Methodology of use of the core quality principles on information to patients

On 26 June 2007 the Pharmaceutical Forum agreed on a set of core quality principles on information to patients on diseases and treatment options:

- objective and unbiased
- patient-oriented
- evidence-based
- up to date
- reliable
- understandable
- accessible
- transparent
- relevant and appropriate
- consistent with statutory information

On the request of the Pharmaceutical Forum, a methodology of use has been developed to facilitate the implementation of the core quality principles on information to patients on diseases and treatment options.

The overarching goal of developing a methodology of use of the core quality principles on information to patients is to set out quality requirements for information material on diseases and treatments to prevent any promotional orientation of the information and ensuring the confidence of patients on the high quality of the information. Thereafter, the main purpose of the methodology in its application is to assist Member States and Stakeholders to develop good quality information and to help patients[1] distinguish high quality information from poor quality information. The methodology of use should not undermine national control system that exists but rather contribute to support evaluations by national competent authority. The clear and reproducible criteria for each of the quality principles should be fulfilled to ensure the distinction between promotional data and good quality information.

This general methodology applies to all kind of information and has the two overall practical objectives of:

- Establishing a guiding framework ensuring the respect and use of the quality principles for providers of information;
- Support the Member States and/ or other organisations, as well as patients and healthcare professionals when assessing the quality of information.

It has been developed in the format of a checklist under which all the essential points of the list should be fulfilled.

[1] AIM and ESIP considers that this methodology is intended for information providers and would be very difficult to be used by patients and citizens.

Checklist ensuring the application of Core Quality Principles for Information to Patient[2]

1. Objective and Unbiased

Information is objective when it is based on facts and not influenced by prejudices or personal perceptions. Information is unbiased when it is impartial, non-directive and balanced.
These two definitions do not relate to the source of information which is a separate issue (see the 'Transparent' principle).

- Information should be comprehensive, complete, impartial, non-directive and balanced.[3]
- Information should rely on exhaustive sources of information covering the total of evidence which should be made public[4].
- A publication should be peer-reviewed and approved by an independent editorial board with proven scientific expertise, with representatives from professional organisations and/or patient and consumer groups.[5]
- A publication should respond to the need of patients and have its aims stated at the beginning of the publication.
- It should be indicated when there are only symptomatic treatments available.
- It should be indicated when products are being studied in clinical trials or made available under compassionate use programmes[6]. Patients should be referred to EUDRACT, the EMEA database, for further information on clinical trials.
- It should always be indicated which choices of treatment exist, even if a full account of alternatives has not been presented in the publication[7].
- It should be indicated how the treatment fits into therapeutic strategies
- Information on how each treatment is administered, how it acts on the body and what are the consequences for every day life should be included as well as the benefits and risks.
- Information on pharmaceutical treatments should contribute to the good use of medicines

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[2] The quality principles and their corresponding texts in italic as listed below were endorsed by the Pharmaceutical Forum on 26 June 2007, see http://ec.europa.eu/enterprise/phabiocom/docs/pf_20070626_progr_report.pdf .
[3] AIM suggest further criteria: The wording and language should be neutral and non-directive and does not see words that appeal to the emotions, fear, creating a need, unrealistic hope or promises so that decisions are made in accordance with the patients' own values.
[4] AIM and ESIP suggests further wording: (including results of positive and negative studies). AIM added that: Information on (on-going) clinical trials should be made available through the EMEA database on clinical trials (EUDRA CT).
[5] ESIP does not agree to characterise the participants.
[6] ESIP and AIM do not agree to the reference to compassionate use programmes as these are not validated information.
[7] AIM and ESIP suggests to replace this criteria by: For diseases, validated treatments should be equally well described (benefits, harms, risks…) along with information on prevention.

- The denomination of the pharmaceutical treatments should include the class names and the names of the active ingredients. References to brand names depend on EU and national legislation.[8]

2. Patient-Oriented and Understandable

Information provided should be patient-centred taking into account patients' needs and expectations in order to empower patients. Patients should be involved in the production and dissemination of information on diseases and treatment options wherever possible.
Information provided should be comprehensible for a patient/citizen.

- The language should be clear, easy to read and appropriate for patients.
- If technical terms are used, there should be an explanation or a glossary at the end of the publication.
- There should be some kind of notice that the publication is designed to support, not replace, the relationship between patient and health professionals.
- There should be an opportunity for feed-back, asking questions or reporting any problems with the publication.
- Patient groups should be involved in information production from the onset or consulted prior to publication whenever possible to ensure the relevance of the information and to test the readability and if the message is understandable to the general public.
- The publication should commence with an overview indicating what it is about, what it covers and who it is meant for.
- The language and layout of the publication should make the information reader - friendly and facilitate the search for specific information.

[8] France, AIM and ESIP do not agree to include a reference to brand names.

3. Evidence-Based

The evidence base for any information resource needs to be clearly stated, including making clear the level of evidence. Information should be verifiable, based on comparisons and backed up by scientific peer review where possible[9].

- The content is based on rigorous and systematic evidence
- The information is developed following a systematic method which aims to minimise bias and maintain neutrality.
- Evidence-based communication techniques should be used to meet the goals of informing, supporting and empowering patients and consumers.
- A main statement, "fact" or recommendation[10] should be accompanied by a level of evidence.[11]
- Information on evidence should be understandable to the general public and not being directive.
- The lack of evidence, contradictory evidence, or uncertainty as well as potential benefits and risks should be clearly stated.

4. Up to Date

Information should be kept up-to-date and the date of publication should be included.

- The date of publication or last revision and the dates of the main sources of evidence used and reported in the publication should be stated.
- The date of the next planned update should be also stated when possible.
- Information should be kept up-to date to remain evidence-based.

[9] France does not agree to the wording "where possible because it is in contradiction with point 2 and point 5.
[10] AIM and ESIP do not agree with the inclusion of "recommendation" in this criteria as information should maintain neutrality.
[11] AIM and ESIP wants to add "According to the methodology of evidence-based-medicines".

5. Reliable

Information needs to be factually correct and not misleading. Information should be scientifically valid and reflect latest knowledge.

- Information needs referencing to make it clear where the evidence for the information has come from.
  - A main statement, "fact" or recommendation[12] should be accompanied by a reference to the source of the publication. It should not be used out of its context.
  - A source of evidence should be listed in a bibliography or reference list at the end of the publication.
- Method and quality review by an independent editorial board on the accuracy of the content and the structure of the publication should be put in place.
- A quality assurance system for the research and selection of information and for the editorial review should be respected.

6. Accessible

Information should be easily accessible via different mechanisms for example, through written documents, websites of certified official bodies etc. Information should also be accessible to people with disabilities.

- Information material[13] should be easily accessible to patients and citizens
- Sufficient supply and dissemination of material should be ensured (e.g. through pharmacies, general practices and hospitals)[14].
- Opportunities to make information accessible to people with disabilities should be put in place.
- Additional official[15] and/or non-commercial sources of high-quality information and contact for support should be listed at the end of the publication under headings such as "Useful addresses" and "Further reading".
- The reader should be encouraged to ask for further clarification or to discuss the content of the publication with a health professional.

[12] AIM and ESIP do not agree with the inclusion of "recommendation" as information should maintain neutrality.
[13] AIM wants to have "independent, validated, high quality information material" added to this criteria.
[14] ESIP does not agree with this criteria.
[15] AIM wants to have "validated additional official" added to this criteria.

7. Transparent

Informed choice requires transparency. That entails transparency of what is known as well as what is not known. Funding, sources of information, evidence for that source and transparency when there is known controversy about a particular treatment, for example, all need to be made clear.

- Existing controversy about particular elements in the information should be indicated.
- The publication should disclose information or a reference on where to find information[16] on the following elements:
  - Name, mission, structure and financial background of the organisation publishing the material
  - Sources of funding for the material and possible conflicts of interest of the sponsor
  - Names, qualifications and possible conflicts of interest of all authors.
  - Names, qualifications and possible conflicts of interest of the editorial board review and disclosure of the process and quality assurance.
  - Method, process and respected quality principles for the submitted information
- Origin of the information should be indicated.

8. Relevant

Information should include issues of relevance and importance to patients' decision-making e.g. including adverse effects. Impact on quality of life and the consequences of the disease on contribution of the patient to society/the work place are important elements of information on disease.

- The information provided on a certain disease should be relevant to the patient's needs and circumstances, especially healthy lifestyle, prevention, treatment options, benefits and risks.[17].
- Information should be neutral and non-directive.
- The publication should not make recommendations that are unrealistic or contain assumptions or language that may be considered inappropriate or offensive.
- The inclusion of comparative information on the different treatment options should be evidence-based and relevant to patients.

[16] ESIP is of the opinion that to achieve full "transparency" the information should be included directly in the publication so the reader should not have to look for it.

[17] AIM wants to include reference to comparative information.

- The reader should be made aware that more specific and tailored information to his/her individual situation could be obtained by consulting a health professional.

9. Consistent with Statutory Information

Information not regulated by statute should, nevertheless, be consistent with the legal requirements of European law (e.g. must not be designed to promote a prescription only medicine, reflecting the prohibition of direct to consumer advertising of prescription only medicines, must not be misleading etc.) and should refer, where appropriate, to statutory information approved through the process of regulation.

- The information material shall be compliant with national and European legislation.
- The information delivered shall be compliant with the legal requirements of information on medicinal products. As for information on medicinal products, information should be in conformity with approved summaries of product characteristics and patient information leaflets and it should not contradict or go beyond the key elements specified in them.
- Copyright laws must be observed.

As for the special requirements internet information calls for, we refer to the report on the implementation of an Austrian health portal, which provides an extensive and feasible methodology for this purpose.[18]

[18] France does not agree to have a reference to the Austrian report in this document. France finds that the quality criteria and other specific criteria for information disseminated by internet have to be added as such in this methodology of use of the core quality principle and there should not be a reference to this Austrian report that has still to be discussed.