minimum standards already laid down for the mutual recognition of qualifications in medicine and the coordinating provisions governing freedom of movement of doctors within the Member States.

Free movement must not lead to any elimination in the Member States or regulations and restrictions concerning conditions of access to the profession, ethical practice, registration and the monitoring and supervision of the profession and its practice, such as:

1. The rules of healing and of protection of public health.
2. The rules of registration of doctors.
3. The rules governing medical practice, of sanctions and the effects of sanction.
4. The rules of medical ethics applicable to providers of services.

CP proposal to the EEC Commission on GATT

Adopted by the Plenary Assembly Barcelona, 5th-6th October 1990 (CP 90/193 Final)

La proposition pour un "multilateral framework for trade in services" du 12 Septembre 1990 préoccupe le Comité Permanent profondement. Nous sommes d'avis que l'integration des médecins dans un tel accord mettra en danger le système sanitaire européen. Le Comité Permanent demande avec insistence à la Commission de contribuer dans le contexte de l'Uruguay Round à ce que les professions de santé fassent l'objet de dispositions restrictives. Il est au moins nécessaire que les partenaires de l'accord acceptent, comme l'avaient fait les Etats membres de la CE, de faire dépendre l'accès de médecins de pays tiers dans l'espace communautaire, des conditions déjà exigées pour la libre circulation des médecins et des professionnels de santé à l'intérieur de la Communauté.

Cela étant le problème du nombre croissant de médecins et les conséquences négatives qui en résultent pour le système sanitaire et le système de la Securité Sociale dans les pays membres sont connus de la Commission.

Les associations européennes des médecins et le Comité Permanent de Médecins de la CE ont aussi attire l'attention sur ce fait.

Le problème serait évidement aggravé par un accés non contrôlé des médecins de pays tièrs.

En conclusion les médecins des pays autres que ceux de la CE, ne doivent pouvoir prester leurs services dans un pays de la CE que s'il est possible de les soumettre aux mêmes exigeances de formation et qualification que celles applicables aux médecins d'un Etat membre de la CE desireux de circuler ou de s'installer dans l'espace communautaire. Il doit en aller de même, bien entendu, des règles professionnelles et déontologiques du pays hôte.

12.10 On freedom of prescription

Opinion of the Standing Committee of Doctors of the EC about the discussion document concerning the elaboration of the proposal referred to in article 9 of directive 89/105/CEE

1. The EC Doctors stress the need of freedom to prescribe the medicine most appropriate in each case to the patient.
   - The doctor is the only one who can decide whether the patient needs some specific medicine or whether some equivalent medicine can be administered to him.
2. The Standing Commitee favours transparency of measures governing pricing of medicinal products, but it questions the efficiency of harmonization, which it furthermore sees very difficult to perform.
3. The Standing Committee thinks it would be interesting to adopt a basic list of therapeutical groups which must compulsorily be included in the Social Security, which member States can add to according to their personal criteria.
   - The reimbursement rate should, in principle, be left to the criterion of member States and if there is a basic list, a minimum reimbursement rate could be fixed.
4. The medical profession supports the concept of original pack dispensing and hopes that the Commission of the European Community will aim to ensure that all medicines are prepackaged following some guidelines to standardize pack sizes.
5. The medical profession strongly supports the concept of a common identification system for medicines, which is a logical extension of proposals for the future authorization system of medicines in the EC. This can only be to the benefit of the industry, the prescriber and the patient.

Motion

The CP wishes to point out that notwithstanding economic and financial criterions, the freedom of prescribing medicinal products should always be ensured; therefore pharmacists must be forbidden to introduce any change whatsoever to a prescription of medicinal products unless specific authorization has been given by the prescribing doctor.

12.11 Report on authorization proposal III/3603-1/90

Santiago de Compostela, 1990 (CP 90/101)

Proposal for a Council Regulation laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary

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