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Subject :	**Pharmaceuticals package** (a) 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 (b) Proposal for a 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 (LA) and Proposal for a 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 (LA) (c) Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, 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 (LA) and Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use (LA) - Progress reports / Exchange of views

(a) 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 the 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 Article 95 of the Treaty and forms part of the "pharmaceuticals package"[2].

2. The objective of the Proposal, defined by the Commission, is to strengthen the legal framework on pharmaceuticals, in order to prevent 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 certain 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.

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1 17504/08.

2 The other proposals of the package introduce or clarify provisions on pharmacovigilance and information to the general public in Regulation (EC) 726/2004 and Directive 2001/83/EC (see 17498/08, 17499/08, 17501/08 and 17502/08).

3. In order to prevent falsified medicinal products from entering the legal supply chain, the Proposal employs, *inter alia,* the following means:
   - an obligatory specific safety-feature on the packaging for prescription-only medicines;
   - audits and notification of manufacturers and importers of API in the European Union, as well as audits of manufacturers of API in third countries;
   - strengthened requirements for import of API, in particular if the regulatory framework in the exporting third country does not ensure a comparable level of protection of human health as in the EU;
   - the extension of certain rules for wholesalers to other economic actors in the distribution chain;

   and
   - obligatory audits of wholesale distributors and harmonised rules for inspections performed by national competent authorities.

4. The European Parliament is expected to give its first-reading opinion, at the earliest, in autumn 2009.

5. The European Economic and Social Committee has been invited to give its advice.

6. Under the Czech Presidency, the Working Party on Pharmaceuticals and Medical devices has discussed the proposal on five occasions. The first examination of the entire proposal was completed on 23 April. The Working Party now continues its discussion on certain provisions that need further consideration.

7. At this stage, all delegations have a general scrutiny reservation on the entire proposal.

8. The Danish, Maltese and United Kingdom delegations have parliamentary scrutiny reservations.

II. STATE OF PLAY

9. All delegations have welcomed the proposal and there is general agreement in the Working Party that there is need for legislation aiming to reduce the risk of falsified medicinal products reaching patients in the EU and to improve the quality and authenticity of API.

10. There is general agreement that preventive measures are needed and that the proposal provides a good basis for the future discussion, nevertheless, many delegations have questions and reservations on individual elements of the proposal. The following issues, *inter alia*, need further discussion:
    - the need for and content of a definition of "falsified medicinal product" and other specific definitions;
    - whether the scope of the proposal should be extended to also cover excipients and intermediate products in addition to API;
    - the safety features, in particular (1) their efficiency in protecting the legal supply chain from falsified medicines; (2) whether a risk-based approach should be applied when deciding on safety features, irrespective of whether the medicinal product is classified as a prescription-only medicine or OTC; (3) types of safety features and whether they should be adopted in comitology or laid down in the proposed Directive; (4) practical implementation;
    - the definition of roles and obligations of actors in the supply chain who do not physically handle medicinal products;
    - practical aspects of and possible impacts from the proposed new requirements on import of API from third countries;
    - the practicalities, the consequences and the potential problems, when creating the list of third countries in which the national rules for manufacturing are at least equivalent to Community standards;

- the applicability of, and the provisions regarding accreditation;
- the cost-effectiveness of certain measures in the proposal;
- the new obligation for wholesale distributors to verify, by auditing, that their suppliers follow good distribution practices;
- the provisions on medicinal products that are introduced into the EU, without intention to be placed on the Community market, *inter alia* the rules on co-operation between national competent authorities and customs authorities;
- how to better express that the Proposal do not interfere with existing legislation on intellectual property rights.

11. Delegations' detailed comments on various articles, as recorded during the meetings or provided in writing, are set out in footnotes to the proposed legal text in a separate document, the first versions of which have already been presented. That document is intended to provide a basis for the continued examination of the proposal.

12. The Czech Presidency has presented a number of initial drafting solutions which address a number of concerns presented by delegations in the Working Party meetings. The Commission representatives have reserved their position on these changes and underlined that they remain committed to the original Proposal.