COUNCIL OF THE EUROPEAN UNION

Brussels, 3 June 2010

10469/10

Interinstitutional File: 2008/0261 (COD)

MI 186
SAN 130
ECO 42
ENT 61
CODEC 503
UD 164

NOTE

From :	General Secretariat of the Council
to :	Council (EPSCO)
No. prev. doc:	5184/5/10 REV5 MI 7 SAN 3 ECO 3 ENT 3 CODEC 5
No. Cion prop. :	17504/08 MI 566 SAN 355 ECO 198 ENT 334 CODEC 1889
Subject :	Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source - Information from the Presidency

Delegations will find enclosed a Presidency progress report intended for the meeting of the Council (EPSCO) on 8 June 2010.

The Council is invited to take note of this progress report and of the oral information on the state of play given by the Presidency.

Annex

Presidency progress report on the proposal for amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

I. INTRODUCTION AND PROCEDURE

1. The Commission submitted this proposal[1] aimed at amending current pharmaceutical legislation in order to better prevent the entry into the legal supply chain of falsified medicinal products to the Council and the European Parliament on 10 December 2008 The proposal, which amends Directive 2001/83/EEC, is based on Articles[2] 114 and 168 (4) of the Treaty on the Functioning of the European Union and forms part of the "pharmaceutical package"[3].

2. The objective of the proposal, defined by the Commission, is to prevent the entry and dissemination of falsified medicinal products through the legal supply chain. To that end, it introduces (1) additional product-related rules, in particular on authenticity features for prescription-only medicines; (2) new rules regarding distribution and import of medicinal products and active pharmaceutical ingredients (API); and (3) rules regarding quality of manufacturing and authenticity of API.

3. On 27 April 2010, the Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament voted its amendments to the proposal[4].

4. The European Economic and Social Committee[5] has given its advice, as has the Committee of the Regions[6].

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1 17504/08.
2 Originally Article 95, changed after the entry into force of the Lisbon Treaty
3 The other proposals of the package introduce or clarify provisions on pharmacovigilance and information to the general public in Regulation (EC) No 726/2004 and Directive 2001/83/EC (see 17498/08, 17499/08, 17501/08 and 17502/08).
4 Not yet officially available.
5 See document INT/472 adopted at the 455th plenary session on 15 and 16 July 2009.
6 See document DEVE-IV-034 adopted at the 81st plenary session on 5 and 7 October 2009.

5. The Working Party on Pharmaceuticals and Medical devices has continued its examination of the proposal on falsified medicines under the Spanish Presidency. Seven meetings have been held in 2010.

6. At this stage, all delegations have general scrutiny reservations on the entire proposal, while the Danish, Maltese and United Kingdom delegations have parliamentary scrutiny reservations.

II. STATE OF PLAY

7. There is a common understanding in the Working Party that it is important to further reinforce the EU legislation on pharmaceuticals in order to protect users of medicinal products obtained via the legal supply chain from medicines that are falsified and to improve the controls of authenticity and quality of API and excipients. To this end many provisions, in particular on API and excipients used in medicinal products, have been strengthened. In order to implement these measures as soon as possible, legislative work on this proposal must be pursued as a high priority, with the aim of reaching an agreement between the Institutions. To this end, as the Czech and Swedish Presidencies did, the Spanish Presidency has engaged in preparatory talks with the Rapporteur of the European Parliament, Ms Marisa Matias (GUE-NGL), with the aim of exploring the similarities and differences between the respective positions of the two Institutions.

8. The Working Party has reached, under the Czech, Swedish and the Spanish Presidencies, tentative agreements on a number of technical aspects that cover the entire proposal. These include:
   - a definition of "falsified medicinal product";
   - a change in the proposed definition of "trading" to "brokering of medicinal products", thereby making clear the responsibilities of all actors in the supply chain;
   - a clarification of the relationship between the proposed new provisions in Directive 2001/83/EC and EU legislation on intellectual property rights;
   - a definition of “excipients”;

- new obligations for manufacturers of medicinal products, such as the verification, by means of audits, that their suppliers of active substances comply with good manufacturing practices and the compulsory application of risk analysis principles to the evaluation of compliance of excipients suppliers with appropriate good manufacturing practices;
- strengthened provisions on the distribution of API;
- increased powers of inspection in order to correspond to the above strengthening of rules;
- the revisions and inspections to be performed for establishing the list of exporting third countries whose regulatory frameworks for API ensure a level of protection of public health equivalent to that in the EU, with a specific reference to the participation of the competent authorities of Member States therein;
- as regards safety features, delegations are in favour of the application of this requirement to any medicinal product at risk of being falsified. The content and purposes of the delegated acts needed for this purpose have been laid down in detail. These safety features may also be used for other specific purposes, such as control of compliance with reimbursement rules. Moreover, Member States may extend the use of the safety features to other medicinal products for purposes relevant for national policies, such as reimbursement;
- a provision has been introduced to create a transitional period of 6 years[7] for those Member States that already have a system for safety features in place;
- clarification of the requirements and responsibilities of manufacturers of medicinal products when replacing or removing safety features;
- the authorisation regime and requirements applicable to entities introducing into the EU medicinal products not intended to be placed on the EU market. In addition, it has been made explicit that these provisions do not prejudice the scope of Directive 2001/83/EC;
- the proposed obligation for wholesale distributors and brokers to notify competent authorities when the products that they receive or are offered are identified or suspected of being falsified has been clarified;

[7] This transitional period starts when the implementation period of 48 months laid down in Article 2(1)(b) of the proposal ends.

- a safeguard clause has been added to the requirements for the import of APIs, to ensure adequate availability of medicines throughout the Union.

9. While contributing constructively to the discussions on the above-mentioned points, the Commission representatives have, in general, reserved their position on changes to the proposal, pending the outcome of the examination in the European Parliament.

10. The proposal includes provisions requiring the accreditation of third party auditors of Good Manufacturing Practices and Good Distribution Practices. A large majority of delegations objects to the accreditation scheme, since they hold that such a system could result in a transfer of responsibility from manufacturers, importers and wholesale distributors as well as make enforcement by national competent authorities more difficult. It has therefore been proposed to delete the provisions regarding accreditation from the text. Some delegations have expressed an interest in the possibility of establishing third party accreditation at a national level.

11. The content of the delegated acts that will define the mechanisms intended to ensure that falsified medicinal products are not introduced into the EU has been specified but some delegations have reserved their positions on this point.

12. A few elements of the proposal may still require further examination by the Working Party with a view to reaching an agreement in the Council. This is the case with the procedure applicable (Article 290 or Article 291 of the TFEU) to certain provisions and the licensing or notification regime applicable to importers, manufacturers and distributors of active substances.

13. A complete text of the proposal, as changed by the above amendments, is set out in document 9076/1/10 REV 1.

14. The text resulting from the ENVI vote on 28 April 2010 contains several amendments, many of which are based on ideas similar to those behind the Working Party changes to the Commission proposal. A few of them, however, introduce new elements compared to the original Commission proposal. Examples are the specification of sanctions for infringements against Directive 2001/83/EC as concerns falsified medicinal products, provisions on future international cooperation in this field and the regulation of the sale of pharmaceuticals via the Internet or mail order pharmacies. As regards the last point, the Parliament document envisages, amongst other measures, the implementation of procedures to identify the legal websites selling medicines and provides for an obligation on Member States to continuously monitor the Internet for illegal sale of medicines.