IVAA Internationale Vereinigung Anthroposophischer Ärztegesellschaften
International Federation of Anthroposophic Medical Associations
Fédération Internationale des Associations Médicales Anthroposophiques

Peter Zimmermann, M.D., Ph.D.
President
Vellamontie 4, FIN-15870 Hollola
Tel: +358 40 5109242, Fax: +358 3 7803905
E-mail: peter.zimmermann@ivaa.info

Hollola, Finland, April 6 2008

**IVAA - International Federation of Anthroposophic Medical Associations - response to the Public Consultation of the EU Commission, DG Enterprise and Industry on *Legal Proposal on Information to Patients***

As member of EPHA (European Public Health Alliance), IVAA pro-actively took part in the drafting of the detailed response of EPHA to the public consultation on the *Legal Proposal on Information to Patients.* IVAA endorses and supports this document of EPHA. In addition to this document, in responding to the consultation IVAA would like to point to the following items:

1. IVAA shares the view that a harmonised practice on information provisions to patients could lead to an improvement of *information to patients* for the citizens in the EU member-states. But any change of rules and existing legislation in regard to *information to patients* has to be based on a complete and reliable impact assessment. A reliable and unbiased impact assessment about practice and experiences of *information to patient*s in the EU member-states is not yet available. IVAA points to the critics, especially the lack of transparency, concerning the outsourcing of a respective Impact Assessment Study by the EU Commission. **In the IVAA's view any revision of rules and legislations prior to the availability of a reliable Impact Assessment seems premature.**
2. Together with many stakeholders, IVAA is of the opinion that the ***core intention*** **of the forthcoming proposal will not contribute** to the *access to good-quality, objective, reliable and non promotional information on prescription-only medicinal products* for citizens in the EU member-states. In spite of the fact that a ban on direct-to-consumer advertising of prescription medicines should be maintained, the envisaged **resetting of the whole set of rules** governing the distinction between advertising and information, quality criteria, content and means of information as well as new forms of monitoring will lead to legal uncertainties. These inconsistencies will be open to exploitation by other interests. More advertising on Prescription Only Medicines will be the consequence. **IVAA regards the existing EU legislation on information to patients and advertising as sufficient.**
3. The intention of the forthcoming proposal to open the possibility for the pharmaceutical industry to *disseminate information* in the electronic media under certain conditions and to limit the responsibility of health professionals in regard to information to patients only to printed media and written material could be seen to enhance the position of the pharmaceutical industry. The inherent conflict between the business interests of this

industry and their willingness to provide objective information will naturally be decided in favour of their business considerations. The existing priority of health professional counselling prior to the information supplied by holders of marketing authorisations should not be changed. **Therefore, IVAA strongly demands that health professionals should remain the primary source for information to patients in all forms of presentation.**

4. **IVAA does not follow the distinction between actively and passively ("push" and "pull") received health information by patients and citizens.** Information for patients has to increase the ability of all patients/citizens for a critical approach towards the medical product. Again, the role of health professionals should not be underestimated: In meeting with health professionals, patients get more involved with the therapy and learn to ask the right questions.
5. IVAA underlines that information on Prescription Only Medicines (POM) and Over The Counter (OTC) medicines should be regarded as two parts of the same sector and clear rulings with specific criteria for each area is required if an unbiased impact assessment study suggests any further revisions.
6. IVAA regrets that the general criteria such as accessibility, transparency, and relevance are insufficiently applied in discussing *quality criteria.* In this important effort to revise the existing legislation on *information to patients* at least some indications about what the EU Commission understands by *unbiased*, *objective* or *patient-oriented* information or what constitutes *approved information* would have been necessary. **In the view of IVAA this information must compile detailed facts on effects, side-effects, duration and costs of treatment and quality of the medicinal product. IVAA further demands the provision of information on alternative therapies.**
7. IVAA is of the opinion that **a central database on the European level could be helpful for health professionals** to improve their access to better information about medicinal products. But IVAA doubts whether such a database would be of much help for patients and citizens due to the lack of technical access, language barriers and necessary medical knowledge etc.
8. As far as the monitoring systems are concerned, IVAA points to necessary impartiality of the regulating bodies and agency. Experience has shown that this can not always be guaranteed, especially when institutions of various administrative traditions and of different governmental levels are involved. A greater part of *marketing authorisation holders* in the process of information provision could quickly outmanoeuvre these monitoring and controlling bodies and agency, given their limited capacities and how overstretched they are.

9. Together with many other stakeholders, IVAA strongly urges the EU Commission **to move the responsibility for *information to patients* from the DG Enterprise and Industry into the domain of the DG SANCO,** which is, in the context of the EU Commission, responsible for health and health information of the citizens EU member-states. For IVAA – and many other health professional organisations – *information of patients* remains to be primarily a question of how to *promote health* of the patients and citizens in the EU member-states and not a question of how to support the industrial sector involved.

**About IVAA**

The IVAA (International Federation of Anthroposophic Medical Associations) represents and coordinates the National Anthroposophic Doctors´ Associations with regard to political and legal affairs on both, European and international levels.

---Anthroposophic medicine has developed remarkably in Europe from its inception in 1920 to the present day and is increasingly recognized in the general public and in the academic world.

---Anthroposophic medicinal products are prescribed by approximately 30,000 doctors in 18 of the 27 EU member states (Austria, Belgium, Czech Republic, Denmark, Eire, Estonia, Finland, France, Germany, Italy, Latvia, Netherlands, Poland, Portugal, Romania, Spain, Sweden, United Kingdom), in Norway, in Switzerland, and in 65 countries worldwide.

---Anthroposophic medicine is officially recognized within distinct limits in Austria, Germany, Italy and Switzerland.

---Anthroposophic medicine is practised in hospitals and other in-patient facilities in Austria, Germany, Italy, Netherlands, Sweden, Switzerland and the UK, including teaching hospitals and other hospitals of public health care.

---Anthroposophic medicine is taught at universities in Germany, Italy, Spain, Switzerland and the UK.

For the Council of IVAA,

Dr Peter Zimmermann