



European Medicines Agency  
*Post-authorisation Evaluation of Medicines for Human Use*

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**EUROPEAN LIFE SCIENCE CIRCLE  
THE INFORMED PATIENT: WHAT THE EUROPEAN UNION HAS TO DO**

**SESSION 2: WHAT LEGAL FRAMEWORK CAN WE BUILD IN EUROPE?**

**6 DECEMBER 2007 – EUROPEAN PARLIAMENT - BRUSSELS**

**EMEA Considerations**

1. The EMEA has, as of its establishment, undertaken various initiatives to improve information to patients. Although the large majority of these initiatives come within the context of the implementation of Community legislation, the Agency also continuously explored what kind of complementary activities it could take to contribute to the informed patient concept. This has resulted in deliverables such as improved transparency in relation to the Agency's work, more patient friendly information and the launch of the EudraPharm database.
2. In line with its legal obligations as well as the Agency's current priorities (as defined in the EMEA Road Map and its annual Work Programmes), further development of the activities in the area of provision of information to the Agency's stakeholders (and notably patients) is foreseen during the coming years. In order to achieve this, there is a need to ensure an appropriate coherence and coordination in relation to the different types of information the EMEA provides, and the tools with which this information is communicated. When defining further plans in this field the EMEA takes due account of patients' expectations as expressed in the frame of the EMEA Scientific Committees' Working Party with Patients' and Consumers' Organisations which was established in 2006 (replacing the former Working Group with Patients and Consumers' Organisations set-up in 2002).
3. When exploring what legal framework can be built in the EU in relation to the informed patient, one needs to have a clear understanding on the ultimate deliverable – the hard endpoint -, which should be the rational use of medicines. In order to achieve this a wide range of issues will need to be addressed, such as:
  - information to patients;
  - general knowledge and education;
  - risk minimisation;
  - dissemination channels, etc.

Proposals for further consideration, aiming at reinforcing the informed patient concept, and requiring legislative changes, are provided below:

- One needs first of all to acknowledge that the main tool to inform patients, i.e. the Package Leaflet, is not really – in its current form – the most appropriate tool to provide patients with the best possible information on the use of a medicine. The Package Leaflet (and also the SPC for healthcare professionals) have developed over the past decades into a more legal tool. Any new legislative initiative should, therefore, address identified weaknesses of current Package Leaflets. The recommendations made within the context of the Pharmaceutical Forum Working Group on Information to Patients on “Pillar II: Statutory Information on Medicines” can serve as a good basis to reflect on further legislative changes in this field. These recommendations address aspects such as information on benefits versus risks, readability and good quality translations of Package Leaflets.
- In addition, one can explore how such (revised) Statutory Information can be supplemented with additional elements to better inform patients, hence leading to the availability of a core set of information. The development at EU level (e.g. the EMEA) of a standardised information package for a particular medicine (which would come on top of legal documents such as the SPC, the Package Leaflet, the EPAR) would further increase the availability to patients of targeted, timely and validated information. When developing such information package, information should be extracted from the various Eudra databases held by the EMEA (e.g. EudraPharm, EudraVigilance, EudraCT) and should be made available in all EU languages. In first instance, this should be limited to centrally authorised products.
- An additional element which needs to be taken into account as regards the informed patient is at which level information needs to be given. It needs to be emphasised that the EU Regulatory System, characterised by a networking model, is rather complex with different roles and responsibilities which differ according to the licensing route of medicines. Furthermore, it needs to be said that the practical implementation of information to patients in some healthcare systems has been characterised by difficulties as regards the availability of (human) resources and financing. The aforementioned standardised information package could be made available at local level, either for direct use in primary healthcare, or to be adapted to the specific needs of primary healthcare in a particular Member State. Pharmaceutical industry could participate in the adaptation to the local needs and the subsequent dissemination of the information at local level.