

## **Annex I**

**List of the names, pharmaceutical forms, strengths of the veterinary medicinal products, animal species, route of administration, indications / withdrawal periods and applicants / marketing authorisation holders in the Member States**

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Austria	Chevita Tierarzneimittel Gesellschaft m.b.H.Kaplanstraß e 10 AT 4600 Wels AUSTRIA	Doxymax 500 mg/g - Pulver zur Herstellung einer Lösung zum Einnehmen für Schweine und Hühner	Doxycycline hyclate	500 mg/g	Oral powder	Pigs, Chicken (broiler)	Chicken: 3-5 days, oral via drinking water	Chicken: 25mg doxycyclin hyclat/kg BW/day = 1g powder/20 kg/day	Meat and offal: Chicken (Broiler) 5 days, Eggs: not for use in laying hen  Indications: infection of respiratory tract caused by Mycoplasma spp. (M.gallisepticum, Escherichia coli, Septicemia caused by Pasteurella multocida
Belgium	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50% Dopharma	Doxycycline hyclate	500mg/g	Water soluble powder	Calves, porcine, poultry	Poultry: 50mg/kg/day	3-5 days500g/10 00L drinking water	Meat and offal: 6 days  Indications: infections by micro-organisms in respiratory or gastro- intestinal system
Belgium	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	Pulmodox 50%	Doxycycline hyclate	500mg/g	Water soluble powder	Calves, porcine, poultry	Poultry: 50mg/kg/day	3-5 days 500g/1000L drinking water	Meat and offal: 6 days  Indications: infections by micro-organisms in respiratory or gastro- intestinal system
Belgium	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50%	Doxycycline hyclate	500mg/g	Water soluble powder	Porcine, poultry	Poultry: 10-20mg/kg/day	3-4 days 100- 200g//1000L drinkwater	Meat and offal: 3 days/10mg/kg 12 days/20mg/kg  Indications: respiratory diseases

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Belgium	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 15% ad. us. vet..	Doxycycline hyclate	150mg/g	Water soluble powder	Porcine, calves, poultry, , fancy birds, pigeons	Poultry: 10-20mg/kg/day	3-5 days 500g/1000L drinkwater	Meat and offal: 7 days  Indications: respiratory diseases caused by germs
Belgium	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	Hydrodoxx 500 mg/g water- soluble powder	Doxycycline hyclate	500mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption  Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Bulgaria	Farma Sis OOD 4 San Stefano Str. Dobrich BULGARIA	Doxinyl 10% Oral Suspension	Doxycycline hyclate	100mg/ml	Oral Suspension	Poultry	Via drinking water	50 -100 ml Doxinyl 10% in 100 l drinking water per day (50-100mg Doxycycline in 1 l drinking water) 3-5 days	Meat - 5 days
Bulgaria	Farma Sis OOD 4 San Stefano Str. Dobrich BULGARIA	Cyvadox 10%	Doxycycline hyclate	100mg/ml	Oral Suspension	Poultry	Via drinking water	0,5-1 ml in 1 l drinking water per day \3-5 days\ 50- 100 mg Doxycycline	Meat - 7 days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Bulgaria	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50% w.s.p.	Doxycycline hyclate	500mg/g	Water soluble powder	Poultry	Via drinking water	500g Doxycycline 50% w.s.p. in 100 l drinking water /3-5 days/	Meat - 4 days
Bulgaria	Farmavet OOD 40 Otec Paisij Str. Shumen BULGARIA	Doxycycline 20% Pulvis solubilis	Doxycycline hyclate	200mg/g	Water soluble powder	Poultry	Via drinking water	50g Doxycycline 20% in 100l drinking water /3-5 days/	Meat - 7 days
Bulgaria	Interchemie Werken De Adelaar BV Hosterweg 26a 5811 Ccastenray THE NETHERLANDS	Doxy – WS	Doxycycline hyclate	200mg/g	Water soluble powder	Poultry	Via drinking water	1kg Doxy- WS in 2000- 4000l drinking water	Meat - 7 days
Bulgaria	Ceva Sante Animale France La Balastiere 33501 Libourne Cedex FRANCE	Doxyvit 50 % WSP	Doxycycline hyclate	500mg/g	Water soluble powder	Poultry	Via drinking water	2-3g Doxyvit 50% WSP in 10l. Drinking water - 5 days /equivalent to 100- 150mg Doxycycline in 1l water	Meat - 7 days
Bulgaria	Ceva Sante Animale France La Balastiere 33501 Libourne Cedex FRANCE	Doxyvit 100	Doxycycline hyclate	100mg/g	Water soluble powder	Poultry	Via drinking water	10mg Doxyvit per kg body weight per day	Meat - 7 days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Bulgaria	Vetpartners OOD Ivan Asen Str. 4270 Parvomaj BULGARIA	Polidoxichem 500/WSP	Doxycycline hyclate	500mg/g	Water soluble powder	Poultry	Via drinking water	50-100mg Doxycycline in 1l drinking water /3-5 days/ equivalent to 0,1-0,2g Polidoxichem 500 WSP in 1l drinking water per day	Meat - 7 days
Bulgaria	Biovet AD 39 Petar Rakov Str. 4550 Peshtera BULGARIA	Vibravet 10% Water soluble premix	Doxycycline hyclate	100mg/g	Water soluble powder	Poultry	Via drinking water	1g Vibravet 10% in 1l drinking water /=67- 100mg Doxycycline/ per day. 5 days	Meat - 7 days
Cyprus	PREMIER SHUKUROGLOU LTD	HIPRADOXI -S	Doxycycline hyclate	100mg	Oral solution	Pigs, Chicken (broiler)	By oral route, via drinking water	Broilers: 50- 100 mg doxycycline hyclate/L water for 3- 5 days	Broilers: meat: 5 days Pigs: meat:6 days
Czech republic	Industria Italiana Integratori TREI S.p.A. Viale Corassori 62 41100 Modena ITALY	DOXIPAN 20	Doxycycline hyclate	20 g/100 g	Powder for oral solution	Chicken- broiler, turkey	Administer orally via drinking water for 5 days.	Broiler: 5 – 7,5 g of product/10 l drinking water turkey: 10 – 20 mg doxycycline/ kg bodyweight	Chicken broiler: Meat and offal: 5 days. Turkey: meat and offal : 10 days  Indications: Chicken broilers: Chronic respiratory diseases and associated infections. Turkeys: Diseases caused G+ and G- micro-organisms and mycoplasmas, especially respiratory

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
									and articular syndrome caused by mycoplasmas and/or staphylococcus.
Czech republic	Pharmagal s.r.o., Murgašova 5, 949 01 Nitra, Slovak Republic	DOXYGAL	Doxycycline hyclate	50 mg/1 g	Powder for oral solution	Poultry	Administer orally via drinking water for 3-5 days.	Therapeutica lly- preventive: 50 mg doxycycline/ 1 l drinking water  Therapeutica lly: 100 mg doxycycline/ 1 l drinking water	Meat and offal: 7 days. Not permitted for use in laying hens from which eggs are produced for human consumption.  Indications: Used for the treatment of the secondary bacterial infections following to viral origin diseases. Poultry: CRD (mycoplasmosis), colibacillosis

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Czech republic	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, Hungary	DOXYVIT 40 %	Doxycycline hyclate	40g/100g	Powder for oral solution	Chicken- broiler, turkey	Administer orally via drinking water for 3-5 days.	1.Continuous therapy: 1,0g DOXYVIT 40% per 3-6 L of drinking water  2.Pulse therapy: 10-20mg doxycycline / kg b.w. , intervals 4-8 hours.	Chicken broiler, turkey: Meat and offal: 4 days. Not permitted for use in laying hens from which eggs are produced for human consumption.  Indications: Treatment and prevention of respiratory, intestinal and systemic infections caused by microorganisms susceptible to doxycycline in broilers and turkeys. Chronic respiratory disease (Mycoplasma gallisepticum, Escherichia coli) Aerosacculitis (Mycoplasma meleagridis) Infectious synovitis (Mycoplasma synoviae) Fowl cholera (Pasteurella multocida) Bordetella turkey infections (Bordetella avium) Infectious coryza (Haemophilus paragallinarum) Colibacillosis (Escherichia coli) Necrotic enteritidis (Clostridium perfringens) Chlamydiosis (Chlamydia psittaci)

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Czech republic	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	KARIDOX 100 mg/ml	Doxycycline hyclate	100 mg/1 ml	Oral solution	Chicken-broiler	Administer orally via drinking water for 3-5 days.	10-20 mg doxycycline/ kg bodyweight/ day (i.e.. 0,5-1,0 ml of product /l of drinking water /day).	Chickens(broilers): Meat and offal: 7 days. Not permitted for use in laying hens from which eggs are produced for human consumption  Indications: Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms susceptible to doxycycline.
Czech republic	Tekro, spol. s.r.o., Višňová 2/484, 140 00 Praha 4, Czech Republic	MEDITEK DOX 100	Doxycycline hyclate	100g/kg	Powder for oral solution	Broiler	Administer orally via drinking water for 3-5 days.	10 mg Doxycycline hyclate/ 1kg bodyweight (1,0kg of product / 1000 l drinking water)	Chickens (broilers): Meat and offal: 7 days  Indications: Prevention and treatment of infection disease of the respiratory and gastrointestinal tract in pigs and broilers caused by the pathogens susceptible to doxycycline. It is efficient on the several bacteria resistant to first generation tetracyclines.



Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Czech republic	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	ORIDOX 100 mg/ml, perorální roztok pro podání v pitné vodě pro brojery a prasata	Doxycycline hyclate	100 mg/1ml	Oral solution	Chicken-broiler	Administer orally via drinking water for 3-5 days.	10-20 mg doxycycline/ kg bodyweight/ day (i.e.. 0,5-1,0 ml of product /ldrinking water/ day	Chickens (broilers): Meat and offal: 7 days. Eggs: Not permitted for use in laying hens from which eggs are produced for human consumption  Indications: Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms susceptible to doxycycline.
Czech republic	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	Pulmodox O.S.P. 5%	Doxycycline hyclate	0.05 g/1g	Powder for oral solution	Poultry	Administer orally via drinking water for 3-5 days.	Poultry till 2 weeks: 1 g of the product per L of drinking water and day Poultry over 2 weeks: 2 g of the product per L of drinking water and day Duration of the treatment : 3 - 5 days.	Chicken (broilers): Meat and offal: 4 days, Not permitted for use in laying hens from which eggs are produced for human consumption.  Indications: Treatment of respiratory infections caused by the pathogens susceptible to doxycycline and chickens (broilers).

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Czech republic	KELA Laboratoria n.v. Industrial Zone De Kluis" St. Lenaartseweg 48 2320 Hoogstraten BELGIUM	Respidox 5 %	Doxycycline hyclate	50 mg / 1 g	Powder for oral solution	Poultry	Administer orally via drinking water for 3 days.	2 g of product/ l drinking water	Poultry : Meat and offal: 7 days Not permitted for use in laying hens from which eggs are produced for human consumption.  Indications: Treatment of the infections caused by the microorganisms susceptible to doxycycline. Poultry: CRD, colibacillosis, inflammation of nasal mucosa, synovitis, salmonellosis, fowl cholera, chlamydiosis
Czech republic	COOPHAVET Saint Herblon 44150 Ancenis FRANCE	RONAXAN P.S. 5%	Doxycycline hyclate	50 mg / 1 g	Powder for oral solution	Chickens	Administer orally via drinking water for 5 days.	10 mg doxycycline / kg bodyweight. / day (i.e.. 1 g of product/5 kg bodyweight.)	Chicken (broilers) : Meat and offal: 4 days, Not permitted for use in laying hens from which eggs are produced for human consumption.  Indications: Treatment of respiratory infections caused by the pathogens susceptible to doxycycline in chickens (broilers).

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Czech republic	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	Doxycycline Calier 500 mg/g	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	6 days Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum
Czech republic	Ceva Animal Health Slovakia spol. s.r.o. Račianska 77 831 02 Bratislava SLOVENIA	DOXYVIT 100	Doxycycline hydrochloride	100 g/1000 g	Powder for oral solution	Poultry (chicken, turkey, goose)	Administer orally via drinking water for 5 days.	10 mg doxycycline/ kg bodyweight per day, i.e. 0,1 g DOXYVIT 100 / kg bodyweight	Meat and offal: 7 days. Not permitted for use in laying hens from which eggs are produced for human consumption.  Indications: Treatment and prevention of respiratory, intestinal and systemic infections caused by micro-organisms susceptible to doxycycline in hens, turkeys and gouses: chronical respiratory disease (Mycoplasma gallisepticum, Escherichia coli), aerosaculitis (Mycoplasma meleagridis), synovitis (Mycoplasma synoviae), fowl cholera (Pasteurella mul tocida), bordetela turkey infections (Bordetella avium), infectious coryza (Haemophilus paragallinarum), colibacillosis (Escherichia coli),

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									necrotic enteritis (Clostridium perfringens), chlamydiosis (Chlamydia psittaci), prevention in stress conditions (vaccination, changes in housing, transportation)
Denmark	Laboratorios Karizoo S.A. Pol. Ind. La Borda c/Mas Pujades 11-12 Caldes de Montbui 08140 SPAIN	Karidox	Doxycycline hyclate	10 %	Oral solution	Chickens, swine	Orally (drinking water) for 3 to 5 days	In chickens: 10-20 mg doxycycline hyclate per kg bodyweight per day for 3 to 5 days (i.e. 0.5-1.0 ml product/litre water/day)	Chickens for slaughter: 7 days Eggs: May not be administered to egg laying poultry if the eggs are intended for human use.  Indications: Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.
Denmark	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	Oridox	Doxycycline hyclate	10%	Oral solution	Chickens, swine	Orally (drinking water) for 3 to 5 days	In chickens: 10-20 mg doxycycline hyclate per kg bodyweight per day for 3 to 5 days (i.e. 0.5-1.0 ml product/litre water/day)	Chickens for slaughter: 7 days Eggs: May not be administered to egg laying poultry if the eggs are intended for human use.  Indications: Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Denmark	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption  Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Estonia	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	Hipradoxi-S	Doxycycline hyclate	100mg/ml	Concentrate for oral solution	chicken (broilers)	oral use via drinking water.	50...100 mg doxycycline/l itre water	Meat and offal: 5 days. Not authorised for use in laying birds producing eggs for human consumption.  Indications: Colibacillosis, C.R.D. and associated infections.
Estonia	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	Hipradoxi-P	Doxycycline hyclate	100mg/g	powder for oral solution	chicken (broilers)	oral use via drinking water.	20 mg doxycycline/ kg bw/day	Meat and offal: 5 days. Not authorised for use in laying birds producing eggs for human consumption.  Indications: Colibacillosis, C.R.D. and associated infections.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Estonia	Maxx Pharma OÜ Kaluri tee 5 Haabneeme 74001 Viimsi Harjumaa ESTONIA	Doxyprim 40%	Doxycycline hyclate	400mg/g	powder for oral solution	chicken, turkeys	oral use via drinking water.	10...20 mg/kg bw/day 5 days	Meat and offal: 4 days. Not authorised for use in laying birds producing eggs for human consumption.  Indications: For the treatment of respiratory, intestinal and systemic infections caused by doxycycline-sensitive organisms.
Estonia	Zoovetvaru uusaru 5 76505 Saue Harjumaa ESTONIA	Doxycin	Doxycycline hyclate	200mg/g	powder for oral solution	chicken (broilers)	for oral administaration, via drinking water.	10 mg doxycycline/ kg bw/day 3-5 days	Meat and offal: 6 days. Do not use in laying birds producing eggs for human consumption.  Indications: For the treatment of infections of the respiratory system and alimentary tract caused by microorganisms sensitive to doxycycline, including mycoplasmas, bordetellosis, chlamydiosis, pasteurellosis anaerobic infections, salmonellosis, staphylococcosis, colibacillosis.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Estonia	Dutch Farm Veterinary Pharmaceuticals B.V. Veemweg 1 3771 MT Barnevald THE NETHERLANDS	Dutch Farm Doxycycline 20% WSP	Doxycycline hyclate	200mg/g	powder for oral solution	poultry	for oral administration, via drinking water.	15 mg Doxycycline hyclate/kg bw/day 3-5 days.	Meat and offal: 7 days. Do not use in laying birds producing eggs for human consumption.  Indications: For the treatment of infections caused by microorganisms sensitive to doxycycline, especially respiratory infections.
Germany	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	DOXYCYCLINE CALIER 500 mg/g, Pulver zum Eingeben über das Trinkwasser für Huhn und Schwein	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	Meat and offal: 6 days  Indications: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum
Germany	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx 500 mg/g Pulver zum Eingeben über das Trinkwasser	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption  Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Greece	Durden Trading Limited 12,Kennedy Av. Nicosia CYPRUS	Stardox	Doxycycline hyclate	500mg/g	Powder for oral solution	Chickens(broile r) Non –egg laying chickens Calves pigs	In drinking water	20 mg/kg X 4-7 days	Meat and offal: 14 days  Indications: CRD caused by Mycoplasma gallisepticum colibacillosis
Greece	NEW VET A.E Fleming 15 15123 Marousi Attikis GREECE	Nexyclin	Doxycycline hyclate	400 mg/g	Powder for oral solution	Chickens(broile r) Turkeys pigs	In drinking water	20 mg/kg	Meat and offal: 4 days  Indications: Respiratory infections caused by Mycoplasma gallisepticum,E.coli Pasteurella multocida,Chlamydia psittaci
Greece	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	Pulmodox	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens(broile r) Non –egg laying chickens Calves pigs	In drinking water	10 mg/kg X 3-5 days	Meat and offal: 9 days  Indications: Respiratory infections caused by Mycoplasma spp, E.coli, Haemophilus paragallinarum, Bordetella avium Enteritis caused by Clostridium perfringens and colinum
Greece	Nutri-Biomed Hellas LTD 1,V.Hugo &Chlois Metamorfosi Attikis 14452 Athens GREECE	Doxyveto	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens(broile r) Non –egg laying chickens Calves pigs	In drinking water	25 mg/kg X 3-5 days	Meat and offal: 9 days  Indications: Respiratory infections caused by Mycoplasma spp, E.coli, Haemophilus paragallinarum, Bordetella avium



Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									Enteritis caused by Clostridium perfringens and colinum
Greece	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycyclin 50 Dopharma	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens(broile r) Calves pigs	In drinking water	25 mg/kg X 3-5 days	Meat and offal: 9 days  Indications: Respiratory infections caused by Mycoplasma spp, E.coli, Haemophilus paragalinarum, Bordetella avium Enteritis caused by Clostridium perfringens and colinum
Greece	Durden Trading Limited 12,Kennedy Av. Nicosia CYPRUS	Doxycycline 150/Durden	Doxycycline hydrochloride	150 mg/g	Powder for oral solution	Chickens(broile r) Non –egg laying chickens Calves pigs	In drinking water	10 mg/kg X 3-5 days	Meat and offal: 4 days  Indications: Respiratory infections caused by Mycoplasma gallisepticum, E.coli, Haemophilus paragalinarum
Greece	AFOI TETOROU ABE 10 km National road Athens-Lamia 14451, Metamorfo si GREECE	Doxycycline 150/Afoi Tetorou	Doxycycline hydrochloride	150 mg/g	Powder for oral solution	Chickens(broile r) Non –egg laying chickens Calves pigs	In drinking water	10 mg/kg X 3-5 days	Meat and offal: 4 days  Indications: Respiratory infections caused by Mycoplasma gallisepticum, E.coli, Ha emophilus paragalinarum

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Spain	LAB. DR ESTEVE Avda Mare de Deu de Montserrat 221 08041 Barcelona SPAIN	DOX ESTEVE	Doxycycline hyclate	100 mg/g	Water soluble powder	Poultry Pigs Bovine	Oral 3-5 days	20 mg / Kg/day	Meat and offal: 9 days  Indications: Infections caused by Mycoplasma spp (Mycoplasmosis, CRD) or Pasteurella multocida (Pasteurellosis).  Meat and offal: Poultry: 5 days Turkeys: 7 days colibacillosis, C.R.D., micoplasmosis.
Spain	S.P. Veterinaria SA Crt. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	DOXI 100 mg/ml POLVO ORAL	Doxycycline hyclate	10 g/ 100 g	Water soluble powder	Poultry Turkeys Pigs	Oral 3-5 days (Poultry and turkeys) 5 days (Pigs)	50 – 100 mg/l drinking water/day (poultry and turkey) 10 mg/kg/day (pigs)	Meat and offal:  Broilers: 5 days Turkeys: 7 days Pigs: 4 days
Spain	FATRO URIACH VETERINARIA, S.L. Constitucion, 1 08960 Sant Just Desvern SPAIN	DOXIDOL	Doxycycline hyclate	10 g/ 100 g	Water soluble powder	Poultry Pigs	Oral 3-5 days	7.5 – 15 mg/kg/day	Meat and offal: 7 days  Indications: Colibacillosis CRD
Spain	DIVASA- FARMAVIC, S.A. CTRA. SANT HIPOLIT, KM. 71 08503 GURB – VIC SPAIN	DOXIVET 20	Doxycycline hyclate	200 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	10 - 20 mg/Kg/day	Meat and offal: 7 days  Indications: Colibacillosis, CRD, Micoplasmosis

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Spain	MEVET, S. A. POLIGONO INDUSTRIAL EL SEGRE, PARCELA409-410 25191 L�rida SPAIN	DOXICIVALL POLVO	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	Meat and offal: 4 days  Indications: Colibacillosis, CRD, Mycoplasmosis
Spain	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	HIPRADOXI-S	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 5 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	LAMONS, S.A. POL.IND.MECANOV A, NAVES 27-28 25191 LLEIDA SPAIN	DOXICICLINA 10 % LAMONS	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 5 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	HIPRADOXI-P	Doxycycline hyclate	100 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/Kg/day	Meat and offal: 5 days  Indications: colibacillosis, C.R.D., and associated infections
Spain	POLICHEM, S.A. Ctra. Reus- Cambrils, Km. 3 43206 Reus SPAIN	DOXICHEM	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Spain	SUPER ´S DIANA, S.L Ctra. Barcelona - Ripoll, Km 17 08150 Parets del Valles SPAIN	DOXBRON	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	COTECNICA - COOPERATIVA TECNICA AGROPECUARIA Ctra. N II KM 494,5 25250 Bellpuig (Lerida) SPAIN	DOXICICLINA 500 USO VETERINARIO COTECNICA	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	CENAVISIA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	LAFIDOX POLVO ORAL	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	LABORATORIOS SYVA, S.A. PARROCO PABLO DIEZ, 49-57 24010 TROBAJO DEL CAMINO SPAIN	SYVADOX 10 %	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	INVESA INTERNACIONAL, S.A. Esmeralda, 19 - 4º 08950 ESPLUGUES DE LLOBREGAT SPAIN	DX-10	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Spain	CENAVIS, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	DOXICICLINA 500 GANADEXIL	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Turkeys	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	DIVASA- FARMAVIC, S.A. CTRA. SANT HIPOLIT, KM. 71 08503 GURB – VIC SPAIN	DOXIVET 5	Doxycycline hyclate	50 mg/g	Water soluble powder	Poultry Turkeys	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	INDUSTRIAL VETERINARIA S.A. Esmeralda, 19 - 4º 08950 ESPLUGUES DE LLOBREGAT SPAIN	DOXINYL	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	JAER, S.A. Barcelona, 411 08620 San Vicens del Horts SPAIN	MASTERMIX DOXICICLINA	Doxycycline hyclate	50 mg/g	Water soluble powder	Poultry Turkeys	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	KARIDOX	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pig	Oral 3-5 days	10 - 20 mg/Kg/day	Meat and offal: 7 days  Indications: C.R.D., micoplasmosis

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Spain	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	SOLDOXIN	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pig	Oral 3-5 days	10 - 20 mg/Kg/day	Meat and offal: 7 days  Indications: C.R.D., micoplasmosis
Spain	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	CALIERDOXINA 50 % P O	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 5 days	20 mg/kg/day	Meat and offal: 7 days  Indications: C.R.D., micoplasmosis
Spain	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	GANAMIX DOXICICLINA 50 % P O	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 5 days	20 mg/kg/day	Meat and offal: 7 days  Indications: C.R.D., micoplasmosis
Spain	S.P. Veterinaria SA Crta. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	HIDRODOX 10 %	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
Spain	VIRBAC ESPAÑA, S.A. Angel Guimera, 179-181 08950 Esplugues de Llobregat SPAIN	PULMODOX P.O.S.	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: C.R.D., micoplasmosis

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Spain	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	DILUDOX	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption  Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Spain	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	DOXICICLINA CALIER 500 mg/g	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	Meat and offal: 6 days  Indications: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum
Spain	LABORATORIOS MAYMO, S.A. Via Augusta, 302 08017 Barcelona SPAIN	MAYDOX PS	Doxycycline hydrochloride	50 mg/g	Water soluble powder	Poultry Turkeys	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days  Indications: colibacillosis, C.R.D., micoplasmosis
France	COOPHAVET Saint Herblon 44150 Ancenis FRANCE	RONAXAN P.S. 5 %	Doxycycline hyclate	50 mg/g	Water soluble powder	Turkey Porcine Broilers Calves	Prevention 1 - 3 days  Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey : 6 days Broilers : 4 days  Indications: Broilers and turkey : Preventive and treatment of infections in respiratory system

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
France	FRANVET ZI d'Etriche-Route d'Avire BP 103 49500 Segré Cedex FRANCE	DOXY 5 FRANVET	Doxycycline hyclate	50 mg/g	Water soluble powder	Turkey, Porcine Hens Calves	Prevention 1 - 3 days  Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey : 6 days Hens : 4 days  Indications: Prevention and treatment of infections in respiratory system
France	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	PULMODOX P.O.S. 5 %	Doxycycline hyclate	50 mg/g	Water soluble powder	Porcine Calves Poultry	Prevention 1 - 3 days  Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey : 6 days Hens : 4 days  Indications: Prevention and treatment of infections in respiratory system
France	Sogeval Laboratoires 200 route De Mayenne 53 022 Laval Cedex FRANCE	DOXYVAL 5 %	Doxycycline hyclate	50 mg/g	Water soluble powder	Turkey Porcine Broilers Calves	Prevention 1 - 3 days  Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey : 6 days Hens : 4 days  Indications: Prevention and treatment of infections in respiratory system
France	Laboratoires Biove 3 rue de Lorraine 62510 Arques FRANCE	ACTI DOXY 5	Doxycycline hyclate	50 mg/g	Water soluble powder	Dindon Porcine Broilers Calves	Prevention 1 - 3 days  Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey : 6 days Hens : 4 days  Indications: Prevention and treatment of infections in respiratory system
France	Ceva Sante Animale France La Balastiere 33501 Libourne Cedex FRANCE	DOXYVIT	Doxycycline hyclate	50 mg/g	Water soluble powder	Turkeys Porcine Broilers Calves	Prevention 1 - 3 days  Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey : 6 days Hens : 4 days  Indications: Prevention and treatment of infections in respiratory system



Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
France	Noe 10 rue Clement Ader ZA Le Patis 78120 Rambouillet FRANCE	COMPOMIX V DOXYCYCLINE	Doxycycline hyclate	50 mg/g	Water soluble powder	Dindon Porcine Broilers Calves	Prevention 1 - 3 days  Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey : 6 days Hens : 4 days  Indications: Prevention and treatment of infections in respiratory system
France	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	SOLDOXIN 100 MG/ML SOLUTION BUVABLE POUR POULES POULETS ET PORCINES	Doxycycline hyclate	100 mg/ml	Oral solution	Porcine Hens Broilers	CHICKEN (broilers): 10 - 20 mg of doxycycline / kg bw / day	3 - 5 days	Indications: CHICKENS (BROILERS) Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.
France	Laborartorios Karizoo S.A. Pol. Ind. La Borda c/Mas Pujades 11-12 Caldes de Montbui 08140 SPAIN	DOXYSOL 10 %	Doxycycline hyclate	100 mg/ml	Oral solution	Porcine Hens Broilers	CHICKEN (broilers): 10 - 20 mg of doxycycline / kg bw / day	3 - 5 days	Indications: CHICKENS (BROILERS). Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.
France	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HYDRODOXX 500 MG/G POUDRE POUR ADMINISTRATIO N DANS L'EAU DE BOISSON POUR POULETS ET PORCS	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption  Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									gallisepticum.
France	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	DOXYCYCLINE CALIER 500 MG/G POUDRE POUR ADMINISTRATIO N DANS L'EAU DE BOISSON POUR POULETS ET PORCINS	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	Meat and offal: 6 days  Indications: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum
Hungary	COOPHAVET Saint Herblon 44150 Ancenis FRANCE	Ronaxan P.S. 5 % oldható por	Doxycycline hyclate	5 g/100 g	Powder for oral solution	Chicken	Chicken younger than 2 weeks: 1 g powder/1 litre of drinking water/day. Chicken older than 2 weeks: 2 g powder/1 litre of drinking water.	10 mg doxycycline/ kg bw/day, for 3-5 days.	Meat and offal: 4 days  Indications: For the treatment of CRD and Mycoplasma diseases, and other infections
Hungary	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50 % WSP	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	500 g product dissolved in 1000 litre of drinking water.	25 mg doxycycline/ kg bw/day, for 3-5 days.	Meat and offal: 4 days  Indications: For the treatment and control of chicken respiratory diseases

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Hungary	Kon-Pharma GmbH. 30625 Hannover GERMANY	Doxy 50 % por belsőleges oldathoz	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken, turkey	Chicken: 500 mg product dissolved in 1 litre of drinking water. Turkey: 400 mg product/ 1 litre of drinking water	30 mg doxycycline/ kg bw/day, for 5 days.	Meat and offal: Chicken and turkey: 11 days.
Hungary	V.M.D. Állatgyógyászati Kft. 1093 Budapest HUNGARY	Doxyveto-50	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	Continuous treatment: 0.2 g product/1 litre of drinking water. Pulse treatment: calculated amount of the product should be dissolved in the drinking water consumed during 8 hours.	10 mg doxycycline/ kg bw/day, for 5 days.	Meat and offal: 10 days  Indications: For the treatment of CRD and pasteurellosis; synovitis in turkey.
Hungary	Novartis Animal Health d.o.o. Verovskava 57 1000 Ljubljana SLOVENIA	Doxyril 50 % por belsőleges oldathoz	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	5 g product/100 kg bw/day, dissolved in the drinking water.	25 mg doxycycline/ kg bw/day, for 3-5 days.	Meat and offal: 6 days  Indications: For the treatment of CRD, pasteurellosis, colibacillosis, Haemophilus and Clostridium infections
Hungary	Animal-Med Kft. 1029 Budapest HUNGARY	Anidox 10 % por belsőleges oldathoz	Doxycycline hyclate	100 mg/g	Powder for oral solution	Chicken	1000 g product dissolved in 1000 litre of drinking water.	10 mg doxycycline/ kg bw/day, for 5 days.	Meat and offal: 12 days  Indications: For the treatment of mycoplasmosis, pasteurellosis, colibacillosis.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Hungary	Animal-Med Kft. 1029 Budapest HUNGARY	Anidox 100 % por belsőleges oldathoz	Doxycycline hyclate	1000 mg/g	Powder for oral solution	Chicken	100 g product dissolved in 1000 litre of drinking water.	10 mg doxycycline/ kg bw/day, for 5 days.	Meat and offal: 12 days  Indications: For the treatment of infections caused by: Mycoplasma gallisepticum, E. coli, Bordetella avium, Haemophilus paragallinarum and Pasteurella multocida
Hungary	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, Hungary	Doxyprim 40 % vízoldékony pulvis	Doxycycline hyclate	400 mg/g	Powder for oral solution	Chicken, turkey	Continuous treatment: 1 g product/3-6 litre of drinking water. Pulse treatment: calculated amount of the product should be dissolved in the drinking water consumed during 4-8 hours.	10-20 mg/doxycycli ne/kg bw/day, for 3-5 days.	Meat and offal: 4 days  Indications: For the treatment of infections caused by: Mycoplasma gallisepticum, E. coli, Bordetella avium, Haemophilus paragallinarum and Pasteurella multocida
Hungary	CHEMIFARMA S.p.A Via Don Eugenio Servadei 16 47100 Forlì ITALY	Doxifarm 50 % WSP	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	40 g product/100 kg bw/100 litre of drinking water.	20 mg doxycycline/ kg bw/day, for 5 days.	Meat and offal: 5 days  Indications: For the treatment of CRD, mycoplasmosis, synovitis, colibacillosis, ileitis (necrotic and ulcerosus), haemophilus-infection.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Hungary	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	Pulmodox 50 % WSP	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	500 g product dissolved in 1000 litre of drinking water.	25 mg doxycycline/ kg bw/day, for 3-5 days.	Meat and offal: 4 days  Indications: For the treatment of CRD and other respiratory diseases, caused by: Mycoplasma spp., Pasteurella spp., E. coli, and Chlamydia psittaci.
Hungary	Phylaxia Pharma Zrt. 8000 Székesfehérvár HUNGARY	Doxyphyl SP	Doxycycline hyclate	300 mg/g	Powder for oral solution	chicken, turkey	40 g product/1200 kg bw/day, calculated amount of the product should be dissolved in the drinking water consumed during 3 hours.	10 mg doxycycline/ kg bw/day, for 3-5 days.	Meat and offal: chicken: 7 days, turkey: 10 days.  Indications: For the treatment of respiratory infections caused by Mycoplasma spp., E. coli, Haemophilus paragallinarum, Bordetella avium, and ileitis caused by Clostridium perfringens and Cl. colinum.
Hungary	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50 % pulvis	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	Dissolved in the drinking water.	10 mg/kg bw and 20 mg/kg bw/day, for 4 days.	Meat and offal: chicken treated with 10 mg/kg bw: 5 days, chicken treated with 20 mg/kg bw: 12 days.  Indications: For the treatment of respiratory and other diseases caused by doxycycline-sensitive bacteria.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Hungary	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	Oridox 100 mg/ml belsőleges oldat	Doxycycline hyclate	100 mg/ml	Concentrate for oral solution	Chicken	100 mg/ml oral concentrate dissolving in the drinking water.	10-20 mg/doxycycli ne/kg bw/day, for 3-5 days.	Meat and offal: 7 days  Indications: For the treatment of respiratory and other diseases caused by doxycycline-sensitive bacteria.
Hungary	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox 100 mng/ml belsőleges oldat	Doxycycline hyclate	100 mg/ml	Concentrate for oral solution	Chicken	100 mg/ml oral concentrate dissolving in the drinking water.	10-20 mg/doxycycli ne/kg bw/day, for 3-5 days.	Meat and offal: 7 days  Indications: For the treatment and prevention of CRD or other Mycoplasma diseases
Hungary	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	Doxyden belsőleges oldat	Doxycycline hyclate	200 mg/ml	Concentrate for oral solution	Chicken	1 ml/20 kg bw/day dissolved in the drinking water.	10 mg doxycycline/ kg bw/day, for 5 days.	Meat and offal: 5 days  Indications: For the treatment of CRD, mycoplasmosis and colibacillosis.
Hungary	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, Hungary	Doxyvit 100 WSP	Doxycycline hydrochloride	100 mg/g	Powder for oral solution	Chicken, turkey, goose	Continuous treatment: 1 g product/1 litre of drinking water. Pulse treatment: calculated amount of the product should be dissolved in the drinking water consumed during 6-8 hours.	10 mg/doxycycli ne/kg bw/day, for 3-5 days.	Meat and offal: Chicken, turkey, goose 7 days  Indications: For the treatment of respiratory and enteric diseases in broiler chickens

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Hungary	Industria Italiana Integratori TREI S.p.A. Viale Corassori 62 41100 Modena ITALY	Doxipan 20 WSP	Doxycycline hydrochloride	200 mg/g	Powder for oral solution	Chicken	5-7.5 g product dissolving in 10 litre of drinking water.	10-15 mg/doxycycli ne/kg bw/day, for 3-5 days.	Meat and offal: 5 days  Indications: For the treatment of CRD, mycoplasmosis, synovitis, colibacillosis, ileitis (necrotic and ulcerosus), haemophilus-infection.
Hungary	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	Hipradoxi-S oral solutio	Doxycycline hydrochloride	100 mg/ml	Concentrate for oral solution	Chicken	100 mg/ml oral concentrate dissolving in 1 litre of drinking water.	10 mg doxycycline/ kg bw/day, for 5 days.	Meat and offal: 5 days  Indications: For the treatment and prevention of CRD or other Mycoplasma diseases
Ireland	S.P. Veterinaria SA Crtá. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	DOXIVEX 10% Concentrate for oral solution.	Doxycycline hyclate	100mg/ml	Concentrate for oral solution	Chickens (broilers) and Pigs	For oral administration via the drinking water. for 3-5 days	Chickens (broilers) : 50 - 100 mg Doxycycline / litre of drinking water / day (equivalent to 0.5 - 1.0 ml DOXIVEX 10 % / litre of drinking water / day) for 3-5 days	Meat & offal: 7 days. Not permitted for use in laying birds producing eggs for human consumption  Indications: Treatment of colibacillosis, chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Ireland	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	Aquadoxx 500 mg/g water- soluble powder	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption  Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Italy	CEVA VETEM S.P.A. Via Colleoni n.15 20041 Agrate Brianza (Milano) ITALY	DOXICICLINA 20% CEVA VETEM	Doxycycline hyclate	Doxycycline 200 g. per 1 kg. of product	Water soluble powder	broiler, turkey	drinking water	Broiler, Turkey: 1 g / 10 kg b.w per 5 days.	Meat and offal: broiler: 7 days turkey : 8 days  Indications: Broiler: Treatment of chronic respiratory disease Turkey: Treatment of infective synusitis
Italy	CHEMIFARMA S.p.A Via Don Eugenio Servadei 16 47100 Forli ITALY	DOXICICLINA 50 % CHEMIFARMA	Doxycycline hyclate	Doxycycline 500 g. per 1 kg. of product	Water soluble powder	broiler, swine	drinking water	Broiler: 20 mg of doxycycline / per 1 kg b.w.(per 3 - 5 days) Swine: 20mg of doxycycline / per 1 kg b.w per 3 - 5 days	Meat and offal: broiler: 6 days Do not use in hens producing eggs for human consumption. swine : 5 days  Indications: Broiler: Chronic respiratory disease caused by: Pasteurella soo, Mycoplasma spp, Haemophilus gallinarum, Bordetella avium, ans Chlamidia psittaci.



Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Italy	SINTOFARM S.P.A. Via Togliatti n.5 42016 Guastalla (Reggio Emilia) ITALY	DOXIFARM 50%	Doxycycline hyclate	Doxycycline hyclate 500 mg. (equivalent to 433,3 mg of Doxycycline) per 1 g. of product	Water soluble powder	broiler, swine	drinking water	Broiler: 25 mg of doxycycline hyclate/ per 1 kg b.w.(per 3 - 5 days) Swine: 20 mg of doxycycline hyclate/per 1 kg b.w per 5 days	Meat and offal: broiler: 6 days Do not use in hens producing eggs for human consumption. swine : 4 days  Indications: Broiler: Treatment and control of respiratory disease caused by Mycoplasma spp, Haemophilus paragallinarum, Escherichia coli. Enteritis caused by Clostridium perfringens and Clostridium colinum
Italy	INDUSTRIA ITALIANA INTEGRATORI TREI SpA Via Affarosa n.4 42010 Rio Saliceto (Reggio Emilia) ITALY	DOXIPAN 54	Doxycycline hyclate	Doxycycline 500 g. per 1 kg. of product	Water soluble powder	broiler, turkey, swine	drinking water	Broiler: 10mg of doxycycline / 1 kg b.w. Turkey: 20mg of doxycycline / 1 kg b.w. Swine: 10mg of doxycycline /1 kg b.w per 5 days	Meat and offal: broiler: 3 days Do not use in hens producing eggs for human consumption. turkey : 10 days swine : 4 days  Indications: Broiler:Chronic respiratory disease. Turkey:Respiratory and joints syndroms caused by Mycoplasmas and/or Staphylococcus
Italy	INTERVET ITALIA S.R.L. Via W. Tobagi n.7 20068 Peschiera Borromeo (Milano) ITALY	NAXOCET	Doxycycline hyclate	Doxycycline hyclate 500 mg. per 1 g. of product	Water soluble powder	broiler	drinking water	Broiler: 20mg of doxycycline hyclate/ 1 kg b.w. per 5 days.	Meat and offal: broiler: 8 days Do not use in hens producing eggs for human consumption.  Indications: Chronic

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									respiratory disease caused by Mycoplasma spp.
Lithuania	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	DOXYCYCLINE 50 %, geriamieji milteliai	Doxycycline hyclate	500 mg/g	Oral powder	Calves, pigs and poultry.	4–7 days with drinking water	Poultry: 40 mg per 1 kg of body weight, or 200–400 g per 1.000 litres of drinking water, during 4–7 days.	Meat and offal: Poultry – 4 days. Do not use in animals producing eggs for human consumption.  Indications: for the treatment of poultry: ornithosis, caused by Chlamydia psittaci, colibacteriosis caused by E. coli, CRD caused by Mycoplasma gallisepticum
Lithuania	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, Hungary	DOXYPRIM 40 % geriamieji milteliai	Doxycycline hyclate	400 mg/g	Oral powder	Chickens, turkeys and pigs.	Should be administered for a period of 5 days in chicken and turkeys together with drinking water.	Chicken and turkeys: 10– 20 mg doxycycline hyclate per 1 kg of body weight daily, administrate d pulse dosed when the daily requirement is given in limited quantity of water to be consumed by the birds within 4–8 hours or supplied	Meat and offal: Edible tissues of chickens and turkeys – 4 days.  Indications: In chickens and turkeys indications include: chronic respiratory diseases (Mycoplasma gallisepticum, E. coli), airsacculitis (Mycoplasma meleagridis), infectious synovitis (Mycoplasma synoviae), colibacillosis (E. coli), fowl cholera (Pasteurella multocida), turkey

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
								continuously as 67–133 mg ml Doxycycline hyclate per 1 litre of drinking water.	bordetellosis (Bordetella avium), infectious coryza (Haemophilus paragallinarum), necrotic enteritis (Clostridium perfringens), chlamydiosis (Chlamydia psittaci).
Lithuania	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	SOLUDOX 50 %, geriamieji milteliai	Doxycycline hyclate	500 mg/g	Oral powder	Pigs and chickens.	Should be administered orally with drinking water for a period of 4 days.	Chickens: 10* mg doxycycline hyclate per 1 kg of body weight daily for 4 days; 20* mg doxycycline hyclate per 1 kg of body weight daily for 4 days. * The highest dose is recommende d in case of infections caused by strains which are moderately susceptible (MIC up to 2 µg/ml), whilst the	Indications: For the treatment of infections caused by micro- organisms susceptible to doxycycline, such as Pasteurella multocida and Ornithobacterium rhinotracheale in chickens.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
								lowest dosage maybe used for (highly) susceptible strains (MIC up to 0.5–1.0 µg/ml)	
The Netherlands	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline- hyclaat 50%	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Calves, non- egg laying chickens and turkeys.	Non-egg laying chickens and turkeys: oral via drinking water. bodyweight per day for 4-7 days.	Non-egg laying chickens and turkeys: 20 mg doxycycline hyclate per kg	Turkeys - meat: 28 days. Non-egg laying chickens - meat: 14 days.  Indications: Turkeys:- Ornithosis caused by Chlamydia psittaci - Colibacillosis caused by E. coli - CRD caused by Mycoplasma gallisepticum  Non-egg laying chickens Colibacillosis caused by E. coli
The Netherlands	Dutch Farm Veterinary Pharmaceuticals B.V. Veemweg 1 3771 MT Barneveld THE NETHERLANDS	Doxycycline 20% W.O.	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate	Powder for oral solution	Non-egg laying chickens	Oral via drinking water. for 3 days	10 mg doxycycline hyclate per kg bodyweight per day for 3 days	Meat: 7 days.  Indication non-egg laying chickens: - Polyarthrititis caused by Mycoplasma synoviae; - CRD, amongst others caused by Mycoplasma gallisepticum; - Colibacillosis caused by Escherichia coli

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
The Netherlands	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline- hyclaat 20%	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate.	Powder for oral solution	Calves, pigs, chickens and turkeys.	Chickens and turkeys: oral via drinking water for 4-7 days.	Chickens and turkeys: 20 mg doxycycline hyclate per kg bodyweight	Turkeys - meat: 28 days. Chickens - meat: 14 days, eggs: 10 days.  Indication turkeys: - Ornithosis caused by Chlamydia psittaci - Colibacillosis caused by E. coli - CRD caused by Mycoplasma gallisepticum Indication  Indication chickens: - Colibacillosis caused by E. coli - CRD caused by Mycoplasma gallisepticum
The Netherlands	Dutch Farm International B.V. Nieuw Walden 112 1394 PE Nederhorst den Berg THE NETHERLANDS	Doxycycline 20% W.O.	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate.	Powder for oral solution	Non-egg laying chickens (broilers).	Oral via drinking water.	10 mg doxycycline hyclate per kg bodyweight per day for 3 days.	Meat: 7 days. Do not administer to chickens producing eggs for human consumption. Indication non-egg laying chickens: - Polyarthrititis caused by Mycoplasma synoviae; - CRD, amongst others caused by Mycoplasma gallisepticum; - Colibacillosis caused by Escherichia coli.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
The Netherlands	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline- hyclaat 50%	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Calves, pigs, non-egg laying chickens.	Non-egg laying chickens: oral via drinking water. for 4-5 days.	Non-egg laying chickens: 20 mg doxycycline hyclate per kg bodyweight per day for 4-5 days.	Non-egg laying chickens - meat: 14 days.  Indication non-egg laying chickens: - Colibacillosis caused by E. coli - CRD caused by Mycoplasma gallisepticum
The Netherlands	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50% WSP	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Non-egg laying chickens.	Non-egg laying chickens: oral via drinking water.	Non-egg laying chickens: 25 mg doxycycline hyclate per kg bodyweight per day for 3-5 days.	Non-egg laying chickens - meat: 6 days.  Indication non-egg laying chickens: - Respiratory infections caused by Mycoplasma spp (M. gallisepticum, M. synoviae en M. meleagridis), E. coli and Haemophilus paragallinarum; - Enteritis caused by Clostridium perfringens en Clostridium colinum.
The Netherlands	Interchemie Werken De Adelaar BV Hosterweg 26a 5811 Ccastenray THE NETHERLANDS	Doxy WS	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate.	Powder for oral solution	Non-egg laying chickens (broilers).	Oral via drinking water.	10 mg doxycycline hyclate per kg bodyweight per day for 3 days.	Meat: 7 days.  Indication non-egg laying chickens: - Polyarthrititis caused by Mycoplasma synoviae; - CRD, amongst others caused by Mycoplasma gallisepticum;

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									- Colibacillosis caused by Escherichia coli.
The Netherlands	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50%	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Pigs and non-egg laying chickens.	Non-egg laying chickens: oral via drinking water.	Non-egg laying chickens: - Pasteurellosis caused by Pasteurella multocida: 10 mg doxycycline hyclate per kg bodyweight per day for 3-4 days. infections caused by Ornithobacterium rhinotracheale (ORT): 20 mg doxycycline hyclate per kg bodyweight per day for 3-4 days	Non-egg laying chickens:- Pasteurellosis – meat: 5 days.- ORT – meat: 12 days.  Do not administer to chickens producing eggs for human consumption

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
The Netherlands	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Doxyfar 50%	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Pigs and non-egg laying chickens.	Non-egg laying chickens: oral via drinking water.	Non-egg laying chickens: <i>Pasteurellosis</i> caused by <i>Pasteurella multocida</i> : 10 mg doxycycline hyclate per kg bodyweight per day for 3-4 - Respiratory infections caused by <i>Ornithobacterium rhinotracheale</i> (ORT): 20 mg doxycycline hyclate per kg bodyweight per day for 3-4 days	Non-egg laying chickens:- Pasteurellosis – meat: 5 days. - ORT – meat: 12 days. Do not administer to chickens producing eggs for human consumption.
The Netherlands	Kepro B.V. Maagdenburgstraat 38 7421 ZE Deventer THE NETHERLANDS	Doxy 200 W.S.P.	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate.	Powder for oral solution	Non-egg laying chickens (broilers).	Oral via drinking water.	10 mg doxycycline hyclate per kg bodyweight per day for 3 days.	Meat: 7 days. Do not administer to chickens producing eggs for human consumption.  Indication: - Polyarthritis caused by <i>Mycoplasma synoviae</i> ; - CRD, amongst others caused by <i>Mycoplasma gallisepticum</i> ;



Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									- Colibacillosis caused by Escherichia coli.
The Netherlands	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50%	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Pigs and non-egg laying chickens.	Non-egg laying chickens: oral via drinking water.	Non-egg laying chickens: 10 mg doxycycline hyclate per kg bodyweight per day for 3-4 days.	Non-egg laying chickens – meat: 5 days.  Indication: Pasteurellosis caused by Pasteurella multocida
The Netherlands	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox 10% Oral Solution	Doxycycline hyclate	Per ml: 100 mg doxycycline (as hyclate).	Oral solution	Pigs and chickens (broilers).	Chickens (broilers): oral via drinking water.	Chickens (broilers): 10-20 mg doxycycline per kg bodyweight per day for 3-5 days	Chickens (broilers) - meat: 7 days.  Indication: Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.
The Netherlands	Huvepharma, Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx 500 mg/g	Doxycycline hyclate	Per g: 500 mg doxycycline hyclate.	Powder for oral solution	Pigs and chickens (broilers).	Chickens (broilers): oral via drinking water.	Chickens (broilers): 20 mg doxycycline per kg bodyweight per day for 3-5 days	Chickens (broilers) - meat: 6 days.  Do not administer to chickens producing eggs for human consumption.
The Netherlands	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	Soldoxin	Doxycycline hyclate	Per ml: 100 mg doxycycline (as hyclate).	Oral solution	Pigs and chickens (broilers).	Chickens (broilers): oral via drinking water.	Chickens (broilers): 10-20 mg doxycycline per kg bodyweight per day for 3-5 days	Chickens (broilers) - meat: 7 days.  Do not administer to chickens producing eggs for human consumption.  Indication: Prevention and treatment of CRD

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									and mycoplasmosis caused by microorganisms sensitive to doxycycline.
Poland	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxymed 50	Doxycycline hyclate	500 mg/g	powder for oral solution	chickens	250-500 ml product/ 1000 liter of drinking water	25 mg doxycyclini hyclate / kg bw/ day for 3-5 days	Meat and offal: 4 days. Not for use in laying hens.
Poland	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50%	Doxycycline hyclate	500 mg/g	Oral powder	chickens	2 g product/ 100 kg bw/ day in case of Pasteurellosis or 4 g product / 100 kg bw/ day in case of <i>Ornithobacterium rhinotracheale</i> infection.	10 mg doxycyclini hyclate/ kg bw/ day in case of Pasteurellosi s or 20 mg doxycyclini hyclate/ kg bw/ day in case of <i>Ornithobact erium rhinotracheal e</i> infection for 3-4 days	Meat and offal: 5 days in case of Pasteurellosis. 12 days in case of <i>Ornithobacterium rhinotracheale</i> infection. Not for use in laying hens.
Poland	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	Hipradoxi-S	Doxycycline hyclate	100 mg/ml	Oral solution	chickens	0,5- 1,0 ml product/ 1 liter of drinking water	50-100 mg doxycyclini hyclate/ 1 liter of drinking water for 3- 5 days	Meat and offal: 5 days. Not for use in laying hens.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Poland	Oropharma n.v. Dijkstraat 30 9140 Temse BELGIUM	Ornicure	Doxycycline hyclate	300 mg/4 g	Oral powder	pigeon, parrot	pigeon: 4g product/ 2 liters of drinking water, parrot: 4 g product/ 0,5 liter	15 mg/ kg bw./ day for 5 days, in case of parrot desease or clinical ornitosis for 3-4 weeks	Not for use in pigeons for human consumption.
Poland	Novartis Animal Health d.o.o. Verovskava 57 1000 Ljubljana SLOVENIA	Doxiryl 50%	Doxycycline hyclate	500 mg/g	powder for oral solution	chicken (broiler)	25 mg doxycyclini hyclate / kg bw/ day	25 mg doxycyclini hyclate / kg bw/ day for 3-5 days	Meat and offal: 4 days. Not for use in laying hens.
Poland	S.P. Veterinaria SA Crtá. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	Doxivex 10%	Doxycycline hyclate	100 mg/ml	Concentrate for oral solution	chicken (broiler)	05-1,0 ml product/ 1 liter of drinking water	50-100 mg doxycyclini hyclas/ 1 liter of drinking water/ day for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7ª Edificio Trade 08028 Barcelona SPAIN	Oridox	Doxycycline hyclate	100 mg/ml	Oral solution	chicken (broiler)	05-1,0 ml product/ 1 liter of drinking water	10 -20 mg doxycyclini hyclas/ kg bw/ day for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox	Doxycycline hyclate	100 mg/ml	Oral solution	chicken (broiler)	05-1,0 ml product/ 1 liter of drinking water	10 -20 mg doxycyclini hyclas/ kg bw/ day for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. Grójecka 6 05-651 Drwalew POLAND	Doxymina 20%	Doxycycline hyclate	200 mg/g	Oral powder	chicken	25-50 g product/ 1 liter of drinking water	10 mg doxycyclini hyclate/ kg bw/ day, for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	V.M.D.n.v./ s.a. Hoge Muew 900 2370 Arendonk BELGIUM	Doxycycline hyclate 50%	Doxycycline hyclate	500 mg	powder for oral solution	chicken	25 mg doxycyclini hyclate / kg bw/ day	25 mg doxycyclini hyclate / kg bw/ day for 3-5 days	Meat and offal: 5 days. Not for use in laying hens.
Poland	INDUSTRIAL VETERINARIA S.A. Esmeralda, 19 - 4º 08950 ESPLUGUES DE LLOBREGAT SPAIN	Doxinyl	Doxycycline hyclate	100 mg/ml	Oral solution	chicken (broiler)	0,5- 1,0 ml product/ 1 liter of drinking water/ day	50-100 mg doxycyclini hyclate/ 1 liter of drinking water for 3- 5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	Biofaktor Sp. z o.o.(Skierniewice) Czysta 4 96-100 Skierniewice POLAND	Doxycyclinum 20%	Doxycycline hyclate	200 mg/ml	powder for oral solution	chicken, turkey	25-50 g product/ 1 liter of drinking water	10 mg doxycyclini hyclate/ kg bw/ day, for 3-5 days	1 Meat and offal: 4 days. Not for use in laying hens.
Poland	Tarchomińskie Zakłady Farmaceutyczne Polfa S.A. Fleminga 2 03-176 Warszawa POLAND	Doxycyclinum wet proszek	Doxycycline hyclate	200 mg/g	powder for oral solution	chicken, turkey,	25-50 g powder/ 1 liter of drinking water	10 mg doxycyclini hyclate/ kg bw/ day, for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	Sogeval Laboratoires 200 route De Mayenne 53 022 Laval Cedex FRANCE	DOXYVAL 20%	Doxycycline hyclate	20 g/ 100 g	Oral powder	chicken (broiler)	5 g produkt/ 100 kg bw/ day or 0,5 g / 1 liter of drinking water	10 mg doxycyclini hyclate/ kg bw/ day, for 3-5 days	Meat and offal: 4 days. Not for use in laying hens.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Poland	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 15%	Doxycycline hyclate	150 mg/g	Oral powder	chicken, turkey, pigeon ,cage bird	10-20 mg doxycyclini hyclas/ kg bw/ day	10-20 mg/ kg bw/ day for 3-5 days. In case of <i>Chlamydia psittaci</i> infection for 30-45 days.	Meat and offal: 7 days. Not for use in laying hens or in pigeons for human consumption.
Portugal	CEVA Saúde Animal –Produtos farmacêuticos e Imunológicos Lda. Ceva Saúde Animal Lda. Rua Doutor António Loureiro Borges 9/9ª 9º A Miraflores 1495-131 Algés PORTUGAL	DOXYPRIM 400 mg / g Pó para Solução Oral para Suínos, Frangos e Perus.	Doxycycline hyclate	Doxycycline hyclate 400 mg / g	Powder for oral solution	Swine, Chicken, Turkey	For oral administration in drinking water	Broilers and Turkeys: 20 mg Doxycycline hyclate/kg bw, for 5 days.	Chicken (Broilers) meat and offal: 5 days; Tukeys meat and offal:6 days;  Not permitted for use in laying birds producing eggs for human consumption
Portugal	DIVASA FARMAVIC DE PORTUGAL Produtos e Equipamentos Veterinários Lda. Parque Empresarial de Vialonga Armazém nº 21 Casal do Bagulho Granja de Alpriate 2625-607 Vialonga PORTUGAL	DOXYVET-10	Doxycycline hyclate	Doxycycline hyclate 10g; Bromexin Cloridrate 1g	Oral solution	Bovine (Calves), Swine, Broilers, Turkeys, Ovine, Goat (Kid)	For oral administration in drinking water	Broilers and Turkeys: 50- 100 mg/liter of water/day, for 3-5 days (Equivalent to 0,5-1 ml of DOXIVET- 10 / liter of water/day	Meat and offal: 5 days

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Portugal	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	VETADOXI 50	Doxycycline hyclate	Doxycycline hyclate 500 mg/g	Oral powder	Bovine (Calves), Swine and Birds	For oral administration in drinking water, milk or feed	25mg/Kg bw in birds; 200g/1000L water/day 3- 5 days; 500g/1000L drinking water birds	Meat and offal: 5 days; Not permitted for use in laying birds producing eggs for human consumption
Portugal	S.P. Veterinaria SA Crtá. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	Hidrodox 10% Concentrado para solução oral para aves (frangos de carne) e suínos	Doxycycline hyclate	Doxycycline (as hyclate) 100 mg	Concentrate for Oral Solution	Chickens (broilers) and swine	For oral administration in drinking water	Broilers: 50 – 100 mg Doxycycline hyclate/L drinking water/day (0,5-1,0 ml of VMP/ drinking water/day) 3-5 days.	Birds (Broilers) meat and offal: 7 days. Not permitted for use in laying birds producing eggs for human consumption
Portugal	Univete SA Rua D. Jerónimo Osório, 5 B 1400-119 Lisboa PORTUGAL	UNIDOXINA 200 mg/ml solução oral para suínos e aves	Doxycycline hyclate	Doxycycline (as hyclate) 200 mg	Oral solution	Chickens (broilers) and swine	For oral administration in drinking water	Broilers and Turkeys: 20 mg Doxycycline hyclate/kg bw, for 5 days.	Chicken (Broilers) meat and offal: 7 days. Not permitted for use in laying birds producing eggs for human consumption

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Romania	DELOS IMPEX' 96 SRL 17, Pictor Ștefan Luchian sector 2 Bucharest ROMANIA	Doxidem 20	Doxycycline hyclate	200 mg/ml doxycycline hyclate	Oral solution	Poultry (not for use in animals from which eggs are produced for human consumption)	Oral	- 75 ml of product/100 litres drinking water/day for 3-5 consecutive days in young poultry up to 4 weeks  '- 150 ml of product/100 litres drinking water/day for 3-5 consecutive days in adult poultry	Meat and offal: 28 days  Indications: Poultry For the treatment of mycoplasmosis, pasteurellosis, colibacillosis, staphylococcosis.  Chronic respiratory disease, infections caused by Pasteurella spp., Mycoplasma spp., Salmonella spp., E. coli., Haemophilus paragallinarium, Staphylococcus, hepatitis caused by Campylobacter and dermatitis.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Romania	DELOS IMPEX' 96 SRL 17, Pictor Ștefan Luchian sector 2 Bucharest ROMANIA	Doxidem 50	Doxycycline hyclate	500 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption)  Pigs	Oral (drinking water)	- 20-40 mg of product/kg body weight/day for 5 consecutive days , per os;  '- 200-300 g of product /1000 litres of drinking water for 5 consecutive days	Meat and offal: 28 days  Indications: Chronic respiratory disease, infections caused by Pasteurella spp., Mycoplasma spp., Salmonella spp., E. coli., Haemophilus paragallinarium, Staphylococcus , hepatitis caused by Campylobacter, dermatitis and other diseases caused by microorganisms sensitives to doxycycline.
Romania	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50% WSP	Doxycycline hyclate	500 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) Calves Pig	Oral (drinking water)	40 mg /kg of body weight or 200-400 g/1000 litres of drinking water for 4- 7 days	Meat and offal: Poultry 4 days  Indications: Ornithosis caused by Chlamydia psittaci in turkeys; '- Colibacillosis caused by E. coli in chickens and turkeys; '- CRD caused by Mycoplasma gallisepticum in chickens and turkeys;



Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Romania	FRANVET ZI d'Etriche-Route d'Avire BP 103 49500 Segré Cedex FRANCE	Doxy 5 Franvet	Doxycycline hyclate	50 mg/g doxycycline (as hyclate)	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) Calves Pig	Oral (drinking water or liquid feed)	1 g of product/1 litre drinking water/day for 3-5 days in poultry up to 2 weeks - 2 g of product/1 litre drinking water /day for 3-5 days in poultry over 2 weeks	Meat and offal: Poultry 4 days  Indications: For the prevention and treatment of respiratory infections caused by doxycycline sensitive microorganisms.
Romania	INDUSTRIA ITALIANA INTEGRATORI TREI SpA Via Affarosa n.4 42010 Rio Saliceto (Reggio Emilia) ITALY	Doxipan 20	Doxycycline hyclate	200 mg/g doxycycline hyclate	Water soluble powder	Poultry pig	Oral (drinking water)	5-7,5 g of product for every 10 litres of drinking water	Meat and offal: Poultry 5 days  Indications: Chronic respiratory disease and associated complications.
Romania	PHYLAXIA PHARMA LTD 1103 Budapest Gergely u.79 HUNGARY	Doxyphyl SP A.U.V.	Doxycycline hyclate	300 mg/g doxycycline hyclate	Water soluble powder	Poultry (chicken, hens, turkeys) v	Oral (drinking water)	10 mg/kg b.w. for 3-5 days or 100 mg of product/1 litre of drinking water	Chickens, hens: 7 days Turkey: 7 days (not for use in animals from which eggs are produced for human consumption)  Indications: For the prevention and treatment of several bacterial infections.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Romania	LABORATORIOS SYVA S.A. Avda. Parroco Pablo Diez, 49-57 24010 Leon SPAIN	Syvadox 10%	Doxycycline hyclate	100 mg/1 ml doxycycline (as hyclate)	Oral solution	Chickens (not for use in animals from which eggs are produced for human consumption)	Oral (drinking water)	50-100 mg doxycycline/ 1 litre of drinking water /day (equivalent to 0,5 – 1,0 ml of product/ 1litre of drinking water /day for 3-5 days	Chickens 7 days (not for use in animals from which eggs are produced for human consumption)  Indications: Colibacillosis, CRD, mycoplasmosis – caused by previously mentioned germs sensitive to doxycycline.
Romania	VMD Berendonk 74 2370 Arendonk BELGIUM	Doxyveto 50S	Doxycycline hyclate	500 mg/g doxycycline (as hyclate)	Water soluble powder	Poultry Swine calves lambs	Oral (drinking water or feed)	20 mg doxycycline/ kg b.w. /day in drinking water or 300 g of product/ 1000 litres of drinking water or 600 g /1000 kg of feed for 3-5 days	Poultry 8 days  Indications: CRD (Mycoplasma gallisepticum), Ornithosis (Chlamidia psittaci), Infectious synovitis (Mycoplasma synoviae), Fowl cholera (Pasteurella multocida).
Romania	CHEMIFARMA S.p.A Via Don Eugenio Servadei 16 47100 Forli ITALY	Doxiciclina 50%	Doxycycline hyclate	500 mg/g doxycycline	Water soluble powder	Broiler chickens swine	Oral (per os, drinking water or liquid feed)	40 g of product/100 kg b.w. (20 mg of doxycycline/ kg b.w) correspondin g to about 15-30 g of product/100 litres of water for 3- 5 days.	Broiler chickens 5 days  Indications: Chronic respiratory disease and other respiratory illnesses, specially produced by Pasteurella spp., Mycoplasma spp., Haemophilus gallinarium, Bordetella avium and Chlamidia psittaci.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Romania	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, Hungary	Doxiprim 40% Soluble Powder	Doxycycline hyclate	400 mg/g doxycycline hyclate	Water soluble powder	Chickens turkeys (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	20 mg doxycycline hyclate /kg b.w.	Chickens and turkeys 4 days (not for use in animals from which eggs are produced for human consumption)  Indications: treatment of respiratory, intestinal and systemic infections caused by doxycycline sensitive organisms: CRD (Mycoplasma gallisepticum, E. Coli), airsacculitis (Mycoplasma maleagris), infectious synovitis (Mycoplasma synoviae), fowl cholera (Pasteurella multocida), infectious coryza (Haemophilus paragallinarum), colibacillosis (E. Coli), turkeys bordetellosis (Bordetella avium), necrotic enteritidis (Clostridium perfringens), chlamydiosis (Chlamidia psittaci). Prevention of secondary bacterial infections due to stress conditions, vaccination, change of housing, transport.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Romania	Novartis Animal Health d.o.o. Verovskava 57 1000 Ljubljana SLOVENIA	Doxyril 50%	Doxycycline hyclate	500 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	25 mg doxycycline hyclate /kg b.w. during 3 to 5 consecutive days	Poultry 4 days (not for use in animals from which eggs are produced for human consumption)  Indication: Respiratory tract Infections caused by Mycoplasma spp. (M. gallisepticum, M. synoviae and M. melagris), E. coli, Haemophilus paragallinarum and Ornithobacterium rhinotracheale. Enteritidis caused by Clostridium perfringens and Clostridium colinum. Septicemia caused by Pasteurella multocida.
Romania	CEVA SANTE ANIMALE ROMANIA SRL 5 Chindiei , sector 4, Bucharest ROMANIA	Doxyvit 50% WSP	Doxycycline hyclate	500 mg/g doxycycline hyclate	Water soluble powder	Poultry (chickens and turkeys) (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	15 mg doxycycline /kg b.w. for 5 consecutive days or 2 g of product /10 litres drinking water and equivalent to 100 mg of doxycycline /litre of drinking water	Poultry (chickens and turkeys) 7 days (not for use in animals from which eggs are produced for human consumption)  Indications: Colibacillosis, CRD and mycoplasmosis, Clostridium perfringens, chlamydiosis, infectious coryza caused by Bordetella avium.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Romania	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox 100 mg/ml oral solution for use in drinking water for chickens and pigs	Doxycycline hyclate	100 mg/ml doxycycline (as hyclate)	Oral solution	Poultry (chickens) (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	10-20 mg doxycycline /kg b.w. for 3 - 5 days.	Poultry (chickens) 7 days (not for use in animals from which eggs are produced for human consumption)  Indications: Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.
Romania	S.C. VIM SPECTRUM SRL 409 Sighisoarei Targu Mures ROMANIA	Vidoxim 10% powder for oral solution for pigs and poultry	Doxycycline hyclate	100 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	1000 g of product/100 0 litres drinking water for 5 days	Poultry 10 days (not for use in animals from which eggs are produced for human consumption)  Indications: Infections caused by Mycoplasma gallisepticum, E. coli, Bordetella avium, Haemophilus paragallinarium and Pasteurella multocida.
Romania	S.C. VIM SPECTRUM SRL 409 Sighisoarei Targu Mures ROMANIA	Vidoxim 100% powder for oral solution for pigs and poultry	Doxycycline hyclate	1000 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	100 g of product/100 0 litres drinking water for 5 days	Poultry 10 days (not for use in animals from which eggs are produced for human consumption)  Indications: Infections caused by M. gallisepticum, E. coli, Bordetella avium, Haemophilus paragallinarium and P. multocida.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Romania	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	Oridox (Soldoxin) 100 mg/ml oral solution for use in drinking water for chickens and pigs	Doxycycline hyclate	100 mg/ml doxycycline (as hyclate)	Oral solution	Chickens (broilers) (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	10-20 mg doxycycline /kg b.w. for 3 - 5 days.	Poultry (chickens) 7 days (not for use in animals from which eggs are produced for human consumption) Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.
Romania	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx 500 mg/g Water Soluble Powder	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption  Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Romania	CEVA PHYLAXIA VETERINARY BIOLOGICALS CO. LTD. 1107 Budapesta Szallas u.5 HUNGARY	Doxivit 100	Doxycycline hydrochloride	100 mg/g doxycycline hydrochlorid e	Water soluble powder	Poultry (chickens, turkeys and goose) pigs	Oral (drinking water)	10 mg doxycycline hydrochlorid e/kg b.w. daily for 5 days	Poultry) 7 days (not for use in animals from which eggs are produced for human consumption)  Indications: CRD (Mycoplasma gallisepticum , E. Coli), infectious coryza (Haemophilus paragallinarum), fowl cholera (Pasteurella multocida),

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									colibacillosis (E. Coli), airsaculitis (Mycoplasma maleagris), chlamydiosis (Chlamidia psittaci), necrotic enteritis (Clostridium perfringens).
Romania	PHARMATEKA BT 1046 Budapest Szigyarto u. 10 / 20 Kossuth Str. Pusztaberki, 2658 HUNGARY	DOXY H 10%	Doxycycline hydrochloride	100 mg/g doxycycline hydrochlorid e	Water soluble powder	Poultry	Oral (drinking water)	1 g of product/ 1 litre of drinking water for 3- 5 days	Poultry 10 days (not for use in animals from which eggs are produced for human consumption)
Romania	s.c. romvac company s.a.Şos. Centurii, nr. 7 Voluntari ROMANIA	Doxiciclina 10%	Doxycycline hydrochloride	100 mg/g doxycycline hydrochlorid e	Water soluble powder	Poultry, including pigeons pigs bovine (calves)	Oral (drinking water)	2 g of product/10 kg b.w./day for 5-8 days	Poultry (chickens) 5 days (not for use in animals from which eggs are produced for human consumption)
Romania	S.C. Crida pharm s.r.l 2 Intrarea Vagonetului Bl. 101, Ap. 47, sector 6 Bucharest ROMANIA	Doxicol 60%	Doxycycline hydrochloride	600 mg/g doxycycline hydrochlorid e	Water soluble powder	Poultry pigs	Oral (drinking water or feed)	broiler 0-14 days: 50g/1000 litres of water; broiler 15 - 28 days: 100g/1000 litres of water;broiler 29 -35 days: 120g/1000 litres of water;	Poultry 5 days (not for use in animals from which eggs are produced for human consumption)  Indications: prevention and treatment of colibacillosis, respiratory diseases, mycoplasmosis.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Slovenia	Novartis Veterina d.o.o. Verovškova 57 1000 Ljubljana SLOVENIA	DOXYRIL 50%	Doxycycline hyclate	50% (500 mg/g)	powder for oral solution	pigs, poultry	Pigs and poultry: once a day, three to five days consecutively in drinking water	Pigs: 20 mg of doxycycline hyclate per 1 kg of BW; Poultry 25 mg of doxycycline hyclate per 1 kg of BW	Meat and offal: poultry: 4 days;  Indications: respiratory infections (M gallisepticum, M, synoviae in M, melagris), Escherichia coli, Haemophilus paragallinarum, Ornithobacterium rhinotracheale; Enteritis (Clostridium perfringens and Clostridium colinum; Septicemia (Pasteurella multocida)



Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Slovak republic	Trei Bio pharmaceutical division, Industria Italiana Integratori Trei Via Affarosa n.4 42010 Rio Saliceto (Reggio Emilia) ITALY	DOXIPAN 20 plv.sol. ad us.vet.	Doxycycline hyclate	20 g/100 g	Water soluble powder	Calves, pigs, poultry- broilers, turkey	for 5 days in drinking water	Poultry- broilers: 5- 7,5 g product/10 litre of drinking water Turkey: 10- 20mg active substance/b. w. correspondin g to 50-100 g product/100 liter d.w. Calves, pigs: 10 mg active substance/b. w./day correspondin g to 0,5 g product/10 kg b.w.	Meat: Broilers 5 days, turkeys 10 days,  Indications: Broilers: chronic respiratory disease and associated complications Turkeys: infections caused by G-positive and G-negative germs, mycoplasmas sensitive to doxycycline especially respiratory and articular syndrom caused by mycoplasma and/or staphylococcus
Slovak republic	DIVASA- FARMAVIC, S.A. CTRA. SANT HIPOLIT, KM. 71 08503 GURB – VIC SPAIN	DOXIVET 10% plv.sol. a.u.v.	Doxycycline hyclate	100 mg/ml	Water soluble powder	Poultry: (chickens and turkeys), bovine and swine	for 4 - 5 days in drinking water	0,5 ml of product/litre of drinking water	Meat: 5 days  Indications: Treatment of CRD, mycoplasmosis, porcine enzootic pneumonia, bronchopneumonias, chlamidiosis, unspecific diarrheas.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen- ded dose	Withdrawal period(s) / Indications
Slovak republic	Novartis Animal Health d.o.o. Verovskava 57 1000 Ljubljana SLOVENIA	DOXYRIL 500 mg/g prášok na perorálny roztok ad us.vet.	Doxycycline hyclate	500 mg/g	Water soluble powder	Pigs, broilers	during 3 to 5 consecutive days in drinking water	Pigs: 20 mg doxycycline hyclate/kg b.w. Broilers: 25 mg doxycycline hyclate/kg b.w.	Eddible tissues: broilers 4 days.  Indications: Treatment of infections caused by microorganisms susceptible to doxycycline, particularly: Broilers: respiratory tract infections caused by Mycoplasma spp. (M.gallisepticum, M.synoviae and M.meleagridis), Escherichia coli, Haemophilus paragallinarum and Ornithobacterium rhinotracheale, enteritis caused by Clostridium perfringens and Clostridium colinum, septicemia caused by Pasteurella multocida

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Slovak republic	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, Hungary	DOXYVIT 40% plv.sol.	Doxycycline hyclate	40 g/100 g	Water soluble powder	Poultry: (chickens and turkeys) and swine	3-5 days in drinking water, poultry in drinking water, pigs: in drinking water, in feed	Chickens and turkeys: 10- 20 mg active doxycycline hyclate/kg b.w.)/day, continual treatment: 1 g product/3- 6 litre of drinking water, repeated treatment: 25-50 mg product/kg b.w.(10-20 mg doxycycline hyclate/kg b.w.) in drinking water	Meat of chickens and turkey: 4 days,  Indications: Treatment and prophylaxis of respiratory, intestinal and systematic infections caused by doxycycline sensitive organism: Chickens, turkeys: chronic respiratory disease (Mycoplasma gallisepticum, E.coli), airsacculitis (M.meleagris), infectious synovitis (M.synoviae), fowl cholera (P. multocida), turkey bordetellosis (Bordetella avium), infectious coryza (Haemophilus paragallinarum), colibacillosis (E.coli), necrotic enteritis (Clostridium perfringens), chlamydiosis (CH. psittaci),

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Slovak republic	Tekro, spol. s.r.o., Višňová 2/484, 140 00 Praha 4, Czech Republic	Meditek DOX 100 plv.sol. ad us.vet.	Doxycycline hyclate	100 g/1000 g	Water soluble powder	Broilers, pigs	3-5 days in drinking water	Broilers: 10 mg doxycyclini hyclate/kg b.w (correspondi ng to 1 kg product/100 0 litre of drinking water)	Meat of broilers and pigs: 7 days.  Indications: Treatment and prevention of respiratory and gastrointestinal diseases caused by organism sensitive to doxycycline: broilers: CRD, mycoplasmosis, aerosaculitis, synovitis, pasteurellosis, infectious cholera, colibacillosis, chlamidiosis, necrotic enteritis
Slovak republic	Pharmagal s.r.o., Murgašova 5, 949 01 Nitra, Slovak Republic	DOXYGAL plv.sol. ad us.vet.	Doxycycline hyclate	5 g/100 g	Water soluble powder	Pigs, poultry, calves, rabbits	Poultry: prevention 5 days, treatment 3 days, in drinking water Pigs, calves, rabbits: 5 days, in drinking water, in feed	Poultry: prevention: 50 mg active substance/1 litre of drinking water (1 g product/1 litre water), treatment: 100 mg active substance/1 litre water (2 g product/1 litre water)	Meat of poultry and rabbits: 7 days  Indications: Poultry: CRD( mycoplasmosis), colibacillosis.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Slovak republic	COOPHAVET Saint Herblon 44150 Ancenis FRANCE	RONAXAN 5 % plv.sol. ad us.vet.	Doxycycline hyclate	5 g/100 g	Water soluble powder	Pigs, poultry, calves	Prevention: 1-3 days, treatment: 3-5 days, in drinking, in feed	10 mg active substance/k g b.w./day (1 g product/5 kg b.w./day) Polutry: - less than 2 weeks old: 1 g product/litre of drinking water/day, - more than 2 weeks old: 2 g/litre water/day	Meat of poultry 4 days  Indications: Poultry: preventive and curative treatment of respiratory infections,
Slovak republic	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	KARIDOX 100 mg/ml roztok pre podávanie hydine a ošípaným perorálne v pitnej vode	Doxycycline hyclate	100 mg/ml	Water soluble powder	Chicken (broilers), pigs	Broilers: 3-5 days, Pigs: 5 days, in drinking water	Broilers: 10 -20 mg of doxycycline/ kg b.w./day, (0,5-1,0 ml of product/litre of drinking water),	Meat and offals: chicken (broilers) 7 days  Indications: Chicken (broilers): prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganism sensitive to doxycycline.

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
Slovak republic	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	ORIDOX 100 mg/ml roztok pre podávanie hydine a ošípaným perorálne v pitnej vode	Doxycycline hyclate	100 mg/ml	Water soluble powder	Chicken (broilers), pigs	Broilers: 3-5 days, Pigs. 5 days, in drinking water	Broilers: 10 -20 mg of doxycycline/ kg b.w./day, (0,5-1,0 ml of product/litre of drinking water),	Meat and offals: chicken (broilers) 7 days,  Indications: Chicken (broilers): prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganism sensitive to doxycycline.
United kingdom	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox 100mg/ml Oral Solution for use in drinking water for Chickens and Pigs	Doxycycline hyclate	100 mg/ml doxycycline (as doxycycline hyclate)	Oral solution	Chickens (broilers) & Pigs	Oral (drinking water)	10-20 mg doxycycline/ kg x 3-5 days	Meat & offal: Chickens (broilers): 7 days  Indications: CHICKENS (BROILERS): Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.
United kingdom	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7 <sup>a</sup> Edificio Trade 08028 Barcelona SPAIN	Soldoxin 100mg/ml Oral Solution for use in drinking water for chickens and pigs	Doxycycline hyclate	100 mg/ml doxycycline (as doxycycline hyclate)	Oral solution	Chickens (broilers) & Pigs	Oral (drinking water)	10-20 mg doxycycline/ kg x 3-5 days	Meat & offal: Chickens (broilers): 7 days  Indications: CHICKENS (BROILERS): Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms

Member state/EEA	Applicant/ Marketing Authorisation Holder	Product name	INN	Strength	Pharma- ceutical form	Animal species	Frequency and route of administration	Recommen ded dose	Withdrawal period(s) / Indications
									sensitive to doxycycline.
United kingdom	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx 500 mg/g Water Soluble Powder	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days  Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
UNITED KINGDOM	VMD NV, HOGE MAUW 900-2370 Arendonk BELGIUM	Doxyveto 50 s plus	Doxycycline hyclate	50% w/w doxycycline hyclate	Powder for oral administrati on	Non-egg laying chickens	Oral (drinking water)	25 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal:6 days  Indications: Respiratory infections caused by Mycoplasma spp., E. coli and Haemophilus paragallinarum. Enteritis caused by Clostridium perfringens and Clostridium colinum

## **Annex II**

### **Scientific conclusions and grounds for amendment of the summary of product characteristics**



# **Overall summary of the scientific evaluation of water soluble powders and oral solutions containing doxycycline hyclate indicated for use in pultry (*see Annex I*)**

## **1. Introduction**

The water soluble powders and oral solutions containing doxycycline hyclate indicated for use in poultry and intended for administration via drinking water, are used for treatment of respiratory and gastrointestinal infections caused by different bacterial pathogens susceptible to doxycycline.

Doxycycline is a tetracycline derivative with uses similar to those of tetracycline. All tetracyclines have a broad spectrum of activity which include Gram-positive and Gram-negative bacteria, chlamydias, rickettsias, mycoplasmas and spirochaetes. Doxycycline tends to be more active against some of these species than other tetracyclines. It is primarily a bacteriostatic antibiotic and has its main mechanism of action on inhibition of protein synthesis.

The United Kingdom expressed concerns that differences in the posology, dose range, duration of treatment and withdrawal periods established across the European Union for all strengths of water soluble powders and oral solutions containing doxycycline hyclate indicated for use in poultry and intended for administration via drinking water may present a potential serious risk to both animal health and human health, and requested the CVMP to give its opinion on the matter.

The procedure involved 179 veterinary medicinal products authorised or pending authorisation in different Member States of the European Union (see Annex I).

## **2. Discussion of data available**

From the overall data submitted by the Applicants/Marketing Authorisation Holders only nineteen responses were with full dossiers developed in accordance with the Article 12(3) of Directive 2001/82/EC. Nine responses were with generic dossiers developed in accordance with the Article 13 of Directive 2001/82/EC. For four responses the written information provided did not contain data pertinent to the questions raised by the CVMP. One response was received after the given deadline for submission and therefore was not accepted and the CVMP performed its assessment without considering the product specific data.

The data made available indicated 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, generic and informed consent).

It was noted that some parts of the data submitted were identical but were submitted by different MAHs.

Only the above mentioned nineteen responses that contained full dossiers developed in accordance with the Article 12(3) of Directive 2001/82/EC were considered of adequate quality for the purpose of answering to the specific issues raised. The data packages submitted consist of bibliographic data available in the public domain and proprietary data.

To support the efficacy of the products concerned altogether 11 original proprietary studies were submitted by the Applicants/Marketing Authorisation Holders including 3 experimental infection studies and 8 clinical field studies. All studies but one has been performed in broiler chickens. This one study was performed in turkeys.

Different product formulations were used in the studies containing, doxycycline hyclate/hydrochloride at different concentrations; almost all included acidifiers in the formulation (usually citric acid).

The documentation of the original proprietary studies was very heterogeneous and in many cases did not comply with current standards. In particular, information about the study conditions (medical history of the study site, housing and feeding conditions, light/dark cycle) as well as the treatment schedule (medication ad libitum for 24 hours/ pulse medication) was missing or very limited.

Based on a GLP compliant dose determination study on broiler chickens artificially infected with *Mycoplasma gallisepticum* a therapeutic dose of 20 mg/kg body weight administered for 5 consecutive days can be derived. Seven clinical field studies in broiler chickens with respiratory disease and confirmed

*M. gallisepticum* infection were presented. Doxycycline hyclate was administered in all but two studies at a target dose of 20 mg/kg body weight per day for 5 consecutive days. One of these studies serve as the confirmatory evidence for the efficacy of this target dose, based on objective parameters such as a significant reduction of the percentage of animals with pathological lesions and total lesion scores typical of the disease and significant reduction in the recovery rate of *M. gallisepticum* after treatment. No adverse effects related to treatment were recorded. The other studies provide with indicative support for the target dose, since a subjective primary endpoint - clinical improvement - was used, and since these studies were poorly documented. In conclusion, a therapeutic dose of 20 mg/kg body weight administered for 5 consecutive days was confirmed for the treatment of respiratory disease caused by *M. gallisepticum* in chicken, on basis of a clinical field study in broiler chickens with respiratory disease and confirmed *M. gallisepticum* infection.

As regards *Pasteurella multocida* infection, two experimental studies in broiler chickens were presented, i.e. one publication (Semjen et al., (1998)<sup>1</sup>, and one proprietary study. The experimental conditions were similar in both studies. Both studies indicate that doxycycline at a daily dose of 10 mg/kg bw for 4 (5) consecutive days was effective in the treatment of induced acute fowl cholera as evidenced by the significant reduction of the mortality rate and pathological lesions characteristic for the disease as well as the recovery rate of the challenge strain, compared to infected unmedicated controls. Doxycycline was also shown to be superior to chlortetracycline used as positive control. However the publication does not provide sufficient information to calculate the actual dose intake of the study animals. In the proprietary study, diarrhoea was one of the main clinical symptoms observed in infected untreated animals, which is not considered typical for *Pasteurellosis*. Mild clinical symptoms and some deaths were observed in treated animals in the post-observation period. Notwithstanding the fact that no clinical field study was presented to confirm the results obtained under experimental conditions, the use of doxycycline for the treatment of respiratory infections associated with *P. multocida* appears justified considering the good susceptibility of this pathogen to doxycycline (MIC90 up to 2µg/ml).

As regards *Escherichia coli* infections, three publications of experimental model studies (George et al., 1977<sup>2</sup>; Goren et al., 1988<sup>3</sup>, Velkers et al., 2005<sup>4</sup>) and one clinical efficacy study were presented. The study published by Goren et al. (1988)<sup>3</sup> was designed as a dose titration study with doxycycline administered at dosages of 25-1000 ppm in drinking water for 5 consecutive days. A clear dose-

---

<sup>1</sup> Semjen G., Magyar T, Laczay P.: Therapeutic efficacy of doxycycline against experimental *Pasteurella multocida* infection in broiler chickens. Act. Vet. Hung. 46 (1), pp.85-93, 1998

<sup>2</sup> George BA, Fagerberg DJ, Quarles CL, Fenton JM.: Comparison of therapeutic efficacy of doxycycline, chlortetracycline and lincomycin-spectinomycin on *E. coli* infection of young chickens. Poult Sci. 1977 Mar;56(2):452-8.

<sup>3</sup> Goren E, de Jong WA, Doornenbal P, Laurensen T.: Therapeutic efficacy of doxycycline hyclate in experimental *Escherichia coli* infection in broilers. Vet Q. 1988 Jan;10(1):48-52.

<sup>4</sup> Velkers FC, te Loo AJ, Madin F, van Eck JH.: Isopathic and pluralist homeopathic treatment of commercial broilers with experimentally induced colibacillosis. Res Vet Sci. 2005 Feb;78(1):77-83.

response relationship could be shown. Compared to infected unmedicated controls, doxycycline was shown to be effective in reducing the mortality rate and pathological lesions characteristic for *Colibacillosis* (pericarditis, aerosacculitis and perihepatitis) as well as the clinical performance of the chickens at dose levels from 400 ppm (corresponding to 96 mg/kg bw) onwards. The most favourable results were obtained at the highest dose tested, i.e. 1000 ppm corresponding to 196 mg/kg body weight for 5 days. At this dose levels mean plasma doxycycline levels of 3.6 µg/ml (measured on the 2nd treatment day) were achieved. In contrast, in the study of George et al. (1977)<sup>2</sup> doxycycline proved to be effective in reducing mortality rate and typical pathological lesions at a dose level of 50 ppm in drinking water for 3 consecutive days, when compared to infected un-medicated controls, and proved to be superior to chlortetracycline and lincomycin-spectinomycin used as positive controls. However the article of George et al. (1977)<sup>2</sup> does not include sufficient information (body weights and water consumption) to calculate the daily actual dose intake of the study animals.

In an experimental setting testing homeopathic medication in the treatment of *Colibacillosis* in broiler chickens, doxycycline was used for control (Velkers et al., 2005)<sup>4</sup>. Given at a daily dose of 250 mg/l drinking water for 5 consecutive days, doxycycline was shown to be efficacious in preventing mortality, reducing the occurrence of *E. coli* lesions and growth depression. However, the publication did not include the necessary information to derive a daily actual dose intake of the study birds.

Comparison of these infection studies that investigate *Colibacillosis* was problematic due to considerable differences in the experimental conditions such as the use of different challenge strains and infectious dose levels, different time of treatment initiation, and differences in the chickens (age, weight, and breed) used. Therefore no clear conclusion can be drawn from these studies.

One GCP compliant open clinical field study was provided on broiler chickens suffering from *Colibacillosis*. Doxycycline was administered at a daily target dose of 25 mg/kg body weight for 3 days. The efficacy evaluation was based on mortality, clinical observations and microbiology. The results indicated that doxycycline effectively improved the clinical performance of the chickens and reduced gradually mortality. Several shortcomings of the study were noted (e.g. lack of a control group).

As regards *Ornithobacterium rhinotracheale* infections, one GCP compliant controlled confirmatory efficacy study in chickens experimentally infected with *O. rhinotracheale* was presented. The study was run in 2 phases, a pilot phase determining the optimal infectious dose followed by a confirmatory phase. Clinical symptoms following infection were almost absent even at the highest infectious dose. However, data of the pilot phase indicate that chickens at the highest infectious dose level, treated with doxycycline at a dose of 20 mg/kg per day for 4 days showed a significant reduction in air sac lesions compared to un-medicated controls. In the confirmatory phase, both the clinical and pathological response to artificial *O. rhinotracheale* infection was low in un-medicated controls. Antimicrobial efficacy as evident from recovery rate of *O. rhinotracheale* was not confirmed. Obviously no attempts were made to determine the actual dose in chickens. This was the only study submitted in support of the *O. rhinotracheale* claim. In conclusion, no therapeutic dose can be confirmed for the treatment of respiratory disease caused by *O. rhinotracheale* on basis of the data submitted.

The data submitted for *Chlamydiosis* were inconclusive and therefore there was insufficient information to support this indication both in chickens and other target species for the currently approved products that are within the scope of this referral procedure.

Three studies were presented concerning the efficacy of doxycycline in turkeys and geese. In turkeys, doxycycline was administered for the treatment of respiratory disease and airo-sacculitis and respiratory disease together with joint syndrome (*Mycoplasma*, *Staphylococcus*). The geese were treated with doxycycline because of respiratory distress (*mycoplasmosis*). As all three studies were poorly documented (e.g. relevant information of diagnostic procedures, microbiology, clinical observations etc were missing) therefore the results can not be interpreted properly.

No or very limited clinical data was presented to support other indications (e.g. infections caused by *M. meleagridis*, *M. synoviae*, *Haemophilus paragallinarum*, *Clostridium perfringens*, *Clostridium colinum*, *Bordetella avium*, etc.) in chickens or in any other target species that are currently approved for the products within the scope of this procedure.

In summary, the Committee considered that the efficacy of doxycycline in the treatment of chronic respiratory disease caused by *M. gallisepticum* was sufficiently supported by a clinical dose determination study and clinical trials under commercial use conditions for use in chicken at a dose of 20 mg/kg for 5 consecutive days. As regards *P. multocida* infections, results of an experimental model study indicate a treatment dose of 10 mg/kg body weight for 4 or 5 days, but no confirmatory clinical data obtained under commercial conditions has been made available. Nevertheless as *P. multocida* was shown to be susceptible to doxycycline with a MIC<sub>90</sub> up to 2 µg/ml and covered by pharmacokinetic/pharmacodynamic analysis, the inclusion of *P. multocida* infections in the indication for chickens appears justified.

With regard to the *E. coli* infections in poultry the data submitted was not sufficient. No therapeutic dosage regimen could be derived from the two submitted experimental *E. coli* infection studies in chickens. Also, the results of the submitted clinical field study in broilers suffering from *Colibacillosis*, treated with doxycycline at a dose of 25 mg/kg for 3 days were not convincing. As evident from pharmacodynamic data, *E. coli* strains showed a very variable susceptibility against doxycycline with MIC<sub>90</sub> values of 2 - 32 µg/ml. The latest resistance rates of *E. coli* isolated from chickens is reported for Germany in a range of 19.3-37% (Wallmann et al, 2007)<sup>5</sup>. It could be argued that doxycycline can be effectively used in the treatment of *E. coli* infections in broilers provided, however, that susceptibility to doxycycline is confirmed before initiation of treatment.

Despite the deficiencies in the submitted studies and lack of data for some indications and dosages on the basis of well established use and the lack of any new pharmacovigilance information in relation to lack of efficacy it can be concluded that the current dosages and indications for the doxycycline containing products can be considered safe and effective.

The residue depletion studies presented by the MAHs indicated that the statistical approach<sup>6</sup> as recommended by the Committee was used for the establishment of withdrawal periods whenever possible. In some studies the residue depletion kinetics of doxycycline were not demonstrated because tissue residues were detected at one or two time points after drug withdrawal only. In these cases the alternative approach<sup>6</sup> was applied or the study was considered to be of confirmatory nature. Residue studies were mainly conducted in chickens. Two residue studies were in turkeys. The daily doses administered to chickens ranged between 10.36 mg/kg body weight, 14.47 mg/kg body weight and 25 mg/kg body weight. A daily dose of approximately 20 mg doxycycline/kg body weight was administered in eight studies. In two studies the concentration of the final product in drinking water was reported, but the animals' actual drug intake in terms of mg per kg body weight was not specified. Treatment duration was five consecutive days in all studies.

As no need for revision of the dose was identified consequently the withdrawal periods of the products concerned do not need revision.

---

<sup>5</sup> Wallmann, J.; Schroer, U.; Kaspar, H.: Quantitative resistance level (MIC) of bacterial pathogens (*Escherichia coli*, *Pasteurella multocida*, *Pseudomonas aeruginosa*, *Salmonella sp.*, *Staphylococcus aureus*) isolated from chickens and turkeys: National Resistance Monitoring by the BVL 2004/2005 (2007) Berl. Munch. Tierarztl. Wochenschr.; 120; 452-463

<sup>6</sup> CVMP Note for guidance: Approach towards harmonisation of withdrawal periods  
<http://www.ema.europa.eu/pdfs/vet/swp/003695en.pdf>

### 3. Benefit Risk Assessment

Having considered all the data submitted by the Applicants/Marketing Authorisation Holders, there was sufficient documented evidence in support of acceptable efficacy of doxycycline hyclate when used in broiler chickens for the treatment of respiratory infection associated with *Mycoplasma gallisepticum*, susceptible to doxycycline, at a daily dose of 20 mg/kg bw for 5 consecutive days. However there was no documented evidence for lack of efficacy in the treatment of respiratory infection associated with *Mycoplasma gallisepticum* with any other of the approved dosage regimens (10-25 mg/kg body weight).

The use of doxycycline hyclate for all claimed indications in chickens as well as the use of doxycycline hyclate in other poultry species was considered well-established. While the data submitted by Applicants/Marketing Authorisation Holders failed to provide sufficient documented evidence to support the established doses for all other indications and species, there was, however, no new information indicating any new risk associated with the use of doxycycline in poultry in relation to lack of efficacy. In the submitted Periodic Safety Update Reports for the concerned products no lack of efficacy has been reported for any of the claimed indications in any of the target species.

Concerning resistance, the results of a recent pan European survey of antimicrobial susceptibility towards antimicrobials among zoonotic and commensal enteric bacteria resistance, published in 2009<sup>7</sup>, revealed a high resistance rate for *E. coli*, isolated from chickens, against tetracyclines.

Therefore, CVMP recommends that the product literature for all concerned products in this procedure should include appropriate prudent use statements in line with what is recommended in the CVMP Guideline on the SPC for antimicrobials (EMA/CVMP/SAGAM/383441/2005)<sup>8</sup> and information on correct administration.

---

<sup>7</sup> De Jong et al.: A pan-European survey of antimicrobial susceptibility towards human-use antimicrobial drugs among zoonotic and commensal enteric bacteria isolated from healthy food producing animals. J. Antimicrob. Chemotherapy 63, 733-744, 2009

<sup>8</sup> CVMP revised guideline on the SPC for antimicrobial products (EMA/CVMP/SAGAM/383441/2005) - <http://www.ema.europa.eu/pdfs/vet/sagam/38344105enfin.pdf>

## Grounds for amendment of the summary of product characteristics, labelling and package leaflet

Whereas:

- the CVMP considered that the use of doxycycline hyclate was well established. There was no documented evidence indicating a new risk associated with the use of doxycycline in poultry in relation to lack of efficacy. In the submitted Periodic Safety Update Reports neither lack of efficacy nor any resistance problem has been reported for any of the approved indications in any of the approved species. Therefore, notwithstanding the fact that documented evidence is lacking for some of the indications and target species currently approved, the overall benefit-risk assessment remains unchanged for the products within the scope of this procedure;
- the CVMP considered that a recent pan European survey of antimicrobial susceptibility towards antimicrobials among zoonotic and commensal enteric bacteria resistance, published in 2009, revealed a high resistance rate for *E. coli*, isolated from chickens, against tetracyclines. Therefore, the inclusion of appropriate standard prudent use statements in line with recommendations of the CVMP guideline on the SPC of Antimicrobials and information on correct administration of the products concerned in this referral procedure was considered appropriate;

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 to include as a minimum the information set out in Annex III for the water soluble powders and oral solutions containing doxycycline hyclate indicated for use in poultry and intended for administration via drinking 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**



## 4.5 Special precautions for use in animals

### Special precautions for use in animals

Due to variability (time, geographical) in susceptibility of bacteria for doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased birds on farm are highly recommended.

A high resistance rate of *E. coli*, isolated from chickens, against tetracyclines has been documented. Therefore the product should be used for the treatment of infections caused by *E. coli* only after susceptibility testing has been carried out.

As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

## 4.9 Amounts to be administered and administration route

To be administered in drinking water.

<approved dose> mg doxycycline hyclate /kg body weight / day, corresponding to mg <product name>per kg body weight, for ...<approved treatment duration> consecutive days.

Based on the recommended dose, and the number and weight of the birds to be treated, the exact daily amount of <product name>should be calculated according to the following formula:

$$\frac{\text{.....mg [product name] /kg body weight/ day} \times \text{Mean body weight (kg) of birds to be treated}}{\text{Mean daily water consumption (l) per bird}} = \text{.... mg [product name] per l drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible.

The uptake of medicated water is dependant on the clinical conditions of the birds. In order to obtain the correct dosage, the concentration in drinking water may have to be adjusted.

The use of suitably calibrated weighing equipment is recommended if part packs are used. The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be freshly prepared every 24 hours. It is recommended to prepare a concentrated pre-solution - approximately 100 grams product per litre drinking water - and to dilute this further to therapeutic concentrations if required. Alternatively, the concentrated solution can be used in a proportional water medicator.

**Amendments to be included in the relevant sections of the labelling**

<b>7. METHOD AND ROUTE(S) OF ADMINISTRATION</b>
---

Read the package leaflet before use.

<b>9. SPECIAL WARNING(S), IF NECESSARY</b>
--

Read the package leaflet before use.

**Amendments to be included in the relevant sections of the package leaflet**

## 9. Advice on correct administration

The following dosage advice should be followed:

<approved dose> mg doxycycline hyclate /kg body weight / day, corresponding to mg <product name> per kg body weight, for ...<approved treatment duration> consecutive days.

Based on the recommended dose, and the number and weight of the birds to be treated, the exact daily amount of <product name> should be calculated according to the following formula:

$$\frac{\text{.....mg [product name] /kg body weight/ day} \times \text{Mean body weight (kg) of birds to be treated}}{\text{Mean daily water consumption (l) per bird}} = \text{.... mg [product name] per l drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible.

The uptake of medicated water is dependant on the clinical conditions of the birds. In order to obtain the correct dosage, the concentration in drinking water may have to be adjusted.

The use of suitably calibrated weighing equipment is recommended if part packs are used. The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be freshly prepared every 24 hours. It is recommended to prepare a concentrated pre-solution - approximately 100 grams product per litre drinking water - and to dilute this further to therapeutic concentrations if required. Alternatively, the concentrated solution can be used in a proportional water medicator.

## 12. Special warning(s)

Due to variability (time, geographical) in susceptibility of bacteria for doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased birds on farm are highly recommended.

A high resistance rate of *E. coli*, isolated from chickens, against tetracyclines has been documented. Therefore the product should be used for the treatment of infections caused by *E. coli* only after susceptibility testing has been carried out.

As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.