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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE

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MEETING OF THE WORKING GROUP ON PATIENT SAFETY OF THE HIGH LEVEL GROUP, 8 MARCH 2007

Subject: Minutes of the Meeting

1. WELCOME

Dr Robida and Dr Bill Kirkup, Co-Chairmen of the Working Group, opened the meeting by welcoming participants and setting out the aims of the meeting. Sir Liam Donaldson sent his apologies. In particular, Dr Robida welcomed new members Bulgaria, Romania and the Council of European Dentists, all attending for the first time.

The main objectives of this meeting were: to reach agreement on the Patient Safety Recommendation for onward transmission to the High Level Group and to discuss the project bid through a call for proposal under the Public Health Programme, to establish, and run concrete work packages under, a EU Network for Patient Safety, led by France.

Other objectives were to update the working group on a number of other patient safety-related initiatives at the EU level, including the Health Services initiative and its link to our patient safety work, and communicating to the working group that patient safety is emerging as a Commission priority, and work on patient safety led by other Commission services, including the European Medicines Evaluation Agency (EMEA), in areas such as pharmacovigilance, medical devices safety, look-alike and sound-alike medicines, patient safety research and e-health.

The draft minutes of the last meeting held on 14 September 2006 were adopted, subject to the Secretariat anonymising comments to show just the Member State or stakeholder organisation that spoke, to satisfy new Community protection of personal data legislation[1], in the absence of any of the working group members having signed a Privacy Statement (which will be addressed outside of this meeting, by e-mail). The agenda was adopted.

2. PATIENT SAFETY RECOMMENDATION

The working group discussed the 'near final draft of the patient safety recommendation (version D) and agreed upon five drafting changes, proposed by Germany, Greece, UK and HOPE. Subject to the Secretariat accurately making these amendments following the meeting,

[1] Regulation (EC) N° 45/2001 on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data.

a *tour de table* produced unanimous support for the final wording of the recommendation to be sent to the High Level Group.

The Secretariat will make the agreed changes and circulate after the meeting for final clearance, including some late comments received from Italy.

3. PATIENT SAFETY NETWORK PROPOSAL - EUNETPAS

France, led by the Haute Autorité de Santé (HAS), had held a separate session with a number of working group Member States and stakeholder organisations earlier that day. HAS and EUNetPaS work package leads and partners presented to the rest of the group on how their project bid was developing.

It was agreed that the Commission can play no role in the development of the project bid because the project partners were planning to bid for Commission funding through the call for proposals by the deadline of 21 May 2007. It also stressed the need for all Member States to be involved in at least one of the project's work packages.

The Dutch Institute for Healthcare Improvement, Greece, Denmark and HOPE (with assistance from Finland) followed HAS's overview of the project and details of the horizontal work packages with presentations on the individual vertical work packages on Patient Safety Culture, Education, Reporting and Learning Systems and Pilot Testing respectively. HAS stressed the need to avoid overlap or duplication of work carried out within the work packages.

HAS mentioned that the biggest challenge remaining was that of agreeing the financial aspects of the proposal. The total cost of the project had been estimated to be around four million euros and working on the usual 60/40 rule, the most the Commission would be able to contribute, if the bid was successful, was around 2.5 million euros.

Ireland asked that all references to 'man months or 'man hours' in the documents be changed to 'person months' or 'person hours'. This request, made on International Women's Day, unsurprisingly met with no resistance.

Dr Robida encouraged Member States and other partners to send all comments on the draft project proposal to HAS as soon as possible. Germany in particular had questions for HAS but was encouraged to contact it direct after the meeting. France had sent Member States a questionnaire asking which organisation (health ministry, institute, agency etc) in each country would be a partner in the project. It needed all responses and other comments by the end of March, including details of which Member States (and others) were willing to sign up to be project partners and at what level of partnership.

The biggest issue for Member States and other working group members was, if they were to sign up to be a partner in the project, how much would it cost them financially to engage at the various levels of partnership for each work package. This information was absolutely essential if they were to make a case for becoming a partner to their ministries or others who agreed funding, following the meeting More than one Member State asked HAS to provide a short paper to this effect to summarise the project and include examples of costs. HAS, with Inserm Transfert, the French agency assisting it with the development of the bid, especially on the financial elements, agreed to do this.

This major issue aside, members were impressed with the hard work which HAS and its partners had put in to proposal. It was much improved on previous versions. When asked, no member of the working group said that they did not want to be involved in at least one work package. This was, of course, not a financial commitment from any to join at this stage but was encouraging to HAS nonetheless.

4. HEALTH SERVICES INITIATIVE

Unit C5 in the Commission's Health and Consumer Protection Directorate-General (DG SANCO) updated the working group on possible Community Action on Health Services. The Commission explained that the open consultation had now closed at that it was now preparing a report on the responses. It stressed that key areas of patient safety such as reporting systems, compensation systems and liability issues were explicitly mentioned in the consultation document and that patient safety was a common theme in the responses received.

The Commission was hoping to have firm proposals in the area of health services later in 2007. Legislation was a possibility but not a certainty in this area. It is possible that instruments to address specific patient safety problems raised by Member States and other respondents would then be subsequently considered.

The Secretariat followed up by telling the working group that patient safety had been recently signalled as a priority for DG SANCO for 2008 (subject to confirmation). It was too early to provide much information on the consequences of this (if confirmed) for working group members at this stage but possible action in the coming months was an internal Commission inter-service consultation, an impact assessment and some type of external 'consultation'. The working group would have an important role to play in developing a strategy for deliverables in the area of patient safety in 2008 in a 'sounding board' role.

The Secretariat would provide more details to members of the working group in due course.

5. OTHER PATIENT SAFETY WORK/INITIATIVES AT THE EU LEVEL

Patient Safety Research

A representative of the Commission's Research Directorate-General described the importance with which patient safety research was viewed. DG Research explained that patient safety featured widely under the 'translating clinical research into clinical practice' and 'quality, solidarity and sustainability of health systems' Health Theme objectives under the 7th European Framework Programme for Research. The deadline for Calls is 18 September 2007.

A conference, *Patient Safety Research: Shaping the European Agenda* is taking place in Porto, Portugal (under its EU Presidency) on 24-26 September 2007. The Commission set out the objectives of that conference and encouraged working group members to attend or pass on details to those in their Member States best served by attending.

Pharmacovigilance

A representative of the Commission's Enterprise and Industry Directorate-General presented on an ongoing initiative to strengthen the EU's pharmacovigilance system. In 2005 there was an independent study to identify the strengths and weaknesses of the current system. This was followed, in 2006, by a public consultation which resulted in calls for an eradication of duplication, a rationalisation, a simplification and clarity of the current system.

The Commission response covers both a better implementation of the current system and proposals to change the legal framework for pharmacovigilance in the EU through its Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance.

Improving implementation of the current framework will include but not be limited to: working with the Commission's Directorate General for Research on funding of studies into the safety of medicines as well as studies into the methodologies used to conduct pharmacovigilance; working with the Member States to resolve implementation issues, including administrative practices that complicate reporting rules for industry; and working with the EMEA to strengthen its coordinating role including supporting full compliance and maximum utilisation of the EU pharmacovigilance database 'Eudravigilance'.

Proposals for change to the legal framework will focus on but not be limited to: maintaining the current split of competences between the Member States and the EMEA, while making clear the respective roles and responsibilities and minimising duplication of effort; strengthening the rules on transparency relating to pharmacovigilance data, assessment and decision-making and involve stakeholders in the processes including reporting (including patient reporting); establishing clear standards for the conduct of pharmacovigilance by both the industry and regulators; freeing up resource by rationalising and simplifying the reporting of suspected adverse drug reactions, both expedited and periodic reporting, making best use of current information technology (including Eudravigilance) and matching the reporting requirements with the level of knowledge about the safety of a specific product; stimulating innovation by establishing a clear legal requirement to conduct post-authorisation safety studies including those in risk management systems; and rationalising EU decision-making on drug safety issues to deliver fast, robust decisions that are equally and fully implemented for all relevant products and across all markets.

Look-alike and Sound-alike Medicines

The Secretariat explained that unfortunately nobody from the European Medicines Evaluation Agency (EMEA) was available to speak to the working group on this issue at this meeting. However, it mentioned an ongoing EMEA consultation – *Guideline on the Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure* – which closes in April 2007. The Secretariat encouraged members to read this consultation document and formally respond to it if they wished to voice concerns over the issue of look-alike and sound-alike medicines or other patient safety-related matters.

Medical Devices Safety

A representative of the Commission's Enterprise and Industry Directorate-General updated the group on the revision process of the EC medical devices legislation. He informed them of the excellent news that the essential requirements text included a general requirement regarding

'design for patient safety', the wording of which he shared with the group. The European Parliament will vote on the proposal on 28 March and that would be followed by a 15 month transposition period and a 15 month implementation period. Presuming that the text remains as drafted, the explicit addressing of the important issue of designing medical devices for safer use in the legislation is a significant achievement and boost to patient safety.

The Commission asked working group members to take this development into account when proposing new patient safety initiatives.

E-Health

A representative of the Commission's Information, Society and Media Directorate-General updated the group on the activities of the I2010 working group on e-health. The programme had been published with a deadline for applications of May 2007. A Recommendation on e-health was also being developed. A first draft would be ready in June 2007 and patient safety working group members were encouraged to contribute to its formulation. The Commission is carrying out a pilot on continuity of care, which includes two areas of great significance for patient safety – patient summaries and e-prescribing.

A conference on e-health is taking place in Berlin on 17-19 April 2007 under the German Presidency. Patient safety was a key theme as 30 million euros was available for patient safety projects in e-health.

A Joined-up Approach

The Secretariat confirmed that it regularly discussed patient safety policies and initiatives with colleagues in other Commission services (both within SANCO and in other Directorate-Generals) which were involved in work with a patient safety perspective. It would continue to do so, to avoid overlapping, duplication or omission.

6. ANY OTHER BUSINESS

PGEU's booklet, *Patient Safety: Maximizing Patient Safety in Europe through the safe use of Medicines*, was distributed to attendees and it is available at www.pgeu.eu in English and French.

7. CONCLUSIONS

Dr Robida concluded that a very good job had been done at this meeting in coming to an agreement of the wording of the patient safety recommendation and the further development of the EUNetPaS project.

HAS will work with its partners and other working group members to address the outstanding concerns relating to the EUNetPas proposal and the Secretariat will revise the recommendation and circulate a 'final' draft to members. It would also provide members with more details of the prioritisation of patient safety for 2008 by DG SANCO.

The next meeting of the High Level Group is scheduled for 14 June 2007 in Brussels (to be confirmed).

Lee McGill, SANCO C5, – draft 2 to PSWG 280307