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NOTE

from:	General Secretariat of the Council
to:	Council
No. Cion prop.:	7315/12 PHARM 14 MI 155 SAN 48 ENT 58 CODEC 567
Subject:	**Employment, Social Policy, Health and Consumers** Council meeting on 6 and 7 December 2012 Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems - *Information from the Presidency* (Other business item)

Introduction

1. On 1 March 2012, the Commission adopted its proposals for a Directive relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems[1] and submitted it to the Council and to the European Parliament. The proposed Directive is intended to replace Directive 89/105/EEC[2]

[1] 7315/12 PHARM 14 MI 155 SAN 48 ENT 58 CODEC 567
[2] OJ L40, 11.12.1989, p. 8-11.

2. The European Economic and Social Committee has adopted its opinion[3].

3. In the European Parliament, the Committee responsible for the examination is the Committee on the Environment, Public Health and Food Safety (ENVI)[4]. Antonyia PARVANOVA (ALDE, BG) has been appointed Rapporteur.

State of play in the Council

4. The Working Party on Pharmaceuticals and Medical Devices has examined the proposal on eight occasions, most recently on 26 November 2012.

5. It is noted that all delegations have a general scrutiny reservation on the entire proposal, that the Danish, French, Maltese and United Kingdom delegations have entered parliamentary scrutiny reservations and that the Luxembourg and Austrian parliaments have issued reasoned opinions in accordance with Article 6 of the Protocol (No2) on the application of the Principles of Subsidiarity and Proportionality in which they state that the proposal goes against the principle of subsidiarity.

6. The legal basis for this proposal, Article 114 of the Treaty on the Functioning of the European Union (TFEU), aims to achieve the objectives of Article 26 thereof, which states that the Union shall adopt measures to ensure the functioning of the internal market. On the other hand, Article 168(7) of the TFEU states that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. …".

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3 INT 642 – CESE 1573/2012 of 12 July 2012.

4 It is also examined by the EMPL, ITRE; IMCO and JURI Committees.

7. The Commission therefore in its proposal has strived to ensure that the proposed requirements to ensure timely and transparent decisions on pricing and reimbursement of medicinal products carefully balance the obligation to preserve the competences of Member States in the field of public health.

8. Most delegations have however expressed various degrees of concerns about the entire proposal or parts thereof, since they hold that many provisions interfere in national competence.

9. During the examination, delegations have, in particular, pointed to the following points as problematic:

   – **Article 8** concerning the remedies procedure, which many delegations believe is in conflict with the principles of subsidiarity and proportionality;

   – **Article 15** setting out an obligation to consult interested parties on any measures falling within the scope of the Directive, in which many delegations find that the requirement to cover any measure is too broad;

   – **Article 16** regarding the obligation on MS to notify draft national measures to the Commission, which many delegations hold to be against the principles of subsidiarity and proportionality;

   – **The time limits** are in general held to be too short.

10. The Commission representatives have stressed that a number of the changes to Directive 89/105/EEC now proposed are to a large extent based on Judgements by the European Court of Justice or reflects the new features and needs of the pharmaceutical sector as regards pricing and reimbursement procedures.

11 In response to the concerns expressed by delegations, the Presidency has proposed to substantially redraft Articles 8 and 15 and to delete Article 16, thereby deleting many provisions that delegations have objected to. The Presidency has also proposed to introduce significant changes in Articles 3, 4, 5 and 7, with a view to extending the time limits proposed by the Commission, and in Article 12, so as to introduce elements of flexibility in the definition of the time limits.

12. These changes were discussed in the meetings of the Working Party on 9 October and 26 November and will be discussed again on 11 December. The changes proposed by the Presidency have, in general, been welcomed but many delegations still have substantial reservations regarding the time limits proposed and on Articles 8 and 15.