Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 September 2019 to 30 September 2019

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

(2019/C 369/02)

— **Issuing, maintenance or modification of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
9.9.2019	Bacterial lysates-containing medicinal products for respiratory conditions	Bacterial lysates containing medicinal products for respiratory conditions	See Annex I	See Annex I	10.9.2019
20.9.2019	Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep	Tylosin	See Annex II	See Annex II	23.9.2019

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

ANNEX I

List of nationally authorised medicinal products

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Daiichi Sankyo Austria Gmbh	Luivac	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use
Austria	Laboratorio Farmaceutico S.I.T. S.R.L.	Buccalin	Streptococcus Agalactiae 1 Giga Units Tablet, Haemophilus Influenzae 1.5 Giga Units Tablet, Staphylococcus Aureus 1 Giga Units Tablet, Streptococcus Pneumoniae 1 Giga Units Tablet	Film-Coated Tablet	Oral Use
Austria	Om Pharma S.A.	Broncho-Vaxom Für Erwachsene	Freeze-Dried (Lyophilised), Standardised Bacterial Lysate 7 mg Capsule	Capsule, Hard	Oral Use
Austria	Om Pharma S.A.	Broncho-Vaxom Für Kinder	Freeze-Dried (Lyophilised), Standardised Bacterial Lysate 3.5 mg Capsule	Capsule, Hard	Oral Use
Belgium	Om Pharma S.A.	Broncho Vaxom	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Belgium	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Bulgaria	Bb - Ncipd Ltd.	Respivax	Haemophilus Influenzae Type B (Hib) 0.625 Giga Cells / 25 mg, Branhamella Catarrhalis Lysate 0.625 Giga Cells / 25 mg, Klebsiella Pneumoniae (Inactivated) 0.625 Giga Cells / 25 mg, Staphylococcus Aureus Inactivated Bacteria 0.625 Giga Cells / 25 mg, Streptococcus Pneumoniae Inactivated Bacteria 0.625 Giga Cells / 25 mg, Streptococcus Pyogenes Inactivated Bacteria 0.625 Giga Cells / 25 mg	Tablet	Oral Use
Bulgaria	Bb - Ncipd Ltd.	Respivax	Haemophilus Influenzae Type B (Hib) 1.25 Giga Cells / 50 mg, Branhamella Catarrhalis Lysate 1.25 Giga Cells / 50 mg, Klebsiella Pneumoniae (Inactivated) 1.25 Giga Cells / 50 mg, Staphylococcus Aureus Inactivated Bacteria 1.25 Giga Cells / 50 mg, Streptococcus Pneumoniae Inactivated Bacteria 1.25 Giga Cells / 50 mg, Streptococcus Pyogenes Inactivated Bacteria 1.25 Giga Cells / 50 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Bulgaria	Om Pharma S.A.	Бронхо – Ваксом За Възрастни	Standardized Lyophylisate Of Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Bulgaria	Om Pharma S.A.	Бронхо – Ваксом За Деца	Lyophilized Bacterial Lysates 3.5 mg Sachet	Granules	Oral Use
Bulgaria	Om Pharma S.A.	Бронхо–ваксом За Деца	Standardized Lyophylisate Of Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Bulgaria	Pierre Fabre Medicament	Рибомунил	Proteoglycanes Of Klebsiella Pneumoniae 1.125 mg Sachet, Ribosomal Fractions (Ribosomes With A Titre Of 70 % Rna) 0.75 mg Sachet, Ribosomes Of Haemophilus Influenzae 5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 30 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 35 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 30 Units Sachet	Granules For Oral Solution	Oral Use
Czech Republic	Daiichi Sankyo Europe Gmbh	Luivac	Lysatum Bacteriale Mixtum 3 mg Tablet	Tablet	Oral Use
Czech Republic	Om Pharma S.A.	Broncho-Vaxom Pro Adultis	Lysatum Bacteriale Mixtum 7 mg Capsule	Capsule, Hard	Oral Use
Czech Republic	Om Pharma S.A.	Broncho-Vaxom Pro Infantibus	Lysatum Bacteriale Mixtum 3.5 mg Capsule	Capsule, Hard	Oral Use
Czech Republic	Om Pharma S.A.	Broncho-Vaxom Pro Infantibus	Lysatum Bacteriale Mixtum 3.5 mg Sachet	Granules In Sachet	Oral Use
Czech Republic	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Sachet, Ribosomes Of Haemophilus Influenzae 0.5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 3 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Sachet	Granules For Oral Solution	Oral Use
Czech Republic	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units Tablet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Germany	Daiichi Sankyo Europe Gmbh	Luivac	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use
Germany	Om Pharma S.A.	Broncho-Munal Erwachsene	Lyophilised, Standardised Bacterial Extract 7 mg Capsule	Capsule, Hard	Oral Use
Germany	Om Pharma S.A.	Broncho-Munal Kinder	Lyophilised, Standardised Bacterial Extract 3.5 mg Capsule	Capsule, Hard	Oral Use
Germany	Om Pharma S.A.	Broncho-Vaxom	Lyophilised, Standardised Bacterial Extract 3.5 mg Capsule	Capsule, Hard	Oral Use
Germany	Om Pharma S.A.	Broncho-Vaxom Erwachsene	Lyophilised, Standardised Bacterial Extract 7 mg Capsule	Capsule	Oral Use
Greece	Gap S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Greece	Gap S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Greece	Rafarm Sa.	Pir-05	Lyophilized Bacterial Lysates 7 mg Tablet	Sublingual Tablet	Sublingual Use
Hungary	Om Pharma S.A.	Broncho-Vaxom Felnotteknek	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Hungary	Om Pharma S.A.	Broncho-Vaxom Gyermekeknek	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Hungary	Om Pharma S.A.	Broncho-Vaxom Gyermekeknek	Lyophilized Bacterial Lysates 3.5 mg Sachet	Powder For Oral Solution	Oral Use
Italy	Abiogen Pharma S.P.A.	Broncho Munal	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Abiogen Pharma S.P.A.	Broncho Munal	Lyophilized Bacterial Lysates 3.5 mg Sachet	Granules In Sachet	Oral Use
Italy	Abiogen Pharma S.P.A.	Broncho Munal	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Italy	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.	Ommunal	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Italy	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.	Ommunal	Lyophilized Bacterial Lysates 3.5 mg Sachet	Granules For Oral Suspension	Oral Use
Italy	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.	Ommunal	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Italy	Bruschettini S.R.L	Immubron	Glycine 43 mg Tablet, Haemophilus Influenzae Type B (Hib) 6 Giga Organisms Tablet, Klebsiella Ozaenae 6 Giga Organisms Tablet, Klebsiella Pneumoniae 6 Giga Organisms Tablet, Neisseria Catarrhalis 6 Giga Organisms Tablet, Staphylococcus Aureus 6 Giga Organisms Tablet, Streptococcus Pneumoniae 6 Giga Organisms Tablet, Streptococcus Pyogenes 6 Giga Organisms Tablet, Streptococcus Oralis 6 Giga Organisms Tablet, Lyophilized Bacterial Lysates 50 mg Tablet	Sublingual Tablet	Sublingual Use
Italy	Bruschettini S.R.L	Lantigen B	Haemophilus Influenzae Type B (Hib) 50.2 agu/Ml, Klebsiella Pneumoniae 39.8 agu/Ml, Staphylococcus Aureus 79.6 agu/Ml, Streptococcus Pneumoniae 63.2dagu/Ml, Streptococcus Pyogenes 126.2 agu/Ml, Moraxella Catarrhalis 39.9 agu/Ml	Oral Drops, Suspension	Oral Use
Italy	Daiichi Sankyo Italia S.P.A	Paspat	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use
Italy	Laboratorio Farmaceutico S.I.T. S.R.L.	Buccalin	Streptococcus Agalactiae 1 000 Mega Units Tablet, Haemophilus Influenzae 1 500 Mega Units Tablet, Staphylococcus Aureus 1 000 Mega Units Tablet, Streptococcus Pneumoniae 1 000 Mega Units Tablet	Gastro-Resistant Tablet	Oral Use
Italy	Laboratorio Farmaceutico S.I.T. S.R.L.	Buccalin	Streptococcus Agalactiae 1 000 Mega Units Tablet, Haemophilus Influenzae 1 500 Mega Units Tablet, Staphylococcus Aureus 1 000 Mega Units Tablet, Streptococcus Pneumoniae 1 000 Mega Units Tablet	Gastro-Resistant Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Lallemand Pharma Europe	Ismigen	Haemophilus Influenzae 6 Giga Cells Tablet, Klebsiella Ozaenae 6 Giga Cells Tablet, Klebsiella Pneumoniae 6 GigaCells Tablet, Neisseria Catarrhalis 6 Giga Cells Tablet, Staphylococcus Aureus 6 Giga Cells Tablet, Streptococcus Pneumoniae 6 Giga Cells Tablet, Streptococcus Pyogenes 6 Giga Cells Tablet, Streptococcus Oralis 6 GigaCells Tablet	Sublingual Tablet	Sublingual Use
Italy	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Italy	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5 mg Sachet	Granules In Sachet	Oral Use
Italy	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Italy	Pierre Fabre Pharma S.R.L.	Immucytal	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Granules For Oral Solution	Oral Use
Italy	Pierre Fabre Pharma S.R.L.	Immucytal	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Tablet	Oral Use
Latvia	Daiichi Sankyo Europe Gmbh	Luivac	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use
Latvia	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 3.5 mg Capsule	Capsule, Hard	Oral Use
Latvia	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 7 mg Capsule	Capsule, Hard	Oral Use
Lithuania	Daiichi Sankyo Europe Gmbh	Luivac	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use
Lithuania	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 7 mg Capsule	Capsule, Hard	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Lithuania	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Lithuania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Granules For Oral Solution	Oral Use
Lithuania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Tablet	Oral Use
Luxembourg	Daiichi Sankyo Europe Gmbh	Luivac	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use
Luxembourg	Om Pharma S.A.	Broncho Vaxom	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Luxembourg	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Malta	Bruschettini S.R.L	Immubron	Glycine 43 mg Tablet, Haemophilus Influenzae Type B (Hib) 6 Giga Organisms Tablet, Klebsiella Ozaenae 6 Giga Organisms Tablet, Klebsiella Pneumoniae 6 Giga Organisms Tablet, Neisseria Catarrhalis 6 Giga Organisms Tablet, Staphylococcus Aureus 6 Giga Organisms Tablet, Streptococcus Pneumoniae 6 Giga Organisms Tablet, Streptococcus Pyogenes 6 Giga Organisms Tablet, Streptococcus Viridans 6 Giga Organisms Tablet, Lyophilized Bacterial Lysates 50 mg Tablet	Sublingual Tablet	Sublingual Use
Malta	Bruschettini S.R.L	Lantigen B	Haemophilus Influenzae Type B (Hib) 50.2 agu/Ml, Klebsiella Pneumoniae 39.8 agu/Ml, Staphylococcus Aureus 79.6 agu/Ml, Streptococcus Pneumoniae 63.2 agu/Ml, Streptococcus Pyogenes 126.2 agu/Ml, Moraxella Catarrhalis 39.9 agu/Ml	Oral Drops, Suspension	Oral Use
Poland	Daiichi Sankyo Europe Gmbh	Luivac	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Instytut Biotechnologii Surowic I Szczepionek Biomed Spółka Akcyjna	Polyvaccinum Forte	Escherichia Coli (Inactivated) 200 Mega Cells / Ml, Klebsiella Pneumoniae (Inactivated) 100 Mega Cells / Ml, Staphylococcus Aureus Inactivated Bacteria 500 Mega Cells / Ml, Staphylococcus Epidermidis Inactivated Bacteria 500 Mega Cells / Ml, Streptococcus Salivarius Inactivated Bacteria 100 Mega Cells / Ml, Streptococcus Pneumoniae Inactivated Bacteria 100 Mega Cells / Ml, Streptococcus Pyogenes Inactivated Bacteria 100 Mega Cells / Ml, Haemophilus Influenzae Inactivated Bacteria 100 Mega Cells / Ml, Corynebacterium Pseudodiphtheriticum Inactivated Bacteria 200 Mega Cells / Ml, Moraxella Catarrhalis Inactivated Bacteria 100 Mega Cells / Ml	Suspension For Injection	Intramuscular Use $ Subcutaneous Use
Poland	Instytut Biotechnologii Surowic I Szczepionek Biomed Spółka Akcyjna	Polyvaccinum Mite	Escherichia Coli (Inactivated) 20 Mega Cells / Ml, Klebsiella Pneumoniae (Inactivated) 10 Mega Cells / Ml, Staphylococcus Aureus Inactivated Bacteria 50 Mega Cells / Ml, Staphylococcus Epidermidis Inactivated Bacteria 50 Mega Cells / Ml, Streptococcus Salivarius Inactivated Bacteria 10 Mega Cells / Ml, Streptococcus Pneumoniae Inactivated Bacteria 10 Mega Cells / Ml, Streptococcus Pyogenes Inactivated Bacteria 10 Mega Cells / Ml, Haemophilus Influenzae Inactivated Bacteria 10 Mega Cells / Ml, Corynebacterium Pseudodiphtheriticum Inactivated Bacteria 20 Mega Cells / Ml, Moraxella Catarrhalis Inactivated Bacteria 10 Mega Cells / Ml	Nasal Drops, Suspension	Nasal Use
Poland	Instytut Biotechnologii Surowic I Szczepionek Biomed Spółka Akcyjna	Polyvaccinum Mite	Escherichia Coli (Inactivated) 20 Mega Cells / Ml, Klebsiella Pneumoniae (Inactivated) 10 Mega Cells / Ml, Staphylococcus Aureus Inactivated Bacteria 50 Mega Cells / Ml, Staphylococcus Epidermidis Inactivated Bacteria 50 Mega Cells / Ml, Streptococcus Salivarius Inactivated Bacteria 10 Mega Cells / Ml, Streptococcus Pneumoniae Inactivated Bacteria 10 Mega Cells / Ml, Streptococcus Pyogenes Inactivated Bacteria 10 Mega Cells / Ml, Haemophilus Influenzae Inactivated Bacteria 10 Mega Cells / Ml, Corynebacterium Pseudodiphtheriticum Inactivated Bacteria 20 Mega Cells / Ml, Moraxella Catarrhalis Inactivated Bacteria 10 Mega Cells / Ml	Suspension For Injection	Intramuscular Use $ Subcutaneous Use
Poland	Instytut Biotechnologii Surowic I Szczepionek Biomed Spółka Akcyjna	Polyvaccinum Submite	Escherichia Coli (Inactivated) 2 Mega Cells / Ml, Klebsiella Pneumoniae (Inactivated) 1 Mega Cells / Ml, Staphylococcus Aureus Inactivated Bacteria 5 Mega Cells / Ml, Staphylococcus Epidermidis Inactivated Bacteria 5 Mega Cells / Ml, Streptococcus Salivarius Inactivated Bacteria 1 Mega Cells / Ml, Streptococcus Pneumoniae Inactivated Bacteria 1 Mega Cells / Ml, Streptococcus Pyogenes Inactivated Bacteria 1 Mega Cells / Ml, Haemophilus Influenzae Inactivated Bacteria 1 Mega Cells / Ml, Corynebacterium Pseudodiphtheriticum Inactivated Bacteria 2 Mega Cells / Ml, Moraxella Catarrhalis Inactivated Bacteria 1 Mega Cells / Ml	Suspension For Injection	Intramuscular Use $ Subcutaneous Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Lallemand Pharma Europe	Ismigen	Haemophilus Influenzae 6 Giga Cells Tablet, Klebsiella Ozaenae 6 Giga Cells Tablet, Klebsiella Pneumoniae 6 Giga Cells Tablet, Neisseria Catarrhalis 6 Giga Cells Tablet, Staphylococcus Aureus 6 Giga Cells Tablet, Streptococcus Pneumoniae 6 Giga Cells Tablet, Streptococcus Pyogenes 6 Giga Cells Tablet, Streptococcus Viridans 6 Giga Cells Tablet	Sublingual Tablet	Sublingual Use
Poland	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Poland	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5 mg Sachet	Granules In Sachet	Oral Use
Poland	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Poland	Pierre Fabre Medicament Polska Sp. Z O.O.	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units Tablet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Poland	Pierre Fabre Medicament Polska Sp. Z O.O.	Ribomunyl	Proteoglycanes Of Klebsiella Pneumoniae 1.125 mg Sachet, Ribosomal Fractions (Ribosomes With A Titre Of 70 % Rna) 0.75 mg Sachet, Ribosomes Of Haemophilus Influenzae 5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 30 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 35 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 30 Units Sachet	Granules For Oral Solution	Oral Use
Poland	Pierre Fabre Medicament Polska Sp. Z O.O.	Ribomunyl	Proteoglycanes Of Klebsiella Pneumoniae 1.125 mg Sachet, Ribosomes Of Haemophilus Influenzae 5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 30 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 35 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 30 Units Sachet	Granules For Oral Solution	Oral Use
Portugal	Almirall Produtos Farmacêuticos, Lda.	Provax	Diplococcus Pneumoniae Type I 6 000 Milli I.U. Tablet, Haemophilus Influenzae 6 000 Milli I.U. Tablet, Klebsiella Ozaenae 6 Milli I.U. Tablet, Klebsiella Pneumoniae 6 000 Milli I.U. Tablet, Neisseria Catarrhalis 6 000 Milli I.U. Tablet, Staphylococcus Aureus 6 000 Milli I.U. Tablet, Streptococcus Pyogenes 6 000 Milli I.U. Tablet, Streptococcus Viridans 6 000 Milli I.U. Tablet	Tablet	Oral Use
Portugal	Daiichi Sankyo Portugal, Unip. Lda	Paspat Oral	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Lusomedicamenta – Sociedade Técnica Farmacêutica, Sa	Lantigen B	Haemophilus Influenzae 50.2 agu/Ml, Klebsiella Pneumoniae 39.8 agu/Ml, Staphylococcus Aureus 79.6 agu/Ml, Streptococcus Pneumoniae 63.2 agu/Ml, Streptococcus Pyogenes 126.2 agu/Ml, Moraxella Catarrhalis 39.9 agu/Ml	Oral Suspension	Sublingual Use
Portugal	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5 mg Sachet	Granules	Oral Use
Portugal	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Portugal	Om Pharma S.A.	Broncho-Vaxom Infantil,	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Portugal	Pierre Fabre Médicament Portugal, Lda.	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Portugal	Pierre Fabre Médicament Portugal, Lda.	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Granules For Oral Solution	Oral Use
Portugal	Pierre Fabre Médicament Portugal, Lda.	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Tablet	Oral Use
Romania	Alvogen Malta Operations (Row) Ltd	Luivac	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use
Romania	Bruschettini S.R.L	Lantigen B	Haemophilus Influenzae Type B (Hib) 50.2 agu/Ml, Klebsiella Pneumoniae 39.8 agu/Ml, Staphylococcus Aureus 79.6 agu/Ml, Streptococcus Pneumoniae 63.2 agu/Ml, Streptococcus Pyogenes 126.2 agu/Ml, Moraxella Catarrhalis 39.9 agu/Ml	Oral Drops, Suspension	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Romania	Daiichi Sankyo Europe Gmbh	Luivac	Bacterial Lysate 3 mg Tablet	Tablet	Oral Use
Romania	Om Pharma S.A.	Broncho-Vaxom Adulți	Lyophilized Bacterial Lysates 7 mg Capsule	Capsule, Hard	Oral Use
Romania	Om Pharma S.A.	Broncho-Vaxom Copii	Lyophilized Bacterial Lysates 3.5 mg Capsule	Capsule, Hard	Oral Use
Romania	Om Pharma S.A.	Broncho-Vaxom Copii	Lyophilized Bacterial Lysates 3.5 mg Sachet	Powder For Oral Suspension	Oral Use
Romania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units / Ml, Ribosomes Of Haemophilus Influenzae 0.5 Units / Ml, Ribosomes Of Streptococcus Pneumoniae 3 Units / Ml, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units / Ml, Ribosomes From Streptococcus Pyogenes Group A 3 Units / Ml	Granules For Oral Solution	Oral Use
Romania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units Tablet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Romania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Granules For Oral Solution	Oral Use
Slovakia	Daiichi Sankyo Europe Gmbh	Luivac	Lysatum Bacteriale Mixtum 3 mg Tablet	Tablet	Oral Use
Slovakia	Om Pharma S.A.	Broncho-Vaxom	Lysatum Bacteriale Mixtum 7 mg Capsule	Capsule, Hard	Oral Use
Slovakia	Om Pharma S.A.	Broncho-Vaxom Pre Deti	Lysatum Bacteriale Mixtum 3.5 mg Capsule	Capsule, Hard	Oral Use
Slovakia	Om Pharma S.A.	Broncho-Vaxom Pre Deti	Lysatum Bacteriale Mixtum 3.5 mg Sachet	Oral Powder	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Slovakia	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Sachet, Ribosomes Of Haemophilus Influenzae 0.5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 3 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Sachet	Granules For Oral Solution	Oral Use
Slovakia	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 3.5 mg Capsule	Capsule, Hard	Oral Use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 7 mg Capsule	Capsule, Hard	Oral Use

ANNEX II

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

Member State EU/EEA	Applicant / Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Axentyl 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Austria	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Austria	Vana GmbH Wolfgang Schmälzl-Gasse 6 1020 Wien Austria	Vanatyl 200 mg/ml - Injektionslösung für Tiere	Tylosin base	200 mg/ml	Solution for injection	Cattle, dogs, goats, pigs, sheep	Sheep: Intramuscular route
Austria	CEVA Santé Animale 10 Avenue De La Ballastiere 33500 Libourne France	Tiljet	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Bulgaria	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin 200 mg/ml solution for injection for cattle, sheep, goats and pigs	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Bulgaria	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Pharmasin 50 solution for injection	Tylosin base	50 mg/ml	Solution for injection	Cats, cattle, dogs, goats, pigs, sheep	Sheep: Intramuscular route
Bulgaria	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylovet B-200 solution for injection for cattle, sheep, goats, swine and dogs	Tylosin base	200 mg/ml	Solution for injection	Cattle, dogs, goats, pigs, sheep	Sheep: Intramuscular route

Member State EU/EEA	Applicant / Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylovet B-50, solution for injection for cattle, sheep, goats, swine, dogs and cats	Tylosin base	50 mg/ml	Solution for injection	Cats, cattle, dogs, goats, pigs, sheep	Sheep: Intramuscular route
Bulgaria	CEVA Santé Animale 10 Avenue De La Ballastiere 33500 Libourne France	Tiljet 200 mg/ml solution for injection for cattle, pigs, sheep and goat	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Denmark	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Tylmasin	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Denmark	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylovet	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Denmark	Ceva Animal Health A/S Ladegårdsvej 2 DK-7100 Vejle Denmark	Tiljet	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Estonia	Interchemie Werken De Adelaar Eesti AS Vanapere tee 14 Püünsi, Viimsi vald 74013 Harju maakond Estonia	Macrolan-200	Tylosin base	200 mg/ml	Solution for injection	Cattle, pigs, sheep	Sheep: Intramuscular route
Estonia	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
France	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	AXENTYL 200 MG/ML SOLUTION INJECTABLE POUR BOVINS, OVINS, CAPRINS ET PORCINS	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route

Member State EU/EEA	Applicant / Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	Bimeda Animal Health Unit 2/3/4 Airton Close Tallaght Dublin 24 Ireland	BILOVET 200 MG/ML SOLUTION INJECTABLE	Tylosin base	200 mg/ml	Solution for injection	Sheep	Sheep: Intramuscular route
France	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 MG/ML SOLUTION INJECTABLE POUR BOVINS OVINS CAPRINS ET PORCINS	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
France	LILLY France 24 Boulevard Vital Bouhot 92200 Neuilly Sur Seine France	TYLAN 200	Tylosin base	200 mg/ml	Solution for injection	Sheep	Sheep: Intramuscular route
France	CEVA Santé Animale 10 Avenue De La Ballastiere 33500 Libourne France	TILJET 200 MG/ML SOLUTION INJECTABLE POUR BOVINS OVINS CAPRINS ET PORCINS	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Germany	CEVA Santé Animale 10 Avenue De La Ballastiere 33500 Libourne France	Tiljet 200 mg/ml solution for injection for cattle, pigs, sheep and goats	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Germany	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylmasin 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Germany	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin 200 mg/ml Injektionslösung für Rinder, Schafe, Ziegen und Schweine	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Greece	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route

Member State EU/EEA	Applicant / Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylmasin	Tylosin tartrate	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Greece	Ceva Hellas LLC 15 Agiou Nikolaou Street 17455, Alimos Greece	Tiljet	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Greece	A. Nikolakopoulos S.A. 115 Galatsi Avenue 11146, Galatsi Greece	Tilocen	Tylosin tartrate	200 mg/ml	Solution for injection	Cattle, sheep, pigs, dogs, cats	Sheep: Intramuscular route
Greece	Anafasis LTD Santorinis 3 Pallouriotissa 1048 Nicosia Cyprus	Tylosin/Anafasis	Tylosin tartrate	200 mg/ml	Solution for injection	Cattle, sheep, pigs, dogs, cats	Sheep: Intramuscular route
Hungary	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml oldatos injekció szarvasmarhák, juhok, kecskék és sertések részére	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Hungary	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TYLMASIN 200 mg/ml oldatos injekció szarvasmarhák, juhok, kecskék és sertések részére	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Ireland	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin 200 mg/ml solution for injection for cattle, sheep, goats and pigs	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Ireland	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylosin Biovet JSC 200 mg/ml solution for injection for cattle, sheep, goats and pigs	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route

Member State EU/EEA	Applicant / Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	CEVA Santé Animale 10 Avenue De La Ballastiere 33500 Libourne France	Tiljet Solution for Injection	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Italy	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	AXENTYL 200 mg/ml soluzione iniettabile per bovini, ovini, caprini e suini	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Italy	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml soluzione iniettabile per bovini, ovini, caprini e suini	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Latvia	Interchemie Werken De Adelaar Eesti AS Vanapere tee 14 Püünsi, Viimsi vald 74013 Harju maakond Estonia	LV Macrolan	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route.
Latvia	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Lithuania	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 50 mg/ml injekcinis tirpalas kiaulėms, galvijams, avims, ožkoms, šunims ir katėms	Tylosin base	50 mg/ml	Solution for injection	Cats, cattle, dogs, goats, pigs, sheep	Sheep: Intramuscular route
Lithuania	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml injekcinis tirpalas kiaulėms, galvijams, avims ir ožkoms	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Poland	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylozyna Biovet JSC	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route

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Poland	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Poland	Ceva Animal Health Polska Sp.zo.o. Ul. Okrzei 1a Warszawa 03-715 Poland	Tiljet 200 mg/ml solution for injection for cattle, pigs, sheep and goats	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Portugal	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	AXENTYL 200 mg/ml soluzione iniettabile per bovini, ovini, caprini e suini	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Portugal	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml soluzione iniettabile per bovini, ovini, caprini e suini	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Romania	S.C. Pasteur - Filiala Filipesti Str. Principala, nr. 944 Filipestii de Padure Jud. Prahova Romania	Tilozina FP	Tylosin tartrate	200 mg/ml	Solution for injection	Sheep	Sheep: Intramuscular route
Romania	Romvac Company SA Sos. Centurii nr.7 07718, Voluntari Jud. Ilfov Romania	Tylavet	Tylosin tartrate	200 mg/ml	Solution for injection	Sheep	Sheep: Intramuscular route
Romania	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	Pharmasin 200 mg/ml	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Romania	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	Tylmasin 200 mg/ml	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route

Member State EU/EEA	Applicant / Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium	PHARMASIN 200 mg/ml SOLUCION INYECTABLE PARA BOVINO OVINO CAPRINO Y PORCINO	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Spain	Biovet JSC 39 Petar Rakov Str. 4550 Peshtera Bulgaria	TILOSINA BIOVET JSC 200 mg/ml SOLUCION INYECTABLE PARA BOVINO OVINO CAPRINO Y PORCINO	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route
Spain	CEVA SALUD ANIMAL, S.A. Avda. Diagonal, 609-615 08028 Barcelona Spain	TILJET 200 mg/ml SOLUCION INYECTABLE PARA BOVINO, OVINO, CAPRINO Y PORCINO	Tylosin base	200 mg/ml	Solution for injection	Cattle, goats, pigs, sheep	Sheep: Intramuscular route