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EMEA/CHMP WORKING GROUP WITH HEALTHCARE PROFESSIONALS' ORGANISATIONS (HCP WG)

FINAL RECOMMENDATIONS AND PROPOSALS FOR ACTION

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EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)

Final Recommendations and Proposals for Action

Executive Summary

The EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) was created following the workshop between the EMEA and a broad range of European healthcare professionals' organisations held on 28 March 2006.

The HCP WG held its first meeting on 17 November 2006 and since then it has developed recommendations for the following priority areas, which have been identified based on the outcome of the above mentioned workshop:

- Information on medicines: The group has looked at how to better inform healthcare professionals about issues relating to the use of medicines, including how to improve the quality of the information provided.

- Pharmacovigilance: The group has discussed how to improve and strengthen the role of healthcare professionals in the European pharmacovigilance system.

- Involvement of healthcare professionals' organisations in the work of the EMEA's scientific committees: The group has discussed on areas where the involvement of healthcare professionals' organisations would ultimately strengthen the outcome of the committees' work.

The document was subject to a 3-month public consultation period. Comments received from 14 individual sources have been taken into consideration in order to finalise the document. The CHMP adopted these final recommendations and proposals for action during its February 2009 meeting.

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Introduction

A workshop with participation from a broad range of European healthcare professionals' organisations was held at the European Medicines Agency (EMEA) on 28 March 2006. The report can be found here.

It was agreed that a dedicated forum of representatives from selected organisations should be established with a view to discuss issues of common interest as well as to further strengthen and structure the interaction with healthcare professionals. A strengthened interaction between the EMEA and healthcare professionals' organisations is a requirement laid down in the EU pharmaceutical legislation[1], and is also in line with the Agency's long term strategy[2].

For this purpose, a Working Group with Healthcare Professionals' Organisations (HCP WG) was established under the remits of the Committee for Medicinal Products for Human Use (CHMP). The group is composed of organisations representing doctors, nurses and pharmacists, and members include both general organisations and organisations with focus on specialised therapeutic areas.

The group acknowledges the EMEA's mission statement, which is to evaluate and supervise medicines to the benefit of public health. The HCP WG, therefore, aims to improve the safe and effective use of medicines by meeting the following objectives:

- Provide clear and useful information to healthcare professionals.
- Develop appropriate communication tools.
- Increase EMEA awareness among healthcare professionals in relation to the safe and effective use of medicines.
- Develop appropriate contacts between the Agency and healthcare professionals' organisations.

The discussions held in the group have resulted in the three sets of recommendations that are annexed to this document.

The HCP WG was co-chaired by G. Nisticó (CHMP member for Italy) and N. Wathion (Head of the EMEA's Unit for Post-Authorisation Evaluation of Medicines) until May 2007. Since then, N. Wathion has been Chairperson. The list of participants to the group is included in Annex 1.

Methodology

The group developed three set of recommendations based on discussions held in the plenary sessions as well as in smaller drafting groups. The discussion sought to focus as much as possible on the organisations' expectations for the interaction with the EMEA. In addition, a 'topic leader' from one of the organisations was assigned to each topic, with a

[1] Regulation (EC) No 726/2004 of European Parliament and of the Council provides responsibilities to the EMEA, its Management Board and its various Scientific Committees to develop contacts with the Agency's stakeholders, including healthcare professionals.

2 EMEA Road Map to 2010.

view to steer and facilitate the drafting process. Members were encouraged to consult colleagues within their respective organisations on all draft versions of the recommendations.

The three sets of recommendations have a slightly different structure, reflecting the context in which they have been discussed and can be implemented.

The recommendations for information on medicines are structured in three sections:

- Recommendations that can be implemented within the current legal framework.
- Recommendations that can be implemented within the current legal framework, but require a harmonised approach at EU level.
- Recommendations that would require the current legal framework to be amended.

The recommendations for pharmacovigilance have been prepared with the acknowledgement that the European Commission, in December 2007, published a series of legislative proposals for the area of pharmacovigilance. These recommendations reflect issues that have been identified by the HCP WG for action within the context of the future legal framework in the area of pharmacovigilance.

The recommendations for involvement of healthcare professionals' organisations in the work of the EMEA's scientific committees are all eligible for implementation within the current legal framework.

The draft recommendations were finalised by the HCP WG during the second quarter of 2008, and forwarded to the CHMP for adoption for release for consultation.

Next steps

Following public consultation, comments have been received from 14 different individual sources. The HCP WG has considered these comments and revised the recommendations accordingly. The final version will be published on the EMEA's website once adopted by the CHMP.

Based on the final recommendations, the HCP WG will identify priority tasks for implementation. These will be included in the group's work programme according to the priority given.

Long term priorities will be implemented, taking into account future developments in the regulatory environment, such as the upcoming pharmacovigilance legislation and the Agency's long-term strategies in related areas.

The HCP WG's recommendations in context

The role of healthcare professionals in healthcare systems, and their relation with patients, is continuously evolving. Patients are often well informed, and capable and willing to take an active role in disease management and treatment decision. This creates a change in the healthcare professional-patient relationship, towards the so-called "partnership in medicine taking". This partnership looks for a shared understanding between patients and prescriber on treatment choices, where the healthcare professional still remains as the main reference and source of information to patients, and where the ultimate goal is to improve the safe and effective use of medicines, hence improving the quality of healthcare.

Regulation (EC) No 726/2004 of European Parliament and of the Council has given additional responsibilities to the EMEA, its Management Board and its various Scientific Committees to develop contacts with the Agency's stakeholders, including healthcare professionals.

Healthcare professionals take part in the evaluation of medicines as individual experts in the European regulatory network. In addition, healthcare professionals are represented in the EMEA Management Board, in the Paediatric Committee, and are also represented in the Committee on Advanced Therapies.

In addition to direct interaction with healthcare professionals' organisations, the legislative provisions also define the framework for provision of clear and useful information to healthcare professionals.

The HGP WG has representation from a broad range of European healthcare professionals' organisations, and seeks to cover different professions as well as the disease areas for which the EMEA receives most applications for marketing authorisation. The annexed recommendations from the HCP WG reflect the views of the organisations that participate in this group. In addition, other organisations with an interest in the topics addressed by the recommendations were also given the opportunity to comment via a general public consultation.

It is important to clarify that the recommendations made by the HCP WG address only one aspect of information on medicines provided to healthcare professionals and patients. The purpose is not to preclude physicians and pharmacists from their professional duties or to interfere in the relationship between the patient and the healthcare professional. The recommendations do not make any distinction between prescription and non-prescription medicines. However, the applicability of some recommendations to non-prescription medicines could require specific considerations.

The recommendations will be implemented in an environment that encompasses a number of related activities. The Commission's legal proposals in the area of pharmacovigilance have already been highlighted. Other initiatives that should be taken into account include the EMEA Road Map to 2010, the work undertaken by the EMEA in relation to information on medicines to patients and the Commission's recent proposal for legislative measures in this area. The final recommendations from the Pharmaceutical Forum in 2008 regarding information to patients are also to be taken into consideration, as they will impact on future discussions.

Furthermore, the EMEA will in 2009, together with its partners in the European regulatory network, will look at the establishment of a network on medical information. The aim of this network is to ultimately provide high quality information on medicines to the patients and the healthcare professionals in the EU Member States in a timely manner.

The HCP WG will follow these and other future developments closely, and take the appropriate measures in terms of coordination and transparency as to make best use of available resources and avoid duplication of initiatives.

Annex 1 – List of participants

HCP organisations

Peter Milla	CESP-EAP, European Academy of Paediatrics
Mike Youle	EACS, European AIDS Clinical Society
Ingolf Cascorbi Michael Orme	EACPT, European Association for Clinical Pharmacology and Therapeutics
Ulf Smith Clifford Bailey	EASD, European Association for the Study of Diabetes
Vagn Handlos	EAHP, European Association of Hospital Pharmacists
Daniel Sereni	EFIM, European Federation of Internal Medicine
Michael Barnes Giandomenico Iannett Giorgio Cruccu	EFNS, European Federation of Neurological Societies
Paul de Raeve	EFN, European Federation of Nurses Associations
Ferdinand Breedveld Josef Smolen Thea Vliet-Vlieland	EULAR, European League Against Rheumatism
Paolo Casali Pascale Blaes	ESMO, European Society for Medical Oncology
Nicolas Danchin Sophie O'Kelly	ESC, European Society of Cardiology
Denis O'Mahony	EUGMS, European Union Geriatric Medicine Society
Eirik Bø Larsen Carl-Eric Thors	UEMO, European Union Geriatric Medicine Society
Ivana Silva	PGEU, Pharmaceutical Group of the European Union
Michael Wilks Edwin Borman	CPME, Standing Committee of European Doctors
Pascal Rod	ESNO, European Specialists Nurses Organisations

Topic Leaders

Information on Medicines	Ivana Silva, PGEU
Pharmacovigilance activities	Michael Orme, EACPT
Involvement in EMEA activities	Mike Youle, EACS

CHMP Scientific Committees and Experts

Jane Ahlqvist Rastad	CHMP Member
Pirjo Laitinen-Parkkonen	CHMP Member
Patric Salmon	CHMP Member
Giuseppe Nisticò	CHMP Member

Observers

Steffen Bager	HMPC Member
Truus Janse de-Hogg	CMD(h) Member
Sandra Petraglia	CMD(h) Member
François Houÿez	PCWP Member
Hildrun Sundseth	PCWP Member
W.H.J.M. Wim Wientjens	PCWP Member

EMEA

Noël Wathion – Chairman	Head of Unit Post-Authorisation Evaluation of Medicines for Human Use
Isabelle Moulon	Head of Medical Information Sector
Juan García Burgos	Scientific Administrator
Anders Blaedel Lassen	Scientific Administrator
Laurent Brassart	Scientific Administrator
Jan Petracek	Scientific Administrator
Eberhard Blind	Scientific Administrator
Priya Bahri	Scientific Administrator

Annex 2 – Draft recommendations: Information on medicines

EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)

Recommendations: Information on medicines

The EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) has agreed on a number of recommendations in the area of information on medicines.

This document concerns information on medicines provided by the EMEA and EU National Competent Authorities. Regulatory statutory information consists in the so-called "Product Information" composed of the "Summary of Product Characteristics – SmPC" (addressed to healthcare professionals), the "Labelling" and the "Package Leaflets – PL" (mainly addressed to patients). The EMEA also publishes a European Public Assessment Report (EPAR) on medicines for which a marketing authorisation application has been assessed by the EMEA. It is published independently of the outcome of the assessment and is publicly available on the EMEA website. EPARs include a summary section in the form of a "Question and Answer" document, which is written in lay language. Finally, public statements are published in specific situations on a case-by-case basis, e.g. when safety announcements need to be communicated urgently.

Recommendations have been made in terms of the type, structure and content of the above-mentioned documents as well as in terms of their dissemination. The recommendations have been classified according to the necessary prerequisites for their implementation.

As highlighted during the EMEA meeting with its stakeholders on provision of information, held on 20 September 2007, particular attention should be paid to the ethical dimension of transparency and provision of information on medicines.

This document does not address other sources of information available to healthcare professionals.

Recommendations that can be implemented within the current legal framework

Recommendations that can be implemented as such by the EMEA

Product information

a) The SmPC is expected to be the reference document to inform health professionals on how to use a medicine safely and effectively, and healthcare professionals should therefore be consulted for preparation and revision of the SmPC guideline[3].

The quality of the information provided in SmPCs should be optimised. It is important to ensure that SmPCs are comprehensive, clear and correspond to healthcare

[3] The SMPC guideline is published on the European Commission's website and can be found here: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/spcguidrev1-oct2005.pdf

professionals' expectations. For example, clear recommendations should be given for monitoring (safety or efficacy) of the treatment when necessary. The provided information should allow the individual healthcare professional to tailor his/her prescription according to the specific need of the patient, particularly (but not only) in specific populations (e.g. children, older persons …). Adverse reactions should be described in terms of frequency and seriousness. Drug interactions should also be described in clear and precise terms. Excess of information, which may result in an overall non-awareness, should be avoided. As a tool which provides information on a particular medicine, the SmPC should be precise and avoid using general references to other medicines (e.g. statements such as "Like other medicines of the same class …") except when it is an official class warning recommended following a class review. Information should be consistent with the core quality principles on information as agreed by the Pharmaceutical Forum[4] (i.e. objective and unbiased, patient-oriented, evidence-based, up to date, reliable …). To avoid excess of information in the SmPC and to provide healthcare professionals with access to the data justifying its recommendations, the SmPC should systematically cross-refer to the public assessment report.

b) Other regulatory guidelines related to the product information should be flagged to healthcare professionals' organisations providing them with a possibility to submit comments and input during the preparatory phase.

c) The possibility for healthcare professionals' organisations to provide input on product information should be investigated. For example, healthcare professionals' organisations could be consulted prior to the 5-year renewal of a marketing authorisation to provide feedback and summarise the practical experience gained in relation to the quality of the product information. Another example to be investigated is the consultation of healthcare professionals' organisations during safety review (e.g. safety referral).

d) The presentation of the labelling (i.e. how it looks like) can be a safety issue when using a medicine in particular medicines for emergency or parenteral use. It is therefore suggested to invite applicants to perform a user test on readability by healthcare professionals in working conditions of dispensation or administration of those medicines (as a way of tackling the 'look alike' and 'sound alike' issues).

e) Authorities, in consultation with healthcare professionals' and patients' and consumers' organisations, should provide further recommendations on the content of labelling and package leaflet, with special consideration for disabled patients, who may be more exposed to risk. For example, guidance is necessary on the expression of strength to avoid medication error, and on the information intended for healthcare professionals to be included in the package leaflet (e.g. instructions for the use of medicines intended for use in a hospital setting). It is also of utmost importance to maintain a strong consistency between the SmPC, the labelling and the package leaflet to facilitate communication between patient and healthcare professional.

f) Healthcare professionals' considerations on the package leaflet should be addressed jointly with representatives of patients' organisations.

g) The wording of the QRD template referring to the section intended "for medical or healthcare professionals" should be simplified to refer to "healthcare professionals" only.

European Public Assessment Report – "EPAR"

h) Healthcare professionals should be consulted on the revision of the EPAR structure. The public assessment report (i.e. the part of the EPAR reflecting the CHMP's

[4] Pharmaceutical Forum - Second Progress Report, 26 June 2007

scientific discussion) should substantiate the information given in the SmPC and provide clear and updated information.

i) EPARs should provide a clear description of the benefit-risk of the product as well as an increased level of detail of the rationale for the outcome of the discussions and the recommendations given by the CXMP[5] . This would include information coming from the comparison with other medicine(s) during the evaluation of its benefit-risk. Information on all relevant outcomes, especially those demonstrating an effect on the quality of life or a reduction in disability should be also made available for a context appreciation of its benefit-risk balance.

j) EPARs should provide more information about the conditions of marketing authorisation and related risk management activities or specific obligations.

Other EMEA documents

k) Multiplication of various documents addressed to healthcare professionals should be avoided. All information related to a given product should be standardised and provided through a limited number of document types, namely product information, public assessment reports and other specific document types (e.g. press releases) for any additional information. Information should be kept updated.

l) Other EMEA documents (such as Summaries of Opinion, safety announcements, public statements, and CHMP press releases) would, from the healthcare professionals' point of view, benefit from the identification of possible areas for improvement in terms of structure and content.

Dissemination of information

m) Knowledge of product information, EPARs and other EMEA documents should be promoted. The accessibility to product information on the EMEA website should be improved, in particular for safety announcements.

n) The EMEA should provide relevant information and news to healthcare professionals on a regular basis through an appropriate information system (e.g. newsletter). Adequate ways of dissemination should be ensured.

o) The EMEA website should be improved. It should provide all information related to a given product under the name of that product.

p) The EU database on medicines (EudraPharm), currently under construction, is supported by healthcare professionals as a reference source of information on medicines in Europe.

q) The possibility of increasing general awareness of the EMEA and its activities at the level of healthcare professionals' organisations should be explored and discussed.

Recommendations requiring a harmonised approach at EU level before implementation

Product information

a) Electronic prescription tools are increasingly used. Product information should be made available electronically in a structure and format, which would allow

[5] CXMP refers here to the EMEA Scientific Committees for human medicines: CHMP, COMP, HMPC, PDCO.

compatibility with these new tools and enable its use by healthcare professionals. This should be considered when further developing the EudraPharm database. Ideally, the system would allow generating automatic warning in case of a particular safety issue.

b) Interaction between medicines is an increasingly complex field. Numerous databases have been developed to address this issue on a national or therapeutic field basis. However, it would be valuable to investigate the possibility of establishing a European regulatory database on medicines interactions.

c) To facilitate the daily use by healthcare professionals, information related to the different strengths or pharmaceutical forms of a product in the same indication(s) should be presented in a single combined SmPC to avoid multiplicity of documents and dispersion of the information.

Dissemination of information

a) It should be made clear that the SmPC, the labelling and the package leaflet are statutory information to be used as validated reference. Dissemination and knowledge of product information should also be promoted through and by the EU regulatory system network. Patients' and healthcare professionals' organisations should be involved in the dissemination of EMEA information at national level.

b) Healthcare professionals' organisations should help keep the individual healthcare professional's knowledge of statutory information on medicines up to date through their meetings and communication tools and promote it as part of continuing professional development.

c) The possibility of using alternative tools to disseminate new and updated product information, e.g. periodic newsletters, should be investigated.

Recommendations requiring amendments to the current legal framework

Product information

a) It should be ensured that a given medicine has the same product information across the EU. This objective has already been achieved for medicines authorised through the centralised procedure but not for all other medicines. In order to ensure the highest level of harmonisation, further efforts should involve healthcare professionals, pharmaceutical industry and regulatory authorities.

b) The current SmPC could be complemented with a summary providing key prescribing information for daily practice. The summary should include appropriate references to the full SmPC for complete recommendations. The summary could also include a section highlighting key information that healthcare professionals should convey to patients when prescribing, dispensing or administrating a medicine. This key information could also appear in the package leaflet. For this purpose, new sections addressed to healthcare professionals could be added in the package leaflet (e.g. "When prescribing, please note…", "When dispensing, please note…" and "When administrating, please note…"). Such initiative on the package leaflet should be discussed jointly with representatives from patients' organisations. It should be explored when, how, and which of these proposals will be beneficial. To gain experience prior to amending the current legal framework, the possibility of having such summaries and sections with key information provided by applicants on a voluntary basis should be investigated.

c) Content and structure of the SmPC could be also updated to take into account the need for compatibility with future information systems (e.g. electronic reporting systems, safety alert systems, electronic health records, e-prescribing, etc.).

d) Based on the experience gained through voluntary user test of the labelling for dispensation and administration, it could be proposed to make this test a mandatory requirement for new labelling.

e) The EU regulatory framework should use the word 'medicine' instead of 'products' or 'medicinal product' or 'drug'.

Dissemination of information

a) During their undergraduate education, healthcare professionals should be trained in statutory information on medicines. The training should explain the role of statutory information and the scientific and legal basis for its preparation. It should also inform on how to get access to official and updated information on medicines.

b) An increase in transparency of information from the EudraVigilance and EudraCT databases should be explored. This should be put in perspective with the current trend of general increase in the level of public transparency at EU wide level.

c) Healthcare professionals are concerned with the quality, comprehensiveness and independence of information provided on medicines through the internet. It would be valuable to promote EMEA as a source of validated and official information on medicines which can be easily located by users among other sources of information. In this respect, it would be valuable to facilitate healthcare professionals' access to internet across the EU.

Annex 3 – Draft recommendations: Pharmacovigilance

EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)

Recommendations: Pharmacovigilance activities

The EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) has discussed areas of interest where co-operation between the EMEA and healthcare professionals' organisation may help further progress and improve the current pharmacovigilance system, and has agreed on a number of draft recommendations.

In December 2008, the European Commission published a new legislative proposal for the area of pharmacovigilance. The HCP WG acknowledges that further discussions and actions in this area should be considered in the context of this proposal.

This document therefore presents a number of recommendations for issues that has been identified by the HCP WG for action once the future legal framework in the area of pharmacovigilance has been further clarified. Nonetheless, the HCP WG believes that the content of the current document could also be considered within the ongoing revision of the pharmacovigilance system.

Spontaneous reporting

The current status of the spontaneous reporting is believed to be suboptimal for modern needs. The group has identified the following recommendations:

a) Adverse drug reactions affecting quality of life are not adequately detected in the current system. Examples include loss of appetite, insomnia, nightmares, hair loss, pain etc. which might, if they are reported, be classified as minor ADRs in the system but still affect the quality of life to such an extent that it leads to discontinuation of treatment. The HCP WG welcomes that the new legislative proposals take into account regular patient reporting and drops the thresholds for expedited reporting, so all suspected adverse reactions are reportable. EMEA may facilitate this process by providing appropriate data processing network, i.e. EudraVigilance.

b) In light of the new legislative proposals, there is a need to discuss the practical issues around direct patient reporting, perhaps in the context of the Good Vigilance Practice.

c) Underreporting and low quality of reports should be systematically addressed. Available tools should generally aim at lowering a reporting threshold, i.e. availability of quick and easy reporting means, motivation via education and feedback. The system should involve all healthcare professionals, i.e. doctors, nurses, pharmacists, community health workers, etc.

d) Spontaneous reporting and analysis of ADR should be adapted to be more sensitive to detect interactions between medicines, not only reactions to individual drugs.

Signal detection and evaluation

The group agreed on the need for better tools and has identified the following recommendations:

a) It is recognised that there are different definitions of a signal and dynamic thresholds for raising it. Transparency of the whole process, including definitions, thresholds and tools used for the signal detection would improve motivation of healthcare professionals in active early involvement in signal detection and evaluation.

b) Healthcare professionals' organisations and academia might help to improve both quality of the signal evaluation as well as compliance of healthcare professionals with consequential regulatory action.

c) Regulators should explore possibilities for learning about potential safety issues from editors of medical journals early, i.e. prior to publication.

Risk communication

Safety messages from regulators often do not achieve risk minimisation. The group has identified the following recommendations:

a) An optimal communication methodology of early pharmacovigilance signals should be developed to involve healthcare professionals' organisations in contributing to early signal investigation/evaluation. This may be facilitated by the proposed representation of healthcare professionals in the Committee on Pharmacovigilance.

b) An optimal communication methodology should be developed for risk minimisation measures and support for implementation of risk management.

c) Nominated experts from relevant healthcare professionals' organisations should be involved in early drafting of safety communications. This may be facilitated by the proposed representation of healthcare professionals in the Committee on Pharmacovigilance.

d) An emergency communication system that can reach a majority of relevant health care professionals in the EU in a very short timeframe (i.e. hours) should be further developed.

Education and training

The group finds that education and research are key factors in the overall system improvement:

a) Relevant healthcare professionals' organisations should be consulted for the preparation of risk minimisation measures within the Risk Management Plans for centrally authorised medicines. Particular attention should be given to those measures involving obligatory training and education to ensure an optimal way of meeting specific risk minimisation objectives.

b) There is a need for better basic education of healthcare professionals about safety of medicines. Healthcare professionals' organisations in co-operation with regulators, academia and other professional bodies, should develop a proposal for a curriculum that would address this need.

c) Use of risk minimisation measures set out by product specific Risk Management Plans, particularly those in form of obligatory training and education, should be

consulted with relevant healthcare professionals' organisations to ensure an optimal way of meeting specific risk minimisation objectives.

d) Regulators should develop, in co-operation with healthcare professionals' organisations, a system of continuous professional education (including CPE/CME credits) in the area of pharmacovigilance.

Area of research

The group finds that there is a need for substantial increase of research activity in the area of pharmacovigilance:

a) Research in the area of pharmacovigilance includes drug utilisation studies, studies on appropriateness of drug treatments, pharmacoepidemiological studies and clinical safety trials. Topics for this research might be proposed by healthcare professionals' organisations in order to help regulators to focus the majority of available resources to the most burning problems. Continuing support to creation of a research network in this area is highly recommended.

b) Research in elucidation of biological causes and possible prevention of ADRs, e.g. pharmacogenomics, should be promoted by regulators, with an emphasis on the populations most at risk.

c) Regulators should further improve the research methodology for assessing effectiveness of risk minimisation measures and then conduct such a research on a regular basis.

d) Data from the pharmacovigilance databases should be accessible to academic researchers, provided the data are anonymised, and access is subject to all appropriate data protection measures.

New approaches in pharmacovigilance

The current methodologies in pharmacovigilance may need to be further developed, perhaps in the context of the Good Vigilance Practices, taking into account the following recommendations:

a) In a majority of cases, medicines are used in combination or as a part of a complex therapeutic strategy of a single disease, or in the treatment of complex patients with multiple co-morbid diseases. Methods of surveillance of such complex therapeutic strategies should be developed and implemented as part of the pharmacovigilance system. Relevant examples include different standards of diabetic care, combination therapy of HIV, protocols used in oncology, or polypharmacy in older patients."

b) IT methodologies should be developed to share databases on adverse drug reactions with databases on genetic variability e.g. the PharmGKB network in order to evaluate further the impact of pharmacogenomics to ADR and to develop strategies to prevent ADR through individualized medicine.

c) In recent years, the use of functional foods and nutraceuticals has increased significantly. It would be important to promote research to investigate its long-term use and its possible interactions with medication as well as to draw attention to possible ADRs cause-effect relationship. A further strengthening of co-operation between food safety surveillance and drug safety surveillance systems is needed.

Annex 4 – Draft recommendations: Involvement of healthcare professionals' organisations in activities of the EMEA's scientific committees

EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)

Recommendations: Involvement of healthcare professionals in EMEA activities

The EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) agreed on the recommendations in the area of involvement of healthcare professionals in EMEA activities, as listed below. The recommendations made in this area can be implemented within the current legal framework.

a) In collaboration with the EMEA/CHMP Working Group with Healthcare Professionals, the EMEA will define a set of criteria to enable the Agency to establish contacts with the appropriate healthcare professionals' organisations. These criteria will be adopted by the EMEA Management Board.

b) The above-mentioned criteria should include a definition of healthcare professionals' organisations. This definition will allow establishing contacts with organisations focused on patient care, and also with other European scientific and academic societies more focused on research activities related to medicines. Overlapping activities and interests very often coexist in scientific associations, making it difficult and artificial to create clear distinctions. In the current context, it is understood that whichever the mission/objectives of the organisation are, a direct or indirect impact or interest in patient care should always be evidenced.

c) The EMEA should set up a procedure inviting European healthcare professionals' organisations to express their interest to be involved in EMEA activities. Eligibility of every organisation wishing to work with the Agency will be assessed by the EMEA against the defined criteria. The EMEA should make public the list of eligible organisations fulfilling the criteria.

d) The EMEA should identify relevant staff members as contact points for the interaction with healthcare professionals' organisations.

e) Two different ways of interaction with individual members of healthcare professionals' organisations are envisaged:

   - Interaction with healthcare professionals as representatives of their organisation.
   - Interaction with healthcare professionals as experts.

   In order to establish clear boundaries, the EMEA/CHMP Working Group with Healthcare Professionals' Organisations has considered the existing "rules of involvement of members of patients' and consumers' organisations in Committees related activities" (EMEA/161660/2005). As such, these rules are considered valid for healthcare professionals, and therefore the document should be revised to cover members of healthcare professionals' organisations.

The document will make clear in all cases that any healthcare professional, either acting as representative of his/her organisation or as an expert, will have to adhere to the provision defined in the EMEA policy on the handling of Conflict of Interests.

Interaction with healthcare professionals as representatives of their organisation

As a general principal and as much as possible, it will be expected to have a well-balanced representation of different HCP organisations in any EMEA activity in which they get involved.

i. A dedicated forum should be established to deal with issues related to the activities of the EMEA Human Scientific Committees (CHMP, COMP, HMPC, PDCO), and to provide recommendations on all matters of interest to healthcare professionals in relation to medicines.

ii. It should be ensured that the 'Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework' (EMEA/P/24143/2004) is fully implemented with regard to the involvement with healthcare professionals. In this aspect, the EMEA should pro-actively consult appropriate healthcare organisations when developing guidelines. Specific procedures to identify and contact relevant healthcare professionals' organisations among other relevant stakeholders at an early stage of guideline preparation (i.e. concept paper) should be developed.

iii. The same process would apply once the draft guideline is released for public consultation before finalisation. If considered appropriate, and in response to specific justified concerns, divergent views or upon request from healthcare professionals' organisations, the EMEA may convene a meeting to review and discuss comments received on the draft guideline, before it is finalised.

iv. The healthcare professionals' organisations should disseminate final guidelines relevant to their area of competence within their organisation, ensuring through their network that they reach individual members such as national and other related organisations. Dissemination of guidelines through publication in their scientific journals should also be considered.

v. The EMEA and healthcare professionals' organisations should ensure exchange of information in order to facilitate consistency between the EMEA and healthcare professional's guidelines (e.g. therapeutic guidelines) where relevant.

vi. The EMEA should create and maintain updated a database. The database will include European and international healthcare professionals' organisations, as well as other scientific organisations such as learned societies and groups of academia, with relevant potential interest in EMEA guidelines. This database will be a tool to guarantee adequate dissemination of guidelines from early stages of their preparation and after their finalisation and entry into force.

vii. Healthcare professionals, through the EMEA/CHMP Working Group with Healthcare Professionals' Organisations, should explore possible contributions to the different EMEA Scientific Committees' procedures. Informative sessions of the current EMEA procedures will be provided to the members of the Working Group.

viii. Healthcare professionals acting as representatives of their organisations should be able to express their opinion at the level of the different EMEA Scientific Committees on any matter related to medicines.

Interaction with healthcare professionals as experts

i. The proposed interaction with a European network of healthcare professionals should be used to strengthen the existing network of European experts in order to ensure that the EMEA can reach the best possible expertise in any matter related to medicines. This can be of particular usefulness in areas related to new therapies and technologies. Experts selected through the European network of healthcare professionals will continue to be involved in the different activities of the Agency, such as scientific assessment and other product related issues, activities in relation to innovation of medicines, and guideline preparation.

ii. Interaction with a view to draw on the expertise of healthcare professionals' organisations and communities in specific areas should also be investigated. This is already being done in some areas, e.g. the European Network of Centres in Pharmacoepidemiology & Pharmacovigilance (ENCePP), and healthcare professionals' organisations should be involved in any future EMEA initiatives of similar character.

f) The EMEA should train healthcare professionals involved in the Agency's activities on the regulatory background of these activities and offer follow-up training as appropriate.

g) The EMEA should consider any similar initiatives in relation to the interaction with healthcare professionals' organisations that may be set up by the National Competent Authorities.

Annex 5 – List of abbreviations

ADR	Adverse Drug Reaction
CHMP	Committee for Medicinal Products for Human Use
EC	European Commission
EMEA	European Medicines Agency
ENCePP	European Network of Centres in Pharmacoepidemiology & Pharmacovigilance
EPAR	European Public Assessment Report
EU	European Union
EudraCT	European Clinical Trials Database
HCP WG	EMEA/CHMP Working Group with Healthcare Professionals' Organisations
HMPC	Committee on Herbal Medicinal Products
MS	EU Member State
NCA	National Competent Authority
PCWP	EMEA Scientific Committees' Working Party with Patients' and Consumers' Organisations
PL	Package leaflet