

Workshop – Future of Telematics in Pharmaceuticals

A workshop aimed to discuss the future strategies of telematics in the pharmaceutical field, in preparation of a Telematic Steering Committee meeting in June 2001, was held at EMEA in London on April 2001.

The Swedish Presidency and the EMEA had invited several stakeholders to present their views. Representatives from regulatory agencies of 12 Member States, Norway, Czech Republic (CADREAC/CAVDRI), EFPIA; FEDESA and AESGP were present.

Mr Paul Weissenberg, Director of Directorate F at DG Enterprise, chaired the workshop.

Presentations were made by

- the Swedish Presidency on behalf of the Member States
- the EMEA
- CADREAC
- EFPIA
- AESGP
- FEDESA
- JRC



Mr Weissenberg made a short presentation of the new structure since one year as regards telematics.

The Commission chairs the **Telematics Steering Committee (TSC)**. (Mr Weissenberg) The Troika countries and 2 permanent (3 years) representatives represent the Member States. Furthermore the EMEA and JRC are members of the TSC. This is a steering body that deals with strategic issues. In its meeting in June 2001, the Committee is expected to decide on a future Strategy *paper* for the European Union in the Pharmaceutical sector together with an Implementation plan.

The **Telematics Management Committee (TMC)** is chaired by the Commission (Mr Brunet) and consists of permanent representatives from the Member States, the chairmen of MRF and VMRF Groups, the chairpersons of the different Implementation groups and the EMEA Head of Unit IT. This Committee has supervision over the TIG:s (see below) and makes recommendations on IT strategy to the TSC.

There are four **Telematic Implementation Groups (TIG:s)**.

- Databases and Tracking is chaired by Portugal.
- E-submissions and ICH Implementation is chaired by France.
- EudraNet is chaired by the Commission.
- EudraVigilance is chaired by EMEA.

After the presentations were made it was obvious that there is consensus between the different stakeholders at the workshop that the projects already pointed out last year when the TIG:s were created are the most important projects.

The funding of these projects were discussed. Some projects are run with financial support from the IDA-TAC committee and JRC runs other projects within the 5th Framework Programme. The IDA funding will most probably be phased out by the end of 2002, mainly due to the fact that several of the projects will enter into a maintenance phase, and the funding from the above mentioned sources are supposed to fund development projects.

It has been suggested that the EMEA shall take the responsibility for the projects of EU dimension. The EMEA is prepared to take on this responsibility contingent on their being allocated sufficient resources and funds to do so which effectively means that such a transfer of responsibility cannot take place prior to January 2003.

EMEA clearly indicates that they have no intention to take on board the maintenance of EudraTrack since they are not responsible for the mutual recognition procedure. This is a very important issue to solve in the near future. JRC handles this system under the 5th Framework Programme, but will be phased out by the end of 2002. All stakeholders, but the industry in particular, were invited by Mr Weissenberg to present to the Commission their possible contribution to future and present projects as regards development of Telematics. Furthermore, other interested parties, representing health professionals and consumers, will also be invited to send their contributions to the Commission.

Conclusions

We all agreed on **goals and objectives**. IT is a tool to implement pharmaceutical policy

- to ensure a high level of protection of public health
- to complete the single market for pharmaceuticals
- to promote and boost the competitiveness of the European industry
- to prepare for the next EU enlargement

Transparency is a key word and guidance for the work to come for all stakeholders and customers, considering that the patient as primary customer. The workshop focussed on the needs of e.g. the industry to know more about the projects going on and to be able to get access to their “own” information within the systems now running. A web-site open for all stakeholders were suggested to enable this.

Efficiency of the operations is important. We must work with rapid processes (both for benefit of the patient and for the industry) and towards the paperless society to form integrated systems.

We must make **best use of our resources**. The organisational matters will have to be addressed. An intelligent network between different stakeholders has been suggested and found appropriate by the Member States. The industry and the candidate countries should also be involved in telematics at appropriate levels.

Telematics is not only on the European agenda. We must consider both the European and the international needs.

The **financing** will have to be solved based on clear lines in the near future so that the funding from 2003 onwards is no real obstacle for progress and success.

To be able to achieve the above mentioned we must focus on **few projects**, but be sure to make them running as soon as possible with the highest possible quality and security.

We, the Presidency and the EMEA, like to thank all contributors and participants.

List of participants



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