

Problems in the EMEA patient information working group

Too drug oriented, too many conflicts of interest

We have read in detail the document EMEA/CPMP/5819/04/Final dealing with patient information, entitled "EMEA/CPMP Working Group with Patients Organisations - Outcome of Discussions: Recommendations and Proposals for Action".

La revue Prescrire has been assessing the quality of patient information for more than 20 years, on behalf of its subscribing doctors and pharmacists. We have therefore followed with interest the activity of the "Working group with Patients organisations" since its creation a few years ago.

We would like to draw the attention of the working group members and the EMEA to a number of methodological problems that undermine the validity of the recommendations offered for public consultation.

Applying the Regulation. We regret that the Working Group's recommendations do not sufficiently take into account the new Regulation 726/2004 that defines the framework of EMEA activities and its implementation schedule. We note that title IV applies immediately, and that EMEA now has an obligation of transparency, in application of European Regulation 1049/2001 on public access to documents, and in keeping with

the spirit of the Charter of Fundamental Rights of the European Union. According to article 73 of Regulation 726/2004, the EMEA management board must ensure that these obligations are implemented within 6 months of the publication of Regulation 726/2004 in the Official Journal (i.e. on 30 October 2004).

Conflicts of interest. We also note that many patient organisations participating in the working group receive various degrees of financial support from drug companies. According to its website, the patient group IAPO, for example (see List of Participants), is funded by drug companies. The fact that an IAPO member is rapporteur for the document entitled *Recommendations in the area of transparency and dissemination of information* (Annex 2) creates a serious conflict of interest.

Public confidence, not to mention the credibility of EMEA's scientific work, demands that all conflicts of interest be clearly listed. Regulation 726/2004 (article 63.2) defines EMEA's obligations regarding conflicts of interest. These obligations also apply to working group members. EMEA must therefore ask members of the Working Group with Patients Organisations to declare their conflicts of interest, and must make them

readily accessible on the EMEA website. To our knowledge, this is not the case.

Package leaflets. Before proposing improvements to package leaflets, we think patient groups should first evaluate their defects and inadequacies, in total independence from drug companies, and in collaboration with health professionals (prescribers, pharmacists and nurses), who, it should be said, are inadequately represented in the working group. To our knowledge, this is not the case.

Currently, package leaflets are full of administrative jargon, their contents appear in no prioritised order, and they are poorly suited to the situations that patients most often encounter. Basically, they serve simply to protect manufacturers and medicines agencies from legal action.

Contrary to what is being recommended, it is in no way desirable to stress a drug's expected benefits to the detriment of its risks. What patients need is balanced, comparative information. As a rule package leaflets contain no data from comparisons with other treatments. Stressing the expected benefits would therefore be equivalent to surreptitious advertising, and would divert patients' attention away from possible adverse effects.

The inadequacies of EPARs. The consultative document asserts that EPARs have benefited health professionals and recommends that EMEA might produce "a patient friendly version reflecting any comparisons with existing therapeutic options". The quality and interest of EPARs were assessed by an ISDB member group on two occasions, in 1998 and 2001 (1,2). Their conclusions were highly critical, and the situation has barely improved since:

- the clinical assessment section is far from systematically complete and detailed;
- the adverse drug reaction section varies widely in quality from one EPAR to another;
- virtually no information is given on CPMP experts' questions or misgivings;
- dissenting or minority voices within the CPMP are not mentioned;
- there are no data from comparative assessments and no information on added therapeutic value relative to existing treatments, which is of course in line with the law, but does not permit a "reflection" of useful comparisons".

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1- "ISDB assessment of nine European public assessment reports published by the European Medicines Evaluation Agency" International Society of Drug Bulletins, 1998.

2- "The failings of the European Medicines Evaluation Agency" *ISDB Newsletter* 2001; 15 (1): 11-13.

Proposals of the Prescrire Editorial Staff

- The patient information on diseases and treatments that EMEA is planning to publish online should include the existing drug and non-drug treatments, as well as preventive measures. The public must not be given the impression that medicines are the only answer to all health problems. The information should also include comparative data on existing treatments (added therapeutic value).
- EMEA should provide European citizens with basic information, in the style of "frequently asked questions", on epidemiology, clinical trial methodology, risk-benefit balance, natural outcome of diseases, placebo effect, and pharmacovigilance. Without a minimum of signposts, patients and the public are easily misled by the plethora of pseudoscientific information that they cannot understand. In these conditions, "communication" is simply a smoke-screen.
- The EMEA search engine should allow drug information searches based on international non proprietary names (INN).
- The information contained in package leaflets should be given in the order of importance of expected benefits and possible dangers, and should clearly distinguish established fact from assumptions. The objective is to optimise compliance without minimising adverse effects.
- The information should be presented as simple questions and answers, accompanied if necessary by pictograms.
- A major place should be set aside for health advice and health education, in order to improve rational use of drugs.