Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 December 2012 to 31 December 2012

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

(2013/C 24/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
17.12.2012	HIPRALONA ENRO-S and its generics	See Annex I	See Annex I	19.12.2012
6.12.2012	Prefluce+l and associated names	See Annex II	See Annex II	10.12.2012

— Suspension of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
20.12.2012	Loraxin	See Annex III	See Annex III	21.12.2012
10.12.2012	Cilazapril Teva and associated names	See Annex IV	See Annex IV	12.12.2012

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

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, APPLICANT/MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
Belgium	GLOBAL VET HEALTH SL C/Capçanes nº 12-bajos Polígono Agro-Reus 43206 Reus SPAIN	QUINOFLOX 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Chickens (Broilers, replacement chickens, broiler breeders), Rabbits
Cyprus	LABORATORIOS KARIZOO, S.A. Polígono Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona SPAIN	K-Flox 100 mg/ml Πόσιμο διάλυμα για ορνίθια κρεοπαραγωγής και κουνέλια	Enrofloxacin	100 mg/ml	Oral solution	Chickens (broilers), Rabbits
Spain	LABORATORIOS HIPRA, S.A.Avda. La Selva,135 17170 Amer SPAIN	HIPRALONA ENRO - S	Enrofloxacin	100 mg/ml	Oral solution	Poultry (Chicken and Turkeys), Rabbits
Spain	UNIVERSAL FARMA, S.L. Gran Via Carlos III 98 - 7ª 08028 Barcelona SPAIN	LEVOFLOK® 100 mg/ml Oral solution for chickens and rabbits	Enrofloxacin	100 mg/ml	Oral solution	Chickens, Rabbits
Spain	LABORATORIOS KARIZOO, S.A. Polígono Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona SPAIN	K-FLOX 100 mg/ml Oral Solution for chickens and rabbits.	Enrofloxacin	100 mg/ml	Oral solution	Chickens, Rabbits
Spain	Global Vet Health, SL Capcanes, 12 bajos Poligono Agro-Reus 43206 Reus SPAIN	QUINOFLOX 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Chickens, Rabbits
Spain	SP VETERINARIA Ctra.Reus-Vinyols, Km, 43330 Ruidoms SPAIN	COLMYC -C	Enrofloxacin	100 mg/ml	Oral solution	Poultry (Chicken and Turkeys), Rabbits

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
France	GLOBAL VET HEALTH SL c/Capçanes, nº 12-bajos. Polígon Agro-Reus. 43206 Reus SPAIN	Quinoflox 100 mg/ml solution for use in drinking water, chicken and rabbits	Enrofloxacin	100 mg/ml	Oral solution	Chickens (Broilers, replacement chickens, broiler breeders), Rabbits
Italy	GLOBAL VET HEALTH, S.L. Capsanes, 12 - Polígono Agro-Reus E-43206 - REUS (Tarragona) SPAIN	QUINOLCEN	Enrofloxacin	100 mg/ml	Oral solution	Chickens, Rabbits
Italy	LABORATORIOS KARIZOO, S.A. Polígono Industrial La Borda Mas Pujades, 11-12 08140 – CALDES DE MONTBUI (Barcelona) SPAIN	K-FLOX 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Chickens, Rabbits
Italy	VETPHARMA ANIMAL HEALTH, S.L. Les Corts, 23 08028 – BARCELONA SPAIN	NIFLOX 100 mg/ml	Enrofloxacin	100 mg/ml	Oral solution	Chickens, Rabbits
Poland	Medivet S.A. Szkolna 17 63-100 Śrem POLAND	MEDOXIL ORAL 100 mg/ml roztwór doustny dla kur i królików	Enrofloxacinum	100 mg/ml	Oral solution	Chickens, Rabbits
Portugal	GLOBAL VET HEALTH SL C/Capçanes nº 12-bajos Polígono Agro-Reus 43206 Reus SPAIN	Quinoflox 100 mg/ml solução para administração na água de bebida para frangos e coelhos	Enrofloxacin	100 mg	Oral solution	Chickens (Broilers, replacement chickens, broiler breeders) and rabbits
Portugal	VETPHARMA ANIMAL HEALTH, S.L. Les Corts, 23 08028 Barcelona SPAIN	LEVOFLOK® 100 mg/ml Solução oral para frangos de carne e coelhos	Enrofloxacin	100 mg	Oral solution	Chickens (broilers), Rabbits

Member State EU/EEA	Applicant/Marketing Authorisation Holder	Name	INN	Strength	Pharmaceutical form	Animal species
Portugal	LABORATORIOS KARIZOO, S.A. Polígono Industrial La Borda Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona SPAIN	K-FLOX 100 mg/ml Solução oral para frangos de carne e coelhos	Enrofloxacin	100 mg	Oral solution	Chickens (broilers), Rabbits
Portugal	Prodivet-Zn, Nutrição e Comércio de Produtos Químicos Farmacêuticos e Cosméticos SA Av. Infante D. Henrique nº 333 H 3º Piso Esc. 411800-282 Lisboa PORTUGAL	Prodirox 100 mg/ml solução oral para frangos e coelhos	Enrofloxacin	100 mg	Oral solution	Chickens (broilers), Rabbits
Portugal	VETLIMA Sociedade Distr. Produtos Agro-Pecuários LDA. Centro Empresarial da Rainha Lote 27 2050-501 Vila Nova Da Rainha PORTUGAL	VETAFLOX 100 mg/ml solução oral para frangos de engorda e coelhos	Enrofloxacin	100 mg	Oral solution	Chickens (broilers), Rabbits
United Kingdom	Global Vet Health S.L. Calle Capcanes n12 Bajos Poligono Agro-Reus 43206 Reus SPAIN	Quinoflox 100 mg/ml Solution for Use in Drinking Water, Chicken and Rabbits	Enrofloxacin	100 mg/ml	Oral solution	Chickens, Rabbits

ANNEX II

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State (in EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Baxter AG Industriestrasse 67 Vienna 1221 Austria	Preflucel Injektionssuspen sion in einer Fertigspritze	15 micrograms haemagglutinin of each of the 3 specified strains as determined by WHO per 0,5 ml dose	suspension for injection in a pre-filled syringe	intramuscular use
Belgium	Baxter S.A. Bd René Branquart 80 7860 Lessines Belgium	Preflucel	15 µg-0,5 ml	suspension for injection	intramuscular use
Czech Republic	Baxter AG Industriestrasse 67 Vienna 1221 Austria	PREFLUCEL	0,5 ml per dose	suspension for injection	intramuscular use
Denmark	Baxter A/S Gydevang 43 DK-3450 Allerød Denmark	Preflucel	15 microgram	suspension for injection in a prefilled syringe	intramuscular use
Finland	Baxter Oy Tammasaarenkatu 1 PL 119 00181 Helsinki Finland	Preflucel	15 mikrog HA/0,5 ml 15 mikrog HA/0,5 ml 15 mikrog HA/0,5 ml	suspension for injection in pre-filled syringe	intramuscular use
Germany	Baxter Deutschland GmbH Edisonstraße 4 85716 Unterschleißheim Germany	PREFLUCEL	15 µgHA 15 µgHA 15 µgHA	suspension for injection in prefilled syringe	intramuscular use

Member State (in EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
Ireland	Baxter Healthcare Limited Caxton Way Thetford Norfolk IP24 3SE United Kingdom	Preflucel suspension for injection in a pre- filled syringe	15 microgram	suspension for injection	intramuscular use
Italy	Baxter S.p.A. Piazzale dell'Industria 20 Rome 00144 Italy	PREFLUCELL	15 micrograms	suspension for injection in a pre-filled syringe	intramuscular use
Norway	Baxter AS Gjerdrums vei 11 N-0484 Oslo Norway	Preflucel	15 µg hemagglutinin of each of the 3 influenza virus strains	suspension for injection in a pre-filled syringe	intramuscular use
Poland	Baxter Polska Sp. z o.o. Kruczkowskiego 8 00-380 Warszawa Poland	Preflucel	A/California/07/2009 (H1N1)- 15 micrograms HA A/Perth/16/2009 (H3N2) like strain used (A/Victoria/210/2009)- 15 micrograms HA B/Brisbane/60/2008 (B)- 15 micrograms HA/HA** per 0,5 ml dose	suspension for injection in a pre-filled syringe	intramuscular use
Portugal	Baxter Médico-Farmacêutica, Lda. Zona Industrial da Abrunheira Edifício 10 Sintra Business Park 2710-089 Sintra Portugal	Preflucel	A/California/7/2009 (H1N1) - like virus → 0,015 mg A/Perth/16/2009 (H3N2) - like virus → 0,015 mg B/Brisbane/60/2008 → 0,015 mg	suspension for injection in a pre-filled syringe	intramuscular Use
Spain	Baxter, S.L. Polígono Industrial Sector 14 Pouet de Camilo, 2 Ribarroja del Turia Valencia 46394 Spain	PREFLUCEL SUSPENSION INYECTABLE EN JERINGA PRECARGADA	A/California/07/2009 (H1N1)- 15 micrograms HA; A/Perth/16/2009 (H3N2) like strain used: (A/Victoria/210/2009)- 15 micrograms HA; B/Brisbane/60/2008 (B)- 15 micrograms HA, per 0,5 ml dose	suspension for injection in prefilled syringe	intramuscular use

Member State (in EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
Sweden	Baxter Medical AB Torshamnsgatan 35 Box 63 164 94 Kista Sweden	Preflucel	(NA)	solution for injection, pre filled syringe	intramuscular use
The Netherlands	Baxter B.V. Kobaltweg 49 3542 CE Utrecht The Netherlands	Preflucel 2011/2012, suspensie voor injectie 0,5 ml	0,5 ml per dose	suspension for injection	intramuscular use
United Kingdom	Baxter Healthcare Limited Caxton Way Thetford Norfolk IP24 3SE United Kingdom	Preflucel	15 mcg hemagglutinin of each of the 3 influenza virus strains	suspension for injection in a pre-filled syringe	intramuscular use

ANNEX III

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS/MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing authorisation holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Czech Republic		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loratadine Vitabalans 10 mg tablety	10 mg	tablet	oral use
Denmark		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loraxin	10 mg	tablet	oral use
Estonia		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loratadine Vitabalans	10 mg	tablet	oral use
Finland	Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loraxin	10 mg	tablet	oral use
Hungary		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loraxin	10 mg	tablet	oral use
Latvia		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loratadine Vitabalans 10 mg tabletes	10 mg	tablet	oral use
Lithuania		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loraxin	10 mg	tablet	oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Norway		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loratadine Vitabalans	10 mg	tablet	oral use
Poland		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loratadine Vitabalans	10 mg	tablet	oral use
Slovak Republic		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loratadine Vitabalans 10 mg	10 mg	tablet	oral use
Slovenia		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loratadine Vitabalans 10 mg tablete	10 mg	tablet	oral use
Sweden		Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	Loratadine Vitabalans	10 mg	tablet	oral use

ANNEX IV

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Cilazapril TEVA 0,5 mg Filmtabletten	0,5 mg	Film-coated tablet	Oral use
Austria	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Cilazapril TEVA 2,5 mg Filmtabletten	2,5 mg	Film-coated tablet	Oral use
Austria	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Cilazapril TEVA 5 mg Filmtabletten	5,0 mg	Film-coated tablet	Oral use
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Praha 5, Czech Republic	CILAZAPRIL TEVA 5 MG	5 mg	Film-coated tablet	Oral use
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Praha 5, Czech Republic	CILAZAPRIL TEVA 2,5 MG	2,5 mg	Film-coated tablet	Oral use
France	TEVA SANTE 110 ESPLANADE DU GENERAL DE GAULLE 92931 PARIS LA DEFENSE CEDEX FRANCE	CILAZAPRIL TEVA 1 mg, comprimé pelliculé sécable	1 mg	Film-coated tablet	Oral use
France	TEVA SANTE 110 ESPLANADE DU GENERAL DE GAULLE 92931 PARIS LA DEFENSE CEDEX FRANCE	CILAZAPRIL TEVA 0,5 mg, comprimé pelliculé sécable	0,5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
France	TEVA SANTE 110 ESPLANADE DU GENERAL DE GAULLE 92931 PARIS LA DEFENSE CEDEX FRANCE	CILAZAPRIL TEVA 2,5 mg, comprimé pelliculé sécable	2,5 mg	Film-coated tablet	Oral use
Poland	123ratio Sp. z o.o. ul. Emilii Plater 53 00-113 Warsaw Poland	Cilazaprilum 123ratio	1 mg	Film-coated tablet	Oral use
Poland	123ratio Sp. z o.o. ul. Emilii Plater 53 00-113 Warsaw Poland	Cilazaprilum 123ratio	2,5 mg	Film-coated tablet	Oral use
Poland	123ratio Sp. z o.o. ul. Emilii Plater 53 00-113 Warsaw Poland	Cilazaprilum 123ratio	5 mg	Film-coated tablet	Oral use
Spain	TEVA PHARMA, S.L.U. C/Anabel Segura, 11 Edificio Albatros B, 1ª planta 28108 Alcobendas (Madrid) Spain	CILAZAPRIL TEVA 1 mg comprimidos recubiertos con película EFG	1 mg	Film-coated tablet	Oral use
Spain	TEVA PHARMA, S.L.U. C/Anabel Segura, 11 Edificio Albatros B, 1ª planta 28108 Alcobendas (Madrid) Spain	CILAZAPRIL TEVA 5 mg comprimidos recubiertos con película EFG	5 mg	Film-coated tablet	Oral use
Spain	TEVA PHARMA, S.L.U. C/Anabel Segura, 11 Edificio Albatros B, 1ª planta 28108 Alcobendas (Madrid) Spain	CILAZAPRIL TEVA 2,5 mg comprimidos recubiertos con película EFG	2,5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Teva UK Ltd, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom	Cilazapril 0,5 mg tablets	0,5 mg	Tablet	Oral use
United Kingdom	Teva UK Ltd, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom	Cilazapril 1 mg tablets	1 mg	Tablet	Oral use
United Kingdom	Teva UK Ltd, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom	Cilazapril 2,5 mg tablets	2,5 mg	Tablet	Oral use
United Kingdom	Teva UK Ltd, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom	Cilazapril 5 mg tablets	5 mg	Tablet	Oral use