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Subject:	**Employment, Social Policy, Health and Consumers** Council meeting on 20 and 21 June 2013 Proposal for a Regulation of the European Parliament and of the Council on Clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC - *Progress report*

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

ANNEX

Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC

PRESIDENCY PROGRESS REPORT

INTRODUCTION

1. On 17 July 2012, the Commission adopted its Proposal for a Regulation on clinical trials on medicinal products for human use and submitted it to the Council and to the European Parliament.

2. Clinical trials are essential in the development of new medicinal products, in improving medical treatment and in promoting competitiveness of the European Union in clinical research. The Clinical Trials Proposal aims to: streamline procedures for the approval of clinical trials applications including multi-national clinical trials; protect the safety and rights of clinical trial subjects; and promote the reliability and robustness of the data generated in clinical trials carried out in the EU.

3. In the European Parliament, the Proposal has been examined by the Committee on the Environment, Public Health and Food Safety (ENVI) with Glenis Willmott (S&D, UK) appointed as the Rapporteur. On 29 May 2013, the ENVI Committee adopted its report on the Clinical Trials Proposal and a mandate was given to the Rapporteur to commence negotiations with the Council.

4. The European Economic and Social Committee issued its opinion on the Proposal on 12 December 2012[1]. The Committee of the Regions has also been invited to give its opinion.

5. It is noted that the European Data Protection Supervisor has issued an Opinion[2] on the Proposal.

STATE OF PLAY

6. In general, delegations have welcomed the Proposal. However, at this stage all delegations have general scrutiny reservations, and the Danish, Polish and United Kingdom delegations have entered Parliamentary scrutiny reservations.

7. The Polish Parliament has issued a reasoned opinion, in accordance with Article 6 of the Protocol (No. 2) on the application of the Principles of Subsidiarity and Proportionality[3], in which it finds the Proposal to be incompatible with the principle of subsidiarity.

8. The Working Party on Pharmaceuticals and Medical Devices met on five occasions during the Cyprus Presidency to examine this Proposal. Under the Irish Presidency, the Working Party had a further ten meetings (on 11 and 31 January, 13 February, 1 and 18 March, 18 and 24 April, 23 May, 3 and 12 June) to continue examination of the Proposal.

9. During these fifteen meetings, a first examination of the entire Proposal (93 Articles) has been completed.

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1 Opinion available in document INT/658 - CES2059-2012_00_00_TRA_AC - 2012/0192 (COD) of 12 December 2012.

2 6670/13 PHARM 8 SAN 59 MI 121 COMPET 98 CODEC 378

3 14986/12 PHARM 75 SAN 235 MI 638 COMPET 626 CODEC 2392 INST 589 PARLNAT 331

10. In addition to the examination of the Proposal at the Working Party meetings, the Presidency has, based on written submissions from, and bilateral discussions with, delegations, undertaken preparatory work on the four technical Annexes to the Proposal that resulted in revised text of the Annexes for examination by the Working Party.

11. In the examination of the Proposal, to date, a number of issues have emerged, including:

- In relation to Chapter II and III regarding the *authorisation and modification of clinical trials*, many delegations have expressed the opinion that the time-limits for authorisation and validation of clinical trials are too short, expressed concerns regarding the provision for "tacit approval" of clinical trials if time-limits are not complied with, and some delegations have sought an explicit reference in the Proposal to the role of ethics committees in the ethical evaluation of clinical trials.

- Chapter V deals with the *protection of subjects and informed consent*. Some delegations have sought an explicit reference to Member State national laws on the protection of subjects. In addition, attention has been drawn to the fact that different approaches are adopted in Member States to the conduct of *clinical trials in emergency situations*. The Commission has emphasised the need for harmonisation of the rules on protection of subjects and informed consent.

- Regarding Chapter XI on the *sponsor and investigator*, many delegations have questioned the provision of the Proposal which replaces the current obligation on sponsors to have a "legal representative" based in the EU with a "contact person", particularly in the context of liability in the event of injury to clinical trial subjects.

- In Chapter XII on *damage compensation, insurance and a national indemnification mechanism*, some delegations have expressed concern about the obligation on Member States to establish a national indemnification scheme for damage compensation in clinical trials and about the issue of compensation for damage to subjects in low-intervention clinical trials.

- Delegations have welcomed the concept of a *centralised EU portal* through which clinical trial applications will be made. However, in the context of the tight timelines for the evaluation of clinical trial applications, many delegations have sought assurances regarding the effective and timely operation, and financing of the portal.

- In Chapter XIII on *supervision by Member States and Union inspections and controls*, the Commission representative has outlined that systems audits of Member States' and Third Countries' regulatory systems are envisaged. However, some delegations have questioned the value and consequences of these systems audits in Member States and in Third Countries.