



European Medicines Agency

**SUBMISSION OF COMMENTS ON <GUIDELINE TITLE> <DOCUMENT REFERENCE>**

**COMMENTS FROM <ORGANISATION / CONTACT PERSON>**

**International Federation of Anthroposophic Medical Associations (IVAA)**

Rue du Trône 194, B-1050 Bruxelles, Phone: +32 2 64 00 200. E-mail: [contact@ivaa.info](mailto:contact@ivaa.info)

Peter Zimmermann, MD, PhD, President, IVAA, Vellamontie 4 as 2, FIN-15870 Hollola, Phone: +358 40 5109242. Fax: +358 3 7803905

E-mail: [peter.zimmermann@ivaa.info](mailto:peter.zimmermann@ivaa.info)

**GENERAL COMMENTS**

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK

Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 95

E-mail: [mail@emea.europa.eu](mailto:mail@emea.europa.eu) <http://www.emea.europa.eu>

©EMEA 2007 Reproduction and/or distribution of this document is authorised for non-commercial purposes only provided the EMEA is acknowledged

**IVAA response to the public consultation of the EMEA/CHMP Working Group with Healthcare Professionals' Organizations (HCP WG)**

**on Information on medicines, Pharmacovigilance and involvement of professionals' healthcare organizations.**

1. The International Federation of Anthroposophic Medical Associations (IVAA) welcomes the in-depth work of the EMEA/CHMP Working Group with Health Professionals' Organizations on information on medicines, on pharmacovigilance and on the further involvement of healthcare professionals' organizations in the activities of EMEA.
2. IVAA takes the assessment of these three topics, the development of recommendations and proposals for actions as well as the decision, to ask for a public consultation of the recommendations, as proof that the Working Group with Healthcare Professionals' Organizations has not only worked successfully in the framework of EMEA/CHMP but contributes substantially to overall objectives and activities of EMEA.
3. In view of the convincing work of the Group between 2006 and 2008, IVAA recommends to continue with a Working Group with Healthcare Professionals' Organizations in EMEA/CHMP. The practical experience of these organizations as well as their direct link to healthcare professionals and to patients offers indispensable added value to EMEA's tasks. IVAA underlines that the involvement of these organizations enables EMEA to generate a multi-level support of the public administrations of health in Europe and opens its considerations to advice of professionals which otherwise might be lost. By involving these professional organizations EMEA adds as well a certain democratic aspect to its work, which is, in general, more concentrated on the administrative strata of our societies.
4. In this context and as the representative of an integrated medicine, IVAA asked for a balanced representation of healthcare professionals' organizations in the EMEA (CHMP) Working Group with Healthcare Professionals' Organizations. IVAA points to the fact that the use of CAM medicines and therapies by patients and citizens in Europe is increasing. IVAA would therefore appreciate if EMEA would invite healthcare professionals' organizations from the strand of CAM medicines and therapies to take part in the Working Group of Healthcare Professionals.

**Recommendations: Information on medicines**

As far as information on medicines is concerned, IVAA agrees with the Working Group with Healthcare Professionals' Organizations that the 'Summary of Product Characteristics' (SPC) should be optimized and follows the recommendations of the Group. IVAA stresses importance to reduce over-information and to include information for healthcare professionals in the package leaflets as well as to address this information jointly with representatives of patients' organizations. All information in leaflets should also be available in health professional databases or pharmaceutical formularies.

Recommendations: Pharmacovigilance activities

IVAA agrees with the need to improve spontaneous and patients' reporting on adverse drug reactions in the current system and the necessity of special continuous attention to be paid to under-reporting as well as with the proposal, to develop an optimal communication methodology for risk minimization measures.

IVAA volunteers to participate in the suggested involvement of healthcare professional organizations for the preparation of risk minimization measures within the risk management plans for centrally authorized medicines.

Adverse side effects of CAM medicines occur much less often as in the context of mainstream medication. Nevertheless IVAA agrees that serious CAM methods should push forward accurate documents and exact analysis of adverse effects. However, IVAA calls for proportionality of measures in regard to the expected benefit.

The responsibility of CAM methods for health safety should lead to accurate pharmacovigilance programs which fit in the specific context of CAM medicines.

IVAA volunteers to participate in such a process and is intended to demonstrate its own scientific recorder on developing an accurate pharmacovigilance system for CAM. Please browse [www.havelhoehe.de/fih/html/publikationen1.html](http://www.havelhoehe.de/fih/html/publikationen1.html) and visit the link "pharmacovigilance" on [www.ivaa.info](http://www.ivaa.info) for reference.

Recommendations: Involvement of healthcare professionals in EMEA activities

As pointed out before, IVAA appreciates and welcomes a strong and continuous involvement of healthcare professionals' organizations in the activities of EMEA.

The development of a set of criteria about how to contact and to engage these organizations and their experts in EMEAs activities will certainly be a first and necessary step. IVAA underlines that these criteria should enable healthcare professionals' organizations from all stands of medical treatment to participate in these activities, including organizations from the CAM sector. Specific criteria of the involvement of healthcare organizations and of healthcare professionals as experts might be helpful.

International Federation of Anthroposophic Medical Associations (IVAA)

Peter Zimmermann, MD, PhD, President

194 rue du Trône, B- Brussels, Tel. 0032 2 64 00 20

E-mail: [peter.zimmermann@ivaa.info](mailto:peter.zimmermann@ivaa.info)

**SPECIFIC COMMENTS ON TEXT**

<b>GUIDELINE SECTION TITLE</b>		
<b>Line no<sup>1</sup>. + paragraph no.</b>	<b>Comment and Rationale</b>	<b>Proposed change (if applicable)</b>

Please feel free to add more rows if needed.

These comments and the identity of the sender will be published on the EMEA website unless a specific justified objection was received by EMEA.

---

<sup>1</sup> Where available