— having regard to Rules 51 and 83(7) of its Rules of Procedure,

— having regard to the report of the Committee on Transport and Tourism (A6-0258/2005),

1. Approves conclusion of the agreement;

2. Instructs its President to forward its position to the Council and Commission, and the governments and parliaments of the Member States and the Republic of Bulgaria.

P6_TA(2005)0344

EC-Croatia Agreement on certain aspects of air services *

European Parliament legislative resolution on the proposal for a Council decision on the conclusion of the Agreement between the European Community and the Republic of Croatia on certain aspects of air services (COM(2005)0159 — C6-0173/2005 — 2005/0059(CNS))

(Consultation procedure)

The European Parliament,

— having regard to the proposal for a Council decision (COM(2005)0159) ([1]),

— having regard to Articles 80(2) and 300(2), first subparagraph, first sentence, of the EC Treaty,

— having regard to Article 300(3), first subparagraph, of the EC Treaty, pursuant to which the Council consulted Parliament (C6-0173/2005),

— having regard to Rules 51 and 83(7) of its Rules of Procedure,

— having regard to the report of the Committee on Transport and Tourism (A6-0259/2005),

1. Approves the conclusion of the agreement;

2. Instructs its President to forward this position to the Council and Commission, and the governments and parliaments of the Member States and the Republic of Croatia.

([1]) Not yet published in OJ.

P6_TA(2005)0345

Fees payable to the European Medicines Agency *

European Parliament legislative resolution on the proposal for a Council regulation amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency (COM(2005)0106 — C6-0137/2005 — 2005/0023(CNS))

(Consultation procedure)

The European Parliament,

— having regard to the Commission proposal to the Council (COM(2005)0106) ([1]),

— having regard to Article 12 of Council Regulation (EC) No 297/95 of 10 February 1995 ([2]), pursuant to which the Council consulted Parliament (C6-0137/2005),

([1]) Not yet published in OJ.

([2]) OJ L 35, 15.2.1995, p. 1. Regulation as last amended by Commission Regulation (EC) No 494/2003 (OJ L 73, 19.3.2003, p. 6).

— having regard to Rule 51 of its Rules of Procedure,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Budgets (A6-0264/2005),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 250(2) of the EC Treaty;

3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;

4. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;

5. Instructs its President to forward its position to the Council and Commission.

TEXT PROPOSED BY THE COMMISSION	AMENDMENTS BY PARLIAMENT

Amendment 1

Recital 4 a (new)

	(4a) In order to respect the principle of proportionality, medicinal products in which the active substances have been in well-established medicinal use within the Community for at least ten years should benefit from a reduced annual fee.

Amendment 2

Article 1, point 2 (b) (II)

Article 3, paragraph 1, point (b), subparagraph 1 (Regulation (EC) No 297/95)

A reduced fee of 90 000 Euro shall apply to applications for a marketing authorisation pursuant to Articles 10(1), 10(3) and 10c of Directive 2001/83/EC of the European Parliament and of the Council. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.	A reduced fee of 90 000 Euro shall apply to applications for a marketing authorisation pursuant to Articles 10(1), 10(3), ***10a*** and 10c of Directive 2001/83/EC of the European Parliament and of the Council. That fee shall cover a single strength associated with one pharmaceutical form and one presentation. ***In exceptional cases, where an extensive workload relating to the evaluation of an application for marketing authorisation pursuant to Article 10a of Directive 2001/83/EC can be demonstrated, a fee of up to 232 000 Euro may be determined in accordance with Article 11(2) of this Regulation.***

Amendment 3

Article 1, point 7

Article 8, paragraph 2 (Regulation (EC) No 297/95)

A scientific service fee shall apply where an application is made for any scientific advice or opinion by a scientific Committee, which is not covered by Articles 3 to 7 or by Article 8(1). This includes ***any evaluation of traditional herbal medicinal products***, any opinion on medicinal products for compassionate use, any consultation on ancillary substances, including blood derivatives, incorporated in medical devices, and any evaluation of plasma master files and vaccine antigen master files.	A scientific service fee shall apply where an application is made for any scientific advice or opinion by a scientific Committee, which is not covered by Articles 3 to 7 or by Article 8(1). This includes any opinion on medicinal products for compassionate use, any consultation on ancillary substances, including blood derivatives, incorporated in medical devices, and any evaluation of plasma master files and vaccine antigen master files.

Tuesday, 27 September 2005

TEXT PROPOSED BY THE COMMISSION	AMENDMENTS BY PARLIAMENT
When it concerns medicinal products for human use, the fee shall be 232 000 Euro.	When it concerns medicinal products for human use, the fee shall be ***not more than*** 232 000 Euro.
When it concerns veterinary medicinal products, the fee shall be 116 000 Euro.	When it concerns veterinary medicinal products, the fee shall be ***not more than*** 116 000 Euro.
	When it concerns the evaluation of traditional herbal medicinal products, the fee shall be not more than 25 000 Euro.
The provisions of Article 3 shall apply to any scientific opinion for the evaluation of medicinal products for human use intended exclusively for markets outside the Community pursuant to Article 58 of Regulation (EC) No 726/2004.	The provisions of Article 3 shall apply to any scientific opinion for the evaluation of medicinal products for human use intended exclusively for markets outside the Community pursuant to Article 58 of Regulation (EC) No 726/2004.
A reduced scientific service fee falling within the range of 2 500 Euro to 200 000 Euro shall apply for certain scientific opinions or services concerning medicinal products for human use.	A reduced scientific service fee falling within the range of 2 500 Euro to 200 000 Euro shall apply for certain scientific opinions or services concerning medicinal products for human use.
A reduced scientific service fee falling within the range of 2 500 Euro to 100 000 Euro shall apply for certain scientific opinions or services concerning veterinary medicinal products.	A reduced scientific service fee falling within the range of 2 500 Euro to 100 000 Euro shall apply for certain scientific opinions or services concerning veterinary medicinal products.
	A reduced scientific service fee falling within the range of 2 500 Euro to 25 000 Euro shall apply for certain scientific opinions or services concerning traditional herbal medicinal products.
The scientific opinions or services referred to in the ***fifth and*** sixth subparagraph shall be included in a list, which shall be drawn up in accordance with Article 11(2).	The scientific opinions or services referred to in the sixth, ***seventh and eighth*** subparagraph shall be included in a list, which shall be drawn up in accordance with Article 11(2).

P6_TA(2005)0346

Protocol to the EEC-Comoros Agreement on tuna fishing *

European Parliament legislative resolution on the proposal for a Council regulation on the conclusion of the Protocol setting out the tuna fishing opportunities and financial contribution provided for in the Agreement between the European Economic Community and the Islamic Federal Republic of the Comoros on fishing off the Comoros for the period from 1 January 2005 to 31 December 2010 (COM(2005)0187 — C6-0154/2005 — 2005/0092(CNS))

(Consultation procedure)

The European Parliament,

— having regard to the proposal for a Council regulation (COM(2005)0187) [1],

— having regard to Articles 37 and 300(2) of the EC Treaty,

[1] Not yet published in OJ.