COMMISSION OF THE EUROPEAN COMMUNITIES

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Report

concerning a demonstration project with a view to introducing a Community system of information on accidents involving consumer products

EHLASS SYSTEM

(European Home and Leisure Accident Survillance System)

(presented by the Commission)

Com 827

REPORT TO THE COUNCIL
ACCORDING TO ARTICLE 3 OF THE COUNCIL DECISION 86/138/EEC
CONCERNING A DEMONSTRATION PROJECT WITH A VIEW TO INTRODUCING
A COMMUNITY SYSTEM OF INFORMATION ON ACCIDENTS
INVOLVING CONSUMER PRODUCTS

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1. Background: Origin and role of the system

The Commission began to consider a monitoring system for home and leisure accidents eleven years ago, but it was in July 1981 that the Council adopted a proposal to establish a pilot project. That started in January 1982 and continued for 30 months. The conclusion drawn from the pilot project was that it would be feasible to set up a Community system to gather and record the necessary information.

In April 1986 the Council approved the establishment of a demonstration project of five years to test whether practical operational procedures could be developed before a decision to set up a permanent system might be taken.

The demonstration project, called the EHLASS system (European home and leisure accident surveillance system), was given the role of identifying the causes, circumstances, nature and consequences of these accidents as well as the consumer products and features involved. The information provided was to be representative both of the situation in each Member State and of the European Community as a whole, so that decisions could be taken based on uniform accurate data to improve the safety and quality of consumer products. By having available accurate data it was hoped that consumer policy efforts could be concentrated on the most important problems and that the best possible value might be secured from the resources and effort committed.

It was clear that the system would target casualty units in hospitals throughout the Member States where all accidents would be recorded in a standard manner and analysed to produce the required information.

The decision envisaged, in addition, that detailed information would be gathered from a variety of other sources so that the hospital data could be put into context and cross checked.

2. Implementation of the decision

In giving effect to the Council decision the Commission set about establishing the necessary hospital network.

a) The functioning of the project

In order to establish the system a three tier organistion was developed.

1) The hospitals

Since the decision in April 1986, hospitals from the Member States have been introduced into the system. By March 1987 eleven Member States had put hospitals into operation and this has built up until, at present, 58 are reporting. The original target of 90 hospitals was reduced to 77 with Germany opting to use household survey as the source of its information.
The hospitals are required to collect the necessary details on all the accidents received into their casualty units and to send on this information to the appropriate ministry in their own state.

The work of collecting and coding the information is carried out by medical or paramedical staff in the hospital or in some instances by external personnel especially recruited for that purpose.

A fee of 28,000 ECU is paid to each hospital each year together with a "starting up" payment of 5,000 ECU.

This has been new work in most hospitals and it has taken considerable efforts to ensure its proper execution. The heavy workload involved in establishing a common methodology in all hospitals has meant that the task of developing the other sources of information required by the decision remains to be implemented.

2) The ministries or competent services

These are responsible for receiving the data from their hospitals and verifying it. Having done so the information is sent to the Commission.

The ministry involved varies, though health services predominate. It should be understood that the decision to set up the system was taken by consumer ministries even though the implementation was to become the responsibility of others in the Member States.

The ministry negotiates the hospital contracts and is responsible for the execution of these and the personnel involved. They also conclude the contract with the Commission and are responsible for its operation, budgetary control and accounting.

3) The Comission

Overall control and management of the working of the system is the Commission's role. It must plan, develop and coordinate all the activities.
It must carry out final technical verification of the data before storing it at the "centre de calcul". It is also responsible for analysing and evaluating this information

To link these three levels a number of groups have been established.

1. The consultative committee on accidents required by the Council decision has two representatives from each Member State. Its role has been to give advice on all aspects of the management, interpretation and use of the information.

2. The project leaders group made up of 12 members whose principle role has been the day to day management of the system in the Member States.

3. The nomenclature/classification group consisting of experts charged with harmonising the coding methods and dealing with the multitude of technical questions which frequently arise.

b) The difficulties met

The development of the basic system has been much more difficult than anticipated. Only two Member States, the United Kingdom and the Netherlands had previously done this work. Everything had to begin for the first time in the other States and it is not surprising that this task was difficult.

At Member States ministry level, much negotiation was necessary to get the relationship into working order because a variety of functions needed to be synchronised for the first time.

These difficulties impacted severely on the Commission whose resources were stretched to the limit.
The combination of these factors considerably slowed down the setting up process and produced quite serious administrative problems.

In order to keep control of a mounting volume of management problems, the Commission this year had to stop adding new hospitals to the network and seek to maintain what had been developed, until it could consider what arrangement should be made to enable the necessary completion of the demonstration project.

As a result of this consideration it has become clear that unless changes are made in the management and approach to the decision, the project would fail in its goal. With the right changes the project can be successfully completed.

The experience gained so far and a preliminary examination of the task involved in getting together the complementary information from poison control centres, family doctors, death certificates, five brigades insurance bodies and companies, consumer associations, manufacturers and associations of manufacturers and research bodies or scientific associations, which is necessary if the hospital system is to be relevent, shows that this work is of major proportions. Because of the complexity of gathering this information particular attention must be paid to the need to secure reliable information which could be taken as representative. Because of differing attitudes and habits in relation to hospitalisation between Member States, as well as differing structures in the various medical systems, great care must be given to getting representativity in the information produced. Alternative approaches to complementary information must be contemplated so that the picture which emerges from the hospitals can be measured against accurate, quantified data. Only by such a route can the project be successful.

c) <u>The value of what has been done</u>

By establishing the hospital network to its present level a valuable common system of gathering and recording information has been developed.

This is of real value in the hospitals, to Member States authorities and to the Community.

The practical management and operational skills required are known and a corps of personnel with first hand knowledge has been developed.

A more realistic evaluation of the remaining tasks can now be made and the changes necessary, as well as the resources, can be applied.

There is an increased awareness at many levels as to the importance of consumer safety and the need for accurate assessment of the risks involved for people in everyday life.

New levels of cooperation between hospitals, ministries and the Commission have been developed and can be further used in the years ahead.

By March 1988, 235,000 cases had been notified and this has increased by about 250,000 cases in the meantime. While the information in these cases is not representative, preliminary analyses can be used to assist in improving future work on the project.

3. Action necessary

In order to put the project on a sound footing with a real prospect of being successfully completed, it will be necessary to make some changes so that the final two years of the project can be undertaken.

These changes are at two levels

1. In Member States
2. At Commission level.

1. There is a need to decentralise some aspects the operation of the project to the Member States while maintaining a common methodology and coordination at Community level.
   This would involve the Member States taking over responsibility not only for collecting the required information from their own hospitals but also for its validation, analysis and evaluation. By creating a national data bank of the information the Member State would report at intervals to the Commission on the accident information in its jurisdiction.
   The Member State would also be required to exercise full and proper financial control for its operation and would ensure the necessary continuity of funding to its hospitals.

2. Within the Commission a reorganisation of work would also be made. In order to better manage the project and to bring essential expertise in statistics into play, the Statistical Office of the European Communities - Eurostat would become responsible for the overall statistical aspects of the project. These include the improvement of the system by adding different surveillance componants as well as different inputs of statistical methodology relating to the planning and coordination of data gathering, validation, centralised data processing and analysis. DG XI would be responsible for the analysis of the results and follow-up studies as well as the necessary actions for policy making.

FINANCIAL SHEET

1. By its decision 86/138 the Council will decide the level of financing for the final two years of the project when they have considered this report. The exact provisions cannot be calculated until the Council accepts or rejects the necessary management changes.

2. The Budget line concerned is No. 6672 - Actions to monitor the safety of Consumer Products.

3. a) The amount on this line for 1989 is 1.5 MECU - on the proposition of Parliament

   b) The amount required to provide for the final 2 years of the decision will be 12 MECU divided equally between the two years.
   1990 - 6 M
   1991 - 6 M.

   These amounts will have to be provided in the appropriate budget exercises.

4. There are no other financial implications in this decision.

5. The basis of the calculation each year is

5,000 ECU starting fee per hospital	
28,000 ECU per hospital per year	
Plus technical and administrative support costs	3.5 M per year
Development of other sources of information	2.5 M per year
Total	6.0 M per year