

ANNEX I

**LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE VETERINARY
MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, WITHDRAWAL
PERIOD AND APPLICANTS/MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES**

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Austria	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet 2 000 000 IU/ml, Konzentrat für eine orale Lösung für Schweine und Geflügel	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs Poultry	For three consecutive days in drinking water	Pigs: 100 000 IU /kg bw/day in two equally divided doses per day Poultry: 75 000 IU /kg bw/day	Pigs: meat: 1 day Broilers and laying hens: 1 day Other poultry: 7 days Eggs: Zero days
Belgium	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Calves, Lambs: meat and offals 7 days. Pigs: meat and offals 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: meat and offals - 7 days. Eggs: Zero days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Bulgaria	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet oral solution	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	Orally: 3 days	Pigs: 100 000 IU/kg b.w./day Poultry: 75 000 IU/kg/b.w./day	Meat: 1 days Eggs: Zero days
Bulgaria	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Calves, Lambs: meat and offals 7 days. Pigs: meat and offals 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other poultry: meat and offals: 7 days. Eggs: Zero days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Cyprus	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLIVET 2.000.000 IU/ml	Colistin sulfate	2 MIU/ml	Oral Solution	Pigs Birds	Pigs: 100 000 IU/kg/day Poultry: 75 000 IU/kg/day	Pigs: 0.50 ml of product per 10 kg of body weight per day for 3 consecutive days Poultry: 37.5 ml of product per tonne of body weight per day for 3 consecutive days.	Meat and offal: Pigs: 1 day Broilers and laying hens: 1 day Other poultry: 7 days Eggs: Zero days
Czech Republic	Ceva Animal Health Slovakia s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	Colivet Sol.	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Chicken (broilers)	Daily.Orally	Broilers: 75 000 IU colistin per kg of bodyweight (i.e. 0.37 ml of product per 10 kg of bodyweight per day for 3-5 days via drinking water) Pigs: 50 000 IU colistin per kg of bodyweight per 12 hrs (i.e. 0.25 ml of product per 10 kg of bodyweight per 12 hrs for 3-5 days via drinking water or milk replacement).	Meat and offal: Pigs and chicken broilers: 2 days. Do not use in laying hens producing eggs for human consumption.
Denmark	Ceva Animal Health A/S Andkærvej 19 7100 Vejle DENMARK	Colivet	Colistin sulfate	2 MIU/ml	Oral Solution	Pigs	Daily.Orally	100 000 IU colistin / kg body weight daily for 3-5 days.	1 day

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Denmark	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLISTINE CEVA 2 MUI/MI CONCENTRE POUR SOLUTION BUVABLE POUR PORCINS ET VOLAILLES	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	3 days	Pigs: 100 000 IU of colistin per kg body weight per day for 3 consecutive days by oral route, i.e. 0.50 ml of product per 10 kg of body weight per day for 3 consecutive days. Poultry: 75 000 IU of colistin per kg body weight per day for 3 consecutive days by oral route, i.e. 37.5 ml of product per tonne of body weight per day for 3 consecutive days.	Meat and offals: Pigs: 1 day Chickens and egg laying hens: 1 day Other poultry: 7 days Eggs: Zero days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLIVET SOLUTION	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: Calves and lambs: 7 days Porcine: 1 day Chicken and egg-laying hens: 1 day Other birds: 7 days Eggs: Zero days
France	Coophavet S.A.S Saint Herblion, B.P. 70089 44153 Ancenis Cedex FRANCE	COFACOLI SOLUTION	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: 7 days. Eggs: Zero days
France	Franvet Zone industrielle d'Etriche Route d'Avire, BP 103 49500 Segré Cedex FRANCE	MILICOLI	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: Porcine, calves, chicken: 1 day Lamb and poultry other than chicken: 7 days Eggs: Zero days

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France	Laboratoires Biové 3 rue de Lorraine 62510 Arques FRANCE	ACTI COLI 2 MUI/ML	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: Pigs: 0 days Chicken: 1 day Other poultry: 7 days Calves: 2 days Lamb: 7 days Eggs: Zero days
France	Laprovét 2 Chemin de la Milletière B.P. 67562 37075 Tours Cedex 2 FRANCE	COLISTINE SOLUTION E.A.F.	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: 7 days. Eggs: Zero days
France	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	SOGECOLI 2 MILLIONS UI/ML SOLUTION BUVABLE	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: Pigs: 0 day Chicken: 1 day Other poultry: 7 days. Calves: 2 days. Lamb: 7 days Eggs: Zero days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
France	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	COLISTINE SULFATE 2 MUI /ML BUVABLE VIRBAC	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: 7 days. Eggs: Zero days
Germany	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Coliplus	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days
Greece	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs Poultry	Drinking water/per day	Pigs: 100,000 IU/Kg BW x 3 days Poultry: 75.000 IU/Kg BW X 3 days	Pigs: 1 day Broilers and laying hens: 1 day Other poultry: 7 days

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									Eggs: Zero days
Greece	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLISTIN 2.000.000 IU/ML/DIVASA -FARMANIC	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days

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Hungary	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days.
Hungary	Coophavet S.A.S Saint Herblion, B.P. 70089 44153 Ancenis Cedex FRANCE	Cofacoli oral solution	Colistin sulfate	2 MIU/ml	Oral solution	Cattle (suckling calf) Pig Chicken	Calf, Pig: 0.25 ml product/10 kg bw twice daily for 3-4 days Chicken, Laying hen: 37,5 ml product /ton of living weight dissolved in drinking water for 3 days.	Calf, Pig: 50 000 IU/kg bw Broiler chicken, laying hen: 75 000 IU/kg bw/day.	Calf: 3 days Pig: 2 days Chicken and laying hen: 2 days Eggs: Zero days.

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Ireland	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLISCOUR 2 000 000 IU/ml, concentrate for oral solution, pigs, poultry	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs Poultry	Daily for three consecutive days. Administration is by the oral route via drinking water.	Pigs: 100 000 IU of colistin per kg body weight per day i.e. 0.50 ml of product per 10 kg of body weight per day Poultry: 75 000 IU of colistin per kg body weight per day i.e. 37.5 ml of product per tonne of body weight per day	Pigs: Meat and offal: 1 day Broilers and laying hens: Meat and offal: 1 day Other poultry: Meat and offal: 7 days. Eggs: Zero days.
Italy	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Calves, Lambs: Meat and offals: 7 days. Pigs: Meat and offals: 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: meat and offals: 7 days. Eggs: Zero days

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Latvia	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet oral solution	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	Oral use. Administration vis drinking water or milk or direct application by mouth. Twice a day for 3 to 5 consecutive days.	Chicken: 75 000 IU colistin per kg per day (0,37 ml of Colivet per 10 kg twice a day) Pig: 50 000 IU of colistin per kg twice a day(0,25 ml Colivet per 10 kg twice a day).	Edible tissues: 1 day Eggs: 1 day
Lithuania	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLIVET SOLUTION, geriamasis tirpalas	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	With drinking water or milk powder. Orally via drinking water.	Pigs: 50 000 IU/kg of body weight, i.e. 0.25 ml Colivet Solution per 10 kg of body weight twice daily for 3-5 consecutive days. Poultry: 75000 IU/kg of body weight per day, i.e. approximately 0.37 ml of Colivet Solution per 10 kg of body weight per day for 3-5 consecutive days.	Meat: 1 day. Poultry: meat and eggs: 1 day
Lithuania	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Colistop, geriamasis tirpalas	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry (broilers chickens)	For oral administration, usually via drinking water. For 3 consecutive days.	Pigs – 102,500 IU/kg BW every 12 hours, for 3 days (equivalent to 0.5 ml of Colistop Solution /10 kg BW every 12 hours, for 3 consecutive days). Broilers chickens: 123,000 IU/kg BW/day, for 3 days (equivalent to 0.06 ml of Colistop Solution /kg BW /day, for 3 consecutive days)	Fattening pigs: 2 days. Broilers chickens: 7 days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Lithuania	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Calves, Lambs: Meat and offals: 7 days. Pigs: Meat and offals: 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: Meat and offals: 7 days. Eggs: Zero days
Poland	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet solution	Colistin sulfate	2 MIU/ml	oral solution	Pig Chickens	Administration via drinking water or milk. For 3-5 days	Chickens: 75000 I.U. colistin /1 kg b.w./day for 3 - 5 days, (0,37 ml of product /10 kg b.w.twice daily for 3 - 5 days Pigs: 50000 I.U colistin /1 kg b.w./day for 3 - 5 days, (0,25 ml of product/10 kg b.w. twice daily for 3 - 5 days.	Meat and offal: 1 day Eggs: 1 day

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Poland	DIVASA - FARMAVIC, S.A. Ctra. Sant Hipòlit, km 71 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 (as colistin sulfate)	2 MIU/ml	Concentrate for oral solution for use in drinking water	Cattle (calves), sheep (lambs), swine and chickens	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days Not permitted for use in animals producing milk for human consumption
Portugal	Ceva Saúde Animal - Produtos Farmacêuticos e Farmacológicos, Lda Rua Doutor António Loureiro Borges, 9/9A - 9ªA Miraflores 1495-131 Algés PORTUGAL	Colivet 2 000 000 UI /ml, concentrate for oral solution for pigs and birds	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs Domestic birds	3 days	Swine: 100 000 UI/kg BW/day Birds: 75 000 UI/kg BW/day	Meat and offal: Pigs: 1 day Broilers and laying hens: 1 day, Other birds: 7 days, Eggs: Zero days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Portugal	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Calves, Lambs: Meat and offals: 7 days. Pigs: Meat and offals: 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: Meat and offals: 7 days. Eggs: Zero days
Romania	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	ENTEROBAS SOLUCION	Colistin sulfate	2 MIU/ml	oral solution	Calves Pigs Poultry	Oral administration (drinking water or as milk replacer) treatment: 4-5 days	Calves and Pigs: 100.000 UI/kg b.w/ day equivalent to 0,5 ml/10 kg b.w./day Poultry: 100.000 UI/kg b.w./day equivalent to 0,5 ml/litre drinking water/day	Meat: calves - 2 days Pigs: 5 days Poultry: 3 days Eggs: do not use in animals from which eggs are produced for human consumption

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Romania	CEVA SANTE ANIMALE ROMANIA SRL 5 Chindiei , sector 4 040185 Bucharest ROMANIA	COLIVET SOLUTION	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	Oral administration (drinking water) treatment: 3 consecutive days	Pigs: 100.000 I.U. of colistin (as sulfate) /1kg b.w. in two equally divided doses/day, i.e. 0,5 ml of product per 10 kg of body weight in two equally divided doses/day Poultry: 75.000 I.U. of colistin (as sulfate) /1kg b.w. per day, i.e. 37,5 ml of product per 1 tone of body weight/day	Meat and offal: pigs 1 day Broilers and layers: 1 day Eggs: Zero days
Romania	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat and offal: 7 day Eggs: Zero days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Romania	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS SOLUTION	Colistin sulfate	2 MIU/ml	Oral solution	Pigs, Broilers	Oral administration (drinking water) treatment: 3 days	Poultry: 0,03 ml/kg b.w/day Pigs: 0,5 ml/ 10 kg b.w. every 12 hours	Meat: 9 days
Romania	Franvet Zone industrielle d'Etriche Route d'Avire, BP 103 49500 Segré Cedex FRANCE	MILICOLI	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	Oral administration (drinking water or milk replacer) treatment: 3 - 4 days	Calves, Pigs and Lambs: 50.000 I.U./kg b.w. or 0,25 ml of product/ 10 kg b.w Poultry: 75.000 I.U./kg /day or 0,25 ml/1 litre water	Meat and offal: 7 days Eggs: Zero days
Romania	S.C. CRIDA PHARM S.R.L. Str. Stadionului nr. 1 Oltenita ROMANIA	COLICRID	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	Oral administration (drinking water) treatment: 3 - 5 days	Pigs: 100.000 I.U. of colistin sulfate /1kg b.w./day, i.e. 0,05 ml of product/ kg of body weight /day Poultry: 100.000 I.U. of colistin sulfate /1kg b.w./day, i.e. 0,05 ml of product/ kg of body weight /day	Meat: pigs: 7 days Poultry: 3 days
Romania	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	SOGECOLI	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Poultry	Oral administration treatment: 3 - 4 days	Calves, Lamb: 50.000 I.U./kg b.w. or 0,25 ml /10 kg b.w. twice a day, morning and evening Poultry: 75.000 I.U./ kg b.w. daily or 0,25 ml/1 litre water	Meat: 7 days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Slovak Republic	Ceva Animal Health Slovakia, spol. s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	COLIVET sol. ad us.vet.	Colistin sulfate	2 MIU/ml	Oral solution	Pigs, Chickens	3 - 5 days in drinking water, milk or direct administration	Pigs: 50 000 IU colistine sulfate/kg b.w. (0,25 ml product/10 kg b.w.) (2 times). Chickens: 75 000 IU colistine sulfate/kg b.w. (0,37 ml product/10 kg b.w.	Meat: 1 day. Eggs: 1 day.
Slovak Republic	Divasa-Farmavic S.A. Ctra San Hipolito 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Calves, Lambs: Meat and offals: 7 days. Pigs: Meat and offals: 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: Meat and offals: Zero days.
Spain	CEVA SALUD ANIMAL, S.A. Carabela La Niña nº 12 5ª planta 08017 Barcelona SPAIN	COLIVET 2,000,000 UI/ML	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Birds	3 days. Orally	Pigs: 100000 UI /Kgbw Birds: 75000 UI/Kg bw	1 day

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Spain	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS SOLUCION	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Birds (Chicken)	3 days. Orally	Pigs: 102500 UI /Kg bw /12 hours Birds: 123000 UI /Kg bw /12 hours	Pigs: 2 days Birds: 7 days
Spain	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLISTINA DIVASA 2,000,000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat: 7 days Eggs: Zero days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
The Netherlands	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat: 7 days Eggs: Zero days.
United Kingdom	Ceva Animal Health Ltd 90 The Broadway Chesham Buckinghamshire HP5 1EG UNITED KINGDOM	Colibird	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Poultry	For three consecutive days in drinking water	75000 IU/kg bw/day	Meat: 7 days. Eggs: Zero days.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
United Kingdom	Ceva Animal Health Ltd 90 The Broadway Chesham Buckinghamshire HP5 1EG UNITED KINGDOM	Coliscour, oral solution of colistin sulphate 2 MIU/ml	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs	Twice daily for five consecutive days (via drinking water or direct oral administration)	50000 IU/kg bw given twice daily	Meat and offal: 1 day
United Kingdom	Divasa-Farmavic S.A. Ctra San Hipolito km 71 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 sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product /10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product /1 tone bw/day for 3 consecutive days.	Meat: 7 days Eggs: Zero days.

ANNEX II

**SCIENTIFIC CONCLUSIONS AND GROUNDS FOR AMENDMENT OF THE SUMMARY OF
PRODUCT CHARACTERISTICS**

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF VETERINARY MEDICINAL FORMULATIONS CONTAINING COLISTIN SULFATE AT 2 000 000 IU/ML AND INTENDED FOR ADMINISTRATION VIA DRINKING WATER TO CALVES, LAMBS, PIGS AND POULTRY SPECIES

1. Introduction

Veterinary medicinal formulations containing colistin sulfate at 2 000 000 IU/ml and intended for administration via drinking water to calves, pigs, lambs and poultry are used for the treatment of infections of the gastrointestinal tract caused by *Escherichia coli* and *Salmonella spp* susceptible to colistin.

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

The United Kingdom expressed concerns that differences in the posology and withdrawal periods established across the European Union for veterinary medicinal formulations containing colistin at 2 000 000 IU/ml and intended for administration in drinking water to any food producing species may present a potential serious risk to public and animal health.

The procedure involved 47 veterinary medicinal products authorised or pending authorisation in different Member States of the European Union (see Annex I).

2. Discussion of data available

The submitted data by the Applicants/Marketing Authorisation Holders showed that the concerned veterinary medicinal products are authorised or pending authorisations via different marketing authorisation procedures (mutual recognition procedures or national procedures) and under various legal bases (full and generic).

It was noted that some parts of the data presented were identical but were submitted by different Applicants/Marketing Authorisation Holders. The data packages submitted consist of bibliographic data, available in the public domain, and proprietary data.

With regard to the efficacy in pigs the pre-clinical data revealed that the selection of dose rate and dose interval for colistin sulfate in pigs was chosen by using a pharmacokinetic/pharmacodynamic (PK/PD) analysis. It was noted that the analysis, based on the determination of colistin sulfate concentration in the gastrointestinal tract after different levels of exposure and minimum inhibitory concentrations (MIC) data from *E. coli* strains collected in five European countries could be questioned as the surrogate endpoint C_{max}/MIC was not validated for local exposure in the gastrointestinal tract and the fraction of active compound bound to the faecal content was not known. This said, it was agreed that the suggested dose of 50 000 IU per kg body weight twice daily was reasonable. This dose was the recommended dose for the majority of the products included in this referral and has thus been in clinical use for many years. For some of the products concerned a treatment period of 5 to 7 days was recommended which was considered too long with respect to the aim of achieving an optimal balance between bacteriological cure rate and risk for resistance development. For some of the products concerned the recommended treatment interval was 3 to 5 days.

With regard to the efficacy in chickens a study report from public literature was provided where *E. coli* infections were treated with colistin sulfate given in feed. These studies provide sufficient support for the treatment of colibacillosis in chickens although the correspondence between the in-feed doses used in these studies and the dose recommended for most products within this referral (75 000 IU colistin per kg body weight once daily for 3 days) was not fully justified.

With regard to gastrointestinal infections caused by non-invasive *E. coli* in calves and lambs the data submitted to support the indication were limited. However, in view of the well established use of the substance in these species and the fact that there was no new information indicating any new risk associated with the use of colistin in calves and lambs in relation to lack of efficacy or human health the Committee considered that the use of colistin in calves and lambs for the treatment of gastrointestinal infections caused by non-invasive *E. coli* can be maintained. The dose currently recommended in all products authorised for calves and lambs is a harmonised dose of 100 000 IU colistin per kg body weight daily. The duration of treatment currently recommended in the products authorised for calves and lambs was mainly 3 days. Two products had a recommended duration of treatment of 3-4 consecutive days.

With regard to treatment of *Salmonella spp.* infection in calves, lambs, pigs and poultry, no or very limited clinical data was presented to support this indication currently approved for the products within the scope of this procedure. The presented clinical data for treatment of salmonellosis in chickens was

not conclusive and the appropriateness of using this substance for treating *Salmonella* infections could be questioned. Due to the poor absorption in the gut colistin would only be effective against non-invasive *Salmonella*. Furthermore, the Committee noted that treatment of subclinical *Salmonella* with the objective to reduce the number of bacteria might interfere with control programmes for this disease¹. The Committee considered that the absence of any data or argumentation from the Applicants/Marketing Authorisation Holders in support of a claim for treatment of *Salmonella* may constitute a risk to public and animal health as treatment might make the bacteria difficult to detect without completely eliminating the infection/colonisation. Complete or partial lack of efficacy can result in persistence of zoonotic organisms in treated animals and in the environment and delays in effective elimination due to treatment failure.

As regards to antimicrobial resistance against colistin it should be noted that firm conclusions regarding antimicrobial resistance could not be reached in the absence of consumption data. However, as colistin has been approved for decades and resistance has remained low to date, in CVMP's view there was sufficient information available to conclude that resistance was not likely to be an emerging issue. The extensive MIC data presented by the Applicants/Marketing Authorisation Holders covering the period during which colistin sulfate has been in clinical use indicates quite clearly that resistance development was not an issue of concern for this substance.

In summary the CVMP considered that there was sufficient information to support the treatment of gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin, when administered at dose of 100 000 IU colistin per kg body weight daily for calves, lambs, pigs and 75 000 IU colistin per kg body weight daily in poultry for 3-5 consecutive days. With regard to the duration of treatment of gastrointestinal infections caused by non-invasive *E. coli* in the target species it was noted that the treatment effect is easily monitored and thus treatment duration can be adjusted according to the course of the disease.

With regard to established withdrawal periods they ranged in the Member States from 1 to 9 days. To support the established withdrawal periods eight residue depletion studies in calves, pigs and chickens were submitted by the Applicant/Marketing Authorisation Holders. The submitted residue depletion studies were reviewed and based on the recommended posology for cattle (100 000 IU colistin per kg body weight daily for 3-5 consecutive days) and the proposed harmonised posology for pigs and poultry (100 000 IU colistin per kg body weight daily for pigs and 75 000 IU colistin per kg body weight daily in poultry for 3-5 days) the withdrawal periods for calves, pigs and chickens were recalculated using the alternative method². In summary withdrawal periods of one day for edible tissues and offal of calves, pigs and chickens and zero days for eggs are considered justified.

No residue depletion studies were provided for lambs and for poultry species other than chickens. Current SPCs establish withdrawal periods of 7 days for these species. Considering the general knowledge that the substance is poorly absorbed from the gastro-intestinal tract the Committee considered that the withdrawal period of 1 day as recommended for calves, pigs and chicken can also be supported for lambs and poultry species other than chickens.

3. Benefit Risk Assessment

Although the quality of the data provided was considered to be poor and in some cases lacking, and so failed to support some of the indications claimed, the Committee considered that there was sufficient documented evidence in support of efficacy of colistin sulfate when used in pigs for the treatment of gastrointestinal infections caused by non-invasive *E. coli*, susceptible to colistin, at dose of 100 000 IU colistin per kg body weight daily for 3-5 consecutive days.

There was also sufficient documented evidence in support of efficacy of colistin sulfate when used in poultry for the treatment of gastrointestinal infections caused by non-invasive *E. coli*, susceptible to colistin, at a daily dose of 75 000 IU colistin per kg body weight daily for 3-5 consecutive days.

Consequently the benefit-risk balance for colistin was considered positive for treatment of gastrointestinal infections caused by non-invasive *E. coli* in pigs and poultry when used with the posologies mentioned.

¹ Commission Regulation (EC) NO 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of Salmonella in poultry (OJ L 212, 2.8.2006, p.3). - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:212:0003:0005:EN:PDF>

² CVMP Note for guidance: Approach towards harmonisation of withdrawal periods <http://www.emea.europa.eu/pdfs/vet/swp/003695en.pdf>

The use of colistin sulfate for the treatment non-invasive *E. coli* in calves and lambs is considered well-established. It was noted that no data were submitted by the Applicants/Marketing Authorisation Holders to support the establishment of optimal duration of treatment for colibacillosis in calves and lambs. However, oral colistin could be useful for treating non-invasive *E. coli* infection in these species and the effect of treatment is easily detected in clinical practice. Furthermore there is no new information indicating any new risk associated with the use of colistin in calves and lambs in relation to lack of efficacy or emerging resistance relevant to public or animal health. In the submitted Periodic Safety Update Reports no lack of efficacy has been reported for the claimed indications in calves and lambs. Consequently the benefit-risk balance for colistin was considered positive for treatment of gastrointestinal infections caused non-invasive *E. coli* infections in calves and lambs with the recommended dose of 100 000 IU per kg body weight daily. With regard to the duration of treatment, considering the fact that treatment effect is easily monitored and thus treatment duration can be adjusted according to the course of the disease the Committee agreed to recommend a harmonised duration of treatment of 3-5 days for all products intended for calves and lambs. In addition it was noted that the recommended daily dose for calves, lambs and pigs should be divided into two if the product is to be administered directly into the mouth of the animal.

By contrast, the CVMP considered that the absence of any data or argumentation from the Applicants/Marketing Authorisation Holders in support of a claim "...for treatment of gastrointestinal infections caused by *Salmonella spp.*..." may constitute a risk to public and animal health as treatment might make the bacteria difficult to detect without completely eliminating the infection/colonisation. Complete or partial lack of efficacy can result in persistence of zoonotic organisms in treated animals (and in the environment) and delay effective elimination of *Salmonella* due to treatment failure. Consequently the benefit-risk balance for colistin was considered negative for treatment of gastrointestinal infections caused by *Salmonella spp.* in calves, lambs, pigs and poultry.

Having considered the residue depletion data submitted by the Applicants/Marketing Authorisation Holders, a withdrawal period of one day for edible tissues and offal from calves, pigs and chickens and zero days for eggs were considered adequate. No residue data were available with regard to lambs and poultry species other than chickens. The withdrawal periods established in the current SPCs for these species is 7 days. In view of the residue data submitted in support of the withdrawal periods in calves, pigs and chickens, and general knowledge that the substance is poorly absorbed from the gastrointestinal tract, the Committee considered that the same withdrawal period of 1 day could be recommended for these animal species.

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

Whereas:

- the CVMP considered the overall submitted data and the general knowledge on the substance resulting from its well-established use in veterinary medicines for over 20 years. The data submitted to the Committee for evaluation was of poor quality and in some cases lacking to substantiate the claims, doses, duration of treatment or withdrawal periods. The only area of potential risks identified was the risk of lack of efficacy in case of invasive strains and the possibility of interference with *Salmonella* control programs. There was no documented evidence indicating an increase in the development of resistance relevant to human or animal health. In the submitted Periodic Safety Update Reports neither lack of efficacy nor emerging resistance development has been reported for the approved indications in any of the approved target species;
- the CVMP considered that colistin administered orally has been used to treat gastrointestinal infections caused by non-invasive *E. coli* infections in calves, lambs, pigs and poultry during decades. Although the clinical documentation provided in connection to this referral is limited, the data as such indicated that non-invasive *E. coli* infections in calves, lambs, pigs and poultry can be treated efficiently using a dose of 100 000 IU colistin per kg body weight daily in calves, lambs, pigs and 75 000 IU colistin per kg body weight daily in poultry and with treatment duration of consecutive 3-5 days
- the CVMP considered that the Applicants/Marketing Authorisation Holders did not provide any data or argumentation in support of a claim "...for treatment of gastrointestinal infections caused by *Salmonella* spp..." in calves, lambs, pigs or poultry. In the absence of any such data it is considered that this use may constitute a risk to public and animal health as treatment might make the bacteria difficult to detect without completely eliminating the infection/colonisation and therefore result in persistence of zoonotic organisms in treated animals and in the environment and delays in effective elimination. Consequently, the use of colistin for the treatment of infections caused by *Salmonella* may interfere with specific control methods and national programmes for the control of *Salmonella*;
- the CVMP considered that a withdrawal period of one day is sufficient for edible tissues and offal of calves, lambs and pigs when administered with dose of 100 000 IU colistin per kg body weight daily for three to five days;
- the CVMP considered that a withdrawal period of one day is sufficient for edible tissues and offal of poultry and zero days for eggs when administered at a dose of 75 000 IU colistin per kg body weight daily for three to five consecutive days;

the CVMP has recommended the variation of the Marketing Authorisations and amendments of the relevant sections of the Summary of Product Characteristics, labelling and package leaflet and where applicable as set out in Annex III of the Opinion for the veterinary medicinal formulations containing colistin at 2 000 000 IU/ml and intended for administration in drinking water to any food producing species as referred in Annex I of the Opinion.

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

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

4.2 Indications for use, specifying the target species

Treatment of gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin.

Delete, where applicable, treatment of gastrointestinal infections other than *E. coli*.

4.9 Amounts to be administered and administration route

To be administered orally.

For calves, lambs and pigs the recommended dose is 100 000 IU of colistin per kilogram body weight daily for 3-5 consecutive days. The recommended daily dose should be divided into two if the product is to be administered directly into the mouth of the animal.

For poultry the recommended dose is 75 000 IU of colistin per kilogram body weight daily for 3-5 consecutive days.

4.11 Withdrawal period(s)

Meat and offal:

Calves: 1 day

Lambs: 1 day

Pigs: 1 day

Poultry: 1 day

Eggs: Zero days

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE LABELLING

6. INDICATION(S)

Treatment of gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin.

Delete, where applicable, treatment of gastrointestinal infections other than *E. coli*.

8. WITHDRAWAL PERIOD

Meat and offal:

Calves: 1 day

Lambs: 1 day

Pigs: 1 day

Poultry: 1 day

Eggs: Zero days

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

4. INDICATION(S)

Treatment of gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin.

Delete, where applicable, treatment of gastrointestinal infections other than *E. coli*.

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

To be administered orally.

For calves, lambs and pigs the recommended dose is 100 000 IU of colistin per kilogram body weight daily for 3-5 consecutive days. The recommended daily dose should be divided into two if the product is to be administered directly into the mouth of the animal.

For poultry the recommended dose is 75 000 IU of colistin per kilogram body weight daily for 3-5 consecutive days.

10. WITHDRAWAL PERIOD

Meat and offal:

Calves: 1 day

Lambs: 1 day

Pigs: 1 day

Poultry: 1 day

Eggs: Zero days