use and establishing a European Agency for the Evaluation of Medicin Products. III/3603-1/90-EN

The Heads of Delegation of the Standing Committee of Doctors of the EC, having considered the mentioned text, agreed with the following comments and suggestions:

Considerant 12
In the second line the reference should be to "The" Scientific Council.

Considerant 15
It is strongly felt that the European Agency for the evaluation of Medicinal Products should be set up by, and responsible to, the Council of Ministers, given the importance and consequences of an inappropriate or inadequate authorization and its political implications.

Title 2
Authorization and supervision of medicinal products for human use

Chapter 1
submission and examination of applications – authorization – renewal of authorization

Article 14
The Standing Committee suggests to insert at indent c) the word "medical" before "practitioners".

At indent d) proposes to omit the word "serious" in line 2, since the Standing Committee believes that any adverse reaction should be given to the knowledge of the competent authorities.

Add an indent e) saying that "continuing regular reports on the clinical efficacy of the medicinal product must be made available to the competent authorities", as not only adverse reactions should be made known but also the beneficial ones.

Chapter 2
Supervision and sanctions

Article 16
In view of the absence of definition of the term "person responsible for marketing", and given the fact that its appearing together with the reference to article 5 (information concerning the product), may lead into error, the Standing Committee calls for a clear definition of this term.

Article 19
Whilst supporting this article in its entirety, the Standing Committee believes that a reference should be made to the duties of Authorities to notify physicians of the withdrawal of license and the reasons for this.

Chapter 3
Pharmacovigilance

Article 22
The Standing Committee is strongly of the opinion that a *physician* should be responsible for pharmacovigilance. It therefore recommends that the word "a person responsible" in line 4 of this article should be replaced by "the physician responsible".

Article 23
In view of the comment on article 22 the Standing Committee recommends that the "person responsible for marketing", paragraphs 1 and 2 of this article, should be replaced by "the physician responsible for pharmacovigilance".

Article 24
Since this article provides that any serious adverse reaction must be reported within 48 hours, the Standing Committee thinks that the person detecting it (nurse, pharmacist, etc.) must report on this fact to the physician, and it should be this last one who subsequently notifies. It therefore suggests to replace in line 5 the Word "qualified health care professional" with the Word "physician".

Title IV
The European Agency for the Evaluation of Medicinal Products

Chapter 1
Actividades de la Agencing

Article 49
Referring to indent c), the Standing Committee points out that "evaluation of reports of adverse reactions" does not mean the same as "pharmacovigilance".

At indent g), in line 3, would wish to be added the word "physicians" before "patients and consumers", since, no doubt about it, the physicians need this information.

Chapter 2
Structure of the Agency

Article 50
It is suggested to replace in paragraph 4, line 2, the word "may", permissive term, with "should", imperative term.

Article 51
It is proposed to insert in paragraph 1, after n The Executive Director", "and the Medical Director (if these are not the same person)".

12.12 CP Statement regarding the Draft Directive on Advertising

On 13 December 1989 the Standing Committee issued its opinion on the Preliminary Draft Proposal for

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,