European Medicines Agency

London 17 March 2005
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REPORT FROM THE WORKSHOP FOR THE EMEA/CHMP WORKING GROUP WITH PATIENTS' ORGANISATIONS

Meeting co-chaired by Dr Frits Lekkerkerker, Dutch Alternate Member of the CHMP and Mr Noël Wathion, EMEA Head of Unit for Post-Authorisation Evaluation of Medicines for Human Use

EMEA - Friday 3 December 2004

On 3 December 2004, the EMEA/CHMP Working Group with Patients' Organisations held a workshop with representatives from a number of partners and stakeholders, including the European Commission, national competent authorities, patients' organisations, healthcare professionals' organisations and pharmaceutical industry. The objective was to discuss the recommendations and proposals for action published for consultation in April 2004.

The Working Group with Patients' Organisations was created following the 1st workshop for patients' organisations (called "Information and Participation") held in May 2002. The purpose of the Working Group is to obtain further improvements in the areas of transparency and dissemination of information, product information, pharmacovigilance and interaction between the EMEA/CHMP and patients' organisations, in order to:

- Provide information adapted to patients' needs
- Develop appropriate communication tools
- Increase the awareness of the public in relation to the use of medicinal products, in the context of the EMEA activities

Three subgroups were established in the areas of transparency and dissemination of information, product information and pharmacovigilance, while the issue of interaction between the EMEA/CHMP and patients' organisations has been discussed in the Working Group's plenary sessions. In April 2004 the Working Group published an initial document on "Outcome of Discussions: Recommendations and Proposals for Action".

A three-month consultation period, where the different partners and stakeholders had the opportunity to comment on the Working Group's proposals, has subsequently been held. Comments and contributions were received from a variety of organisations and their representatives. All of these were invited to participate in the workshop.

The Working Group and the subgroups have carefully reviewed the comments. This second workshop provided an opportunity to present and discuss the amendments and revisions made to the initial proposed recommendations as a result of this consultation process.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.eu.int http://www.emea.eu.int

The recommendations fall into three categories: Recommendations that are within the current legal framework and can be implemented as such by the EMEA, recommendations that will need a harmonised approach by the member states and recommendations that require changes in the legal framework. It is proposed to implement some of the discussed recommendations in 2005 – 2006 while others are based on longer-term visions, especially where harmonisation and changes in the legislation are required.

A separate document containing the priority actions for 2005 – 2006 will be published in the beginning of 2005.

The workshop was structured around presentations on each of the four areas of recommendations and followed by a plenary discussion. An overview of the topics presented and discussed during the workshop is provided in the remaining part of this report. Links to the presenters' slides are given in the text. The agenda and the list of participants are provided in Annex 1 and Annex 2 respectively.

Introduction

Mr Thomas Lönngren, EMEA Executive Director, opened the meeting by welcoming the participants. He emphasised the importance of the workshop with respect to patient involvement in the work of the EMEA. The ongoing strengthening of this relation is very important as part of meeting the challenges created by major changes in the EMEA's environment of operation – changes that will affect the regulation of medicines in the years to come. Among these are the rapid development of new technologies, globalisation issues and the research & development environment for the pharmaceutical industry. Another important issue, which is of great concern to the patient associations, is the safety of medicines. The European Commission has given clear signals that the regulatory bodies have a role to play in the communication and interaction with patients and healthcare professionals in this area.

Mr Lönngren stressed that the EMEA has a well-established tradition for working with patients, and that this tradition is being further strengthened in 2005 when two representatives from patients' organisations will be included in the Management Board. Following the revised Community legislation, the Council will appoint them in consultation with the European Parliament.

In addition, the new legislation includes provisions to be put in place at the level of the EMEA with respect to the implementation of better access to comprehensive and more patient friendly information.

Looking to the future tasks, the Work Programme and Budget for 2005 – 2006 will take into account the necessary action for implementing the requirements of the new legislation. Furthermore, the EMEA Road Map to 2010 is its in final phase of preparation. This document spells out the more long-term vision of the Agency and includes a patients' information component.

Mr Noël Wathion from the EMEA subsequently held a brief introductory remark touching upon the next steps to be taken after the conclusion of the consultation process. He elaborated in particular on the importance of the EMEA Road Map to 2010 which was presented to the Management Board in December 2004 in a revised version.

The Road Map is an important tool in the process of strengthening the collaboration between the EMEA and the patients' representatives. Interaction with patients and improved information are among the elements included in this strategy, and will be implemented through a new sector for medical information that is currently being established.

Additionally, those of the Working Group's recommendations that affect the EMEA and can be implemented as such, will be so, while discussions on how to implement recommendations requiring harmonised approach and changed legislation will begin. The Road Map sets out a detailed route towards implementation as well as a timeframe with regard to priorities.

Dr Frits Lekkerkerker from the CHMP then did the last part of the introduction by briefly summarising the history and background for the Working Group as well as reflecting on the expectations, observations and experiences that in his view have characterised the process.

Overall it has been a very positive experience for the CHMP. The patients' organisations came up with the initial idea behind the collaboration with the EMEA and have displayed a very active participation on a highly competent basis. At the same time, useful experience has been gathered with respect to the financial and structural restraints, which can be inherent in the work of patients' associations.

Furthermore, Dr Lekkerkerker gave an overview of the type and content of comments received on the recommendations during the consultation phase. Quite a number of general as well as detailed comments have been accumulated during the process. In general, the reactions have been positive with respect to welcoming the initiative and having the EMEA play a coordinating role. Several comments and discussion points regarding the content have been carried forward from partners and stakeholders, and are summarised in Dr Lekkerkerker's slides from his presentation.

Session 1

The first session of the day was chaired by Dr Lekkerkerker and started out with a presentation on product information by Mrs Lesley Greene from Eurordis. The recommendations under this topic relate in particular to the content, layout and readability of package leaflets (PLs). The participants discussed the recommendations made for improving PLs quite extensively, especially concerning the methods on testing for readability.

Indicators for such testing are quite difficult to establish and the point was made that taking a strict scientific approach to this should consequently be considered. The Working Group however, expressed a commitment to establish readability standards where a variety of stakeholders, including patients, will be eligible to provide input. Mrs Hilde Boone from the EMEA mentioned that revision of the readability guideline will begin next year, and that the European Commission welcomes all comments interested parties might have.

Apart from the readability aspect, the volume of information in the PLs raised concerns. It was discussed whether the content of the information in the PLs might sometimes be characterised as 'information overload', i.e. that a more balanced approach towards the information included in the PLs might be beneficial.

The representative from the Icelandic national competent authority voiced concern that, from an economic point of view, small markets might be not be considered attractive for the industry to

enter. She suggested that the PL could be distributed to patients at the pharmacy alongside the given product, thus allowing a more flexible and inexpensive way of updating product information. The Working Group did not take this proposal on board, as it would not be in line with the current Community legislation. Furthermore, the issue is also related to the national legislation in the member states. However it was agreed to look at alternative tools for disseminating product information.

The increase of font size was of particular concern to the industry with regard to perceived consequences for major changes in package sizes as well as new requirements for production lines and storage space. This would require a harmonised approach and careful consideration.

The group agreed to amend the recommendations to reflect the main points brought up in the discussion as outlined above.

Mr Emmanuel Trenado from EPHA gave the second presentation in Session 1 on the subject of pharmacovigilance. The Working Group describes pharmacovigilance as the surveillance and investigation of adverse drug reactions (ADRs) after short-term and long-term use of medicines in order to promote the appropriate and safer use of available medicinal products including risk minimisation. Mr Trenado emphasised that pharmacovigilance is an increasing concern, recently illustrated by the worldwide withdrawal of Vioxx from the market.

The methods used for reporting ADRs, as well as the communication of safety issues to the public, are being improved in an ongoing process. However, much effort is still needed, in particular with respect to raise public awareness of pharmacovigilance as an important part of the public health agenda.

The participants generally agreed that information about safety and risks of medicinal products is an extremely important issue. In addition, there is a need to communicate the information in a constructive manner, so as the issue of risks are not disproportionately emphasised compared to the clinical benefit.

The means of informing patients caused a debate with some participants expressing the need for the EMEA to publish the raw data on safety and risks for each authorised product, hereby allowing the optimal background for patients to make 'informed choices'. The other and dominating standpoint was however, that raw data must be interpreted in order to be useful for the patient and to obtain the appropriate balance of benefits and risks in the information material.

No amendments were made to the proposed recommendations on this topic.

Session 2

Mr Wathion chaired the second session, which started with a presentation on transparency and dissemination of information, given by Mr François Houÿez, Eurordis. He reported a need for better, more transparent and more visible information on medicinal products in the EU. The information provided by the EMEA should be better structured, available through a variety of communication tools and be formulated in a more patient friendly language.

Representatives from the pharmaceutical industry raised concerns about the patient friendly European Public Assessment Reports (EPARs) as well as the public Questions & Answers

documents on specific products. They expressed a wish for the EMEA to discuss these with the industry before release so as to ensure that no confidential information will be published and that the information is harmonised between the different sources.

The Working Group recognises that many of the practical issues relating to strengthening transparency and dissemination of information need to be further discussed. Also, a more elaborate definition of the target groups (e.g. if a distinction should be made between the European and the national patients' organisations) is necessary. However, these issues will be a part of the ongoing process of implementing the recommendations.

The recommendations were not amended, apart from a slight change of wording for clarification purposes.

The second theme of session 2 was the EMEA/CHMP interaction with patients' organisations, presented by Dr Isabelle Moulon from the EMEA. The participants heard that it is a priority for the EMEA to interact with patients in the work of the organisation. Therefore, a number of recommendations set out to strengthen this relationship, including establishment of a framework for interacting with patients as experts or as representatives of their organisations. Furthermore, a new recommendation had been added, which is to provide training on the regulatory environment to patients so as to facilitate their understanding of and participation in the matters discussed at the EMEA.

The issue of public hearings, such as those organised by the U.S. Food and Drug Administration (FDA) during the medicine evaluation process, was up for debate. The group discussed whether emphasis on transparency, better information etc. are more in tune with the European setting than such hearings.

No changes were made to the recommendations in this area, but it was agreed that the subject of public hearings should be further discussed.

General discussion

After the presentation and the topic-specific discussions, Dr Lekkerkerker chaired a brief round of general comments on the overall consultation process.

The main point raised here was that the relationship between the doctor and the patient is, and will continue to be, a fundamental aspect of health care information to patients. It was suggested that a general remark should be added to the recommendations, underlining that information obtained via any EMEA source can constitute only one part of a complete information scenario, another important part being the dialogue between the patient and health care professionals. It has never been the objective of the EMEA to in anyway interfere with this relationship, and the participants recognised the call for inclusion of such a sentence.

Several aspects of implementation issues regarding the recommendations were brought up as general remarks. Among these were a call for for better awareness of the EMEA website and the possibilities of developing alternative tools other than the Internet for access to information. With respect to these issues, it was pointed out that cooperation from other partners, and from national competent authorities in particular, will be necessary.

Closing remarks

On behalf of the Working Group, Mr Albert van der Zeidjen from IAPO took the opportunity to express his acknowledgment to the colleagues, partners and stakeholders who have all been demonstrating an encouraging willingness to participate and have made the process a positive experience.

Likewise, Dr Daniel Brasseur, Chairman of the CHMP, attached a few remarks to the work that will follow from the recommendations agreed upon, and in particular to what tasks need to be undertaken in this respect. In his brief presentation he concluded on the issues discussed during the workshop and summarised the next steps forward in the four main areas for recommendations and action.

Annex I: Workshop Agenda

Annex II: List of Participants

European Medicines Agency

Annex 1

London, 3 December 2004
Doc. Ref: EMEA/21688/04

EMEA/CHMP WORKING GROUP WITH PATIENTS' ORGANISATIONS
FRIDAY 3 DECEMBER 2004 – 13.00 – 17.00

EMEA, 7 WESTFERRY CIRCUS, CANARY WHARF
LONDON E14 4HB, UK
MEETING ROOM: 4A

Chairpersons: Frits Lekkerkerker & Noel Wathion

AGENDA

13.00- 13. 35 Welcome and opening notes by Mr Thomas Lönngren, EMEA Executive Director (*10 min*)

Next steps: implementation of the recommendations by Mr Noel Wathion (*10 min*)

General remarks on the recommendations by Dr Frits Lekkerkerker (*15 min*)

"Recommendations and Proposals for Action"

Chairperson of Session 1: Dr Frits Lekkerkerker

13.35 – 14.15 Product Information presentation by Mrs Lesley Greene/Mrs Hilde Boone (*10 min*) Discussion (*30 min*)

14.15 – 14.55 Pharmacovigilance presentation by Mr Emmanuel Trenado/Mrs Pryia Bahri (*10 min*) Discussion (*30 min*)

Chairperson of Session 2: Mr Noel Wathion

14.55 – 15.35 Dissemination of Information and Transparency presentation by Mr François Houyez/Mr Martin Harvey-Allchurch (*10 min*) discussion (*30 min*)

15.35- 16.15 EMEA/CHMP Interactions with Patients' Organisations presentation by Mr Jean Georges/Dr. Isabelle Moulon (*10 min*) discussion (*30 min*)

16.15 – 16.50 General discussion

16.50-17.00 Closing remarks by Dr. Daniel Brasseur, Chairman of CHMP and Mr Albert van der Zeidjen, on behalf of the Working Group

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.eu.int http://www.emea.eu.int

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Annex 2

London, 1 December 2004
Doc. Ref: EMEA/140304/2004

WORKSHOP - EMEA/CHMP WG WITH PATIENTS' ORGANISATIONS
3 DECEMBER 2004
LIST OF PARTICIPANTS
13H-17H

Working Group:

Frits Lekkerkerker (CHMP) and Noel Wathion (EMEA) – Chairmen

Daniel Brasseur – CHMP Chairman
Tomas Salmonson – CHMP Member
Fernando de Andrés-Trelles – CHMP Member
Anne Castot – Acting PhVWP Chairperson
Beryl Keeley – CHMP Expert

Francois Houyez – European Organisation for Rare Diseases (Eurordis)
Andreas Reimann – European Organisation for Rare Diseases (Eurordis)
Lesley Greene – European Organisation for Rare Diseases (Eurordis)
Albert van der Zeijden - International Alliance of Patients Organisations (IAPO)
Rod Mitchell – International Alliance of Patients Organisations (IAPO)
Mauro Guarinieri – European AIDS Treatment Group (EATG)
Emanuel Trenado – European Public Health Allicance (EPHA)

Isabelle Moulon – EMEA
Nathalie Seigneuret – EMEA
Victoria Palmi-Reig – EMEA
Anabela de Lima Marcal – EMEA
Priya Bahri – EMEA
Hilde Boone – EMEA
Alexios Skarlatos – EMEA
Martin Harvey-Allchurch – EMEA
Anders Blaedel Lassen – EMEA

Representatives of Organisations from which comments have been received:

James Copping – European Commission
Erkki Palva – Finnish National Agency for Medicines
Christophe Kopp – La Revue Prescrire
David Sless – Medicines Labelling Group (MLG)
Yong Kwok – Medicines Labelling Group (MLG)
Ture Sjoblom – EFPIA
Barry Arnold – EFPIA
Heide Preuss – European Cancer Patient Coalition (ECPC)
Jesme Baird – European Cancer Patient Coalition (ECPC)
Ilona van den Brink – Dutch Medicines Evaluation Board (MEB)
Liesbeth Breeveld – Dutch Dutch Medicines Evaluation Board (MEB)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.eu.int http://www.emea.eu.int

Klaus Menges – Bfarm
Charles Bouchard – Merck Sharp & Dohme (Europe) Inc.
Angelika Joos – Merck Sharp & Dohme (Europe) Inc.
Bernhard Grewin – Standing Committee of European Doctors (CPME)
Theo Evers – European Plasma Fractionation Association (EPFA)
Flora Giorgio-Gerlach – Pharmaceutical Group of the European Union (PGEU)
John Ferguson – Pharmaceutical Group of the European Union (PGEU)
Rannveig Gunnarsdottir – Icelandic Medicines Control Agency (IMCA)
Nadene McClay – European Generic Medicines Association (EGA)

CHMP Members (who are not members of the Working Group):

Mr Michal Pirozynski
Mrs Leila Farah