Pigs, chickens (except hens producing eggs for human consumption)	Oral
Italy	Fatro S.p.a. Via Emilia, 285 40064 Ozzano Emilia Italy	BACOLAM	Amoxicillin trihydrate Colistin sulphate	500 mg/g 2 500 000 IU/g	Powder for oral solution	Calves, sheep and goats, pigs, ponies, chickens, turkeys (excluding hens)	Oral
Italy	Intervet Productions S.r.l. Via Nettunense, km 20,300 04011 — Aprilia Italy	NADASIN	Amoxicillin trihydrate Colistin sulphate	500 mg/g 200 mg/g	Oral powder for use in drinking water or liquid feed	Calves, pigs, chickens (other than laying hens), turkeys	Oral
Italy	Vetorquinoi Italia S.r.l. Via Piana, 265 47032 Bertinoro Italy	NEOMIX COMPLEX	Neomycin sulfate Colistin sulphate	200 mg/g 20 000 IU/g	Oral powder, for use in drinking water or liquid feed	Calves, piglets, broilers and turkeys	Oral

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Italy	Vétoquinol Italia S.r.l. Via Piana 265 47032 Bertinoro Italy	ZEMAMIX	Amoxicillin trihydrate Colistin sulphate	100 mg/g 40 mg/g	Oral powder	Pigs	Oral use
Italy	Virbac S.r.l. Via Caldera 21 20153 Milano Italy	STABOX COLI	Amoxicillin trihydrate Colistin sulphate	100 mg/g 800 000 IU/g	Premix for medicated feeding	Pigs, chickens (except hens producing eggs for human consumption)	Oral
Latvia	Ceva Santé Animale 10 Avenue de la Ballastière 33500 Libourne France	Quinocol Oral Solution	Enrofloxacin Colistin sulphate	100 g 41,67 g	Solution for oral use	Chicken, turkeys	Oral use
Lithuania	Lavet Pharmaceuticals Ltd Ottó u. 14. H-1161 Budapest Hungary	AMOXCOL, geriamieji milteliai	Amoxicillin trihydrate Colistin sulphate	640 mg/ml 3 200 000 IU/ml	Water soluble oral solution	Pig, chicken	Oral
Lithuania	COOPHAVET S.A.S. B.P. 7 Saint Herblon 44153 ANCENIS Cedex France	COLISULTRIX, geriamieji milteliai	Trimethoprim Colistin sulphate	3,75 g/100 g 50 MIU/100 g	Oral powder	Calves, lamb, kid, piglets, poultry and rabbits	Oral
Lithuania	COOPHAVET S.A.S. B.P. 7 Saint Herblon 44153 ANCENIS Cedex France	BELCOSPIRA ORAL, geriamieji milteliai	Spiramycin adipate Colistin sulphate	65 MIU/100 g 50 MIU/100 g	Oral powder	Calves, lamb, kid, foals, piglets, poultry and rabbits.	Oral

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	VEETOQUINOL Magna Verinois 70200 Lure France	COLIDIARYL	Erythromycin estolate Colistin sulphate	83 400 IU/g 16 600 IU/g	Powder for oral use	Lamb, goat, piglets, foals, calves	Oral use
Luxembourg	VEETOQUINOL Magna Verinois 70200 Lure France	SEPTOTRYL-COLISTINE	Colistin sulphate Sulfamethoxyypyridazine	2 MIU/tablet 1 g/tablet	Tablet	Lamb, dogs, foals, calves	Oral use
Netherlands	Dopharma B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands	AMOXY-COL WSP	Amoxicillin trihydrate Colistin sulphate	150 mg/g 500 000 IU/g	Powder for oral use via drinking water	Pigs	Oral, via drinking water
Poland	Dopharma B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands	Amoxy-col WSP	Amoxicillin trihydrate Colistin sulphate	150 mg/g 500 000 IU/g	Powder for oral solution	Pigs	Oral use
Poland	Fatro S.p.A. Via Emilia 285-40064 Ozzano Emilia Italy	Bacolam	Amoxicillin trihydrate Colistin sulphate	100 mg/g 500 000 IU/g	Powder for administration in drinking water or milk	Cattle, chickens, pigs	Oral use
Poland	SkanVet Poland Sp. z o.o. Skierzeszwo, ul. Kiszowska 9 62-200 Gniezno Poland	Colamox 3200/640	Amoxicillin trihydrate Colistin sulphate	640 mg/g 3 200 000 IU/g	Powder for oral solution	Chicken, pigs	Oral use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Drwalewskie Zakłady Przemysłu Biotetycznego S.A ul. Grójecka 6 05-651 Drwalew Poland	Spiracol AD	Spiramycin adipate Colistin sulphate	100 000 IU/g 1 30 000 IU/g	Powder for use in drinking water	Cattle, chickens, pigs	Oral use
Portugal	DIVASA FARMACIA DE PORTUGAL Produtos e Equipamentos Veterinários, Lda. Praceta Jaime Cortesão, No 1 — R/C Loja Esq. 2625-170 Póvoa de Santa Iria Portugal	NUTRIVET TOTAL, pó para suspensão oral, para vitelos e cordeiros	Ampicillin trihydrate Colistin sulphate	0,7 g 1 500 000 IU	Powder for oral suspension for administration in drinking water	Calves and lambs	Oral
Portugal	VETLIMA-Sociedade Distribuidora de Produtos Agro-Pecuários, S.A. Centro Empresarial da Rainha, Lote 27 2050-501 Vila Nova da Rainha Portugal	COLIMIX (116 g/kg/40 g/kg), pré-mistura medicamentosa para alimento medicamentoso para suínos	Amoxicillin trihydrate Colistin sulphate	116 g/kg 40 g/kg	Premix for medicated feeding stuff	Pigs	Oral
Portugal	Fatro S.p.A Via Emilia No 285 Ozzano Emilia Italy	Premaxol, 100 mg/g + 40 mg/g de pré-mistura medicamentosa para alimento medicamentoso para suínos, frangos e galinhas (excepto poedeiras)	Amoxicillin trihydrate Colistin sulphate	100 mg/g 40 mg/g	Premix for medicated feeding stuff	Pigs and chickens (except laying)	Oral

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Industria Italiana Integratori Trei S.p.A Viale Corassori, 62 41100 Modena Italy	DUOBAN	Doxycycline hyclate Colistin sulphate	60 mg/g 1 200 000 IU/g	Premix	Pigs	Mixed in feeding stuffs
Romania	Industria Italiana Integratori Trei S.p.A Viale Corassori, 62 41100 Modena Italy	MICROAMOX COLI	Amoxicillin trihydrate Colistin sulphate	100 mg/g 600 000 IU/g	Premix	Pigs	Mixed in feeding stuffs
Romania	COOPHAVET SAS Herblon 44150 Ancenis France	COLISULTRIX	Trimethoprim Colistin sulphate	37,5 mg 500 000 IU	Powder for oral solution	Calves, lambs, kids, pigs, rabbits and poultry	Oral administration in drinking water or liquid feed
Romania	SC ROMVAC COMPANY SA Sos. Centurii nr.7 077194 Voluntari Romania	GALIPROTECT C	Oxytetracycline hydrochloride Colistin sulphate	12 mg/tablet 5 mg/tablet	Tablets	Poultry (grouse and web-footed)	Oral administration individually
Romania	Lavet Pharmaceuticals LTD. Otto u.14. H-1161 Budapest Hungary	AMOXYCOL	Amoxicillin trihydrate Colistin sulphate	640 mg/g 3 200 000 IU/g	Powder for oral solution	Pigs, chickens	Oral administration in drinking water

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Slovakia	Pharmagal spol. s.r.o. Murgašova 5 949 01 Nitra Slovakia	Amikol perorálny prášok	Amoxicillin trihydrate Colistin sulphate	57,5 mg/g 8,1 mg/g	Oral powder	Pig, calves, poultry (chicken, turkey), pigeon	Oral administration, after incorporation into the feed
Slovakia	Pharmagal spol. s.r.o. Murgašova 5 949 01 Nitra Slovakia	Amikol premix na medikáciu krmiva	Amoxicillin trihydrate Colistin sulphate	57,5 mg/g 200 000 IU/g	Premix for medicated feeding stuff	Pig	Oral administration, after incorporation into the feed
Slovakia	Pharmagal spol. s.r.o. Murgašova 5 949 01 Nitra Slovakia	Amikol-S prášok na perorálny roztok	Amoxicillin trihydrate Colistin sulphate	575 mg/g 81 mg/g	Powder for oral solution	Pig, calves, poultry (chicken, turkey), pigeon	Oral administration via drinking water
Slovakia	Pharmagal spol. s.r.o. Murgašova 5 949 01 Nitra Slovakia	SUTRICOL prášok na perorálny roztok	Colistin sulphate Sulfadimidine sodium Trimethoprim	300 000 IU/g 50 mg/g 12,5 mg/g	Powder for oral solution	Broiler chicken, pig, rabbit, calve	Oral administration via drinking water
Slovakia	Pharmagal spol. s.r.o. Murgašova 5 949 01 Nitra Slovakia	TETRAKOL prášok na perorálny roztok	Chlortetracycline hydrochloride Colistin sulphate	120 mg/g 120 000 IU/g	Powder for oral solution	Pig, calves, poultry (chicken)	Oral administration via drinking water
Spain	CENAVISIA, S.A. Camí Pedra Estela s/n. Reus (Tarragona) 43205 Spain	TRISOL	Ampicillin trihydrate Colistin sulphate	200 mg/g 1 025 000 IU/g	Oral powder	Lambs	In drinking water use
Spain	LABORATORIOS MAYMO, S.A. Via Augusta, 302. Barcelona 08017 Spain	COLIPHUR 100 000/ 1 200 000 IU/ml solución para administración en agua de bebida	Neomycin sulfate Colistin sulphate	100 000 IU/ml 1 200 000 IU/ml	Solution for use in drinking water	Pig for fattening	In drinking water use