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REPORT

on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission
(COM(2006)0919 – C6-0030/2007 – 2006/0295(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Françoise Grossetête

PR_COD_1am

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission (COM(2006)0919 – C6-0030/2007 – 2006/0295(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2006)0919)[1],

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0030/2007),

– 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 (A6-0277/2007),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

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

Text proposed by the Commission	Amendments by Parliament
Amendment 1 RECITAL 4	
(4) In particular, power should be conferred on the Commission to adapt certain provisions and annexes, to adopt arrangements and principles and guidelines, ***and*** to lay down specific conditions of application. Since these measures are of general scope and are designed to amend/delete non-essential elements of Directive 2001/83/EC and/or to supplement *this* Directive by the addition of new non-essential elements,	(4) In particular, power should be conferred on the Commission to adapt certain provisions and annexes, to adopt arrangements and principles and guidelines, to lay down specific conditions of application, ***and to adopt the list of herbal substances and the final measures in relation to suspension and revocation of marketing authorisations.*** Since these measures are of general scope and are designed to amend/delete non-essential

[1] Not yet published in OJ.

they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.	elements of Directive 2001/83/EC and/or to supplement *that* Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Amendment 2
ARTICLE 1, POINT 1 A (new)
Article 16 f, paragraph 1 (Directive 2001/83/EC)

	(1a) Article 16f(1) is replaced by the following:
	'1. A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, designed to amend non-essential elements of this Directive by supplementing it, shall be established in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a). This list shall contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product.'

Amendment 3
ARTICLE 1, POINT 6 A (new)
Article 107, paragraph 2, subparagraph 4 (Directive 2001/83/EC)

	(6a) The fourth subparagraph of Article 107(2) is replaced by the following:
	'The final measures designed to amend non-essential elements of this Directive by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).'

Amendment 4
ARTICLE 1, POINT 9, POINT (B)
Article 121, paragraph 4 (Directive 2001/83/EC)

(b) Paragraph 4 is deleted.	***deleted***

Or. fr

Justification

La proposition de la Commission de supprimer le paragraphe 4 repose sur la décision 1999/468/CE qui précise entre autres les conditions de publication et d'accès aux documents des institutions et des agences et organes de l'Union. Cette suppression se justifierait par la nécessité de ne pas répéter ce point dans la législation communautaire. Or l'accès aux documents ne se fait que sur demande, alors que le paragraphe 4 rend obligatoire la publication du règlement intérieur du comité.

Par ailleurs, il n'y a aucune raison de refuser dorénavant cette publication du règlement intérieur du comité, acceptée lors de la révision du code communautaire relatif aux médicaments à usage humain, sachant qu'à cette date la décision 1999/468/CE était déjà d'application.

Enfin, cette publication du règlement intérieur était un point de l'accord général sur la révision du code communautaire, notamment en matière de renforcement de la transparence.

EXPLANATORY STATEMENT

The adjustment of the medicinal products for human use Directive to the revised Comitology Decision 1999/468/EEC shall take fully into account the newly introduced regulatory procedure with scrutiny.

Your rapporteur is of the opinion that the list of herbal substances and the final measures in relation to suspension and revocation of marketing authorisations should be adopted under the new regulatory procedure with scrutiny.

PROCEDURE

Title	Community code relating to medicinal products for human use (implementing powers conferred on the Commission)
References	COM(2006)0919 – C6-0030/2007 – 2006/0295(COD)
Date submitted to Parliament	22.12.2006
Committee responsible Date announced in plenary	ENVI 17.1.2007
Rapporteur(s) Date appointed	Françoise Grossetête 27.2.2007
Date adopted	26.6.2007
Result of final vote	+: 41 –: 1 0: 0
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Pilar Ayuso, Johannes Blokland, Hiltrud Breyer, Dorette Corbey, Chris Davies, Mojca Drčar Murko, Edite Estrela, Jill Evans, Anne Ferreira, Matthias Groote, Satu Hassi, Gyula Hegyi, Jens Holm, Dan Jørgensen, Urszula Krupa, Peter Liese, Jules Maaten, Alexandru-Ioan Morţun, Riitta Myller, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Guido Sacconi, Amalia Sartori, María Sornosa Martínez, Antonios Trakatellis, Evangelia Tzampazi, Thomas Ulmer, Marcello Vernola, Åsa Westlund, Glenis Willmott
Substitute(s) present for the final vote	Milan Gaľa, Umberto Guidoni, David Martin, Jiří Maštálka, Justas Vincas Paleckis, Alojz Peterle
Substitute(s) under Rule 178(2) present for the final vote	Corina Creţu
Date tabled	5.7.2007