a Council Directive on advertising of medicinal products for human use.

Having taken knowledge of the Draft Proposal for a Directive dated March 1990, the Standing Committee wishes to make known the following comments made at the heads of delegation meeting:

Chapter I
Scope, definitions and general principles

Article 1
The Standing Committee, as expressed in its report on the preliminary draft Proposal for a Council Directive on pharmaceutical advertising, III/8118/89, rev. 2, believes that the objectivity which should preside the information about medicinal products might be limited when the pharmaceutical industries add economic incentives to that information, whether in money or in kind, so as trips, staying in luxurious hotels, entertaining, etc.

It thinks, however, that in article 1, third insert, the words "or to congresses" should be omitted, given the importance of these for the physicians training.

Chapter II
Advertising to the general public

Article 3
The Standing Committee, as per the comments addressed to the DG III on the preliminary draft Proposal for a Council Directive, III/8118/89-FR, rev. 2, does not see the need to expressly mention a list of illnesses in paragraph 2 of this article, for it believes that these are included in paragraph 1 and are not well defined and also the list is incomplete.

Nevertheless, should this list be kept, it is thought that to avoid any doubts due to the interpretation of the word "psychotropic", a further insert should be added to the list under paragraph 2 "anxiety and depressive illness".

Chapter III
Advertising to Health professionals

Article 9
The Standing Committee is of the opinion that this article, the way is worded, might forbide ever activity of the pharmaceutical industry in the field of medical education, namely in continuing medical training, fact that would not be in the interest of the consumers, nor of the physicians or other health professionals.

It therefore proposes that a further article be added:

> "9. A. Nothing in this directive shall inhibit a producer from supporting medical educational activities as such. Such support may however only be attributed to the manufacturer by name in accordance with the Code of Conduct for the Pharmaceutical Industry, and no reference may be made to the proprietary name of any medicinal product produced by him".

Chapter IV
Monitoring of avertising of medicinal products

Article 11
The Standing Committee believes that, whichever it is the body or committee to supervise the accordance with this directive on advertising of medicinal products, there should be included independent practising medical members outwith the pharmaceutical industry.

Clinical Trials
With regard to the guideline on clinical trials, document III/3976/88, the Standing Committee points out that the constitution, protocols, working procedures and response time of the Ethics Comittee supervising the clinical trials on medicinal products should be publicly available, opinion addressed to that DG III on 20 September 1989.

In what concerns to the composition of such Ethics Committee, the Standing Committee, based upon the American experience, is open to this being a multidisciplinary body.

New version of article 4 of directive 65/65
In what concerns to this new article, proposing a new sequence of basic details on medicinal products, the Standing Committee agreed that no substantial change is included, thus it has no comments to give.

12.13 Report on quality assurance

Valencia, 1991 (CP 91/97)

Quality assurance

The initial paper of quality assurance was adopted by the Hospital Doctors committee by its last meeting with a request that a list of various definitions be elaborated for further discussion.

Quality assurance is the name given to the whole process which enables all evaluation activities including clinical review, utilisation and review of non-clinical services.

It is a process of assessing the quality of health care in order to guarantee optimum standards.

Whithin a hospital there are five elements that make out the primary process of patient care, namely:

a) medical care,
b) nursing care,
c) paramedical care,
d) supportive services,
e) hotel services.

Therefore quality assurance requires:

a) making the above mentioned process explicit
b) formulating of criteria of different aspects,
c) the measurement and change of the hospital care process,

d) coordinating the five processes,
e) creating of optimum circumstances in which people work,
f) adjustement of health care delivery towards demand and
g) improving the motivation of people to do their work even better.

Many of these activities are already performea in various ways in different departments within hospitals. However, the drawing together of all the various parts under a common direction is the primary need.

It is far more than just a costcontainment exercise. The outcome of the quality assurance system is quality of care, defined as "the extent of conformity between the actual care and the criteria set up for this care".

The ten commonest terms used in quality assurance are as follows:

1. Accreditation:
   The process by which an agency or organization evaluates and recognizes a programme of study or an institution as meeting predetermined standards.
2. Assessment:
   The thorough study of a known or suspected problem in quality care, designed to define causes and necessary action to correct the problem.
3. Criteria:
   Professionally developed statements of optimal health care structure, process, or outcome.
4. Monitoring:
   The ongoing measurements of a variety of indicators of health care quality to identify potential problems.
5. Outcome:
   A change in the current and future health status of the patient that can be attributed to antecedent health care.
6. Policy:
   A chosen course of action signifianntly affecting large numbers of people.
7. Process:
   The various diagnostic procedures applied the therapeutic regimens installed and the types of followup or other practices undertaken on behalf of the patient.
8. Programme:
   An organized response to eliminate or reduce one or more problems where the response includes one or more objectives, performance of one or more activities, and expenditures of resources.
9. Standard:
   The expression of the range of acceptable variation from a norm or criterion.
10. Structure:
    The characteristics of the providers of care, of the tools and resources at their disposal, and of the physical and organizational settings in which they work.

Implementation

Implementing quality assurance is the acceptance of a systematic choice making process and contineous evaluation of its outcomes. It should emphasize: voluntary participation, with supportive management resulting in a team rather than an individual pattern of care.

All hospital activities are included and all staff (not only medical) are involved. It should build upon and develop those departemental systems already in existence.

Therefore there is a circle of activities needed going from planning, to executing, evaluating and finally restarting again in a contineous circle of improving care.

12.14 Motion in opposition to guide on good pharmacy practice in Europe

(CP 94/132 Final)

Statement concerning the text published by the Pharmaceutical Group of the EU (CP 94/43).

Adopted at the CP Plenary held in Lisbon, 25-26 November 1994, by the CP and the Organisations associated with the CP: UEMS, UEMO, PWG, AEMH, FEMS, CIO, WMA.

The CP, and the associated organisations, meeting in Lisbon on 25 November 1994, considered the text published by the Pharmaceutical Group of the European Union entitled "Good Pharmacy Practice in Europe" (CP 94/43).

The meeting noted the numerous objections which have been expressed to the document by all the CP national delegations and all the Associated Organisations. The meeting further expressed its agreement in the name of all participating bodies that the underlying philosophy of the document is unacceptable as it attributes to the pharmacists in Europe professional responsibility for matters beyond their sphere of competence, including matters which can only be under the responsibility of the patient's physician.

While noting the positive benefit of a good cooperation between physician and pharmacist in the interests of the patient and agreement with accepted national practice, the CP finds the PGEU document to be in conflict with these interests.

The CP and the Assiciated Organisations, therefore, hereby express disagreement with the document in question and resolve to bring it to the attention of the Pharmaceutical Group of the European Union and all other relevant sectors to which the PGEU document may have been transmitted.