12.15 Joint Statement by the CP and the European Federation of Pharmaceutical Industries' Association (EFPIA)

Adopted in Athens, April 1995
(CP 95/016 Rev. 2)

The medical profession, represented by the Standing Committee of European Doctors (CP) and the pharmaceutical industry, represented by EFPIA, each aware of its responsibilities vis-à-vis patients and society, consider it essentiel to establish a framework for their relationship, particularly in the fields of information, advertisement, medical press, clinical trials and continuing medical education for doctors.

These two independent organisations have agreed to meet regularly, in order to seek, jointly and with due regard for patients interests, greater efficiency and the independence of each party, the best approach in each of these specific fields. Their work will be geared to the following objectives:

Clinical trials and pharmaco-epidemiological studies
The cooperation between the pharmaceutical industry and the medical profession in conducting clinical trials and pharmaco-epidemiological studies is essentiel to the development of medicinal products as well as to their through knowledge and their optimal use.

Each trial or study must pursue a scientific and therapeutically relevant aim without being developed primarily for promotional purposes. This aim must be stated beforehand. Protocols must be drafted in such a way as to ensure that this aim is achieved and to ensure the validity of the conclusions of the study.

In the performance of these trials and of pharmacological studies, ethical and professional rules (namely the Helsinki Declaration) as well as scientific principles and quality assurance (namely codes of good clinical practice) must govern the relationship between the investigator and the promoter, and the investigator and the patient.

Medical information
To ensure that medicinal products are used appropriately, both from a clinical and a scientific viewpoint, the prescribing doctor needs to be well informed about the full range of therapeutic means available to him.

Due to the body of knowledge it accumulates, namely through its collaboration with the medical profession, the pharmaceutical industry is an important source of information to doctors.

Doctors must be in a position to obtain objective, complete and unbiased information on issues relating to drugs' effects.

This information must be governed by strict codes and ethical principles in accordance with existing legislation and Codes of good practice. The latter need to be emphasised and widely distributed.

Continuing medical information
The pharmaceutical industry has traditionnaly supported medical training. Co-operation in this field shall be transparent, conducted according to professional codes and shall safeguard the independence of continuing medical education.

12.16 Good Clinical Practice, CP Comments

(CP 96/138 Final)

Re: Draff Directive on the approximation of provisions laid down by law, regulation or administrative action relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use.

(Comments of the CP transmitted to Mr *DeBoyser* [DG III], 26 September 1996)

Introduction
The draft directive on the implementation of Good Clinical Practice has a clear goal: to harmonize the ethical and scientific review and approval of clinical pharmaceutical research in the EC. Its encompasses phase I to IV studies, mono or multi-centre trials in one or more EC countries.

In order to reach this goal several new elements are introduced:

- in the case of multi-centre trials a single opinion of an ethics committee shall suffice for a particular member state (art. 3.1.)
- the scientific evaluation of a multi-centre trial in more than one member state can be performed by one of the competent authorities involved (art. 5.2.)
- approval by a competent authority for any pharmaceutical trial is needed before starting the trial (art. 5.2., 5.3. and 5.4.)
- the starting of a database concerning approved trials, accessible only by the competent authorities (art. 6.1.)
- a system of inspection of research sites (art. 10.)
- a system of clinical safety reporting (art. 11.).

Comment
In general it can be applauded that additional rules are being developed regarding the implementation of Good Clinical Practice. It is of major importance that some of the current problems are addressed. These problems can be identified as:

1. the absence of one 'location' for the ethical and scientific review of multi-centre studies within member states
2. the absence of information on clinical trials in progress, their results, those withdrawn or stopped (and the reasons why) and the safety risks involved