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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

(c) Presidency Progress Report

on the

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

as regards information to the general public on medicinal products

for human use subject to medical prescription

I. INTRODUCTION AND PROCEDURE

1. The Commission submitted two Proposals aiming to amend the current pharmaceutical legislation as regards information to the general public on prescription-only 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 objective of the Proposals, defined by the Commission, is to provide for a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public with a view to enhancing the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines.

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.

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

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1 17498/08 MI 561 SAN 350 ECO 193 ENT 329 CODEC 1883

2 17499/08 MI 562 SAN 351 ECO 194 ENT 330 CODEC 1884

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

II. STATE OF PLAY

7. A large majority of delegations do not support the Proposals since they do not consider them as an appropriate way of providing patients with objective and unbiased information on prescription-only medicinal products.

8. All delegations have expressed their wish to concentrate on the examination of the other proposals of the "Pharmaceuticals' package" which, in most delegations' view, are more important and provide significant improvement in the public health area.

9. Most delegations have expressed strong concerns, holding, *inter alia*, that:
   - the content of the Proposals does not meet the intended objectives;
   - there is no distinction between "information" and "advertising" (the necessity of which was emphasized in the Council Conclusions of 9 June 2008) and therefore, the Proposals do not provide sufficient guarantee that the prohibition of advertising of prescription-only medicinal products to the general public[3] will not be circumvented;
   - the monitoring mechanisms foreseen will be costly to implement and will create administrative burdens for national competent authorities. The resources needed for this purpose could be of greater benefit if used in another area of public health;
   - the relationship between patients and health professionals might be changed in a way that is counterproductive for the patients' health.

   A majority of these delegations do not consider the Proposals as an appropriate basis for continued negotiations, although some delegations in this group would be prepared to discuss the Proposals if they would be significantly changed.

[3] Article 88(1a) of the current Directive 2001/83/EC.

10. Many of these delegations underline that information to the general public concerning prescription-only medicinal products should be given by competent authorities, health professionals or independent bodies in cooperation with health professionals and national competent authorities and not directly by the pharmaceutical industry.

11. Four delegations have objections to the Proposals based on constitutional arguments, mainly the conflict between national legislation on freedom of expression and right to information on the one side and the provisions restricting the choice of dissemination channels and the monitoring before publication foreseen in the Proposals on the other side.

12. Two delegations have welcomed the Proposals in guarded terms and underlined the need for rules regarding information to the general public.

13. Two delegations did not express their final position, in particular because an internal discussion on national level is still ongoing.

14. Some delegations hold that the Proposals, if adopted as proposed, may have significant negative consequences on healthcare budgets caused by possible unjustified increase in the use of medicinal products.

15. A majority of delegations find that the Proposals do not adequately take into account the Council Conclusions of 9 June 2008 that aimed to ensure that patients have access to good-quality, objective, reliable, complete, comprehensible, and non-promotional information on medicinal products and other treatments.

16. Some delegations have provided comments and suggestions on specific provisions of the Proposals. These are set out as footnotes to the proposed legal texts in a separate document. Many other delegations have, because of their general concerns about these Proposals, decided to refrain from entering into a detailed examination.