European Medicines Agency

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EMEA's provision of information to the EMEA's stakeholders

Brainstorming meeting

20 September 2007

Chairperson:

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Head of EMEA Unit for Post-Authorisation Evaluation of Human Medicines

1. Introduction

A brainstorming meeting on provision of information to the EMEA's stakeholders was held on 20 September 2007 at the EMEA premises in London. The meeting had representation from the Agency's main stakeholder groups, namely patients' & consumers' organisations, healthcare professionals' organisations, veterinarians' organisations, and representatives from both human and veterinary pharmaceutical industry.

The objective of the meeting was to discuss with stakeholder representatives how to continuously develop the Agency's provision of information within the current legal framework and in the context of the further implementation of the EMEA Road Map to 2010.

It was clarified that the EMEA's vision on provision of information to stakeholders, as laid out in the above-mentioned Road Map, is still valid. However, a number of areas in which the EMEA is or will be involved – such as advanced therapies – have since then become additional priorities. These need to be analysed in the context of the Road Map and the related initiatives planned up to 2010. In addition, the stakeholders' general expectations to the Agency's work should be continuously considered. The EMEA therefore invited a number of stakeholder representatives to a brainstorming meeting to allow for their input before proceeding with the further implementation of the EMEA Road Map to 2010 in terms of provision of information.

1.1 Scope of the meeting

The meeting addressed the EMEA's provision of information to stakeholders in its widest sense. In order to stimulate the discussion, the participants were provided with an update on the current status of provision of information, and the further outlook in relation to Road Map initiatives was summarised. Particular emphasis was given on areas such as transparency, proactive information to stakeholders and the development of a coherent communication platform based on the various tools with which the EMEA provides information.

It was also highlighted that many initiatives related to provision of information have shifted towards an increased focus on both patients/consumers and healthcare professionals. Provision of information

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to the pharmaceutical industry remains an important task, but it is recognised that there is a particular need for further improvements in the provision of information to other stakeholder groups.

The participants agreed on three main objectives to guide further initiatives in this field:

- Improving transparency of regulatory activity and providing for more openness in decision-making, with particular emphasis on the rationale for such decision-making.

- Adapting current EMEA information practices and developing new ones in order to address future challenges in a coherent way.

- Incorporating the various tools with which the different types of information are provided into a coherent communication platform.

Meeting these objectives should allow the EMEA to raise awareness about the Agency and its activities at the level of patients, healthcare professionals and the general public.

2. Summary of discussions

In addition, the discussions at the brainstorming meeting touched on a variety of topics with a very active participation from stakeholder representatives, all of whom provided valuable input and ideas for consideration in the further implementation of the EMEA Road Map to 2010.

Highlights from the discussions are given below.

2.1 Improving transparency

Some participants carried forward the view that the EMEA is still a relatively unknown organisation, particularly as an official source of information on centrally authorised medicines. Both patients and healthcare professionals seem to lack knowledge about the information made available by the EMEA. Some participants found that there is a need to improve the general awareness of the Agency and its responsibilities, which are defined by legislation and carried out in the context of the EU 'Regulatory System Network'. In addition, there was broad support to the implementation of the EMEA Transparency Policy, which is being developed in the context of widening public access to documents while ensuring protection of confidential information. The participants highlighted the ethical dimension of transparency and provision of information. In this respect, and according to its legal obligations, the EMEA should be a leading body at EU level. It was suggested to initiate a public discussion on the EMEA's policy on access to documents. This should include making available an overview of the types of documents that can be expected to be accessed on request (mainly in the area of product related information).

It was mentioned that, as part of the ongoing transparency initiatives, assessments related to periodic safety update reports (PSURs) may in the future become subject to publication. The participants welcomed this initiative as part of the general improvements in transparency.

2.2 EMEA information practices

The EMEA, as per its legal role, has its focus on providing information on quality, safety and efficacy of medicines as well as information on the regulatory process. The Agency provides the information on medicines at different levels (e.g. Summary of Product Characteristics (SPC) for healthcare professionals, Package Leaflet (PL) for patients). However, these documents do not always reach their target audience, nor fulfil their needs and expectations. Therefore, participants considered the need to improve quality in terms of content and structure of the documents, as well as to ensure adequate ways of dissemination so that they effectively reach their audiences.

Representatives from healthcare professionals' organisations agreed that, by providing more and better quality information on medicines to patients, the relationship between patients and healthcare professionals would be strengthened. This can contribute to improve the overall quality of healthcare in the EU. To achieve this objective, the information to patients must be clear, simple and easy to read. In addition it must be ensured that it reaches the patients, as to avoid misinformation derived from e.g. non-validated sources.

There was a call for considering different levels of detail when providing information. This is already being done for the information made available to the public through the European Public Assessment Reports (EPARs). The EPAR reflects how the 'Committee for Medicinal Products for Human Use' (CHMP) has assessed the information provided by the applicant company. It provides the grounds for the CHMP opinion in favour of authorising the medicine, and it is published together with a summary, which is written in lay language with the intention to inform the general public. It was suggested that other types of information on medicines should also be available in different levels of detail. The healthcare professional representatives for example, highlighted that concentrated brief information (such as a summary of the SPC) would be useful, in particular for clinicians.

It was also raised that product information for healthcare professionals should be compatible and allow for being used by future information systems (e.g. electronic reporting systems, safety alert systems, electronic health records, e-prescribing, etc.). This entails the possibility of product information being provided in a way that would enable direct use by doctors and pharmacists in a clinical setting, on the level of the national healthcare systems. The proposal implies considerations on issues such as standardisation of terminology. There is therefore a need for the EMEA to investigate with healthcare professionals what kind of information they find beneficial to receive and in what detail and format.

As a general remark it was pointed out that the term 'product' can be misleading (e.g. understood as general consumer products) and there is a preference among stakeholders to instead use the term 'medicines'.

2.3 Information tools

There was a detailed discussion on the different tools currently used by the EMEA to provide information. The group agreed that communication tools should be adapted to the needs of the audience. Currently, the EMEA's communication tools can be classified as medicines (product) related (EPARs, statutory product information, Eudra systems, etc.) and non-medicines related information tools (guidelines, annual reports, etc.). The EMEA's website is a main general communication tool, used for providing medicines related, non-medicines related and corporate information to the stakeholders and general public.

2.3.1 Functionality of the EMEA website

An important consideration refers to how best approach the different audiences seeking information on the EMEA website. It was explored among the participants whether it would be beneficial to present the information provided via the EMEA website in a more targeted manner, i.e. by differentiating between user groups/audiences (currently, the information at entry-level is differentiated by grouping of topics). A considerable majority among the participants favoured that information should be structured by general topics, where all audiences would get access to the website through a single entry point. A suggestion to allow for audience differentiation (e.g. patients, healthcare professionals, regulators) on a case by case basis at a secondary level was welcomed. It was also recommended to keep the current differentiation between human and veterinary medicines.

The participants acknowledged that there is currently a wide range of information available on the EMEA website, but that in many cases the information is not easily accessible. A better structure of information with a view to increase user friendliness was requested. A first level should provide background and explanatory text in lay language, easily understandable by the general public. Additionally, clear access to all scientific documents should be provided to all users. The current

classification of scientific guidelines was highlighted as an example of an area where the presentation of the information has been improved. Other suggestions for improvement included providing a better overview of regulatory and procedural guidance, as well as including an overview of common abbreviations used and a terminology thesaurus.

In addition, it was suggested that the website should allow for the creation of individual profiles through which tailored information could be provided to users, in particular healthcare professionals – the emphasis being on creating a website that is simple, straightforward and easy to use.

It was acknowledged that there is an inherent discrepancy between what information is available on the EMEA website and what people would expect to find, e.g. information on clinical trials and medicines that are not authorised by the EMEA. This refers back to the discussion on the limited public knowledge and understanding of EMEA's legal role and derived activities. The participants recognised that the EMEA cannot exceed its remits, which is to provide information on centrally authorised medicines. It was highlighted, however, that the EudraPharm project is intended as a direct source of complete information on all medicines marketed in the EU.

There was agreement on the need for better website search functions for information on medicines, e.g. by inn-name, indication and therapeutic area. However, the participants were also reminded that the EMEA now has an advanced search engine on the website. Making full use of its functions should provide more precise search results than when just using 'simple' searches.

The possibility of establishing online archives for easier location of previous and outdated versions of documents was welcomed by participants. In addition, it was suggested to mark documents as revised or corrected, and accompany these with a track changes version, so readers can easily identify exactly what has been revised.

Participants were informed that the EMEA will soon launch an online questionnaire. All stakeholders are encouraged to participate as to obtain the broadest possible feedback on the website.
Post-meeting note: The survey was carried out between February and April 2008.

2.3.2 Other considerations on information tools

The participants were of the opinion that a clear distinction should be made between information on medicines and information not related to medicines. With regard to the information on medicines, some concerns were raised on the way it is presented, and in particular in relation to the current EPAR structure. It was found a very useful suggestion to organise all information related to a given medicine under the name of that medicine.

With regard to the EPARs' content, the participants suggested to include more and clearer information about the rationale for the outcome of discussions at the level of the scientific committees, the conditions of the marketing authorisation and the follow-up measures.

The EMEA has set up a specific framework for interaction with patients' and consumers' organisations and is currently in the process of developing a framework for interaction with healthcare professionals' organisations. The latter have requested that the EMEA engages in further communication and interaction with academia and other scientific societies with a view to making the rationale for decision making more transparent. In addition, the EMEA was encouraged to further involve patients' and healthcare professionals' organisations in order to properly disseminate the information at national level.

Finally, it was pointed out that internet access is not equally available in all EU Member States, and this could impede the access to information provided via the EMEA website. The EMEA will therefore look into the possibilities of increased use of non-web based information tools such as e.g. periodic newsletters, safety updates etc. to healthcare professionals.

2.3.3 Eudra systems

The Eudra systems (EudraPharm, EudraVigilance, EudraCT, EudraGMP) were presented to the participants as product related tools. They found the principles behind the Eudra tools very useful but requested that the full implementation of these takes place as soon as possible. The Chair clarified that, apart from implementing the necessary technical requirements, a wider access to safety information requires the development of an appropriate policy. For instance, the EudraVigilance system is currently fully accessible to national competent authorities, and it is foreseen that access at different levels will be given to industry, healthcare professionals and the general public. In addition, selected information from both the EudraCT and EudraGMP systems will become available to the public at a future stage. The EMEA aims at publishing the above mentioned policy in a draft version for stakeholder consultation during 2008.

It was highlighted that information from Eudra tools should be integrated with the EMEA website in a coherent and logical manner. Adequate links should be provided from the information on medicines to the different databases (i.e. EudraPharm, EudraVigilance, EudraCT, EudraGMP). It was also recommended that EudraPharm should provide information about the availability of medicines at national level for both human and veterinary medicines.

3. Conclusions

The Chair summarised the discussions of the day and noted that overall, the participants found the suggested initiatives for the further implementation of the EMEA Road Map in the area of provision of information to stakeholders both useful and relevant. In addition, the Chair thanked the participants for their contributions and took note of the various comments and suggestions carried forward, which will be taken into account when revising the implementation plan of the EMEA Road Map.

BRAINSTORMING MEETING ON THE EMEA'S PROVISION OF INFORMATION TO THE EMEA'S STAKEHOLDERS

List of participating stakeholder organisations

Organisation	
Association of the European Self-Medication Industry	AESGP
Association of Veterinary Consultants	AVC
European Aids Clinical Society	EACS
European AIDS Treatment Group	EATG
European Association for Bioindustries	Europabio
European Association for Clinical Pharmacology and Therapeutics	EACPT
European Association of Hospital Pharmacists	EAHP
European Biopharmaceutical Enterprises	EBE
European Cancer Patient Coalition	ECPC
European Consumers Organisation	BEUC
European Federation of Associations of Health Product Manufacturers	EHPM
European Federation of Nurses Associations	EFN
European Federation of Pharmaceutical Industries and Associations	EFPIA
European Generic Medicines Association	EGA
European Knowledge Platform for Small & Medium-sized Pharmaceutical Companies	Europharm SMC
European Organisation for Rare Diseases	EURORDIS
European Patients Forum	EPF
European Public Health Alliance	EPHA
European Scientific Cooperative on Phytotherapy	ESCOP
European Society for Medical Oncology	ESMO
European Union of General Practitioners	UEMO
Federation of Veterinarians of Europe	FVE
International Alliance of Patients' Organisations	IAPO
International Federation for Animal Health	IFAH-Europe
International Patient Organisation for Patients with Primary Immunodeficiencies	IPOPI
Pharmaceutical Group of The European Union	PGEU
Society for Medicinal Plant Research	GA
Standing Committee of European Doctors	CPME