EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE

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Brussels, 30 June 2008

HLG/PSWG/2008/06

MEETING OF THE WORKING GROUP ON PATIENT SAFETY OF THE HIGH LEVEL GROUP, 17 JUNE 2008

Subject: Minutes of the Meeting

1. WELCOME AND MINUTES OF THE LAST MEETING AND ADOPTION OF THE AGENDA

Mr Martin Fletcher, acting co-Chair of the Working Group, opened the meeting by welcoming participants and setting out the aims of the meeting together with Ms Basia Kutryba, also co-Chair of this Working Group.

The main objectives of this meeting were: for the working group to receive feedback on the early findings of the recent open consultation on patient safety; for the working group to hear about, and to provide feed back on the Commission's early thoughts on the possible content of its patient safety proposal; for the working group to receive information from the Commission on the recast of the medical device legislation and to update the working group on the EUNetPaS project.

The draft minutes of the last meeting held on 13 March 2008 were adopted without amendment. The agenda was also adopted without amendments.

The meeting was attended by all Member States except Estonia, Lithuania, Malta and Romania and all stakeholder organisations other than the Council of Europe, EFTA, OECD, WHO and the Council of European Dentists.

2. THE COMMISSION'S PATIENT SAFETY CLWP 2008 INITIATIVE – THE SYSTEMIC ISSUES

a) DG SANCO C5 Presentation on, and discussion of the recent patient safety consultation

Ms Katja Neubauer presented the results of the recent patient safety consultation as assembled by Ms D. Aliki Papathanassiou. 185 replies had been received, 30 of which came from competent authorities at either national, regional or local level. Ms Neubauer stressed that there was strong support for all nine possible areas for action put forward by the Commission at national and/or EU levels. She pointed out that all the contributions to the consultation were available on SANCO's web page. A summary report and a breakdown of all participants would follow before the summer break.

France welcomed this consultation but commented on the rather closed character of the questionnaire that led to an off-line response by the French national competent authorities. France requested a separate analysis of responses given by different groups of stakeholders with a particular focus on competent authorities. PGEU picked up one of the consultation's results which is that HAI and medication-related problems seem to represent the two major causes of adverse events, and asked whether these two areas will be given the same degree of importance in the forthcoming Commission proposal.

Ms Neubauer explained that medication errors will be addressed in the forthcoming patient safety initiative, which will focus on trying to reduce **all** errors, but will not merit a specific focus in this initiative. She noted that medication related events were also being addressed in the pharmacovigilance legislation that was in the process of being reviewed. Regarding the consultation, the Commission had opted for this form of questionnaire in order to be able to carry out a statistical analysis of the replies received. A thorough analysis was being conducted by Commission services and would include a breakdown of the different groups of stakeholders. The summary report would also touch upon the off-line contributions but would not include them in the statistical analysis.

Actions

The Commission's PSWG Secretariat to carry forward analysis of the replies to the open consultation and inform the PSWG when the summary report is available on the Commission web pages.

b) The Commission's proposal on patient safety

Ms Neubauer presented the Commission's initiative on patient safety. She informed the working group that this initiative would address patient safety in general terms and also include recommendations on the prevention and control of healthcare-associated infections. She outlined that the impact assessment for this proposal had been submitted to the Impact Assessment Board on 13 June and was scheduled for discussion on 2 July. She stressed that out of the four possible policy options identified, a Commission Communication and a Council Recommendation had emerged as the most appropriate, since it would represent a strong commitment for Member States whilst allowing them to continue to organise healthcare nationally as they do at present. In developing the systemic patient safety parts of its proposal, the Commission would build on the recommendation on patient safety from the PSWG to the High Level Group, the recommendation on patient safety by the Council of Europe and on the results of the public consultation.

The discussion was opened by Ms Neubauer, who asked for feedback on the nine possible areas for action put forward by the Commission at national and/or EU levels.

Ireland supported action at the EU level that would help Member States in the efforts to address patient safety at the national level. In particular EU-wide data sharing, learning

and identification of best practice would be welcome. Finland expressed the wish that the work of the Council of Europe (CoE) be carried forward by the EU by taking into account the CoE's recommendation on patient safety. In respect of medication safety, Finland stressed that the focus should be put on health professionals and not so much on pharmacovigilance. France questioned the title of the initiative, pointing out that the fact that the terms ′quality′ and ′health services′ appeared in the current title could be confusing and give rise to discussions in the Council, as the content only related to patient safety.

CPME stressed the need for a systematic error analysis since harm to patients was rarely the result of an individual failure, but usually the result of a chain of failures. CPME saw the added value of an EU initiative, mainly in the areas of education, training, reporting systems and research. PGEU agreed with this statement and stressed the need for research specific to the different healthcare settings, such as primary and secondary care. This should be taken into account when setting research priorities at the EU level. EPF agreed and stressed the need for patient and public involvement in the education strategies for health professionals and in defining patient safety research priorities.

Mr Kevin McCarthy (DG RTD) explained that precisely this approach is being encouraged by FP7 (its 7th Framework Programme for Research). Ms Flora Giorgio (DG INFSO) referred to ongoing EU-supported projects; e.g. ICT use to improve patient safety and looked forward to providing more information in writing to the working group.

Germany supported the first six out of the nine possible areas of action and the use of CoE's recommendation as a basis for the Commission's proposal. When tackling patient safety, it was important to offer solutions and not only statistics about the levels of harm. Germany raised the question of the role of EUNetPaS in the forthcoming Commission initiative and expressed the wish that the working group be involved in the drafting of the patient safety initiative.

Actions

The Commission's PSWG Secretariat to explore how the working group could be involved in the drafting of the forthcoming patient safety proposal.

Mr Fletcher handed over the chair to Ms Basia Kutryba, who introduced Mr John Brennan from DG ENTR.

3. EUROPEAN COMMISSION'S OTHER PATIENT SAFETY – RELATED INITIATIVES

Mr Brennan presented an update on EU medical devices issues where he highlighted the current public consultation on the Commission’s web-site regarding a recast of the medical devices Directives. He outlined the motivation behind the recast which is seen as necessary to strengthen the current legislation, in particular to address future challenges such as new and emerging technologies. He informed the working group that the public consultation will be open until 2 July 2008 and encouraged the participation of the PSWG members.

4. EXTERNAL PATIENT SAFETY PROJECTS

Ms Kutryba introduced Dr Jean Bacou of the Haute Autorité de Santé, France, who presented the first results of the EUNetPaS project as well as the financial agreement between the HAS and the Commission's Public Health Executive Agency. Dr Bacou provided an overview of the goals of the vertical work packages I to IV of the EUNetPaS project and that they were likely to address many of the issues that were likely to be included in the recommendation from the PSWG to the High Level Group. In his view, the development of national platforms and their involvement in EUNetPaS will be the key for later implementation. A short discussion followed, with EFN, the Commission's representatives and France, among others, addressing the need for DG SANCO to facilitate the coordination between the various Commission initiatives on patient safety. EFN suggested that MEPs should be involved in patient safety projects. Although all participants agreed that for some projects the endorsement by MEPs can be interesting, such endorsement cannot be formally required.

Action

Dr Bacou invited the participants to the project conference that will take place on 22 and 23 September 2008 in Paris. The formal invitation will follow before the summer break. Mr. McCarthy requested that an invitation be extended to the two successful patient safety research projects from the 2nd call under FP7.

5. ANY OTHER BUSINESS AND CLOSE OF THE MEETING

(i) Ms Kutryba introduced Ms Ivana Silva of PGEU, who gave a short presentation on a recently published booklet on adherence to medication as an example of sharing experience among stakeholders. Other Member States expressed an interest in following up the distributed information tool of ongoing projects and research.

(ii) Ms Neubauer shared two pieces of information: 1. about a possibility of small research grants in the field of patient safety, offered by the WHO, and 2. about the recently published document: ′Guidance on developing quality and safety strategies with a health system approach′ by the European Regional WHO Office.

(iii) Ms Kutryba presented a short summary of the conclusions drawn at the Slovenian Presidency conference ′Ready for the future – Defining European healthcare through innovation and quality′ held at Kranjska Gora on 5 and 6 June.

Ms Kutryba gave members the provisional date of the next meeting of the group, namely 12 September 2008.

The co-Chairs thanked members for their attendance and input and closed the meeting.