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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

(b) Presidency Progress Report

on the

Proposals for amending Directive 2001/83/EC and Regulation (EC) No 726/2004

as regards pharmacovigilance of medicinal products for human use

I. INTRODUCTION AND PROCEDURE

1. The Commission submitted two Proposals aimed at amending the current pharmaceutical legislation as regards pharmacovigilance of medicinal products for human use to the Council and the European Parliament on 10 December 2008. The Proposals are based on Article 95 of the Treaty and form part of the "Pharmaceuticals' package". One of these Proposals amends Regulation (EC) 726/2004[1] and the other amends Directive 2001/83/EC[2].

2. The objectives of the Proposals, defined by the Commission, are to strengthen and rationalize the Community pharmacovigilance system in order to deliver measures that are equally and fully implemented for all relevant products for human use across the Community, with a view to preventing unnecessary patient exposure to risks. In particular, they aim to provide for clear roles and responsibilities for the key responsible parties, to strengthen transparency on medicines safety, communication and companies' pharmacovigilance systems; to ensure the proactive and proportionate collection of high quality data relevant to the safety of medicines and to involve stakeholders, including patients, in pharmacovigilance.

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

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

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1 17501/08 MI 563 SAN 352 ECO 195 ENT 331 CODEC 1886

2 17502/08 MI 564 SAN 353 ECO 196 ENT 332 CODEC 1887

5. Under the Czech Presidency, the Working Party on Pharmaceuticals and Medical devices has examined the Proposals on six occasions.

6. At this stage, all delegations have a general scrutiny reservation on the entire Proposals.

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

II. STATE OF PLAY

8. In general, delegations have warmly welcomed the Proposals. There is general agreement in the Working Party that the legislative work on these important proposals must be pursued with high priority with the aim of reaching an agreement between the Institutions.

9. Most delegations agree to the objectives of the proposals and they hold that the proposals meet these objectives. However, many delegations have reservations on individual provisions.

10. There is broad agreement in the Working Party that, in accordance with the Proposals, a new scientific committee responsible for pharmacovigilance should be established within the EMEA. However, while the Proposals foresee a Pharmacovigilance Committee composed of 10 members appointed by the EMEA Management Board and 5 members appointed by the Commission, nearly all delegations hold that all Member States must be represented in this Committee. A concrete suggestion built on this idea has been submitted and can be used as a ground for further discussion as it is supported by fourteen delegations. In this context, it has also been discussed that the Member States should have the right, but not the obligation, to actively participate in the work of the Committee.

11. As regards the proposed role of the Pharmacovigilance Committee, which is to issue a recommendation that serves as advice for the Committee for Medicinal Products for Human Use (CHMP) and the coordination group (CMD), an alternative suggestion has been discussed with the aim to clarify that the CHMP and CMD must rely on the recommendation of the Pharmacovigilance Committee unless they have well-founded reasons for not accepting the recommendation.

12 The composition and the role of the Pharmacovigilance Committee in relation to the other scientific committees of EMEA (including CAT) also need further discussion.

13. Delegations thoroughly discussed the proposed definitions, in particular the definition of "adverse reaction". Some delegations support the proposed definition of adverse reaction while some other delegations would prefer to maintain the current definition (potentially with minor changes). Some delegations suggested to have two separate definitions, one covering adverse reactions within the use in compliance with the summary of the product characteristics (SPC) and the other covering off-label use. The potential need for a definition of "medication error" has also been discussed and first suggestions for a definition have been provided. Some delegations also pointed out that the proposal uses terms which are not yet defined in EU legislation (misuse, medication error). Therefore the proposed definitions, as well as the missing definitions, require further discussion.

14. The impact and the practical aspects of the proposed list of medicinal products for human use under intensive monitoring have been discussed, in particular its management by the EMEA and the inclusion of a special statement into the package leaflet (PIL). Many delegations expressed their misgivings that the inclusion of the statement in the PIL might give rise to unsubstantiated concerns for patients and unjustified administrative burdens for marketing authorisation holders, *e.g.* in the case of removal of a product from the list, variation of the marketing authorisation is required.

15. Many delegations do not agree with the proposed inclusion of the summary of essential safety information in the SPC and PIL since they are afraid it might be counterproductive. Further discussion is required.

16. The discussion also showed that the following topics*, inter alia*, need further examination:
    - Post-authorisation safety studies (PASS);
    - Risk management system for all products;
    - Setting up and maintenance of national safety web-portals, their content and their linkage to the European medicines safety web-portal;
    - Direct reporting to Eudravigilance database by marketing authorisation holder, patient´s reporting;
    - Scope and procedural matters of the Community procedure;
    - Public hearings as part of the pharmacovigilance assessment by the Pharmacovigilance Committee;
    - Binding nature of opinions of CMD for Member States;
    - Proposed amendments to the provisions aimed at improve access to medicinal products (Article 63(3); Article 126a (2), (3)).

17. Delegations' detailed comments on various articles, as recorded during the meetings or provided in writing, will be 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 proposals.