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.

Legal framework
Granting of market authorization, classification, patient information and advertising are to a large extent subject to European regulations.

Distribution, pricing and reimbursement lie to a large extent within national discretion and their authorities.

The most important EU Directives
92/26
Art. 3 of this Directive sets out the rules governing the classification of medicinal products into medicinal products subject to medical prescription and medicinal products not subject to medical prescription:

> Art. 3
> "Medicinal products shall be subject to medical prescription where they: are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct of indirect danger to human health, or contain substances of preparations thereof the activity and/or side effects of which require further investigation, or are normally prescribed by a doctor to be administered parenterally.

Interpretation: Medicinal products, which are likely to present a direct or indirect danger to health – even when used correctly – are subject to medical prescription, others not.

Sub-categories for medicinal products, which are available on medical prescription, may be fixed according to the following classification:

a) medicinal products on renewable medical prescription
b) medicinal products subject to special medical prescription
c) medicinal products on restricted medical prescription.

92/27
This Directive sets out the rules governing the labelling and package information leaflets of medicinal products for human use.

92/28
This Directive sets out the rules governing the advertising of medicinal products for human use.

92/73
This Directive sets out the provisions for homeopathic medicinal products.

65/65/EEC
This Directive sets out the rules for marketing approval and Community trade (invoking the EU regulation 2309/93: centralized Community authorization procedure).

This Directive has been extended by provisions for vaccines, toxines, serines, allergens, radioactive substances and package leaflets.
89/381
This Directive sets out the provisions for medicinal products derived from human blood or human plasma.

75/318
This Directive sets out the rules governing physiochemical, biological of microbiological tests of proprietary medicinal products and the testing of their teratogenic, and other, potential.

75/319
This Directive sets out the rules for authorization to place medicinal products on the market and contains other legal and administrative provisions.

Other important declarations, decisions, etc.

- Decision CE 645/96 of the European Parliament and the Council of March 29, 1996.
- Position of the Economic and Social Committee on the "Free movement of medicines in the European Union – elimination of existing trade barriere".
- WHO-Declaration of Alma Ata.
- WHO Study on self-medication in Europe.

Pros and cons of self-medication and of guided, pharmacist-assisted self-medication
The following assertions, theories, presumptions, questions and arguments are repeatedly used in discussions: the accuracy and the conclusiveness of the mentioned assertions, however, is not being analyzed or examined in this context. In some points there is agreement by all partners, others are strongly contested by the pharmaceutical industry and pharmacists – as for instance the assertion that increased self-medication leads to increased consumption of pharmaceuticals, as well as the assertion, that increased self-medication furthers exclusively the interests of pharmacists and the industry.

The experience of physicians on the other hand leads them obviously to take a sceptical attitude towards the concept of self-determination of patients, the argument, that any delayed diagnosis constitutes a risk and leads to additional costs, is increasingly put forward. Physicians are in addition increasingly concerned with the necessary protection of the patient with regard to exploitation, whether by misguided or non-guided self-medication.

Pros:
- The development of the "zeilgeist" (the patient assumes the responsibility for his own health) leads to increased self-medication.
- Economies for social health insurances, reduction of costs (resulting from medical consultation, saving of time, etc.).
- Self-medication is a fact.
- Cooperation between the health professions is necessary.

- Positive experiences of patients with self-medication.
- Fears and concerns of physicians are exaggerated, there exist barely negative experiences concerning self-medication.
- The counselling potential of pharmacies must be used to a larger extent. Increased resposibility of the patient for himself.
- Strengthening of the patients' consciousness of their own health.
- Deepening of the patients' knowledge and consciousness of costs Declaration of the WHO and of other institutions on self-medication EU Directive 92/26.

Cons:
- Massive increase in use of OTC in some categories with little tangible benefit to patients e.g. a wholesale over consumption of vitamins or paracetamol poisoning.
- Inappropriate use due to incorrect self diagnosis.
- Inappropriate use due to incorrect diagnosis made by other persons (friends, acquaintances, pharmacist).
- Interactions with other medicines.
- Different proprietary names of the same substances are misleading for patients.
- No therapy without prior diagnosis.
- Delayed correct diagnosis and incidence of complications leading to serious adverse health consequences and increased costs.
- Ability of individual patients and communities to accurately assess and/or assume responsibility for their health will vary widely.
- Habituation to use of medicines.
- Consumer protection: who protects patients against useless or potentially harmful self medication?
- Promotion of self medication furthers primarily the interests of the industry and pharmacists: the connection with "good pharmacy practice in Europe", and the desired change in the role of the pharmacist is evident.
- Appropriate advise by pharmacists will often be impossible, due to differens role and training.
- There may be an undesirable conflict between the commercial interests and the interests and the professional reputation of the pharmacists.
- Even highly educated patients will only have a limited capacity to assess the appropriability of self medication.
- EU Directive 92/26.

Classification of medicinal products

In the European Union, medicinal products are in general classified into medicinal products subject to medical prescription and medicinal products not subject to medical prescription according to the Directive 92/26.

Medicinal products subject to medical prescription are in some countries divided into sub-categories according to the Directive 92/26, mostly into medicinal products subject to special or restricted medical prescription. Some of these countries have additional sub-categories for medicinal products subject to medical prescription.

The category of *medicinal products not subject to medical prescription* may be classified into reimbursable and non reimbursable medicines, although there is no correlation between the reimbursability and prescription duty.

There is another additional classification into medicinal products, which may be bought only in pharmacies, and others, which may be bought outside pharmacies (Ireland). In some countries, medicines destined for self-medication are designated as such: Farmaci di automedicazione (Italy), Vendra livre (Portugal), Especialidades Farmaceuticas Publicitarias (Spain), General Sale List Medicines and Pharmacy Medicines (Great Britain).

Advertising

Pursuant to Directive 92/28EEC "advertising to the general public of medicinal products which are available on medical prescription only is prohibited. Persons qualified to prescribe medicinal products must be able to carry out these functions objectively without being influenced by direct or indirect financial inducements. Advertising of medicinal products shall be subject to effective, adequate monitoring."

Further provisions of Directive 92/28EEC:

"Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for the use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary."

"Member States shall prohibit the mentioning in advertising to the general public of therapeutic indications such as: tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer and other tumoral diseases, chronic insomnia, diabetes and other metabolic illnesses."

"The advertising of a medicinal product to the general public shall not contain any material which gives the impression that medical consultation or surgical operation is unnecessary, ..."

"suggesting that the health of the subject can be enhanced by taking the medicine ..."

"suggesting that the safety or efficacy of the medicinal product is due to the fact that it is 'natural'".

According to this Directive advertising of non-prescription medicines to the general public in EU Member States is permitted; in some countries, however, advertising of reimbursable medicines is prohibited (France, Italy). In some countries self control on a voluntary basis has been introduced. In Ireland, advertis-

ing of medicinal products containing codeine as well as advertising of antidiarrheal medicines is prohibited, in Great Britain the advertising of a list of 18 indications is prohibited.

Phytotherapeutics
The majority of these medicinal products are dispensed without medical prescription. Some of them are classified as foodstuff, or health products, or as cosmetics. They are sold in pharmacies, drugstores and health shops.

Homeopathic medicines
Homeopathic products are mostly registered as medicinal products, the authorization procedure is often simpler.

The dispensing person depends partly on the dilution.

Vitamins and mineral substances
Vitamins and mineral substances are partly registered as foodstuff, partly as medicinal products – depending on the dosage, or according to medical indications.

Distribution
Medicinal products subject to medical prescription are dispensed in public pharmacies, in some countries there are dispensing doctors, i.e. physicians authorized to provide dispensing services to patients (Austria, France, lreland, Great Britain and the Netherlands), who ensure in some areas a considerable percentage of the provision of the population with medicines.

Phytotherapeutics, which however for the most part are not being granted market authorization as medicinal product, are in most of the countries sold in drugstores and health shops. In the Netherlands, 65% of non-prescription medicines are sold in drugstores. There exists direct mail selling of parapharmaceutical products, as for instance in Belgium.

The ratio of public pharmacies with regard to inhabitants is:

Austria:	1: 7490
Belgium:	1: 1922
Finland:	1: 6700
France:	1: 2560
Germany:	1: 3890
Ireland:	1: 3250
Italy:	1: 3700
Netherlands:	1:10060
Norway:	1: 2500
Portugal:	1: 4250
Spain:	1: 2150
Sweden:	1:10390
Great Britain:	1: 4810

Dispensing physicians (in Austria "Hausapotheken") lower the ratio inhabitants: dispensing outlets of medicinal products in some countries to a considerable extent (as for instance in Austria 1: approx. 4000).

Survey about self-medication
Questions:

1. Is there a legal basis for dispensing?
2. Is dispensing subject to a prescription by a physician?
3. Who dispenses prescribed medicines?
4. Who is authorized to dispense over-the-counter medicines?
5. Who decides whether a medicinal product is subject to medical prescription or not?
6. Has the Directive 92/26 been implemented, if yes, on the basis of which definition?
7. What is the total number of all registered and approved medicinal products?
8. What is the percentage of medicinal products which may be dispensed without prescription?
9. What is the percentage of prescription medicinal products subject to additional restrictions?
10. Are there substances in your country available over the counter, about which you have objections from the medical point of view?
11. Does the social-security system in your country assume the costs of over-the-counter products?
12. Please, give a short personal account on the problems and experiences your country has in the field of self-medication.

Survey analysis
The following countries were provided questionnaires:

Austria, Belgium, Denmark, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden.
Oberserver: Malta, Switzerland, Cyprus.
No answer: Greece.

1. Is there a legal basis for dispensing?
There is in all countries a legal basis for dispensing.

2. Is dispensing subject to a prescription by a physician?
The majority of medicinal products is in all countries subject to medical prescription.

3. Who dispenses prescribed medicines?
In all Member States dispensing is in principle incumbent on pharmacies. In Great Britain, Ireland, the Netherlands, Austria and in a part of Switzerland (Eastern Switzerland) physicans are also authorized to dispense medicines. In Spain medicinal products may be dispensed by health care centres and primary care centres of the national health service to their patients.

4. Who is authorized to dispense over-the-counter medicines?
OTC-medicines are in principle dipsensed by pharmacies. Such products may in some cases be distributed by drugstores or other sales outlets (Finland, Great Britain, Ireland, Luxembourg, the Netherlands, Austria: dispensing doctors, so-called "Hausärzte").

5. Who decides whether a medicinal product is subject to medical prescription or not?
The decision whether a medicinal product is subject to medical prescription or not is taken in all countries by national authorities, which are found regularly in the area of the ministry of health, the decision being taken either by pharmaceutical agencies within the sphere of influence of the ministry, or at least after deliberation of the authorities with experts.
6. Has the Directive 92/26 been implemented, if yes, on the basis of which definition?
The Directive has been implemented in all countries.

7. What is the total number of all registered and approved medicinal products?
The number of registered medicinal products varies from 2355 (Norway) to 20.000 (France), in France, however, only a part (7355) of these products are on the market (Cyprus: 1200).

8. What is the percentage of medicinal products which may be dispensed without prescription?
The percentage of non-prescription medicinal products is subject to considerable variations. In most of the countries this percentage comes to 10% and 20% (Denmark, Luxembourg, Norway, Austria, Portugal, Sweden, Spain). In Finland, this percentage is slightly higher (25-30%), in Belgium (44%) and in France (62%) it is considera bly hig her.

Among non EU Member States it is Switzerland which has a percentage above average (50.8%), whereas the percentage in Malta and Cyprus is distinctly low (20%).

9. What is the percentage of prescription medicinal products subject to additional restrictions?
The percentage of prescription medicines subject to additional restrictions (prescription reserved to the hospital or to specialists) is low (in the majority of countries under 10%).

10. Are there substances in your country available over the counter, about which you have objections from the medical point of view?
Some medical organisations have put forward medical reservations against the present OTC status of the following medicines: analgesics and antiphlogistics (Finland), H_2 antagonistics (Great Britain), paracetamol (Ireland), medicinal products with interactions (Spain).

11. Does the social-security system in your country assume the costs of over-the-counter products?
Normally, costs of OTC medicines are not assumed by social insurance systems. In the Netherlands, in Great Britain and in Austria, there is a small number of OTC medicines of which the costs are assumed by the social insurance system. In the same way, several social security systems in Sweden do assume the costs of some OTC medicines, but only on condition that they have been prescribed by a physician. In Denmark (in the case of chronically ill patients and retired persons) as well as in Great Britain and in Luxembourg, the costs of OTC medicines are reimbursed by way of exception conditional upon a prescription of a physician. In Spain, 60% of the costs of OTC medicines are reimbursed (in the case of retired persons 100%), in Switzerland the cotsts of approximately 25% of OTC medicines are reimbursed.

12. Please, give a short personal account on the problems and experiences your country has in the fjeld of self-medication!
The following medical organizations have a critical position with regard to the increasing trend towards self medication: Finland, Great Britain (where OTC medicines may only be dispensed by pharmacies, not by physicians), the Netherlands {concern of increasing health care costs as patients increasingly opt for reimbursable medicines), Austria and Spain.

Explanatory note:
The OTC market is *not* identical with the self-medication market and consists of three components:

1. Prescribed non-prescription medicines
2. Self-medication with registered non-prescription OTC products
3. Self-medication with non-registered OTC products.

The percentage of prescribed non-prescription medicines is varying and lies presumably 20-30% above the overall market of non-prescription medicines mentioned above. Exact data are not available.

Considerations of the medical profession from the medical-political point of view

- Although self-medication has become a fact in Europe, we, the medical profession take a critical attitude towards the growing importance of self-medication.
- We, the medical profession, declare ourselves for the cooperation with the other health professions, in particular for the cooperation with pharmacists. This cooperation is conditional upon the mutual maintenance and respect of the limits and possibilities. For this reason we reject advising that the activities of pharmacists going beyond a prescribed medicinal product.
- We consider our principle, that any treatment is conditional upon prior diagnosis, to be also true for the field of self-medication; the absolute prerequisite of any treatment is the medical diagnosis with the exception of some diseases and disturbances – which are easily recognized as such by laymen and pharmacists.
- We, the medical profession, consider the attempt to expand self-medication in Europe as an unjustified combination of commercial, financial and para-medical arguments, which finally do not contribute to the safety of the patient in the case of illness.
- We, the medical profession feel bound, to protect

our patients from useless and incorrect use of medicines.
- We, the medical profession consider increased self-medication one means to seduce patients to consume pharmaceutical products in initiating a habit forming reflex. This habituation is to be rejected categorically by the medical profession for the majority of fields of medicine, and in particular in the field of psychic diseases.
- Increased self-medication, however, may in addition lead to a demonopolization of dispensing by pharmacists. The development of electronic media will probably introduce new channels for the advising on and selling of medicinal products. This development will bring about alternatives as for instance direct mail selling of medicinal products, dispensing by drug stores, or a general dispensing right for all physicians.

Profile criteria for self-medication and guided, pharmacist-assisted self-medication

The following criteria must be observed:

Economic Importance of Self Medication

1. Pharmaceutical market (as per May 1996)

	Overall pharmaceutical market Mio. of the national currency	Overall pharmaceutical market in Mio. ECU	Overall market of non-prescription medicines in Mio. of the national currency	Overall market of non-prescription medicines in Mio. ECU	Self-medication with registered products in Mio. of the national currency	Self-medication with registered products in Mio. ECU	Percentage of the overall market of non-prescription medicines with regard to the entire market (%)
Austria	28.154	2.120	3.164	238	2.255	170	11.25
Belgium	96.410	2.476	21.455	551	17.097	439	22.3
Finland	4.688	812	838	145	36	6	17.9
France	117.200	18.220	40.037	6.224	21.416	3.329	34.2
Germany	46.800	24.702	16.400	8.656	8.500	4.487	35.0
Ireland	228.8	292	50,4	64	35,3	45	22.0
Italy	20,126.000	10.515	3,590.000	1,876	2,991.000	1.563	17.8
Netherland	6.476	3.052	855	403	765	360	13.2
Norway	4.521	558	516	64			11.4
Portugal	212.643	1.090	31.897	164			15.0
Spain	1,000.652	6.258	147,557	923	117.720	736	14.7
Sweden	13.369	1.615	1.380	167	1.487	180	10.3
Switzerland	3.388	2.171	1.231	789	911	584	36.3
UK	6041,3	7.506	1.659	2.061	1.240,9	1542	27.5

Data of Denmark and Greece are not available.

2. Per capita consumption of pharmaceuticals (as per May 1996).

	Population in million	Overall pharmaceutical market per capita in ECU	Percentage of non-prescription medicines in the overall market (%)	Per capita expenses for non-prescription medicines in ECU
Austria	7,933	265	11.2	30
Belgium	10.01	247	22.3	55
Finland	5,066	160	17.9	29
France	57,66	316	34.2	108
Germany	80,954	307	35.0	107
Ireland	3,563	82	22.0	18
Italy	57,057	184	17.8	33
Netherlands	15,29	200	13.2	26
Norway	4,312	130	13.2	15
Portugal	9,876	110	15.0	17
Spain	39,083	160	14.7	24
Sweden	8,745	185	10.3	19
Switzerland	6,989	311	36.3	113
UK	58,191	129	27.5	35

No data are available of Denmark and Greece.

3. Price formation and value-added tax (as per May 1996).

Base point: 100	Wholesale price (%)	Pharmacy price (%)	VAT (%)	Pharmacy price excl. VAT	Pharmacy price incl. VAT
Austria	16,60	33,30	20	180	216
Austria – most expensive products	9,2	11	20	123,8	148,5
Belgium	nofix 13,0	nofix 31,0	6	nofix	nofix
Finland	5	28	12	146,2	175
France	14,80	36,20	2,1; 5,5	184,1	194,2
Germany	17,40	40,50	15	203,3	233,8
Germany – most expensive products	10,80	23,2	15	145,6	167,4
Ireland	13	25	21 nonoral	153	185,1
Italy	17,80	35,70	4	189,2	196,7
Netherlands	18	33	6	182,1	193
Norway	6	20-5 NOK	23	160,1	196,6
Portugal	nofix		5		
Spain	12	29,90	4	162	168,5
Sweden	4,50	17,70	0 pm. 25 npm	133,4	133,4-166,8
Switzerland	15	35,40	2	182,1	185,8
U K	nofix		0	200	200

1. Indication: harmless, generally known disturbances of health or feelings of ill-health.
2. Self-medication is clearly only appropriate for a limited period of time; accordingly, OTC products should only be dispensed in small packs, taking into account the use by a smaller group of persons (f.i. family).
3. OTC medicinal products must have minimal potential for side-effects and/or interaction and clearly must not be teratogenic.
4. The benefit for patients must be proved.
5. Self-medication and guided, pharmacist-assisted self-medication for pregnant and nursing women, babies and infants requires a very high degree of caution. In general, a confirmed medical diagnosis is a prerequisite of self-medication within this group.
6. Certain indications shall not be treated by way of self-medication and guided, pharmacist-assisted self-medication: f.i. diabetes, asthma, tumoral diseases, sexually transmitted diseases, infectious diseases and metabolic illnesses.
7. The package leaflet must contain adequate indications on necessary medical consultation.
8. The following conditions are by no means eligible for the purposes of self-medication and guided, pharmacist-assisted self-medication:
   - symptoms lasting more than a few days (3-5 days)
   - symptoms which recur or deteriorate
   - intense pains
   - unsuccessful prior treatment
   - suspected negative reactions
   - serious symptoms and siges
   - conditions and diseases appearing in combination with psychiatric problems e.g. anxiety, agitation, excitability, depression, lethargy etc.
9. Antibiotics (even for topical use) must be excluded. Selfmedication and/or guided-pharmacist-assisted self medication is inappropriate where bacterial infection is involved.

Indications

The following indications are some examples which are eligible for the purposes of self medication and guided, pharmacist-assisted self medication, the criteria mentioned above, however, must govern self-medication:

1. Colds, influenza, paragrippal infections.
2. Cough.
3. Sore throat and pharyngitis.
4. Allergic rhinitis (in the case of confirmed diagnosis).
5. Stomatitis (after exclusion of serious diseases as f.i. immunodeficiency).
6. Heart bum (in the case of a confirmed diagnosis).
7. Vomiting and diarrhea.
8. Haemorrhoids (in the case of confirmed diagnosis).
9. Sunburn.
10. Warts.
11. Headaches.
12. Muscular pain.

13. Vitamin deficiency – with the exception of the vitamines A, D, K.

Dr *Reiner Brettenthaler*
8.11.1996
Austrian Delegation with the CP
Trad. Mag. P.

I would like to express my thanks to Dr. Otto Pjeta (Austrian Delegation), Dr. Felix Wallner LL.D. (Austrian Delegation), Prof. Detillieux (French Delegation), Dr. MacNamara (UEMO, Ireland), Dr. Lemy (Belgium Mag. Holler (Austrian Medical Association), Dr. H. Hammer (Austrian Medical Association) for their kind assistance.

I would like to thank in particular the CP Office headed by Mrs. Lale.

12.19 Motion concerning Diagnostic Related Groups

Adopted, April 1996 (CP 96/069)

The introduction of classification systems for Diagnostic Related Groups (DRG) being used to regulate the payment of hospitals services gravely concerns the CP because of the consequences which can arise.

The DRG system ist originally a tool of tarification. It cannot become a criterion to judge of the opportunity and of the quality of health care.

The CP states that the application of DRGs should not limit the freedom and the autonomy of the doctor in the choice of the means of diagnostic and therapy and that it should not generate negative consequences on the quality of health care.

12.20 CP Motion on Blood Alcohol Levels and Road Safety

Adopted at Athens, November 1997
(CP 97/091 Final)

The Standing Committee of European Doctors (CP) supports moves to reduce road accidents and increase driving safety across the European Union by reducing the permitted blood alcohol concentration in drivers to a maximum of 50 mg per 100 ml. We call on the Council of Ministers and the European Commission to introduce legislation to this effect, and offer our full support in bringing this about.

Alcohol and driving do not mix.

12.21 Motion on CFK-free aerosol

Adopted, November 1996
(CP 96/148 Rev. 1)

The Heads of Delegation of the Standing Committee of European Doctors, meeting in Athens, on November 1996, and acting at the suggestion of the CP Subcommittees in Preventive Medicine and Environment and Organisation of Health Care, Social Security, Health Economics and Pharmaceutical Industries.

Noting that CFK-free aerosols are now admitted and available in the European Union,

Recommend that Physicians of the European Union should prescribe, if medically possible, medication containing a propellant that has demonstrated not to be harmful to the Environment.

Urge the pharmaceutical Industry to banish CFK's and to replace it by propellant that have demonstrated not to be harmful to the Environment.

12.22 European Health Card

(CP 98/021 Final – available on CP website or from Secretariat)

12.23 Generics, Substitution

(CP 1999/043 – available on CP website or from Secretariat)

12.24 Conditions of Practice for Doctors Caring for Drug Addicts

(CP 1999/002 Final – available on CP website or from Secretariat)

12.25 Motion on the proposal for a directive on advertising and sponsorship of tobacco products

(CP 98/053)

The Standing Committee of European Doctors during thc meeting of its Board on 4 April 1998, decided to strongly support the common position adopted by the Council of Ministers with a view to adopt a directive on advertising and sponsorship of tobacco products as well as the recommendation of Pr Cabrol, rapporteur from the European Parliament on this legislative proposal.

Moreover, on this occasion,the Standing Committee of European Doctors underlined the fact that doctors should show the example and stop smoking.