The European Agency for the Evaluation of Medicinal Products

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EMEA/CPMP Working Group with Patients Organisations

Outcome of Discussions: Recommendations and Proposals for Action

Executive Summary

The EMEA/CPMP Working Group with Patients Organisations was created following the EMEA/CPMP Workshop for Patients Organisations held on 31 May 2002.

The Working Group held four meetings whereby it looked at further improvements to be achieved in the areas of

(1) transparency and dissemination of information,

(2) product information,

(3) pharmacovigilance, and

(4) interaction between the EMEA/CPMP and Patients Organisations.

Patients Organisations were encouraged to steer as much as possible discussions in the different areas, e.g. through the leadership of subgroups addressing the different topics, in order to take as much as possible patients' expectations into account.

As a result of the discussions, recommendations have been established. Such recommendations fall into three categories:

(1) recommendations which can be implemented as such by the EMEA,

(2) recommendations which require a harmonised approach at European Union (EU) level before implementation, and

(3) recommendations which require amendments to the current legal framework.

The CPMP, in its March 2004 meeting, agreed on a 3-month consultation exercise with the EMEA's partners and stakeholders.

The recommendations and proposals for action stemming from the Working Group are the first element of the EMEA's reply to the G10 Recommendations from the High Level Group on Innovation and the Provision of Medicines, and the Resolution of the Council of Health Ministers of 1 and 2 December 2003. The final recommendations from the Working Group will be incorporated in an "EMEA Strategy on Interaction with Patients".

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EMEA/CPMP Working Group with Patients Organisations

Outcome of Discussions: Recommendations and Proposals for Action

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Introduction

The EMEA/CPMP Working Group with Patients Organisations was created following the 1st EMEA/CPMP Workshop for Patients Organisations "Information and Participation", held on 31 May 2002[1]. Building on the conclusions of the Workshop, the EMEA /CPMP Working Group with Patients Organisations looked at further improvements to be achieved in the areas of transparency, dissemination of information, product information and pharmacovigilance, in order to:

(1) provide information adapted to patients' needs,

(2) develop appropriate communication tools, and

(3) increase the awareness of the public in relation to the use of medicinal products, in the context of the EMEA activities.

The EMEA/CPMP Working Group is co-chaired by F. Lekkerkerker (Dutch CPMP Member) and N. Wathion (EMEA Head of Unit for Post-Authorisation of Human Medicines); the list of participants is attached as Annex 1. The EMEA/CPMP Working Group met for the first time on 8 May 2003[2]. Subsequent meetings were organised on 30 September and 4 December 2003, and on 3 February 2004.

Methodology

The EMEA/CPMP Working Group decided to create 3 subgroups, i.e. on transparency and dissemination of information, on product information and on pharmacovigilance. The proposals stemming from each subgroup were discussed at the level of the EMEA/CPMP Working Group. In addition, it was agreed to discuss the more general topic of interaction between the EMEA/CPMP and patients organisations in the Working Group. It should be emphasised that patients organisations were encouraged to steer as much as possible discussions on the different topics, e.g. through the leadership of the subgroups, in order to take as much as possible expectations of the patients into account. Where possible, representatives from patients organisations consulted their respective associations.

It should be stressed that the recommendations made by the EMEA/CPMP Working Group have taken into account recent initiatives, such as the outcome of the EU Review 2001 of pharmaceutical legislation and the recommendations stemming from the G10 High Level Group on Innovation and the Provision of Medicines[3].

Three types of recommendations have been made by the EMEA/CPMP Working Group:

(1) recommendations which can be implemented by the EMEA within the current legal framework,

(2) recommendations which can be implemented within the current legal framework, but need to be further discussed with the European Commission and National Competent Authorities in order to achieve a harmonised approach at EU level, and

(3) recommendations which need amendments to the current legal framework.

The recommendations finalised by the EMEA/CPMP Working Group were forwarded to the CPMP for consideration. The CPMP, during its plenary meeting on 23-25 March 2004, endorsed such recommendations (see Annexes 2-5) and agreed on a 3-month consultation exercise with the Agency's partners and stakeholders (see Annex 6 for the list of consulted parties).

1 http://www.emea.eu.int/pdfs/human/patientgroup/245702en.pdf
2 http://www.emea.eu.int/pdfs/human/patientgroup/261303en.pdf
3 http://pharmacos.eudra.org/F3/g10/g10home.htm

Next Steps

Comments made in the context of the consultation exercise will be reviewed by the EMEA/CPMP Working Group during its meeting on 31 August 2004. The recommendations will be finalised at a 2nd Workshop for Patients Organisations to be held in Autumn 2004, during which the EMEA/CPMP Working Group will also present its action plan for:

(1) follow-up on the recommendations, and

(2) monitoring of the implementation.

The final recommendations will be incorporated in an "EMEA Strategy on Interaction with Patients" and will either lead to an implementation by the EMEA or further discussion with the European Commission and National Competent Authorities as outlined above.

Annexes

EMEA/CPMP Working Group with Patients Organisations

Outcome of Discussions:
Recommendations and Proposals for Action

Annex 1

Participants

Patients Organisations

Charlotte de Roo (Member)	BEUC, The European Consumer's Organisation
Jackie Glatter (Alternate)	BEUC, The European Consumer's Organisation
Wendy Garlic (Alternate)	BEUC, The European Consumer's Organisation
Mauro Guarinieri (Member)	EATG, European Aids Treatment Group
Polly Clayden (Alternate)	EATG, European Aids Treatment Group
Andrew Hayes (Member)	ECL, European Cancer Leagues
Arlene Spiers (Alternate)	ECL, European Cancer Leagues
Mary Baker (Member)	EFNA, European Federation of Neurological Associations
Jean Georges (Alternate)	EFNA, European Federation of Neurological Associations
Christophe Talheim (Member)	EPF, European Patients Forum
Colin Webb (Alternate)	EPF, European Patients Forum
Emmanuel Trenado (Member)	EPHA, European Public Health Alliance
Andreas Reimann (Member)	EURORDIS, European Organisation for Rare Diseases
Lesley Greene (Alternate)	EURORDIS, European Organisation for Rare Diseases
Francois Houyez (Alternate)	EURORDIS, European Organisation for Rare Diseases
Albert van der Zeijden (Member)	IAPO, International Alliance of Patients Organizations
Rod Mitchell (Alternate)	IAPO, International Alliance of Patients Organizations

CPMP Members and Experts

Frits Lekkerkerker – Co-Chairman	CPMP Member, The Netherlands
Daniel Brasseur	CPMP Chairman, Belgium
Fernando de Andrés-Trelles	CPMP Member, Spain
Tomas Salmonson	CPMP Member, Sweden
Anne Castot	Acting PhVWP Chairman, France
Beryl Keeley	Expert, United Kingdom

EMEA

Noël Wathion – Co-Chairman	Head of Unit Post-Authorisation Evaluation of Medicines for Human Use
Isabelle Moulon	Head of Sector Safety & Efficacy of Medicines
Martin Harvey-Allchurch	Head of Executive Support
Priya Bahri	Scientific Administrator
Hilde Boone	Scientific Administrator
Leng Heng	Scientific Administrator
Anabela de Lima Marcal	Scientific Administrator
Nathalie Seigneuret	Scientific Administrator
Alexios Skarlatos	Administrator

Annex 2

Recommendations in the Area of Transparency and Dissemination of Information

Topic leader: **Albert van der Zeijden (IAPO)**

The EMEA/CPMP Working Group agreed on the recommendations in the area of transparency and dissemination of information, as listed below. In addition, the following general comments were made:

- The Group felt that the EMEA has an important role in the provision of patient-friendly disease specific information. The EMEA and its role/activities should, therefore, be better known to the general public.
- Patients need independent and validated information to help them understand and participate in the treatment decisions.

I Recommendations implementable within the current legal framework

I.1 Recommendations implementable as such by the EMEA

Synthesis/presentation of information on medicines

a) In consultation with patients organisations, the EMEA should ensure that all information concerning specific medicines is designed to meet the needs of different user groups, e.g. acute and chronic patients or the general public. Ideally this should:

- Include availability of all information intended for patients in all official EU languages.
- Take account of different levels of education and ability. Follow established health literacy guidelines, i.e namely clear and easy to understand messages, relevant and tailored content, culturally and linguistically appropriate format.
- Involve readers, including pilot testing on key audiences.
- Allow feedback from patients on the readability of patient information (e.g. package leaflet, public statements).

Transmission/dissemination of information on medicines

b) While the EMEA website is the Agency's primary tool for information dissemination, other tools should be used in particular to inform patients and the public who do not have access to the Internet.

- The EMEA needs to further develop its website and printed general information.
- All printed information should include a reference to the web site.
- The EMEA and patients/consumers organisations should encourage the inclusion of information on organisations where patients can find additional relevant information.

- The structure of the EMEA website should be reorganised to facilitate access of patients to information (e.g. possibility of searching drugs by disease name, medication class, therapeutic indication).
- The EMEA should introduce multi-lingual navigation of the website.
- The EMEA should create disease specific e-mail lists in order to provide alerts on any new information posted on the website (e.g. safety updates, summaries of opinions, European Public Assessment Reports (EPARs), guidance documents).

c) The EPAR has shown to be of benefit mainly for healthcare professionals, although not necessarily understandable for most patients.

- The EMEA should develop a patient friendly version of the EPAR, including a section reflecting any comparisons with existing therapeutic options done during the assessment.
- The EMEA needs to ensure that a clear description/presentation of post authorisation specific obligations and commitments and their deadlines/completion will be available for patients and the general public.

d) The EMEA should produce "Questions and Answers " documents on a case-by-case basis to address specific situations affecting the use of medicines.

e) The EMEA should consider making product-by-product press releases with patient friendly information (at time of opinion and post-authorisation).

f) Patients organisations should be included in the EMEA press release mailing.

g) Timing of information dissemination should be reconsidered by the EMEA, acknowledging the need for information to be provided before CPMP opinion (e.g. confirmation of submission of applications, procedural timetable for specific products).

<u>Transparency and awareness of the EMEA</u>

h) Freedom of access to information answers the needs of patients and so will be the starting point for the EMEA. The necessity of limitations to this freedom has to be demonstrated on a case-by-case basis.

i) EMEA needs to clearly define the concept of "commercially confidential information" in order to allow for transparent communication.

j) The EMEA and its role/activities should be widely publicised and better known by the public.

- In general the EMEA should be more proactive in collecting, communicating and providing information to patients and the European citizens in general. While doing this the transparency of the Agency and the European system as a whole will naturally increase.
- The EMEA should undertake a public awareness strategy. This should include:
  - proactive press and media campaigns;
  - a user friendly web site;
  - publication of leaflets and printed materials;
  - use patient and healthcare professional groups as relay points.

I.2 Recommendations requiring a harmonised approach at EU level before implementation

Screening, identification and collection of information on medicines

a) The collection of comprehensive information on medicines should be based on a collaborative approach between regulatory bodies, health education officers, patients groups and consumers organisations.

   The EMEA should take the initiative to bring together representatives of regulatory bodies, health education officers, patients groups and consumers organisations to improve the level of collection of information on medicines with regard to the interests of patients.

b) Information on all medicines authorised in the EU should be made available.

c) Data sources include EudraVigilance (database on pharmacovigilance), EuroPharm (database on information on all authorised medicines) and databases of National Competent Authorities.

   Patients organisations should provide input on their expectations on what information should be publicly available from these databases.

Analysis and validation of information on medicines

d) Levels of validation of information should be reflected on the information provided (i.e. reliability of data source).

   Patients organisations should develop a template against which information provided by patient groups and other external sources could be validated ("kite mark"). Patient organisations could consider signing-up to some self-regulation mechanism concerning the information to be presented.

Transmission/dissemination of information on medicines

e) There is a need to inform European patients about the availability of medicines across Member States.

   The EMEA should include a link to the EuroPharm database on the website to allow access to accurate and up-to-date information about the availability of medicines across Member States.

f) Member States should make a listing of national patients associations publicly available (e.g. on their website).

II Recommendations requiring amendments to the current legal framework

Not applicable.

Annex 3

Recommendations in the Area of Product Information

Topic leader: Mary Baker (EFNA)

The EMEA/CPMP Working Group agreed on the recommendations in the area of product information, as listed below. It should be noted that, in the context of the discussions, "product information" refers to "package leaflets".

I Recommendations implementable within the current legal framework

I.1 Recommendations implementable as such by the EMEA

a) Companies using the centralised licensing route should involve patients associations when preparing/drafting a Package Leaflet (PL) at an early stage. In addition, patients associations could be involved in Readability Testing and in the review by the Quality Review of Documents Group (QRD) of the English PL (e.g. join the Day-150 meeting).

The EMEA should contact the relevant European patients association in the disease area and invite 1-2 representatives to attend the Day-150 meeting at the EMEA where the PL will be reviewed together with the company. If no EU association would exist in the disease area concerned, representatives from a national organisation or a general consumer representative with the appropriate expertise could be invited. A confidentiality agreement should be signed by the patients representatives.

A voluntary trial period for this initiative could be set-up with interested companies.

b) The PL of a Centrally Authorised Product should include a reference to the EMEA Website where patients can find the latest information available on the product (as part of the EPAR).

A statement at the end of the PL such as "The latest approved information on this product is available on the Website of the European Medicines Evaluation Agency (EMEA): + *web address*" should be included.

For Orphan Drugs only, a reference to the Eurordis website should be given in the PL in addition to the EMEA website: "General information on rare diseases is available on the Website of the European Organisation for Rare Diseases (Eurordis): http://www.eurordis.org/".

c) Patients should be given the possibility to send comments to the EMEA on the readability/quality of PLs published on its website (in the EPAR). The EMEA, where appropriate, could inform the companies and patients associations about the feedback received.

A statement such as "to send your opinion on the readability/quality of the package leaflet text, please click here. Relevant feedback will be compiled and provided to the MAH" could be included on the EMEA Website (e.g. EPAR).

d) Changes made to the PL should be identified by:

- Adding a tabulated tracking sheet to the EPAR, giving a concise overview of the chronology of the PL and its changes.
- Indicating at the end of the PL itself which sections were last revised. The reference to the revised PL section should be clear and simple (e.g. section 2 – pregnancy).

e) The listing of Local Representatives of the Marketing Authorisation Holder at the end of the PL for all Member States is considered not useful and takes up too much space in the printed leaflet which could be better used. Only the Local Representative relevant for the MS concerned where the pack is marketed, should be included in the PL.

In addition, a reference to the EMEA Website should be printed above the company contact details (see also point b above).

f) Important new or updated draft guidelines published on the EMEA website which will impact on Product information (e.g. relevant CPMP guidelines, EU guidelines, QRD guidance, etc ….) should be flagged to patients associations so that they can provide comments and provide input during the consultation period on the draft documents.

An electronic mailing list should be set-up, as well as a system to identify which draft guidelines need to be sent.

I.2 Recommendations requiring a harmonised approach at EU level before implementation

a) The PL of a specific product should give the same information to all patients in the EU. There should be no differences between Member States (MSs) and between patients. Whereas this objective is already achieved in the Centralised Procedure, harmonisation of the PL text for products approved via the Mutual Recognition Procedure would be desirable.

A standardised format and standardised requirements should apply across EU. This should ideally also apply to the content of PLs of products containing the same active substance(s).

The legislation and PL guidance provide for a standardisation of structure and format of a PL, but the available guidance could be further developed and optimised (e.g. QRD recommendations, review of Commission's guidelines – see also point I.2.c).

Even if a PL should give the same content in all language versions, strict literal translations may lead to unnatural, unreadable PLs which are difficult to understand. Therefore, different language versions of the same PL should allow for regional translation flexibility, whilst maintaining the same core meaning. In addition, companies and authorities should work together to ensure good-quality translations, possibly involving patients associations.

The readability of PLs should be increased as to improve the quality of the leaflets to a level which is understandable to most patients. Companies are strongly encouraged to perform readability testing.

b) In order to provide a good balance between information on benefits versus risks, the benefits of taking/using the medicine should be made more prominent and better explained in the PL. The text should also distinguish more clearly between prevention and treatment.

Although the first section of a PL is "what the product is and what it is used for", the information provided in this section is usually very short. Especially for long term treatment and prevention products, further information on the demonstrated benefits for the patient should be included to give full information to patients and in order to improve compliance/concordance. However, it should not lead to the inclusion of any additional and promotional claims from the company outside the approved indications.

Guidance on the issues above should be developed when reviewing the Guideline on Readability (see point c below)

c) It is recommended to review the Commission's Guideline on Readability (1998), with active involvement of patients associations at an early stage. The EMEA should co-ordinate this task and should set-up a working group involving people with different expertise (Patients Associations, QRD experts, industry representatives, experts on readability and information design, etc …).

As part of the general review of the Guideline, the following points should also be addressed:

- In the Review of the pharmaceutical legislation (Directive 2001/83) it is specified that "Results of consultations with target patient groups should be reflected in the PL". The Group welcomes this new provision. Further details however on what is required and when should be developed.
- The inclusion of harmonised and well-known signs/symbols/pictograms in the PL to aid visual navigation and highlight important sections or statements should be investigated.
- Where a product has been approved with conditions, or under exceptional circumstances, or is available under a pre-authorisation programme, a patient-friendly statement should be included in the PL to alert patients to this.
- The issue of good-quality translations should be addressed (see also I.2.a)
- The presentation of side-effects should be looked at: quantification, usefulness, comprehension, understanding …
- The interaction with 'illicit/recreational drugs' should be tackled.

II Recommendations requiring amendments to the current legal framework

a) Rather than using the term "Package Leaflet", the term "Patient Information Leaflet" would be preferred as this reflects better the purpose of the leaflet. It is noted that "Package Leaflet" is however the term used in the current and future European legislation.

Even though flexibility of this term in translations exist, it would be better if the 'official' English term in the EU legislation would be Patient Information Leaflet, because 'package' refers to the product and not to the purpose of such leaflet.

b) It was noted that the current and revised legislation (Dir 2001/83) provides for a specific order for the PL particulars. As experience with this order is currently lacking, relevant feedback should be kept and analysed for future recommendations to amend the Directive accordingly.

Annex 4

Recommendations in the Area of Pharmacovigilance

Topic leader: Emmanuel Trenado (EPHA)

The EMEA/CPMP Working Group agreed on the recommendations in the area of pharmacovigilance, as listed below. In addition, the following general comments were made:

- Pharmacovigilance encompasses 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.
- When medicinal products enter the market, clinical experience is limited[4]. After marketing authorisation, further knowledge on their characteristics and toxicity is gained continuously and previously unknown ADRs and interactions may be identified at any time.
- One major tool in pharmacovigilance today is spontaneous reporting by healthcare professionals, a method of passive surveillance[5]. Throughout Europe, the level of spontaneous reporting of ADRs is low (so-called underreporting).
- Due to underreporting and missing data in case reports (incomplete or low-quality information) of ADRs, spontaneous reporting systems have their limitations but have nevertheless identified previously unknown ADRs in many cases. However, one cannot be sure to efficiently identify all ADRs by means of spontaneous reporting.
- Spontaneous reporting by patients to healthcare professionals will be encouraged by competent authorities in accordance with revised EU legislation on medicinal products.
- Given the limitations of spontaneous reporting, epidemiological studies and other methods of active surveillance may be used to investigate and quantify the risks of medicinal products.
- There is lack of adequate awareness among the public about pharmacovigilance as an issue of public health.
- To effectively distribute new information to prescribers and patients remains a major challenge. This is in particular true for delivering information that balances the benefits and risks for individual patients appropriately. Safety information should not jeopardise therapeutic adherence.
- The success of any pharmacovigilance system depends on the capacity to communicate safety information effectively to the users of medicinal products.

[4] The nature of clinical trials is as follows: Study size of usually several thousand patients sets a threshold for detection adverse reactions at a frequency lower than 1:1000; limited length of studies of usually several months rather than years does not permit detection of long-term adverse effects; patients with special conditions (e.g. rare diseases, children) may not be studied at all.

[5] Spontaneous reporting here describes the notification of a suspected adverse drug reaction by a healthcare professional following his/her own observation in a patient or brought to his/her attention by the patient him/herself.

I Recommendations implementable within the current legal framework

I.1 Recommendations implementable as such by the EMEA

I.1.1 Audit of pharmacovigilance

System and process audit of pharmacovigilance systems

The EU pharmacovigilance system at the level of regulatory authorities will be assessed by the European Commission (EC). Efforts to develop good pharmacovigilance practices for implementation by Member States with the goal to achieve best practice should be completed. It is recommended to also assess the pharmacovigilance systems of the Marketing Authorisation Holders (MAHs).

a) The EMEA/CPMP/PhVWP should finish ongoing work on the guideline for Good Pharmacovigilance Practices intended for regulators to facilitate both system and process audit (internal or external).

b) There is a plan at the level of the CPMP/PhVWP to develop a similar guideline for industry (in addition to existing regulatory guidance). This plan should be followed-up.

c) The EMEA should follow-up the implementation of the CPMP Position Statement on compliance of MAHs with pharmacovigilance obligations, now enforced by revised EU legislation on medicinal products.

d) The EMEA should implement a transparent tracking procedure on post-authorisation commitments and make it available to the public.

I.1.2 Transparency and communication

Public information and education campaigns on better use of medicinal products

e) The EMEA should provide general and product-specific material directed to patients (for Centrally Authorised Products (CAPs) and products subject to Referrals).

f) Each time a Direct Healthcare Professional Communication is provided on a safety issue for a CAP, a patient-tailored communication should be published by the EMEA.

g) The EMEA should support the concept of 'tear-off fact sheets' to support prescribers in informing patients on drug safety[6].

Public access to information on pharmacovigilance

h) The EMEA should publish on an as-needed basis the conclusions of product-related discussions within the CPMP/PhVWP.

[6] For example, the UK's Medicines Healthcare Products Regulatory Agency (MHRA) issues fact sheets called "Key Information for patients receiving treatment with medicines known as x" (http://medicines.mhra.gov.uk/ourwork/monitorsafequalmed/currentproblems/currentproblems.htm).

I.1.3 Improved reporting

Education campaigns on pharmacovigilance directed towards healthcare professionals

i) The EMEA should follow-up plans at the level of the CPMP/PhVWP to develop good pharmacovigilance practices for healthcare professionals.

I.1.4 Active pharmacovigilance methods and pharmacovigilance planning

Risk management programmes

Risk management programmes for the collection of pharmacovigilance data and risk minimisation should be defined at the time of granting a marketing authorisation.

j) The CPMP has released the ICH-E2E guideline for public consultation and the EMEA has circulated such guideline to the EMEA/CPMP Working Group with Patients Organisations for comments. The EMEA will forward such comments to the CPMP/PhVWP and the ICH Expert Working Group.

Collaborative post-authorisation safety studies

k) The EMEA should approach patients organisations to support appropriate studies for CAPs, which are often undertaken by the MAHs (e.g. as successfully done for the Oversight Committee on metabolic disorders for anti-HIV medication).

Surveys on adverse drug reactions by patients organisations

l) Results from the French joint (TRT-5/AFSSAPS) pilot study on anti-HIV medication should be communicated by the EMEA to the EMEA/CPMP Working Group with Patients Organisations for consideration of further recommendations with regard to surveys.

m) The EMEA/PhVWP should support the development of a standard protocol.

I.2 Recommendations requiring a harmonised approach at EU level before implementation

I.2.1 Audit of pharmacovigilance

Outcome audit of pharmacovigilance

a) The impact of regulatory decisions and public communications concerning appropriate and safer use of medicinal products should be assessed. Procedures for evaluating public health impact of the regulatory action and of public communication on drug safety should be set up.

b) Patients organisations should set up procedures for evaluating public communication on drug safety within their membership, possibly in co-operation with the National Competent Authorities (NCAs)/EMEA and MAHs.

I.2.2 Transparency and public communication

Public information and education campaigns on better use of medicinal products

c) The EMEA and NCAs should provide support for patient education on better use of medicines. Funding of such campaigns should be addressed.

d) The recommendations listed under section I.1.2 (e, f, g) should preferably be taken up in a EU wide context, hence requiring Member States' involvement, in order to achieve a harmonised approach.

e) Patients organisations should prepare patient education programmes jointly with healthcare professionals on appropriate use of medicinal products.

Public access to information on pharmacovigilance

f) Public access to information on product related pharmacovigilance should be further improved.

I.2.3 Improved reporting

Education campaigns on pharmacovigilance directed towards healthcare professionals

g) Curricula for studies and continuous training for healthcare professionals should be reviewed in order to raise pharmacovigilance awareness.

h) Learned societies should be approached to provide educational programmes on the benefit of pharmacovigilance and the application of proper diagnostic criteria for ADRs.

Reporting incentives for healthcare professionals

i) Feedback mechanisms to healthcare professionals should be established in order to stimulate reporting.

j) Publication of safety-related information in scientific journals and in bulletins of healthcare professional associations, including observations on adverse drug reactions submitted by healthcare professionals to such journals/bulletins should be encouraged.

Improvement of reporting forms

k) Feedback from healthcare professionals on available reporting forms and reporting via Internet should be obtained in order to further improve reporting by healthcare professionals.

Patient reporting

l) Patients organisations should be allowed to send in summarised reports to the NCAs. These reports should be based on direct patient reporting on ADRs to the patient organisations. In order to produce meaningful reports, the patients organisations should have in place an appropriate structure to validate reports.

m) First experience from patient reporting currently obtained in some Member States (e.g. in Denmark on direct-to-authority reporting, in the Netherlands on reporting through the national pharmacovigilance system LAREB, in the UK through a national healthcare-supported telephone helpline) should be communicated to the EMEA/CPMP Working Group with Patients

Organisations for consideration of further recommendations on patient reporting.

I.2.4 Active pharmacovigilance methods and pharmacovigilance planning

Collaborative post-authorisation safety studies

n) Working groups between patients organisations and NCAs should be established at national level for general collaboration and more specifically, for setting up, together with MAHs as appropriate, collaborative studies.

Registries

o) Patients organisations should promote the creation of patients registries to collect data on ADRs, tolerability and impact on quality of life, in particular for orphan drugs for rare diseases.

p) Patients organisations should share experience from already existing registries.

Surveys on ADRs organised by patients organisations

q) Patients organisations should exchange best practice in undertaking this kind of surveys.

II Recommendations requiring amendments to the current legal framework

II.1 Audit of pharmacovigilance

Outcome audit of pharmacovigilance

The impact of regulatory decisions and public communications concerning appropriate and safer use of medicinal products should be assessed.

a) Competent authorities jointly with learned societies and health insurance schemes should implement a policy to collect prescription and drug utilisation data. In some Member States this requires amendment to legislation.

Annex 5

Recommendations in the Area of Interaction between the EMEA/CPMP and Patients Organisations

The EMEA/CPMP Working Group agreed on the recommendations in the area of interaction between the EMEA/CPMP and Patients Associations, as listed below.

I Recommendations implementable within the current legal framework

I.1 Recommendations implementable as such by the EMEA

a) In collaboration with patients organisations, the EMEA/CPMP should produce a policy, clearly identifying the type of organisations it will interact with, based on criteria to be defined by the working group (e.g. representation at EU level, funding, how to address areas where no European patients organisations exist, etc).

b) The EMEA should subsequently publish the above policy and the list of patients organisations with whom it is interacting. The EMEA will invite other organisations fulfilling the defined criteria to express their interest to participate to the EMEA activities, as necessary.

c) The EMEA should identify one Staff Member as a contact point for interaction with patients organisations.

d) For each topic discussed by the Working Group, it is proposed to have one contact point from the EMEA and one from the patients organisations who could be contacted by patients for further information.

e) Different frameworks for interaction with patients should be defined:

- interaction with patients as representatives of their association
- interaction with patients as experts

Clear rules will be established by the EMEA. A patient invited as an expert will have to adhere to the same rules as all other experts participating in EMEA activities, especially with regard to declaration of interests and confidentiality undertaking.

<u>Interaction with patients as representatives of their association</u>

- The EMEA/CPMP Working Group with patients organisations should become an established working group. New terms of reference (e.g. mandate, scope, frequency of meetings) should be agreed upon to work in particular on the implementation of all recommendations stemming from the current exercise, as well as all the provisions foreseen in revised European pharmaceutical legislation relevant to interaction with patients.
- The EMEA should pro-actively consult appropriate disease specific patients' organisations when developing guidance documents, intended to give guidance on the development of new medicinal products. It is therefore proposed that the EMEA will send Concept papers to the relevant patients associations asking for input which will be taken into consideration during the development phase. A Concept paper is a document which is primarily intended to state clearly the need for discussing specific issues, innovations or controversial key-points in any stage of the development of medicinal products with a view to laying down

the foundation for a future guideline. It should point out what should be discussed in the guideline, but should not elaborate already on solutions.

The same process would apply once the guidance document is released for public consultation before finalisation. Exceptionally, specific meetings could be organised to discuss with the relevant Working Parties some of the issues or comments, if needed.

- The possibility for having Ad-hoc on-call informal meetings between the CPMP and patients organisations to discuss disease-specific topics, as foreseen in revised Community legislation, should be further defined (e.g. assessment of quality of life, new emerging therapies, evaluation of individual risks associated with these emerging therapies).
- Patients organisations should be able to participate to Working Groups of the CPMP (for example paediatric expert group, scientific advisory group) to present patients views on specific topics.
- The EMEA should provide feedback from these meetings in a transparent manner. Reference is made to the availability of the minutes of the meetings of the EMEA/CPMP Working Group with Patients Organisations on the website, as an example of adequate transparency.
- The patients organisations' representatives will be responsible for disseminating all information within their organisations and to consult with them as appropriate. Patients organisations should publicise their involvement in the EMEA/CPMP Working Group with Patients Organisations.

<u>Interaction with patients as experts</u>

- The participation in the CPMP or its Working Groups (for example paediatric expert group, scientific advisory group) on appropriate occasions should be envisaged. Reference is made to the positive experience with the Ad-Hoc Working Group on Anti-Retroviral Medicinal Products. For instance, the participant could use his expertise as a patient to provide input for instance into the design of pivotal trials, the data required for licensing a new medicinal product and the elaboration of a risk management programme.

I.2 Recommendations requiring a harmonised approach at EU level before implementation

a) The EMEA should promote its model of involvement of patients to the Heads of Agencies in order for National Competent Authorities to consider any appropriate action at national level.

II Recommendations requiring amendments to the current legal framework

a) In order to further increase the transparency of EMEA/CPMP activities it is proposed to have public hearings in the context of the scientific evaluation process, in line with the FDA. It needs to be emphasised that this is not foreseen in current or future Community legislation.

Annex 6

List of Consulted Parties

European Institutions

- European Commission – Enterprise Directorate-General
- European Commission – Health and Consumer Protection Directorate-General
- European Commission – Information Society Directorate General
- European Parliament – Committee on the Environment, Public Health and Consumer Policy

National Competent Authorities in the EU Member States (including Accession Countries) and EEA/EFTA Countries

- Ministries, responsible for human medicines
- Heads of Agencies, responsible for human medicines

European Industry Associations

- AESGP –Association of the European Self-Medication Industry
- EFPIA – European Federation of Pharmaceutical Industries and Associations
- EFPIA/EBE – European Federation of Pharmaceutical Industries and Associations / Emerging Biopharmaceutical Enterprises
- EGA – European Generic medicines Association
- EPFA – European Plasma Fractionation Association
- EuropaBio – European Association for Bioindustries
- Europharm SMC – European Pharmaceutical SMEs Association
- Eye-Care Industries EEIG

European Healthcare Professionals Associations

- CPME – Standing Committee of European Doctors
- ICN – International Council of Nurses
- PGEU – Pharmaceutical Group of the European Union
- UEMO – European Union of General Practitioners

European Patients Associations

- BEUC – European Consumers' Organisation
- EATG – European AIDS Treatment Group
- ECL – European Cancer Leagues
- EFNA – European Federation of Neurological Associations
- EPF – European Patients' Forum
- EPHA – European Public Health Alliance
- EURORDIS – European Organisation for Rare Disorders
- IAPO – International Alliance of Patients' Organisations

Other Organisations

- British Medical Journal Publishing Group Ltd
- CCNet – Cochrane Consumer Network
- European Academy of Sciences and Arts
- GIRP – European Association of Pharmaceutical Full-line Wholesalers