COUNCIL OF THE EUROPEAN UNION

Brussels, 12 June 2013

10365/13

Interinstitutional File: 2012/0035 (COD)

PHARM 29
MI 491
SAN 194
ENT 154
COMPET 390
CODEC 1300

NOTE

from:	General Secretariat of the Council
to:	Council
No. Cion prop.:	7452/1/13 REV 1 PHARM 12 MI 197 SAN 93 ENT 77 CODEC 571
Subject:	**Employment, Social Policy, Health and Consumers** Council meeting on 20 and 21 June 2013 Amended proposal for a Directive of the European Parliament and of the Council on 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*

Delegations will find in the Annex a report describing the state of play prepared by the Presidency with a view to the meeting of the Council (EPSCO) on 20 and 21 June 2013.

ANNEX

Amended proposal for a Directive of the European Parliament and of the Council on 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

INTRODUCTION

1. On 1 March 2012, the Commission adopted its proposal 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].

2. The European Economic and Social Committee has adopted its opinion[3] on 12 July 2012.

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

---

1 7315/12 PHARM 14 MI 155 SAN 48 ENT 58 CODEC 567
2 OJ L40, 11.12.1989, p. 8-11.
3 INT 642 – CESE 1573/2012.
4 It is also examined by the EMPL, ITRE; IMCO and JURI Committees.

4. The European Parliament adopted its position at first reading on 6 February 2013 with 559 votes in favour, 54 against and 72 abstentions. The European Parliament thereby introduced amendments which aimed to address the main concerns raised by the Member States with a view to facilitating a possible compromise.

5. On 20 March 2013, the Commission adopted its Amended proposal for a Directive of the European Parliament and of the Council on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems[5]. In amending its proposal the Commission took due account of the position of the European Parliament thereby seeking to address Member States' concerns.

STATE OF PLAY IN THE COUNCIL

6. Following the plenary vote in the European Parliament, the Working Party on Pharmaceuticals and Medical Devices has, under the Irish Presidency, held discussions in relation to the amended proposal on 4 occasions, most recently on 3 June 2013.

7. It is noted that all delegations maintain a general scrutiny reservation on the entire proposal and that the Danish, French, Maltese and United Kingdom delegations have entered parliamentary scrutiny reservations.

---

[5] 7452/1/13 REV 1 PHARM 12 MI 197 SAN 93 ENT 77 CODEC 571 (COM(2013) 168 final)

8. It is further noted that the Luxembourg[6] and Austrian[7] parliaments have issued reasoned opinions on the proposal and that the Spanish parliament[8] has issued a reasoned opinion on the amended proposal in accordance with Article 6 of the Protocol (No2) on the application of the Principles of Subsidiarity and Proportionality in which they find the proposal to be incompatible with the principle of subsidiarity.

9. While acknowledging that the position adopted by the European Parliament and the amended Commission Proposal are positive developments, many delegations have expressed various degrees of concern about the proposal. The Presidency has put forward proposals to address concerns in relation to certain parts of the text, in particular as regards:
   - **Articles 3 and 7** (concerning price approval and inclusion in health insurance systems) – the Presidency has made a number of proposals regarding the time-limits;
   - **Article 8** (concerning the remedies procedure) – the Presidency has proposed deletion of almost all of the text in this Article;
   - **Article 15** (concerning consultation of interested parties) – the Presidency proposed a text to provide that Member States in certain circumstances can adopt or amend legislation without the requirement to consult interested parties;
   - **Article 17** (concerning reporting) – the Presidency proposed to amend the text by limiting the reporting obligations for Member States, in order to address the issue of administrative burden.

---

6 9473/12 PHARM 33 MI 293 SAN 96 ENT 114 CODEC 1170 INST 315 PARLNAT 214

7 9467/12 PHARM 32 MI 292 SAN 95 ENT 113 CODEC 1169 INST 313 PARLNAT 212

8 9704/13 PHARM 21 SAN 171 MI 417 COMPET 311 CODEC 1117 INST 242 PARLNAT 114

10. The changes proposed by the Presidency have, in general, been welcomed. However it is clear that further detailed discussions are needed on a number of issues, including:

- the scope of the proposed Directive, with particular regard to the issue of voluntary contractual agreements;

  and

- the time limits for decisions on pricing and reimbursement to be applied, in particular with regard to generic medicinal products. In this regard a detailed discussion is also required as to how these time limits are calculated (Article 12).