COUNCIL OF THE EUROPEAN UNION

Brussels, 14 February 2011

17149/10
ADD 1

PV/CONS 66
AGRI 508
PECHE 320

ADDENDUM to DRAFT MINUTES

Subject: **3050th** meeting of the COUNCIL OF THE EUROPEAN UNION (**AGRICULTURE AND FISHERIES**), held in Brussels on 29 November 2010

PUBLIC DELIBERATION ITEMS [1]

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[1] Deliberations on Union legislative acts (Article 16(8) of the Treaty on European Union), other deliberations open to the public and public debates (Article 8 of the Council's Rules of Procedure).

LEGISLATIVE DELIBERATIONS - "A" ITEMS

1. Regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products

PE-CONS 46/10 MI 331 SAN 192 ECO 80 ENT 121 CODEC 909
+ REV 1 (es)
+ REV 2 (el)
+ REV 3 (de)

The Council approved the amendment set out in the European Parliament's position at first reading and adopted the proposed act amended accordingly, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 114 and point (c) of Article 168(4) of the TFUE)

Statement by the Commission

"Following the request made by the European Parliament and the Council on the grading of the head of the European Medicines Agency, the Commission in order not to delay the adoption of this important proposal undertakes to re-publish the vacancy notice for the next head of the European Medicines Agency with the grade AD15 instead of AD14.

The Commission considers that the right place to deal with the issue is the ongoing horizontal discussion on the role of EU agencies within the Inter-institutional working group on agencies. The discussion on this aspect is open in the inter-institutional working group, and if this discussion leads to different conclusions on the appropriate publication level, then this grading could be reconsidered for future publications."

Statement by the Netherlands, Belgium, Bulgaria, Ireland, Spain, Finland and Sweden

"From the wording of the definition of a post-authorisation safety study[1] (PASS) as proposed in the Pharmacovigilance legislation (Regulation (EC) No 726/2004) and the wording of the definition of non-interventional studies currently given in the Clinical Trial Directive (2001/20/EC), it follows that a study which can not be classified as a non-interventional trial is automatically considered to be a clinical trial falling under Directive 2001/20/EC.

[1] PASS definition: Any study with an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

We have concerns in particular as regards the part of the definition of a non-interventional study in the Clinical Trial Directive[1] which reads "*a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation*". As we understand it, this would mean that all studies addressing safety concerns not falling under the terms of the marketing authorisation (whether it involves uses according to well-established clinical practice, abuse, overdose, off-label use, misuse for illegal purposes, etc.) would be considered Clinical Trials.

A PASS can be interventional or non-interventional; however, in the case of a "non-interventional PASS", according to our understanding of the definition in the Clinical Trial Directive, the Pharmacovigilance Risk Assessment Committee set up in accordance with the proposed changes to Regulation (EC) 726/2004 will only be allowed to assess studies "with(in) the terms of marketing". Therefore studies addressing safety concerns that do not fall under a Marketing Authorisation would not come within the remit of the future Pharmacovigilance Risk Assessment Committee.

We hold that this legal problem must be solved during the revision of the Clinical Trial Directive and therefore request that the Commission treat this revision as a matter of urgency, with a view to ensuring that it will be possible for the PRAC to assess studies addressing safety concerns for uses of medicinal products not falling under a Marketing Authorisation."

2. Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use

= Adoption of the legislative act

PE-CONS 47/10 MI 332 SAN 193 ECO 81 ENT 122 CODEC 910

+ REV 1 (es)

+ REV 2 (el)

+ REV 3 (de)

The Council approved the amendment set out in the European Parliament's position at first reading and adopted the proposed act amended accordingly, the Slovenian delegation abstaining, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 114 and point (c) of Article 168(4) of the TFUE)

[1] "a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data."

Statement by the Netherlands, Belgium, Bulgaria, Ireland, Spain, Finland and Sweden

"From the wording of the definition of a post-authorisation safety study [1] (PASS) as proposed in the Pharmacovigilance legislation (Regulation (EC) No 726/2004) and the wording of the definition of non-interventional studies currently given in the Clinical Trial Directive (2001/20/EC), it follows that a study which can not be classified as a non-interventional trial is automatically considered to be a clinical trial falling under Directive 2001/20/EC.

We have concerns in particular as regards the part of the definition of a non-interventional study in the Clinical Trial Directive [2] which reads '*a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation*'. As we understand it, this would mean that all studies addressing safety concerns not falling under the terms of the marketing authorisation (whether it involves uses according to well-established clinical practice, abuse, overdose, off-label use, misuse for illegal purposes, etc.) would be considered Clinical Trials.

A PASS can be interventional or non-interventional; however, in the case of a 'non-interventional PASS', according to our understanding of the definition in the Clinical Trial Directive, the Pharmacovigilance Risk Assessment Committee set up in accordance with the proposed changes to Regulation (EC) 726/2004 will only be allowed to assess studies 'with(in) the terms of marketing'. Therefore studies addressing safety concerns that do not fall under a Marketing Authorisation would not come within the remit of the future Pharmacovigilance Risk Assessment Committee.

We hold that this legal problem must be solved during the revision of the Clinical Trial Directive and therefore request that the Commission treat this revision as a matter of urgency, with a view to ensuring that it will be possible for the PRAC to assess studies addressing safety concerns for uses of medicinal products not falling under a Marketing Authorisation."

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1 PASS definition: Any study with an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

2 "a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data."

Statement by Slovenia

"Slovenia supports the general aims of the Directive of the European Parliament and of the Council as regards pharmacovigilance and the Directive 2001/83/EC on the Community code relating to medicinal products for human use. Nevertheless Slovenia abstained from the vote, because it continues to oppose Article 126a of the Directive.

Slovenia is particularly concerned about possible negative effects of the application of Article 126a. The aim of the article is to improve the availability of medicines. Slovenia however believes that the provision will have only a limited impact on this availability, while at the same time potentially causing other public health concerns, particularly in small Member States.

Slovenia's concern is that, although regulated as an option, Article 126a could create a parallel route for supplying the market with medicinal products while avoiding important regulatory obligations. This could lead to an undesirable penetration of the medical products to the markets without respecting regular marketing authorisation procedures including all Marketing authorisation holder (MAH) obligations. The provision implies no obligation to assume responsibility for pharmacovigilance, advertising to health care professionals, handling variations, labelling, patient information, summary of product characteristics and other activities normally required from MAH. It also remains unclear to whom the sanctions should be addressed to in the case of non compliance with the acquis.

Slovenia believes that the simplification of Article 126a is at the very least premature, because the Commission has not yet presented a report on the implementation of the existing provisions, which it was expected to do already in April 2008. Such a report would allow a comprehensive discussion on modification of the current system. Slovenia expects the Commission to undertake all appropriate analysis and on their basis take further action in solving the issue of availability of medicines on small markets."

3. Regulation of the European Parliament and of the Council laying down a scheme of control and enforcement applicable in the area covered by the Convention on future multilateral cooperation in the North-East Atlantic fisheries

= Adoption of the legislative act

PE-CONS 48/10 PECHE 216 CODEC 945

+ REV 1 (pl)

The Council approved the amendment set out in the European Parliament's position at first reading and adopted the proposed act amended accordingly, the Swedish delegation abstaining, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: 43(2) of the TFUE)

Statements by the European Parliament, the Council and the Commission on Article 48

1. "The European Parliament, the Council and the Commission note that any of the provisions of a non-essential character of the basic legislative act, which now are listed under Article 48 of the Regulation (delegation of powers), can become at any time in the future a significant element of the existing NEAFC control scheme from a political point of view, in which case the European Parliament, the Council and the Commission recall that either of the legislators, the Council or the European Parliament, can immediately exercise either the right to object to a draft Commission delegated act or the right to revoke the delegated powers as provided respectively under Article 46b and Article 46c of the Regulation.".

2. "The Council and the Parliament agree that the inclusion of any provision of the NEAFC control scheme in this Regulation as a non-essential element, now listed under Article 48, does not imply per se that such provisions will automatically be considered by the legislators as being of a non-essential character in any future Regulations."

3. "The European Parliament, the Council and the Commission declare that the provisions of this Regulation shall be without prejudice to any future position of the institutions as regards the implementation of Article 290 TFEU or individual legislative acts containing such provisions."

Statement by the Commission

"The Commission expresses concern that the limited powers delegated to it by the co-legislators may hinder the timely implementation in EU law of measures taken by NEAFC in the future that revise or update the control scheme of this Organisation.
The Commission therefore declares that it considers this Regulation to be without prejudice to any future position of the institution as regards the recourse to Articles 290 and 291 TFEU for the transposition of Regional Fisheries Management Organisation measures.
The Commission furthermore reserves the right to propose amendments to the Regulation increasing the number of measures which should be adopted by delegated or implementing acts in case the transposition through the ordinary legislative procedure leads to delays which would jeopardise the EU's ability to comply with its international obligations."

Statement by Sweden

"Sweden abstains in order not to prevent a unanimous agreement in Council.
Sweden considers that it is necessary with a swift procedure of amendments in order for the European Union to fulfil its international obligations. This principle is still maintained by Sweden in so far that the principle of delegated acts should be used. It is Sweden's view that Council decisions on implementing international agreements and as such already binding, in which the European Union took part, should be considered as non-essential. Hence Article 48 of the Regulation in question could be delegated to the Commission.
However, Sweden does not wish to prevent a unanimous agreement in Council and therefore abstains."

4. Regulation of the European Parliament and of the Council concerning authentication of euro coins and handling of euro coins unfit for circulation

= Adoption of the legislative act

PE-CONS 38/10 GAF 9 FIN 399 UEM 270 CODEC 830
16468/10 CODEC 1287 GAF 14 FIN 585 UEM 290

The Council approved the amendment set out in the European Parliament's position at first reading and adopted the proposed act amended accordingly, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 133 of the TFUE)

AGENDA ITEMS - PUBLIC DEBATES

8. Commission Communication on the CAP towards 2020:
Meeting the food, natural resources and territorial challenges of the future

[Public debate in accordance with Article 8(3) of the Council's Rules of Procedure (proposed by the Presidency)]

– Presentation by the Commission
– Exchange of views

16348/10 AGRI 477 AGRISTR 14 AGRIORG 51

The Council took note of the presentation by the Commission representative of the Communication on the CAP towards 2020 and delegations' initial reactions, including the announcement by the future Hungarian Presidency of its full commitment to take work forward in the first months of 2011 with a view to having Council conclusions adopted in March 2011.

The Council further noted the Presidency's intention to hold a first policy debate on the Communication at the Council session on 13 December 2010, along with a lunch debate on the concept of "active farmer".

Finally the Council mandated its preparatory bodies to conduct an in-depth examination of the Communication.

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