NOTE

from : the UK Delegation

to : the Working Party on Health Questions

n° Cion Prop. : 9400/92 ECO 221 [COM(92) 422 final SYN 287]

Subject : Draft Directive on the protection of individuals with regard to the processing of personal data

Delegations will find attached a note from the UK Delegation, previously presented at the meeting of 15 September 1994, for further discussion within the Working Party and which develops its concerns that medical research could be adversely affected by the proposed Directive.
NOTE TO THE HEALTH WORKING GROUP

The attached paper is from the UK delegation to the Health Working Group on the subject of the Draft 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).

This draft Directive has been discussed in the past by the Health Working Group, especially regarding concerns that medical research could be adversely affected by the Directive. The Economic Questions Working Group is currently considering the issue of research and statistical analysis, but so far they have not found a solution which would alleviate concerns regarding medical research. The UK proposes that the Article on Research which was proposed by the Belgian Presidency should be reconsidered.

The UK hopes that:

- Health Working Group delegates can consider this paper at the meeting on 15 September, consult with their ministries, and return to the subject at the meeting on 28 September, when a discussion can take place;

- Following this discussion, the Chairman of the Health Working Group can write to the Chairman of the Economic Questions Working Group, pointing out the Health Group's concerns and summarising the discussion which took place.

Since it is the Presidency's intention to discuss this Directive at the Internal Market Council of 31 October, it is necessary to act quickly. However, the issue of research and statistical analysis is one of the main questions still to be resolved in the Directive, so there is a good opportunity for the Health Group to have some influence.
DRAFT DIRECTIVE ON THE PROTECTION OF INDIVIDUALS WITH REGARD TO THE PROCESSING OF PERSONAL DATA

Implications for health research

Note to the Health Working Group from the UK Delegation

1. The UK Health Departments have been considering the draft 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 Directive seeks to secure a comparable high level of protection across the EC to facilitate the free movement of data.

2. The UK firmly supports the need to protect individuals whose data are processed. With the processing of personal health data, there is a need to strike the right balance between the interests of the individual and the interests of the wider community. Personal health data are protected by existing national law and by health professionals' ethical obligations. The Economic Questions Working Group has already agreed that there should be a special provision in the Directive (Article 8.2b) to ensure that the Directive does not harm the processing of personal health data which is necessary for the proper functioning of health care services. This is a very welcome step.

3. However, the UK still remains concerned about the potential impact of the Directive on the use of health data for statistics and medical research. As at present drafted, the Directive could not only harm essential research activities carried out in member states, but could also conflict with the Community's own
aims in the health field, such as the setting up of an epidemiological network. As the EC Treaty specifies that "health protection requirements shall be a constituent part of the Community's other policies", it is important that this Directive does not hinder the proper carrying out of medical research which can lead to better understanding of diseases and their treatment.

4. The following are the provisions in the Directive which cause concern:

Explicit consent must be obtained from each patient whose records are used for research or processed to prepare statistics (Article 8). Some studies may involve analysis of thousands of old records. It would be impossible to obtain explicit consent from everyone whose record was used. If consent is withheld or cannot be obtained, research results would be invalidated, with serious consequences for public health and the development of more effective health services. Statistics would be incomplete.

Data may be kept in an identifiable form for no longer than is necessary for the purpose for which they were collected (Article 6(e)). It is important to retain records in an identifiable form so that data may be linked for research needs, perhaps 20, 30 or 40 years after the data are first collected. For example, research into unexpected side effects from particular drugs.

Data must be collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. This would appear to rule out research or statistical analysis on data collected for health care purposes unless the potential use of those records for research purposes
was made explicit at the outset. However, it is often impossible to predict in advance which records may be needed for research or statistics. For example, research into cancer occurring near industrial sites may require the examination of the health records of employees, schoolchildren or the local population, which could not have been foreseen at the time the data in those health records were collected.

5. The Directive does not contain a provision for Member States to lay down exemptions, on grounds of important public interest, from the prohibition on processing health data other than for the specific purposes identified in Article 8.2b. However the UK believes that it should not be necessary to provide exemptions for research and statistical analysis, which are clearly vital to the public interest. The needs of health research and statistics should be provided for in the Directive itself.

6. It is of course important to protect personal data which are used for statistical analysis or research. Personal data should only be processed for research projects which are properly authorised by member states, and only authorised researchers should be allowed access to the data. The confidentiality and security measures set out in the Directive must apply to data processed for research in the same way as to other types of processing. Published research or statistics must not identify individuals.

7. The Economic Questions Working Group is currently attempting to find agreement on the question of research and statistical analysis, and we hope that it will take the above issues into account. The best first step would be to reconsider the Article on research proposed by the Belgian Presidency (attached in annex), as it goes a long way towards meeting the concerns identified.
ANNEX

(BELGIAN) PRESIDENCY PROPOSAL

Scientific and statistical research
(Article 9a)

1. Processing of personal data may be carried out, even without the consent of the data subject and even where the data referred to in Article 8 are involved, if its exclusive objective is scientific or statistical research and provided the following conditions are met:

   - the research is in pursuit of an aim of general interest;
   - the research could not be completed unless the data kept their personal nature at some stages of the processing;
   - the research findings will not be presented in a form enabling the data subjects to be identified, except in the event of authorization by the supervisory authority referred to in Article 30;
   - the controller must, during processing, substitute an identification number specific to the processing for any item likely to allow direct identification of the data subject; the table of concordance between the numbers and the elements enabling the data subject to be identified must not be consultable under the same procedure as the data involved in processing;
   - the controller must, prior to the commencement of processing, make to the supervisory authority referred to in Article 30 a statement containing the information referred to in Article 18 and the maximum period for which the data will be kept or the absence of such period.

(1) Cf ADD 3 of document 7695/93 ECO 173.
2. The controller of processing for research purposes may obtain communication of data deriving from other processing operations, even where the latter originally pursued a different objective, provided the conditions laid down in paragraphs 1 and 5 are fulfilled.

3. Where processing is authorized on the basis of paragraphs 1 and 5, its controller shall be exempt from the obligation to inform the data subject. Controllers who communicate data to the controller of such processing shall likewise be exempt from the obligation to inform the data subject of such communication.

4. Data may be kept for an unlimited period in a processing operation which complies with the conditions laid down in paragraphs 1 and 5 where its objective is the provision of data for scientific or statistical research processing operations.

5. Member States may, after consulting the supervisory authority, prohibit certain specific processing operations for research purposes or the communication of personal data for the purposes of such processing operations or impose additional special conditions.