Article 11
In this article a system of clinical safety reporting is proposed. Essentially the system implies that:

- adverse events are reported to the sponsor (art. 11.2.)
- serious adverse events are immediately reported to the sponsor except for those events identified as not requiring immediate reporting (art. 11.1.)
- serious unexpected adverse reactions are to be reported to the member state in whose territory the reaction occurred within 7 to 15 days (art. 11.4.)
- each twelve months a line risting of all suspected serious adverse reactions, and a summary overview of the subjects safety, will be provided by the sponsor to the competent authorities (art. 11.6.)
- each member state shall notify the Agency of reports on suspected serious adverse reactions (art. 11.7.).

Concerning this article some comments can be made:

- it is not clear whether an ethics committee should ever be informed. As a minimum ethics committees should be adequately informed about serious adverse events and/or reactions, including of course cases of death. Ethical committees have responsibilities to those involved in any trial.
- it is not clear what criteria might be used to identify serious adverse events that need not be reported to the sponsor immediately. We consider all serious adverse events and reactions must be reported to the sponsor and the ethics committee as well. Cases to be reported to the competent authorities immediately need to be specified.
- 'unexpected adverse reactions' is not defined in art. 1.
- we fear that the frequency and amount of information concerning suspected serious adverse reactions to the competent authorities (line risting each twelve months) is insufficient and must be strengthened and made consistent with current pharmacovigilance systems.

Summary
In summary, the medical profession as represented by a working group of experts of the Comité Permanent, welcomes this initiative by the European Commission. In addition to our overall comments on the draft, we have identified specific proposals with regard to Articles 2, 3, 5 and 11. We would be happy to elaborate these views and comment on any future draft produced by the Commission.

CP Ad Hoc Working Group on GCP

Professor *Detilleux*
Dr *Dillmann* (rapporteur)
Professor *Doppelfeld*
Dr *Harvey*

12.17 Motion on CP as an International Association

Adopted at Rhodes, November 1995
(CP 95/131 Rev. 1)

The CP at its meeting in Rhodes:

– considers that an International Association has to be constituted;
– the statutes of this association will correspond to the rules of the CP orders;
– each National Delegation shall have one representative on the Board;
– the Associated Organisations shall have observer status within CP;
– the CP requests the group of jurists to examine the most convenient legal statutes, according to the Belgian law or any other one;
– the CP requests that the draft statutes and supplementary rules of such an association be submitted at the next meeting.

12.18 Self Medication in Europe

Adopted at Athens, November 1996
(CP 96/36 Final)

Common position of the CP, UEMO, UEMS

Definitions
Self-medication is the use of over-the-counter medicines by patients (or their parents/guardians where appropriate e.g. minors) without either diagnosis- or symptom-oriented advice by a physician or a pharmacist.

Guided, pharmacist-assisted self-medication is the use of over-the-counter medicines after symptom-oriented advice by a pharmacist.

Treatment is the use of over-the-counter and prescription medicines after the diagnosis-oriented advice by a physician.

The aim of self-medication and of guided pharmacist-assisted selfmedication is the prevention, relief or the healing of symptoms or signs associated with minor ailments. Another aim of self-medication maybe towards substitution therapy (such as vitamins and mineral substances).

The aim of medical treatment is the prevention relief or the healing of diseases.

Responsibility
In the case of guided, pharmacist-assisted self-medication, the pharmacist bears the full legal responsibility for advice and/or products dispensed. Where in the case of "Treatment" it is the physician who has the responsibility.