NOTE

from: Presidency

Subject: Use of personal-data files in medical research (Personal-record research)

The Presidency has submitted the note on the above topic annexed hereto in preparation for the meeting of the Council and the Ministers for Health meeting within the Council on 27 May 1993.
The Presidency wishes by means of this note to draw attention to the proposal for a Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data (COM(92) 422 final SYN 287). The proposed Directive affects the area of health and has thus been placed on the agenda with a view to discussion of the consequences it may have for epidemiological research.

The proposal for a Directive lays down the principles to be followed in national legislation in order to ensure a uniform level of protection in relation to the processing and exchange of personal data.

The aim of the proposed Directive is to secure a high level of protection with regard to the processing of data on individuals.

The following provisions will be of particular significance for personal-record research in the health field:

- The proposal covers all processing of personal data. This means inter alia the collection, recording, alteration or adaptation and disclosure of personal data.

- Personal data may be used only in accordance with the purpose for which they were collected and be processed only if certain detailed criteria are met.

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(1) Personal-record research is research based on data gathered from personal records. This means that the researcher does not base his data on direct personal contact with the person or object from which the data derive.
In certain cases the express and written consent of the individual is required for the collection and disclosure of sensitive data.

Where personal data are collected and disclosed, there is an extensive obligation to inform the individual.

It is proposed that the following questions be discussed:

1. What consequences will the proposal for a Directive have for epidemiological research and personal record research in the health sector?

2. Is there a risk that the provisions of the Directive might hamper the discovery of unexpected and hitherto unknown connections between, say, the causes and effects of health-dangering conditions?

3. What consequences will the proposed Directive have for the efforts to find the causes of an illness's occurrence, also as regards health promotion and prevention policy?

4. Will there be a need for special exemptions for personal-record research in the health field?

   If so, could the level of security be maintained if individual research projects were given prior scientific and ethical approval by an independent national authority?

The Presidency hopes that it will be possible, on the basis of the Health Ministers' debate, to draw some conclusions which can be fed into the Council's further discussions of the proposal for a Directive.