– expresses the firm wish that the Community Action Plans aiming at reducing the mortality rate due to cancer can be continued beyond 1994.

At a time when the image of Europe needs to be improved in the eyes of its citizens, the "Europe against Cancer" Programme, through its pragmatic and educational approach, sets an example.

5.9 Violaki Report on Ageing and Illness

(CP96/145 Final)

This report is available in full on the CP website: www.cpme.be

6. Computerization of medical data

6.1 See item 2.13

6.2 Statement on proposed council directive on the protection of individuals with regard to the processing of personal data

(CP 93/055 Final)

Statement of the Standing Committee of Doctors of the EC on the Amended proposal for a Council pirective on the protection of individuals with regard to the processing of personal data and on the free movement of such data (92lC 311/04 and COM(92) 422 final – SYN 287)

The Standing Committee of Doctors of the EC (Comité Permanent) makes the following statement on the amended proposal:

Preamble

I.

With this proposal, the Commission is aiming at establishing Community legislation governing data protection in all Member States of the E.C.

Art. 1 of the proposed Directive is designed to oblige the Member States to adapt their national legislation to the provisions of the Directive. Although the scope of the Directive is not to apply to the processing of data in the course of an activity which falls outside the scope of Community law (Art. 3, Para. 2. Item 1), it is obvious, even in cases of purely national application, that the level of protection of the Directive and that of national data protection legislation cannot differ from one another. Thus, European data protection legislation will also be a determining factor for national legislation in all sectors.

II.

According to Art. 3, Para. 1, the scope of the Directive is "the processing of personal data wholly or partly by automatic means, and {to} the processing otherwise than by automatic means of personal data which forms part of a file or is intended to form part of a file". Thus, medical documentation containing health data and organised records concerning the medical data of patients also generally fall within the scope of the Directive if they are personal. For this reason, the Standing Committee of Doctors of the E.C. deems it necessary to issue a statement concerning the amended proposal.

III.

The Standing Committee of Doctors of the E.C. agrees with the EC Commission that data protection legislation in the internal market needs to be harmonized in the interests of a uniform level of protection. This is also welcome in view of the fact that data protection legislation is an expression and form of the basic rights to personal privacy, as they are recognized in the constitutions of the Member States and in the European Convention on Human Rights (cf. Art. 8). The EC Commission also referred to this subject in its Recommendation of 29 July 1981 concerning a Convention of the Council of Europe on the protection of human rights in the automatic processing of personal data (81/679/EEG) {EC Official Journal No. D 246, dated 29.08.1981, page 31}:

> "Data protection is a necessary part of the protection of the individual. It has the nature of a basic right. It is desirable that a uniform level of data protection be established among the Member States of the European Community. This would be an important contribution to the realisation of civil rights on the European level."

Reference should also be made to the Recommendation of the European Council : "Recommandation du Comité des Ministres aux Etats Membres relatives à la réglementation applicable aux banques de données médicales automatisées" (Recommendation No. R [81] 1), which develops principles for the regulation of data protection in the use of medical databases which take into account the application of the principles of medical confidentiality.

However, it is even more important that European Law establish *clear regulations* and *balanced solutions* for the conflict between the interests of data processing and the right to personal privacy.

IV.

The Commission's Proposal combines various types of protection principle (processing bans on the one hand, supervisory rights of authorities, and reporting and registration obligations on the other) contained in the data protection legislation of the Member

States of the European Community. As a result, the protection principles are combined in favour of the protection of privacy, but partially to the detriment of the free movement of information and professional practice.

It remains to be stated that the Directives, through this concept, go above and beyond the regulations of the European Council Conventions mentioned above.

V.

The proposals of the Commission do not consider the members of those professional groups which must maintain confidentiality in the processing of personal data. This also applies to doctors, in particular. Patient data and health information fall under the special protection of medical confidentiality in all Member States of the European Community. As an expression of the concurrent opinion of European doctors, the "Principles of Medical Ethics", which were adopted on 6 January 1987 by the Conférence Internationale des Ordres et des organismes d'attributions similaires (CIO), and also approvingly acknowledged by the Standing Committee of Doctors of the EC (Document CP 87/4), regulate the following in reference to the obligation to maintain professional confidentiality:

> "The doctor is necessarily the patient's confidant. He must guarantee to him complete confidentiality of all the information which he may have acquired and of the investigations which he may have undertaken in the course of his contacts with him. The death of a patient does not absolve a doctor from the rule of professional secrecy. A doctor must respect the privacy of his patients and take all steps necessary to prevent the disclosure of anything which he may have learned in the course of his professional practice. Where national law provides for exceptions to the principles of confidentiality, the doctor should be able to consult in advance the Medical Council or similar professional organisation.

Doctors may not collaborate in the establishment of electronic medical data banks which could imperil or diminish the right of the patient to the safety protected confidentiality of his privacy. A nominated doctor should be responsible for ethical surveillance in the case of every computerised medical data bank. Medical data banks must have no links with other data banks."

The principles of medical confidentiality must also be taken into consideration within the framework of the aforementioned EC Directive on data protection in two ways:

1. Insofar as more stringent requirements and more extensive protection of patient data result from medical confidentiality in a Member State, then this protection may not be infringed upon by European data protection legislation.
2. The proposed solutions of the data protection Directives, which concern the obligation to inform and the obligation to inform of disclosure in particular, must consider that patient data are protected in a special way by professional confidentiality, meaning that no additional "bureaucratic" regulations – which make the availment of medical treatment and the course thereof more difficult – should be included.

Proposals
VI.

The following remarks pertain to the individual proposed regulation :

1. The term "file" (Art. 2, Letter c; Art. 3, Para. 1) lacks clarity in its definition. This definition of file would de facto affect the doctors "documentation, which they keep on their patients and their patients" health data, particularly when the doctors use automatic data processing (personal computers), as is increasingly common. Important consequences of the extensive applicability of the Directive's regulations to professional medical practice thus result.
   We suggest that the followin point of information be included in the Directive after the definition of the file: all data collected by a doctor shall not be considered as a file for the purpose of this Directive nor will this personal data collected by a doctor be accessible or transmissible to third parties and it shall be covered by professional secrecy.
2. Art. 7 offers only an inadequate definition of "consent" for professional medical practice, because the data which are the object of medical practice generally come under Art. 8. Additionally, in his medical work, the doctor also records data of "third parties" – i.e. not just on the patient himself – (e.g. in psychotherapy treatment or family case histories, etc.). Consent is particularly lacking in this case (Art. 7, letter a), so that the statutory definition of Art. 7, under which the common procedural method for medical treatment can be classified, is questionable. It must also be pointed out here that the special position of doctors – and also of other professions, e.g. lawyer – is characterised in that the collection of data is subject to professional confidentiality. *This causes a majors problem unless the information on family case histories concerning third parties remains personal to the doctor in accordance with the point of information concerning the definition of the file.*
3. Art. 8 places "data concerning health or sexual life" under special protection. This is generally justified. The proposed Directive forbids the processing of this data and permits it in exceptional cases only. In reference to professional medical practice, this is again too rigid, because, according to Art.

2, Letter b, the term "data processing" also refers to the collection of data (Art. 11). This means that Art. 8 would be applicable to the collection of medical data by the doctor in the doctor-patient relationship. Due to the fact that Art. 8, Para. 2, Letter a, requires that the affected person – i.e. the patient – give his written consent to data processing, i.e. to the collection as well as to other use by the doctor, the regular and typical procedures in professional medical practice are hindered by such a procedure. Art. 8, Para. 3, does allow the Member States to lay down exemptions from the provisions in Art. 8, Para. 1 (and thus from the written form requirement also), in national legislative provisions on the grounds of important public interests. The reasons behind the proposed Directive (No. 17) indicate that the medical profession was also apparently considered in this context:

> "... furthermore, provisions for exceptions, defining the framework and the corresponding security measures for the processing of these types of data and based on legislation or approval from the supervisory authorities, may be included on the grounds of important public interest, particularly *for the medical profession. ...*"

For Article 8 to guarantee medical confidentiality it would be necessary to include in articular under items 5 and 3 that the provisions must respect medical confidentiality.

4. The obligation to inform the data subject during data collection, pursuant to Art. 11, is likewise too rigid and too complicated for professional medical practice. The doctor-patient contact is not primarily geared to the acquisition of information; rather, health data is "collected", so that the doctor can fulfil his duty to treat the patient. *This provision does not apply to the treatment of data that were collected as a dossier by the doctor but only to files that are connected or can be connected.*
5. The obligation to inform of disclosure and the right to access in Arts 12 and 13 must be rejected in the context of professional medical practice.
   a) The global definition of the data to which the right to access pursuant to Art. 13 refers, becomes questionable if all of a doctor's records would have to be made available to the patient. Various medical treatment records, which could be considered to be data on the patient, are records based on medical evaluations and assessments, not on objectifiable findings (e.g. X-rays or laboratory results). Such non-objectified records do not have to be made accessible to the patient; a right to access does not exit. *Therefore, the Directive should include the elucidation that within the framework of the doctors' obligation to allow access the Member States must ensure that only data containing objectifiable findings must be made accessible to the patient.*
   b) *The concept of doctor refered to in Article 13 (1) must be further detailed in order to relate to the treating doctor only with the additional remark that communication amongst practitioners is regulated by rofessional ethics.*
6. The obligation according Art. 18, to notify a supervisory authority when processing data, is not applicable to medical activity. Therefore, Art. 19 must make it clear that the supervisory authority need not be notified when processing is carried out on the basis of a professional activity whose results are subject to professional confidentiality.
   It was considered that the concept in Art 18 and the provisions under Art 17 do in fact entail acceptable protection for the citizen.
7. Art. 30 (Supervisory authority) allows the supervisory authorities to demand access to documents which are the object of medical confidentiality. This must be rejected. The purpose of data protection controls does not justify the infringement of medical confidentiality.
   Concerning data of a medical nature supervision can never lead to affect medical confidentiality.
8. Art. 29 states that the Commission may publish "codes of conduct for the purposes of information". The Standing Committee of Doctors of the EC points out that "codes of conduct governing information" may only be a matter for the deontological Codices, insofar as they affect professional medical practice. Therefore, the Standing Committee insists that such additional measures, which are unnecessary in the field of professional medical practice, must at least be compatible in all respects with rules set down in the professional codes of the individual countries, and that they agree with the principles of medical ethics of the Conférence Internationale des Ordres (CIO) of 1987, as quoted above under III.
   The Standing Committee of Doctors of the EC considers that Article 29 should not be included in the Directive.