COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 07.03.1996
COM(96) 78 final

96/0052 (COD)

COMMISSION COMMUNICATION

concerning communicable disease surveillance networks in the European Community

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Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DECISION

creating a network for the epidemiological surveillance and control of communicable diseases in the European Community

(presented by the Commission)

COMMISSION COMMUNICATION

CONCERNING COMMUNICABLE DISEASE

SURVEILLANCE NETWORKS

IN THE EUROPEAN COMMUNITY

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I. INTRODUCTION:

The outbreak of disease due to the Ebola virus in Zaire in 1995, and before that, the epidemic of plague in India in 1994 have focused public attention on the need to take action against infectious diseases. It is a long-established fact that infectious diseases caused by various microbial agents tend to spread through populations irrespective of borders, essentially as a result of the movements of people and, to a lesser extent, the movement of goods and the consumption of water and foodstuffs. Additional factors include climatic change (global warming), increased resistance to antibiotics, the immunological status of individuals, and living conditions (socio-economic problems). The more that people travel about, and the further they travel, the greater the risks of these diseases spreading in the form of epidemics in unprotected populations and, as a corollary, the greater the health risks to populations. From Asian flu and cholera, to the HIV virus responsible for AIDS, examples abound both in history and in the present day. The agents responsible for communicable infectious diseases do not respect geographical frontiers. And despite substantial progress in the field of public health protection, the exposure of populations to the risk of contracting these diseases is increasing all the time.

In order to take the appropriate measures necessary to block the progress of these infectious diseases or prevent their appearance, national health authorities clearly need to have as precise a picture as possible of the epidemiological situation. This can only be achieved through the systematic collection, analysis and interpretation of data on these diseases, followed by their dissemination to those responsible for public health. Taken together these activities amount to epidemiological surveillance, an essentially practical process the aim of which is to produce information so that swift action can be taken. In the case of communicable diseases all the specialists agree that the cornerstone is surveillance, with the results being used in order to control and prevent these diseases. Epidemiological surveillance has proved its worth over and over again, the outlay required being amply repaid by the savings made in terms of disease avoidance.

In this general context, and since infectious diseases can spread easily in the European Union unless suitable measures are taken, it is obviously necessary to agree on the measures required for communicable disease surveillance. In this respect the Council and the Ministers for Health of the Member States meeting within the Council adopted on 13 November 1992 a Resolution, No. 92/C 326/1[1], inviting the Commission to report briefly on the existing arrangements established between the Member States or by the World Health Organisation (WHO) for the surveillance of communicable diseases, including food-borne diseases; to identify needs and shortcomings; and to put forward proposals for improvements. And the European Parliament, in its Resolution on public health policy after Maastricht[2], invited the Commission to set up a trans-frontier network to devise working definitions of notifiable diseases, to collect, update, analyze and disseminate Member State data on notifiable diseases and to work with national and

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1 OJ of 11.12.1992.

2 OJ No C 329, 6.12.1993, p. 375

international agencies on such matters. Additionally, in its Conclusions 94/C 15/04[3] of 13 December 1993 the Council requested the Commission to put forward proposals for the setting up of an epidemiological network in the Community. In its Communication COM(93) 559 of 24 November 1993 on the framework for action in the field of public health and its Communication COM(94) 413 of 9 November 1994 on AIDS and certain other communicable diseases, the Commission proposed specific Community measures in this respect, notably the creation and development of surveillance networks.

Without claiming to be exhaustive, this present Communication reviews the existing inter-institutional collaborative arrangements for the surveillance of communicable diseases in the European Union. After an explanation of the specific nature of the epidemiological surveillance of communicable diseases, there then follows an attempt to analyse the strengths and weaknesses of the present situation on the basis of certain objective criteria the aim of which is to meet the requirement for a high level of health protection within the European Community. Finally, proposals are put forward for short-and medium-term surveillance actions for the prevention and control of communicable diseases in Europe, with due regard to the fundamental principles which underpin the construction of Europe, namely subsidiarity and Community added value.

II. THE SPECIFIC NATURE OF THE EPIDEMIOLOGICAL SURVEILLANCE OF COMMUNICABLE DISEASES

Before setting out into this vast area it is essential, in order to avoid potential ambiguities and misunderstandings, to define the context and the concepts used and to outline the scope of the activities concerned. Such clarification is necessary because we need to have a clear and simple idea of what can be achieved by the Community in this area, and because both nationally and at international level there is a profusion of ongoing, but little known, initiatives and a confusing interlacing of different systems. And on top of all this, there is a specific quality to the surveillance of communicable diseases which needs to be appreciated from the European dimension.

1 DEFINITION OF SURVEILLANCE

For the surposes of the present communication and decision, epidemiological surveillance is defined as the ongoing systematic collection, analysis and interpretation of health data essential to the planning, implementation and evaluation of public health practice, closely integrated with the dissemination of these data to those who need to know for their work or for decision-making. Surveillance is therefore the observation of certain health phenomena affecting populations or groups of populations, through the collection of different types of data, so that swift action can be taken if necessary to correct these phenomena. In principle, such observation is an ongoing process, continuing for as long as the phenomena are liable to occur. It is therefore an active and dynamic process which, from the public health point of view, can only concern situations which are liable to evolve rapidly if no steps are taken to correct them.

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[3] OJ of 18.1.1994.

In the language of the epidemiologist, the term "surveillance" is in practice used to cover three types of case: communicable diseases; pollution-related health risks; and the safety of biological products intended for incorporation to humans. In this latter case the term "vigilance" is used, for example haemovigilance in the case of blood or blood products. Naturally, surveillance can also be carried out for non-communicable diseases such as cancers, cardiovascular diseases or mental diseases. But because these diseases develop slowly, and because of the nature of the information which needs to be collected on them, and because there is no call for the type of urgent action called for to block a rapidly spreading epidemic, the term "epidemiological observation" is used instead in these cases.

2 OBJECTIVES OF SURVEILLANCE

In the field of communicable diseases the objectives of epidemiological surveillance are, firstly, to ascertain the incidence (number of new cases occurring over say a month or a year) and the characteristics of a particular infectious disease, and to study its pattern of spread through time, space and social categories, so as to be able to take appropriate counter-measures. The second objective is to detect disease clusters or epidemics, or even abnormal health incidents, through a system of warning indicators, so that measures can be taken to break the specific transmission chain. And the third objective is to describe and measure the risk factors for contracting a communicable infection, so as to be able to select and implement the most appropriate preventive measures and recommendations.

These three interdependent objectives, taken together, constitute the basis for the activity referred to as the control of communicable diseases. It is not some form of checking up on individuals by State officials, as is sometimes erroneously feared, but merely a question of doing everything possible to stop the spread of a disease and re-establish normal conditions, i.e. a high level of health protection.

In addition to dealing with *de facto* situations, surveillance also serves as an instrument for evaluating preventive policies, particularly vaccination policy. Finally, surveillance can form the basis for hypotheses which can then be verified by means of epidemiological surveys.

3 PRINCIPLES AND METHODS OF SURVEILLANCE

Communicable diseases have certain basic characteristics which were described in an earlier Commission communication (COM(94) 413 of 9 November 1994, paragraphs 6 to 15), to which the reader is referred. To some extent these characteristics dictate the surveillance methods which need to be employed, since these diseases are not all alike, far from it.

In practice, and according to epidemiology specialists, surveillance can be carried out on the basis of clinical and/or biological criteria (the data being furnished for example by general practitioners and test laboratories) or on the basis of surveys (either exhaustive or sample, depending on the type of disease under investigation: rare and serious infectious diseases require exhaustive surveys, e.g. compulsory notifications or mortality

registers, whereas common and less serious infectious diseases require sample surveys, based on networks of sentinel doctors and sentinel laboratories). The validity of the surveillance depends on the frequency of data collection, which may be continuous or periodic (but repeated at sufficiently close intervals). Data may be collected passively (i.e. by awaiting the arrival of the information) or actively (i.e. through regular or permanent contact with the information source).

Surveillance also depends on the geographical level (i.e. local, national or international), and the data transmission medium must be the most appropriate for the requirements, particularly as regards speed (e.g. written questionnaire, telephone, fax or electronic data transmission). Additionally, a truly rigorous surveillance operation should make use of at least two independent and complementary surveillance systems for the same disease: the exhaustiveness and representativeness of the data collected can then be verified by comparing the data from the different systems.

Obviously, to enable an overall picture of the situation to be obtained all the surveillance data must be collated at a certain central level, which means the national level in most countries (leaving aside those with a federal structure). The same applies at European level: the data need to be centralised so that they can be processed and sent out to the health players.

4 THE DIFFERENT SURVEILLANCE SYSTEMS

A number of different surveillance systems on communicable diseases are in use nationally or regionally.

a) The classic system is the compulsory notification system: general practitioners are obliged to notify the health authorities whenever they diagnose a particular disease, at the same time furnishing a certain number of additional details. The centralisation of the data allows a close watch to be kept on the general situation. This system works reasonably well in some countries, less so in others (under-reporting) and in most cases is based on clinical diagnosis with no specific case definition. Since there is no weeding out of duplicate notifications or of unconfirmed cases it cannot be relied on to give an accurate picture of the situation. The system is most effective when the incidence of a disease is not too high: like any passive surveillance system it is not able to record all cases of a disease.

b) For the above reasons, the compulsory notification system is very often replaced or augmented by networks of sentinel general practitioners. These are volunteers, forming a representative sample of 1 to 4% of the total number of general practitioners in their country in terms of age, sex, type of practice and place of practice. These doctors increasingly tend to be linked up electronically and their surveillance results are updated weekly so that a close watch can be kept on the pattern of occurrence of the diseases under surveillance. This system is used in particular for common diseases with a high incidence, since trends can quickly be spotted and information can be exchanged and warnings issued rapidly, almost in real time.

c) Networks of medical biology sentinel laboratories, recruited on the same principles as those used for the sentinel doctors, furnish information on microorganisms (viruses, bacteria, germs, etc.) which they have identified in their day-to-day work, usually in tests to confirm clinical diagnoses. Several such networks have been set up for particular diseases, and they play an important role in sounding the epidemiological alarm. Not all Member States have set up such networks, which require considerable organisation and constant motivation, i.e. a significant outlay in terms of resources.

d) Specialist reference centres for communicable diseases provide additional support through their expertise (identification of strains, epidemiological analysis); through the warnings they are able to provide when poorly identified clusters or isolated cases of rare, serious diseases occur; and through the technical advice they are able to give the health authorities.

e) The range of surveillance systems is completed by periodic or one-off surveys, e.g. for studying prevalence (nosocomial infections), evaluating preventive measures (vaccination cover) or determining the incidence of certain unmonitored diseases. Other information sources (death certificates, sales of medicaments and vaccines, health certificates, hospital morbidity records, etc.) are also used in order to validate the surveillance systems indirectly.

5 QUALITY OF SURVEILLANCE SYSTEMS

The usefulness of a country's surveillance system to public health officials will depend on the quality of the system, i.e. its capacity to provide an accurate picture of the epidemiological situation, as assessed by reference to a number of criteria. This is even more true at international level: a surveillance system at Community level would serve little purpose if data were not comparable.

a) The sensitivity of a surveillance system, i.e. the proportion of cases picked up by the system compared with the total number of cases actually occurring in a given population, is a key assessment criterion. By this yardstick, the sensitivity of the compulsory notification systems ranges from 5% (of cases reported by comparison to the true total) to almost 100%. In these circumstances, where the notification rate achieved is below a threshold of somewhere between 50 and 80% there must be serious doubts about the usefulness of the system, and the system will need to be improved or augmented with other information sources.

b) The representativeness of a surveillance system is, by definition, a key criterion in sample-based systems such as the sentinel networks. This is particularly true when the sensitivity of the accompanying compulsory notification system is low, since this could drastically alter the true picture and lead to a false assessment of the situation.

c) The notification period, if too long, can cause problems, especially in situations where effective action is needed in order to control an epidemic as quickly as possible. Thus, while annual or quarterly notification of new cases may be appropriate for diseases which do not require immediate control measures, it is frankly inappropriate for diseases

where rapid intervention is required. This factor is particularly important when we are dealing with a vast geographical area such as the European Community.

d) The reliability of the results collected depends directly on whether cases are defined, or whether a person can be examined by several different doctors in succession, or is seen several times by the doctor because of relapses.

e) The confidentiality of the data collected raises ethical and legal problems in particular when the notification questionnaire enables the individual to be identified and includes questions on the sexual behaviour of the individual or questions which can identify the individual as being HIV positive. There are strong reasons, therefore, for making the questionnaires anonymous.

f) Other factors also play a part in the assessment of surveillance systems: two key factors which can compromise the usefulness and smooth functioning of a surveillance system are, firstly, the absence of additional data frequently essential for the epidemiological surveillance of a given disease, and, secondly, the lack of sufficient manpower to enable surveillance activities to be maintained at an appropriate level and the data to be analysed exhaustively.

III. INTERNATIONAL COLLABORATION PROJECTS IN THE FIELD OF DISEASE SURVEILLANCE

Historically, and quite naturally, many of the existing international communicable disease surveillance projects involving different countries or their specialist institutions have been set up on the initiative of, and under the aegis of, the World Health Organisation. The WHO's span in Europe extends far beyond the discontinuous territory of the countries which make up the European Community. Leaving aside the diseases covered by the International Health Regulations (IHR), these cooperation projects are voluntary, and their effectiveness depends on the commitment shown by the partners in collecting relevant data and transmitting the data for analysis and dissemination.

These useful – in some cases vital – transnational activities necessarily have a cost, both in terms of investment and operation. The European Community, and more specifically the European Commission, has provided substantial financial support, usually in cooperation with WHO.

In order to obtain as complete a picture as possible of the networks of public health players specialising in the surveillance of communicable diseases, the Commission requested a small group of experts, at the end of 1993, to produce an inventory of such networks, using a questionnaire for completion by health experts in the Member States. For the purposes of the survey, international collaboration was taken to be any activity geared towards improving the fight against one or more communicable diseases, and for which personnel had been enlisted, whether for a limited duration or otherwise, in at least three European countries. The list of collaboration projects identified, together with a description of each of them, is described in the Annex.

1 SYSTEMS SET UP BY WHO

This is not meant to be an exhaustive analysis of all of WHO's activities in this field. It is simply a brief outline of the systems operated by WHO which concern the European Community.

a) The International Health Regulations (IHR), adopted by the 22nd World Health Assembly in 1969 and subsequently amended for cholera by the 26th Assembly in 1973, and for smallpox by the 34th Assembly in 1981, are designed to help prevent the international spread of diseases. The Regulations oblige all countries which are party to this international Convention (this includes all the Member States of the European Community but not the European Community itself) to take measures to stop the spread of epidemic outbreaks due to three communicable diseases: plague, cholera and yellow fever. Breaking with traditional control measures such as quarantine, which are usually inappropriate, these measures consist of the continuous epidemiological surveillance of imported cases, the early detection of infections and their notification to WHO within 24 hours, and the rapid and widest possible dissemination of all relevant information. These three diseases are not rife in Europe, being imported diseases which have their sources in other parts of the world. WHO is the pivot for the Member States for the notification of cases.

The system remains something of a formality, however, and does not produce extensive cooperation between the participating countries when incidents of these diseases occur on their territories. No international convention can be expected to foresee all disease eventualities. In some cases diseases and disorders other than those covered by the IHR, for example certain African haemorrhagic fevers, can be tackled by the national authorities in the same spirit. But in the light of experience the system's practical feasibility is such that it is difficult to see how Community cooperation could be of value in this area.

b) The other international exchange systems under the WHO's aegis are concerned more with passive surveillance. Some of them merit closer attention.

* The Expanded Programme on Immunisation (EPI), established by WHO in 1974, aims to control six diseases of children throughout the world (diphtheria, neonatal tetanus, whooping cough, poliomyelitis, measles and tuberculosis) through appropriate immunisation cover. For the WHO's European zone, which covers 50 countries (including Russia and the 15 Community Member States), WHO objective No. 5 is slightly different, namely to control six diseases (the same six as above, but with mumps and congenital rubella replacing tuberculosis and whooping cough) in the general population by the year 2000. The Member States are in addition committed to the following four objectives: eradication of poliomyelitis by the year 2000; elimination of neonatal tetanus by 1995; 95% reduction in measles mortality and 90% reduction in measles morbidity by 1995; routine vaccination against hepatitis B by 1995 if the prevalence of HBs antigen carriage is more than 8%, and vaccination of exposed groups against hepatitis B by 1997 if the prevalence of HBs antigen carriage is less than 8%.

These objectives are merely recommendations, i.e. they have no binding force, and their attainment therefore depends on the goodwill of the national public health authorities, whose representatives sit in a management group and an advisory committee. These authorities send in their surveillance results, in principle on an annual basis: the results are of course a vital tool for verifying the implementation of any immunisation programme. But the fact is that the Member States are far from being united in their surveillance methods (case definitions) and their methods of determining vaccination coverage, thus hampering proper comparison of national situations.

* Two other systems, the Collaborating Centre for Health and Disease Surveillance (Rome) and the Surveillance Centre for the Control of Food-borne Infections and Intoxications in Europe (Berlin) no longer appear to fulfil present day requirements.

2 SYSTEMS SUPPORTED BY THE EUROPEAN COMMUNITY

At the level of the European Community, Council Directive 92/117/EEC[4] of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications provides for a system for collecting information on specified zoonoses and zoonotic agents. Under Article 5, Member States are obliged to produce a report by 31 March each year on the trends and sources of the zoonotic infections recorded during the previous year, and the Commission is obliged to evaluate the information thus obtained and report to the Standing Veterinary Committee before 1 October each year. Leaving aside these developments, which are not directly within the remit of this Communication, initiatives in the field of communicable disease surveillance have been developed over the last decade in four areas. The first were in the Research sector, followed by technology development initiatives in the Telecommunications and Internal Market sectors, where substantial resources have been allocated. Since the entry into force of the Treaty establishing the European Community, the Commission has been endeavouring to support innovatory initiatives or to accompany the Community's overall activities in the context of the Framework for action in the field of public health. The need to coordinate these crucial public health activities so as to ensure clarity and coherence is now greater than ever.

a) The Eurosentinel system is the product of a concerted initiative launched in 1988, funded for three years by the Biomed programme (medical and public health research). Its mandate was to promote the establishment of networks of sentinel general practitioners and to coordinate their activities in certain Member States, with the ultimate target of establishing a European sentinel surveillance network using electronic data communication resources. At national level these sentinel GPs form networks for the rapid dissemination, in standardised form, of information they gather during the course of their work, and they report their observations to a central national structure. In the case of Eurosentinel the central structures are linked up to a central unit within the Institut d'Hygiène et d'Epidémiologie in Brussels, the role of which is to receive and store all

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[4] OJ No L 62, 15.03.1993, p. 38.

information relating to activities in the field of sentinel surveillance, to assist and technically advise the networks, to organise scientific meetings and to publish a regular newsletter.

Placed under the aegis of the Project Management Group, Eurosentinel has the task of observing the international incidence of four health matters, based exclusively on clinical diagnosis: measles, mumps, prescription of HIV screening tests and influenza syndromes. Initially comprising the existing networks of five countries (Belgium, France, Netherlands, United Kingdom and Switzerland), Eurosentinel has since been joined by new networks set up in four other countries (Ireland, Portugal, Spain and Italy). These networks, of variable coverage and quality, are far from uniform in their organisation. Their results, based exclusively on clinical diagnosis (with no biological confirmation), are tinged with uncertainty, the more so as there is no common definition of cases. Despite the discontinuation of Community support the system continues to function thanks to the support of health authorities of these Member States.

b) *Telematic Networks between Administrations*

i) CARE - Early warning system

Public health authorities, whether at local, regional or national level, have the responsibility to ensure that the necessary information concerning cases of communicable diseases liable to lead to epidemics or epidemic outbreaks is available and is communicated in good time to all decision-making bodies and/or bodies responsible for implementing appropriate measures.

The effectiveness and efficiency of national administrations in carrying out these tasks will be greatly enhanced by the setting up of an EU-wide modern, cost-effective and user-friendly telematics system, linking health administrations in the Member States, so that they can exchange reliable information, results and experience in real time, consult each other prior to introducing counter-measures as in the case of epidemics, coordinate their responses, particularly where these might have economic and social consequences, and improve the formulation of policies and the planning, financing and administration of health services.

The Council decision of 6 November 1995 on support for IDA (telematic interchange of data between administrations in the Community)[5] foresees two projects in the field of health, namely CARE (two sub-projects : early warning system and pharmacovigilance) and REITOX (European network of information on drug addiction).

The two CARE sub-projects under IDA are spin-offs of earlier efforts on the European Nervous System (ENS-CARE) supported by the Commission under the 3rd Framework Research and Technological Development Programme over the period 1991 to 1993; its current situation permits the gradual passage from the pilot to the exploitation phase, with

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5 OJ No L 269, 11.11.1995, p.23.

the general architecture and infrastructure for communicable diseases, health data and indicators and pharmacovigilance.

Under current IDA plans, CARE-Early warning system (CARE-EWS) work will concentrate over the next two years on development of the pilot system between national administrations, while strictly adhering to the general system architecture foreseen for IDA. Apart from the infrastructure and architecture aspects of a system such as CARE-EWS linking national administrations, the content of information to be exchanged will have to be determined. This will have to be specified by the Commission in collaboration with the administrations. To this end, the Commission is presenting a proposal for a decision by the European Parliament and the Council concerning the setting up of a European Community system for the epidemiological surveillance and control of communicable diseases.

The Commission has already presented a communication and a proposal for a decision on a programme concerning health data and indicators.[6] The latter programme, as distinct from the effort directed towards communicable disease surveillance, aims at providing the necessary information on health status and health determinants and would, as appropriate, draw from information generated by communicable disease surveillance. It does not, however, have the objective of securing the rapid sharing of detailed, validated and in most cases confidential information, and the coordination of responses, when cases of communicable diseases liable to lead to epidemic outbreaks occur.

ii) The G7 Global Healthcare Applications Project

The G7 Global Healthcare Applications Project contains a sub-project, "Towards a Global Public Health Network", a key element of which is the design of an international data exchange in the areas of communicable disease surveillance through new telecommunication technologies. These activities take into account the experience acquired from the "Wonder project" run by the USA's "Centers for Disease Control", as well as the recommendations made to the President of the United States by the National Science and Technology Council in the report "Infectious disease - a Global Health Threat". This detailed report presents an overview of the problems and of the obstacles to combating infectious diseases and proposes a step-by-step model for the adoption of appropriate measures, including a Worldwide Communication Network.

c) *European Centre for the Epidemiological Monitoring of AIDS*

This Centre, financed by the European Community in the context of the BIOMED research programmes and the Europe against AIDS programme, was set up in 1987 in Paris. It is responsible for the surveillance of AIDS and HIV infection in the European Community and the other territories covered by WHO Europe, with whom it collaborates. The Centre receives non-aggregated data on diskette every three months from all the countries in the WHO's European zone, which extract the data from their national data bases. They include various indicators concerning the disease and its diagnosis, together

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6 COM 95 (449) of 16.10.1995.

with comments on the trends over the past three months. The data are depersonalised so that it is not possible to identify the individuals concerned, whatever their geographical location. The Centre also produces tables of figures and collects data concerning anonymous screening programmes.

d) *Ongoing surveillance activities*

Currently, because Member States' surveillance systems differ so widely, the data issued by Member States on communicable diseases are not intercomparable. In addition, not enough epidemic outbreaks are detected and correctly investigated. In such circumstances it is only rarely that appropriate recommendations can be formulated, because there is a lack of epidemiologists trained in this type of intervention. Field epidemiology, which involves the application of epidemiological methods to surveillance, to data production, to public health action and to the monitoring of infectious diseases, is the approach which is needed in order to contain and, if possible, clear up epidemics. In this context, there is clearly a need for collaboration as regards training students in the epidemiology of communicable diseases.

The development of a cadre of public health personnel with a common knowledge base, common skills and a common approach to epidemiology could greatly stimulate harmonised activities in the field of public health, and especially in the field of communicable disease prevention. For this reason the Commission has since 1994 been providing financial support, under the programme on AIDS and other communicable diseases, for a field epidemiology training programme coordinated by the IHE in Brussels. The project involves sending ten or so epidemiologists from the Community to locations in other Member States for a two-year period in order to acquire experience and skills in the field of epidemiological intervention (control of communicable diseases) - something which is lacking in the Community at present. Thanks to this innovative project a new network of specialists in the surveillance of communicable diseases is gradually emerging, and this network should be up and running properly within the next two or three years.

In a similar context, the AIDS Centre in Paris is currently coordinating a feasibility study for the creation of a European bulletin of communicable diseases, which would publish surveillance data on a monthly basis. The producers of the national bulletins have already set up a coordination structure, in liaison with the national institutions responsible for surveillance in the Member States, with a view to setting up such a bulletin permanently at European level. This bulletin would regularly publish data from existing and future surveillance networks and from epidemiological surveys; would compare the different national approaches to public health; and would collect information of international interest from the Member States' national bulletins.

3 OTHER NETWORKS

As shown in the Annex, other international networks of a similar nature have been set up by surveillance professionals in the public sector, sometimes in collaboration with the private pharmaceutical industry, as is the case for influenza. Other networks concern meningitis, listeriosis and paediatric diseases.

IV. REVIEW OF THE EXISTING SITUATION AND PROPOSALS FOR FUTURE COMMUNITY ACTION

1 ASSESSMENT OF THE EXISTING SITUATION

Since detailed information on all the factors necessary for a rigorous assessment is not available, it is not easy to provide an in-depth analysis of the existing situation concerning disease surveillance at Community level, still less so to deliver a judgment on it. However, it is useful to review the situation on the basis of a checklist, whether this be of diseases grouped together thematically, or of modes of transmission, or of the criteria which determine the quality of a surveillance system, as mentioned at point II.5.

The criteria for assessing the pertinence of a surveillance operation and the suitability of the existing system or systems can be organised as follows:

a) By type of disease:
- . diseases preventable by vaccination
- . sexually transmitted diseases, hepatitis B, AIDS/HIV
- . hepatitis (C and unclassified)
- . food-borne diseases
- . zoonoses (for the record)
- . imported diseases
- . respiratory diseases (tuberculosis)
- . nosocomial infections

b) By modes of transmission:

1. water-borne:
   - cholera, hepatitis A, legionellosis (water quality)

2. zoonotic:
   - brucellosis, trichinosis, campylobacter, echinococcosis, rabies, *Yersinia*, etc.

3. food-borne:
   - salmonellosis *(S. enteridisi, typhimurium*, virchow, *napoli)*
   - listeriosis
   - E. coli
   - shigella
   - etc.

4. inter-human:
   - AIDS
   - STDs (syphilis, chlamydiases, genital herpes)
   - tuberculosis
   - hepatitis B and C
   - influenza and influenza syndromes
   - meningitis: *Haemophilus influenzae B*; meningococci, A,B,C; pneumococcus
   - etc.

5. blood: - HIV/AIDS
- hepatitis B and C
- etc.

6. environmental: - legionellosis
- aspergillosis (nosocomial infections)
- etc.

7. particular: - Creutzfelt-Jakob disease
- etc.

c) By the criteria determining the quality of a surveillance system:

. sensitivity
. representativeness
. notification frequency
. reliability
. confidentiality
. follow-up (resources allocated)

In the light of this general review it could be possible to compare the existing situation with what could theoretically be done in the way of disease surveillance. The Commission, working in close cooperation with the Member States' authorities responsible for communicable disease surveillance, intends to put forward appropriate proposals for the adoption of measures necessary to improve this type of epidemiological surveillance in the Community. It is already clear that tuberculosis and hepatitis C, which the Commission mentioned in its Communication (COM(94) 413), should be considered under this approach as meriting particular attention.

As a general rule, it appears that collaborations are becoming more sophisticated, with increasingly standardised methodology and better technical support. Projects which were developed within single institutions, without an effective partnership between partners, have tended to be less successful. Of course, the opposite is true (when the various opposing elements are all brought together). Historically, projects had not always had clear objectives underpinned by an effective setting of criteria and scientific standards. Ongoing, independent scientific input is essential for a project to be successful, and has not always been present.

The strength of any collaboration depends on the quality of the data at the point where it originates and therefore relies on the quality of national systems, which are heterogenous. Procedures such as coordinating and improving existing systems (rather than developing new systems) and developing uniform agreed case definitions, are important to the development of effective collaborations. Clearly, within any one collaboration one partner might take the lead, or have a greater role than others.

2 CONCLUSIONS

After examination of the various international cooperation schemes for communicable disease surveillance, and after consultation by the Commission of national experts and of those responsible for disease surveillance in the Member States, a certain number of conclusions, on which there is agreement, can be drawn.

a - There is a growing need for European collaboration on the prevention of communicable diseases and such collaboration should be accorded the highest priority. Reasons for this include: the increasing mobility of populations due to tourism, business and migrations in general; the increasing freedom of movement for goods; the re-emergence in Europe of once familiar infectious diseases such as tuberculosis and poliomyelitis; the emergence of new infections, such as those due to various strains of *E. coli 0157* secreting cytotoxins; the breakdown of communicable disease prevention measures in various parts of eastern Europe, etc.

b - In order to promote effective preventive action against communicable diseases, European Community collaboration in the fields of public health surveillance and microbiology is essential. At present, there is not even a list of structures and laboratories to enable analyses and identifications to be carried out at Community level.

c - The fact that various joint surveillance projects are being considered, or are starting to see the light of day, shows that the need for European collaboration is widely recognised. However, since there are clearly gaps, overlaps and wide variations (in terms of quality, quantity, uniformity over time, and reliability) in the data yielded by the present systems, these activities need to be coordinated within the Community.

d - There are currently wide differences in the Member States' vaccination programmes and schedules. The improvement of surveillance and of research to facilitate the harmonisation of vaccines would bring much-needed rationalisation to this area of public health.

e - In order to improve surveillance at European level there is a need to identify more precisely those areas in which there is duplication of activity and to establish priorities for the implementation of collective projects. Accordingly, there is a need to promote collaboration between experts from the national institutions responsible for communicable disease surveillance. Activities in this domain ought to be coordinated with the activities already being carried out by the World Health Organisation, particularly WHO/Euro.

f - The establishment of contact networks, which are necessary for the development of these activities, would be facilitated by the organisation of regular meetings between the experts responsible for the national surveillance programmes. These meetings should be devoted to the public health problems inherent in communicable disease surveillance, microbiology and identification of the problems and priorities at European level.

g - All the Member States without exception should participate in such a network, with full account being taken of the fact that the degree of surveillance and prevention of communicable diseases varies substantially from country to country. Since infectious

diseases know no frontiers, consideration should be given to extending the network to include neighbouring non-Member States or countries with special relations with the Community (such as the USA), on a basis yet to be defined.

h - Several of the existing European surveillance networks for certain specific infections could serve as models for other infections, since they employ standard case definitions and methodologies agreed on jointly by the participants and transmit their regularly updated data to a coordinating centre at regular intervals. The following are examples of high interest:

- The system for notifying AIDS and HIV cases to the European AIDS Epidemiological Surveillance Centre in Paris, resulting in trend data which constitute a useful basis for preventive action. This example could be followed in order to develop similar information systems for hepatitis, tuberculosis and sexually transmitted diseases.

- The EWGLI information system for laboratory-diagnosed legionellosis cases, coordinated by the Public Health Laboratory Service's (PHLS) Communicable Disease Surveillance Centre in London, which permits the swift detection of epidemics with a common source. It provides trend data, enabling preventive measures to be taken as quickly as possible. A similar system, SALMNET, is proposed for salmonellosis and could also be applied to listeriosis and infections due to strains of *E. coli 0157* secreting verotoxin.

i - To achieve greater harmonisation in areas such as quality control and the most sophisticated techniques (e.g. phage typing and genotype establishment, identification of viruses responsible for African haemorrhagic fevers) used for identifying micro-organisms with ever greater precision.

3 FUTURE ACTIONS

a) On the basis of these conclusions, there will be two major strands to the Community's future actions concerning communicable disease surveillance and control:

- Firstly, the establishment of a system for the surveillance and control of communicable diseases at Community level, requiring the exchange, at appropriate moments, of accurate and reliable information concerning diseases for which specific case definitions, identifications and verifications are required. It is proposed to set up this system on the basis of a European Parliament and Council decision, and to exploit the infrastructure set up by the IDA programme.

- Secondly, various measures such as the development and coordination of intra-Community collaborations; assistance for pilot projects to facilitate the setting up and smooth running of the key elements of surveillance systems at national level; exchanges of experience, notably through meetings of experts; cooperation with non-member countries and international organisations competent in this field; the training of field epidemiologists; the production and dissemination of information tools, such as epidemiological surveillance bulletins; support for European microbiologists for the

creation of an inventory of collaborative ventures in Europe and of national resources currently available in the relevant fields of microbiology. These measures will be undertaken in the context of the future programme concerning AIDS and certain other communicable diseases, for which the Council adopted a common position on 2 June 1995 (OJ 95/C 216/02)[7] and which was the subject of a conciliation procedure, pursuant to Article 189b of the Treaty, on 19 December 1995.

b) As regards the setting up of a system for the surveillance and control of communicable diseases at Community level, the Commission, in its communication of 24 November 1993 on the framework for action in the field of public health, outlined the principles and strategies to be followed in implementing Community activities directed towards the attainment of the health protection objectives laid down by Articles 3(o) and 129 of the Treaty establishing the European Community. The role of the Community is to underpin the efforts of the Member States in the public health field, to assist in the formulation and implementation of objectives and strategies, and to contribute to the continuity of health protection provision across the Community, setting as a target the best results already obtained in a given area anywhere in the Community.

The Commission's proposal for the creation of such a network advocates that the Member States should participate fully in its organisation and implementation. The network's task will be to ensure coordination in the collection, processing and exchange of information necessary for the prevention and control of communicable diseases. Focusing on disease prevention, and following the principles of subsidiarity and proportionality, this Community action is designed to help the authorities responsible for public health to take, at State level, measures to block the progression of these infectious diseases or to prevent their appearance.

c) Consequently, this proposal seeks to establish a system of close cooperation and effective coordination between Member States in the field of surveillance, both routine and emergency, with a view to improving the prevention and control in Europe of a certain number of serious communicable diseases which necessitate the introduction of measures for the protection of populations. The proposal is modelled on Community instruments already adopted in similar areas for the accomplishment of similar objectives. The data in question will be collected in aggregated form and will in no case enable individuals to be identified. Thus, they will not conflict with Community instruments concerning the protection of personal data, such as Council Directive C 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data[8]. They will however comply with the Community provisions concerning systems of information exchange between administrations.

d) The setting up of this network for the surveillance of communicable diseases takes account of, and is based on, the situation already existing in this field at European level. It also aims to avoid unnecessary duplication of work by ensuring that all Member States

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7 OJ No C 216, 21.8.1995, p. 2.

8 OJ No L 281, 23.11.1995, p.31

have the same conception of surveillance, as a result of defining with them the type of information required and the arrangements appropriate for each group of communicable diseases. Finally, other parties will be associated with the network: these will include the competent international organisations (notably WHO), the surveillance networks to which Member States already belong, and non-member countries. Cooperation with the USA towards the setting up of a global early warning and response system has already begun within the framework of the EU-USA action plan, and also within the framework of the G7 Global Healthcare Applications Project, in which Canada and Japan are also involved. An important aspect of this latter project is the application of new technologies to the international exchange of data in the field of communicable disease surveillance.

e) The recently created Task Force on Vaccines and Viral Diseases should also help to coordinate efforts to establish a European Communicable Disease Surveillance System building on existing pilot activities and legislative initiatives. Its main thrust should be to ensure adequate information flows between the vaccine research community and the surveillance networks and to focus on endemic identifiable infections as well as voluntary data constituencies on specific outbreaks. Furthermore, the Task Force would catalyze the integration of common European expertise into the surveillance system at a level of specific laboratory facilities.

f) The implementation of the decision will yield added value in a number of ways:

- It will ensure the setting up of a system of continuous, well-structured, reliable and effective communication at Community level between national communicable disease surveillance authorities, something which is lacking at present;

- It will facilitate the rapid, reliable and commonly agreed identification of cases of communicable diseases occurring inside the Community, or occurring outside and therefore being imported or likely to be imported;

- It will give the competent authorities the opportunity and the means to consult together on the preventive measures to be taken, and it will help them in the coordinated introduction of such measures and the evaluation of their effectiveness;

- It will give the authorities the support they need for analysing and interpreting data and for deploying the necessary measures to stop communicable diseases from spreading.

ANNEX

I - EXISTING COLLABORATIONS

A - Surveillance

1 - WHO Collaborating Centre for Health and Disease Surveillance

Diseases surveyed

Notifiable diseases or diseases otherwise subject to systematic/obligatory reporting at a national level.

Data sources

Periodical bulletins of communicable disease surveillance prepared by participating countries, according to the variable criteria which may apply, and supplemented by retrospective cumulative data from WHO Regional Office and the statistical office of WHO Headquarters.

International reporting

Twenty five countries submitted data by post to the centre at the Instituto Superiore di Sanita in Rome. Data is available for Albania, Austria, Belgium, Bulgaria, Czechoslovakia, Denmark, Germany, Finland, France, Greece, Hungary, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, Morocco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Spain, Sweden, Switzerland, Turkey, United Kingdom, Russia and Yugoslavia.

International feedback

Eight bulletins summarising disease occurrence by YEAR by COUNTRY have been produced since the scheme's inception.

Inputs

100% provided by participants. Start up moneys of $3,000 US were provided by WHO Regional Office.

Dates of i) commencement and ii) completion

i) 1983 ii) ongoing.

Value

Four enquiries have been received in the last 3 years. The quality of the data reported nationally does not merit the effort of international collation in the views of the Collaborating Centre.

2 - Expanded Programme on Immunisation

Diseases surveyed

Incidence of Diphtheria, Tetanus, Pertussis, Poliomyelitis, Measles, Mumps, Rubella. Immunisation coverage.

Data sources

Generally based on passive reporting via notification schemes in countries[11]. Assessment of vaccine coverage uses different approaches in different countries (see below, "Research in Methodologies of Immunisation Programmes Management in Europe").

International reporting

Tabulated data is sent periodically to WHO European Regional Office in Copenhagen.

International feedback

A publication summarising immunisation coverage and incidence of six target diseases (Diphtheria, Measles, Pertussis, Poliomyelitis, Tetanus and Tuberculosis) is produced 6 monthly.

Inputs

Submission of tabulated data to WHO by participating countries.

Dates of i) commencement and ii) completion

i) Longstanding ii) Ongoing

Value

International comparisons have given an impetus to beneficial modifications of national schedules. Identification of risk areas (eg Diphtheria in the countries of the former USSR).

3 - Eurosentinel

Diseases surveyed

Range of communicable diseases.

Data sources

Clinical diagnoses from various networks of sentinel General Medical Practitioners (GPs). Case definitions used vary between networks but are invariably physician based.

International reporting

Weekly totals of disease occurrence are sent by fax to the Institute of Hygiene and Epidemiology, Brussels. Data is available from Belgium, France, The Netherlands, Portugal, Spain, Switzerland and United Kingdom.

International feedback

A Bulletin of the Institute of Hygiene and Epidemiology is prepared periodically, as resources permit, on behalf of the collaborating networks. This tabulates disease occurrences by country by week and is posted to collaborators.

Inputs

Submission of tabulated data to Institute of Hygiene and Epidemiology by participating networks. The Institute of Hygiene and Epidemiology estimate their input to co-ordinate the scheme to be 1 hour of medical staff time, 1 hour of scientific staff time and 4 hours of clerical staff time per week with all inputs since 1991 provided nationally.

Dates of i) commencement and ii) completion

i) 1988 as EC concerted action programme. ii) 1991 but the Institute of Hygiene and Epidemiology has continued the scheme on an informal and unfunded basis since then as a service to the collaborating networks.

Value

Acts as a clearing house for information about activities in the field of sentinel practice schemes and a source of scientific support for them. During the 1989 influenza epidemic the data was used to review spread through Europe and to encourage vaccination and to brief the media in certain countries.

Potentially the scheme could support the development of sentinel networks in those countries which do not possess them and also organise international studies based in those participating networks which are already established.

4 - *WHO Surveillance Programme for Control of Foodborne Infections and Intoxications in Europe.*

Diseases surveyed

Foodborne disease, defined as "a disease of an infectious or toxic nature caused by or thought to be caused by the consumption of food or water".

Data sources

Reporting from the responsible surveillance institution. Criteria for including data differ. Some countries consider a disease as foodborne only when the causative agent was identified in the patient as well as the food; other countries find it satisfactory when there is epidemiological evidence and yet others include all diarrhoeal diseases.

International reporting

Reporting procedures vary between countries. Data is sent to the Institute of Veterinary Medicine - Robert von Ostertag Institute (FAO/WHO Collaborating Centre for Research and Training in Food Hygiene and Zoonoses, Berlin. Data is, or until recently was, available from Albania, Austria, Belgium, Bulgaria, Cyprus, Czechoslovakia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden, Switzerland, Turkey, United Kingdom, USSR, Yugoslavia.

International feedback

Five reports have been published since the schemes inception. The most recent covered the period 1986-1989 and was published in 1992. Data is presented in a series of country reports with little attempt at inter-country comparisons. More immediate feedback is provided by newsletters which are published approximately 4 times per year.

Inputs

Submission of tabulated data to Robert von Ostertag Institute by participating networks.

Dates of i) commencement and ii) completion

i) 1980 ii) Ongoing. The programmed is intended to become of the 4 components of the Food Safety Pilot (ie application), one of the 4 subsidiary projects of the European Nervous System (ENS) /CARE Telematics programme, funded by European Commission to develop European electronic communications networks.

Value

Stimulus to national authorities in their efforts to strengthen the prevention and control of foodborne diseases.

5 - British Paediatric Surveillance Unit (BPSU) and Union of European Paediatric Societies and Associations

Diseases surveyed

Rare infectious diseases and infection related conditions in patients under 16 years of age. (Up to 12 disorders at any one time). Rare non infectious conditions are also surveyed. Infectious diseases which are, or have been, surveyed are HIV/AIDS, Neonatal Herpes, Sub-acute Sclerosing Pan Encephalitis, Haemolytic Uraemic Syndrome, Congenital Toxoplasmosis, Rheumatic Fever, Congenital Rubella, MMR associated Meningo-encephalitis, Acute Flaccid Paralysis, Haemophilus influenzae type B (HiB) vaccine failures.

Data sources

Defined diagnoses of conditions under surveillance reported monthly by a postal report card ("orange card") by 1,160 participating hospital paediatricians.

International reporting

This is made to BPSU at the British Paediatric Association Offices in London. An important feature is the requirement to make a nil return if no cases of the diseases under surveillance have been seen by the paediatrician. Data is available form the United Kingdom and Ireland. Similar but separate schemes have now commenced in Germany and the Netherlands.

International feedback

Six annual reports have been published since the schemes inception. The most recent was published in 1993. Regular scientific publications are made.

Inputs

Submission of report cards to BPSU by participating clinicians.

Dates of i) commencement and ii) completion

i) 1986 ii) Ongoing. The Union of European Paediatric Societies and associations formed a working group in 1991 to develop a network of European paediatric surveillance units. The group includes 9 countries and has applied for EC funding as a concerted action programme for 1993.

Value

The scheme has enhanced ascertainment and the provision of data of good quality for a variety of rare conditions. It has been imitated in other countries and is being considered by other specialties.

6 - EURO.NES Scheme for Surveillance of Nosocomial Infection

Diseases surveyed

Nosocomial infections and Pneumonia in Intensive Therapy Units (ITUs) to identify risk factors, evaluate control measures and assess the feasibility of a surveillance system.

Data sources

For a one month period participating physicians in ITUs form a convenience sample of volunteering hospitals reported to national centres the isolation from their patients of microorganisms which were hospital acquired. Data was available on the age and sex of the patient and the severity of clinical illness, the procedure undergone, intercurrent illness/therapy, smoking habits and the existence of infection at admission.

International reporting

Data was posted to the University of Lyon, France. Data was obtained from Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom.

International feedback

Analysis of risk factors has been received back from coordinators. Scientific publication is awaited.

Inputs

Study costs within countries met by participants. EC provided software, organised meetings and funded collaborative aspects.

Dates of i) commencement and ii) completion

i) 1990 ii) 1992: data analysis continuing. Fieldwork was of 1 month's duration.

Value

Potential for setting standards for in-patient care.

7 - WHO Influenza Surveillance

Diseases surveyed

Laboratory isolation of influenza virus or serological evidence of influenza infection.

Data sources

Specimens submitted by clinicians to diagnostic laboratories within countries.

International reporting

Data is sent by post or fax to the WHO Influenza Collaborating Centres on Influenza Reference and Research in London and Atlanta, USA. Data is obtained from 46 laboratories in 25 developed countries and 64 laboratories in 52 other countries, covering nearly all parts of the world.

International feedback

A weekly influenza report is received by fax from Atlanta giving disease occurrence by time and place. Data also features in the notices of influenza activity in the WHO Weekly Epidemiological Record.

Inputs

Submission of data by responsible institutes in participating countries.

Dates of i) commencement and ii) completion

i) 1990 ii) Ongoing.

Value

The scheme is critical for knowing the correct strains to incorporate in vaccines. When allied to other systems it could allows the epidemiological characteristics of different strains to be evaluated.

Potentially a model for international collaboration in communicable disease surveillance as well as permitting the computation of the velocity of spread of influenza internationally.

8 - Influenza (EUROGROG)

Diseases surveyed

Laboratory isolation of influenza virus or serological evidence of influenza infection combined with clinical diagnoses via sentinel schemes and other non-specific indicators of activity (eg. hospital activity, sickness absence, consumption of specific pharmaceuticals.

Data sources

Specimens submitted by clinicians to diagnostic laboratories and various other indicator activities within countries.

International reporting

Data is sent by post or fax to the Institut Pasteur in Paris.

International feedback

A weekly influenza bulletin is sent by post from Paris giving activity (disease occurrence by week by country or French Department) in 23 countries.

Inputs

Submission of data by responsible institutes in participating countries.

Dates of i) commencement and ii) completion

i) 1984 ii) Ongoing.

Value

The scheme allows the epidemiological characteristics of different strains to be evaluated.

Potentially a model for international collaboration in communicable disease surveillance as well as permitting the computation of the velocity of spread of influenza internationally. Could lead to more accurate information on, and greater harmonisation of, action thresholds.

9 - European Working Group on Legionella Infection (EWGLI)

Diseases surveyed

Laboratory evidence of Legionellosis defined according to strict diagnostic criteria in patients with a clinical or radiographic diagnosis of pneumonia.

Data sources

Case reporting via clinicians and diagnostic laboratories to responsible national co-ordinating centres within countries.

International reporting

Data is sent by post, fax or computer network to the PHLS Communicable Disease Surveillance Centre (CDSC), London, the centre having been moved from the National Bacteriological Laboratory, Stockholm with a view to incorporating the scheme into the Early Warning Pilot, one of the 4 subsidiary projects of the European Nervous System (ENS) /CARE Telematics programme, funded by DGXIII to develop European electronic communications networks (Appendix VII). Data is obtained from Austria, Belgium, Czechoslovakia, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom, USSR, Yugoslavia.

International feedback

A computer disk is sent by post from London, monthly, giving disaggregated data on diagnostic status, time (onset and report date), resort visited, period of visit, person (characterised by age, sex and country of residence) and institute of report. Cluster alerts are also issued.

Inputs

Submission of data by responsible institutes in participating countries.

Dates of i) commencement and ii) completion

i) 1987 ii) Ongoing.

Value

Unique data source for some participating countries where Legionellosis is not subject to any reporting/notification requirements. Permits control activity where clusters identified. Strengthens the efforts of national institutions in controlling disease. Model for international collaborative effort.

10 - European Monitoring Group on Meningococci (EMGM)

Diseases surveyed

Meningococcal meningitis and septicaemia.

Data sources

Case reporting via national centres with responsibility for meningococcal surveillance.

International reporting

Data is sent to King's College School of Medicine and Dentistry, University of London. Data is obtained from Albania, Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, Yugoslavia.

International feedback

Periodic reports are provided giving incidence by country by year. Data on age, outcome and prophylactic and curative therapy is also provided. Data on serogroups and subtypes from reference laboratories and sulphonamide resistance is also given.

Inputs

Submission of data by responsible institutes in participating countries. The co-ordinating centre is funded by the UK National Meningitis Trust (a charity).

Dates of i) commencement and ii) completion

i) 1991? ii) Ongoing. Application to the EC is intended.

Value

Standardisation of surveillance and laboratory techniques and reagents. Development of an audit process for meningococcal disease management in Europe.

11 - WHO Collaborating Centre for Rabies Surveillance and Research

Diseases surveyed

Human and animal rabies.

Data sources

Case reporting via clinicians, veterinary surgeons and diagnostic laboratories to responsible national co-ordinating centres within countries.

International reporting

Data is sent to the WHO Collaborating Centre for Rabies Surveillance and Research at the Federal Research Centre for Virus Disease of Animals, Tubingen, Germany. Data is obtained from Austria, Belgium, Bulgaria, Croatia, Czechoslovakia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, Yugoslavia.

International feedback

A quarterly report is produced tabulating cases by species, by district, by quarter.

Inputs

Submission of data by responsible institutes in participating countries.

Dates of i) commencement and ii) completion

i) ? ii) Ongoing.

Value

Identifies changes in epizootic cycle. Informs animal immunisation programmes and decisions on offering immune prophylaxis to humans.

12 - European Centre for the Epidemiological Monitoring of AIDS

Diseases surveyed

AIDS and HIV infection.

Data sources

Every three months the national representatives in charge of AIDS surveillance systems provide individual anonymous data on diagnosed AIDS cases. Data from HIV seroepidemiological studies, including information on methods and results, are also provided.

International reporting

All the countries in the WHO European Region, including all the European Union Member States, participate in the surveillance system. A uniform AIDS case definition and standardised methods of data transmission are used. The Centre collects, analyses and disseminates results at European level.

International feedback

The data collected are recorded in quarterly reports which include updated results of AIDS surveillance and various articles from seroepidemiological surveys or European multicentre studies. There are separate quarterly reports for the WHO European region and for the European Union countries. Twice a year, the EU report includes detailed information for each country. Scientific publications are produced by the Centre and also by other users of the data sets which are available to surveillance and research teams of participating countries.

Inputs

Data are sent to the Centre on diskettes or by E-mail. Representatives of the participating countries receive copies of the compiled data sets (quarterly) and sets of slides presenting the data (twice a year). The quarterly reports are distributed to a network of 900 correspondents. Standardised tables are also available on Internet.

Dates of i) commencement and ii) completion

i) 1984 ii) ongoing

Value

The Centre regularly provides standardised information allowing the evaluation of the HIV/AIDS epidemic situations and trends at European level. It reinforces efforts of national and international institutions to control the epidemic and is a working model of international collaboration.

(5)

B - Training

1 - Institut pour le Développement de l'Epidémiologie Appliquée (IDEA)

Participants

Public health professionals.

Duration and Locations

3 weeks at Veyrier du Lac, France.

Subject matter

Field epidemiology including a surveillance project (usually a knowledge, attitudes, practice survey).

Instruction is in French.

Assessment (including formal qualifications awarded)

Those who complete the course receive a certificate of completion.

Benefit to participants

Enhancement of abilities in field investigation.

Value

Additional practical skills to organisation sending student.

Dates of i) commencement and ii) completion

i) 1984 ii) Ongoing.

2 - *Seminars on Infectious Disease, Communicable Disease for Environmental Health, Surveillance of Infection.*

Participants

Public Health Professionals: c40/seminar.

Duration and Locations

5 days: Glasgow (UK).

Subject matter

Epidemiology and control of infection suitable for an international audience.

Assessment (including formal qualifications awarded)

None.

Benefit to participants

Exchanges of ideas and establishment of international working relationships.

Value

Establishment of avenues for information exchange.

Dates of i) commencement and ii) completion

i) Longstanding ii) Ongoing

C - Information

Eurosurveillance: European Communicable Disease Bulletin

Diseases

Communicable diseases.

Data sources

Articles published in national bulletins of the European Union Member States, original articles regarding investigation or of recent outbreaks reports, review articles based on European data.

International reporting

The production of the bulletin is coordinated by a French-English permanent team. The scientific committee is composed of members of the National Public Health Centre and the European Centre for the Epidemiological Monitoring of Aids in France, and of the PHLS - Communicable Disease Surveillance Centre in England. The 15 Member States of the European Union are represented by editors of national surveillance bulletins or by surveillance representatives in the case of Member States without such bulletins. They compose the editorial board.

International feedback

A French-English pilot issue was published and distributed to professionals involved in public health in 1995 (12 000 recipients). An electronic version was set up on Internet. Monthly routine production should follow the feasibility study conducted in 1995, which was funded by DGV of the Commission of the European Communities.

Inputs

Two meetings of the editorial board and six meetings of the scientific committee each year, to select, appraise and finalise articles. Regular contacts by fax or E-mail ensure close collaboration within the network. The publishing and mailing of the bulletin are carried out by the European Centre for the Epidemiological Monitoring of Aids.

Dates of i) commencement and ii) completion

i) 1995 ii) 1998 (for the project submitted to the Commission)

Value

The feasibility study revealed genuine interest from readers (evaluation questionnaire) and the European collaborators.

Eurosurveillance aims at increasing the circulation of information in the field of communicable diseases epidemiology between national surveillance systems and professionals involved in Public Health within the European Union. Moreover, the establishment of close, regular contacts between experts in charge of national communication should develop the quality and speed of information exchanges beyond the bulletin itself and should contribute to better control of communicable diseases in the European Union.

D -Other

Research in Methodologies of Immunisation Programmes Management in Europe

Diseases

Diphtheria, Tetanus, Pertussis, Poliomyelitis, Measles, Mumps, Rubella.

Activity

National Immunisation Programme Managers have met together to expedite developments in three areas:

1 Methods used to assess vaccine coverage.

2 Assessment of surveillance methods used to detect adverse reactions.

3 Investigation of outbreaks of vaccine preventable disease (predominantly to concentrate on measles).

International co-ordination

International Children's Centre, Paris.

Inputs

Funded as EC Concerted Action.

Dates of i) commencement and ii) completion

i) 1991 ii) Ongoing

Value

Pooling of structural and process data from participating countries. Allows sharing of experience and notice to be given of potentially helpful technologies (ie salivary testing for anti-measles antibodies).

II - PLANNED COLLABORATIONS

A - Surveillance

1 - SALMNET

Diseases to be surveyed

Laboratory confirmed human Salmonella infection.

Data sources

Reporting from the responsible national collaborating centre to the European coordinator. Discussions and exchange of isolates is being co-ordinated by the PHLS Central Public Health Laboratory, London, to harmonise phage typing on a European basis.

International reporting

Reporting would be by regular submission of a floppy disk to the European coordinator by each collaborating centre. An exploratory workshop in London was attended by representatives from Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom.

International feedback

An aggregate database would be created and returned to each country. The PHLS "Exception Reporting Scheme" will be used to analyse the data to identify anomalously high levels of isolation and facilitate outbreak recognition.

Date of i) commencement

i) 1993. The programme has been fundend as an EC Concerted Action under the BIOMED1 Scheme (Science, Research and Development). The programme is intended to become one of the communicable disease components of the Early Warning Pilot (ie application), one of the 4 subsidiary projects of the European Nervous System (ENS) /CARE Telematics programme, funded by the Commission to develop European electronic communications networks.

Value

Identification of European wide Salmonella problems. Enhancement of the ability to detect multi-state outbreaks. Harmonisation of reference techniques.

2 - CARE.ENS Influenza Surveillance

Diseases to be surveyed

Laboratory isolation of influenza virus or serological evidence of influenza infection combined with clinical diagnoses via sentinel schemes.

Data sources

Reporting from the responsible national collaborating centre to the European coordinator.

International reporting

Reporting would be by computer network to the European coordinator at Université Citi 2, Paris, by each collaborating centre.

International feedback

It is intended that a disaggregated database will be created for online interrogation by participants in the network.

Date of i) commencement

i) 1990. The programme is intended to become one of the communicable disease components of the Early Warning Pilot, one of the 4 subsidiary projects of the European Nervous System (ENS) /CARE Telematics programme, funded by the Commission to develop European electronic communications networks.

Value

May expedite data feedback.

3 - WHO Global Surveillance Programme for Recognition and Response to Emerging Diseases.

Diseases to be surveyed

New, emerging or re-emerging diseases and drug resistant micro-organisms.

Data sources

Enhanced laboratory reporting at country level to the existing WHO collaborating centres, which will be strengthened.

International reporting

This will be to WHO Headquarters at Geneva (Division of Communicable Diseases in close co-ordination with Divisions of Epidemiological Surveillance, Health Situation and Trend Assessment and Emergency and Humanitarian Action).

Reporting of bacterial resistance to antibiotics would be by computer network (WHONET).

International feedback

To be developed.

Date of i) commencement

i) 1994.

Value

Enhancement of capabilities at country level. Development of stronger intervention capacity at WHO/HQ level to facilitate prompt, co-ordinated action. Training components will be incorporated and research opportunities will develop.

4 - European Study Group on Haemolytic Uraemic Syndrome

Diseases to be surveyed

Clinical diagnoses of haemolytic uraemic syndrome and laboratory isolations of VT+ *E.coli*

Data sources

Paediatric dialysis units and diagnostic microbiology laboratories.

International reporting

Some reporting is already carried out by post to the University of Wurzburg in Germany. Italy submits some data currently. Interest has been indicated from Belgium and United Kingdom.

International feedback

None as yet.

Date of i) commencement

i) Italy and Germany have shared data since 1988. The programme had been proposed for funding as an EC Concerted Action under the BIOMED1 Scheme of the European Commission (Science, Research and Development).

Value

The diseases are of relatively low incidence, although the sequelae are serious. European surveillance may expedite risk factor identification.

5 - European Network on Congenital Toxoplasmosis

Diseases to be surveyed

Congenital Toxoplasmosis for which a clinical and laboratory based case definitions are to be developed.

Data sources

Participating countries institutions are to be asked to identify geographically defined populations of pregnant women in urban, and, if possible, in rural areas. Data on seroprevalence will be compared. A multi centre randomised trial of therapy has also been proposed and a long term cohort study of the offspring of women who sero-convert in pregnancy.

International reporting

Different aspects of the work will be reported to different co-ordinating centres. Participating in the inaugural workshop were Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Poland, Sweden, Switzerland, United Kingdom. Overall co-ordination is from the Statens Seruminstitut, Copenhagen.

International feedback

None as yet.

Date of i) commencement

i) 1993 The programme has been funded as an EC Concerted Action under the BIOMED1 Scheme of the Commission (Science, Research and Development).

Value

Analysis of data from a variety of localities will give indications as to routes of infection. Standardisation and quality assurance at a European level becomes possible of diagnosis and treatment. Resolving uncertainties about the outcomes of treatment may be expedited.

6 - Nordic countries case-control study of listeriosis

Diseases to be surveyed

Listeriosis.

Data sources

Physicians in participating countries will make a notification of listeriosis to the national institute for infectious disease control by fax. Data is tabulated by year by county by person (characterised by age, sex, occupation, clinical disease status and whether pregnant).

International reporting

Data will be reported by computer diskette by post to co-ordinating centres at Oslo and in Uppsala University. Participating countries will be Denmark, Finland, Norway, Iceland.

International feedback

None as yet. Format to be decided.

Date of i) commencement

i) 1991 (Planning)

Value

Increasing the understanding of the contributory factors to disease development and spread.

B - Training

European Field Epidemiology Training Program

Participants

Medical, Veterinary and Public Health Graduates from European countries. Initially 6-12 in number.

Duration and Locations

1 month theoretical training at a rotating location followed by 22 months field attachment in a country other than that from which the student comes.

Subject matter

Applied epidemiology of Communicable Diseases and Environmental Hazards.

A working knowledge of English and the language of the country where field attachment is to be performed is required in practice although languages will not be used as a criteria for admission to the course.

Assessment (including formal qualifications awarded)

None although certain educational objectives will be set such as the ability to:
1) Influence decision makers in Public Health.
2) Assume service responsibility in epidemiology and respond to disease clusters.
3) Develop and maintain an international perspective.

Benefit to participants

Comprehensive training in field epidemiology and decision making in acute Public Health problems.

Value

Development of a cadre of professionals with a commitment to addressing Public Health problems at the European level.

Develop a common approach to many problems based on a common training which will facilitate harmonisation of approaches to problems and decision making in Europe.

Date of i) commencement

i) 1995 probably represents the earliest practicable year in which students can be taken.

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DECISION

creating a network for the epidemiological surveillance
and control of communicable diseases
in the European Community

EXPLANATORY MEMORANDUM

1 In its communication COM(93) 559 of 24 November 1993 on the framework for action in the field of public health, the Commission outlined the principles and strategies to be followed in implementing Community activities directed towards the attainment of the health protection objectives laid down by Articles 3(o) and 129 of the Treaty establishing the European Community. The role of the Community is to underpin the efforts of the Member States in the public health field, to assist in the formulation and implementation of objectives and strategies, and to contribute to the continuity of health protection provision across the Community, setting as a target the best results already obtained in a given area anywhere in the Community.

2 In accordance with Article 129 of the Treaty establishing the European Community, the Commission presents proposals for the adoption by the European Parliament and the Council of incentive measures intended to contribute towards ensuring a high level of human health protection. These measures are geared towards encouraging cooperation between the Member States, lending support to their actions and promoting coordination of their policies and programmes, and towards fostering cooperation with third countries and with international organisations competent in the sphere of public health. This present Commission proposal, based on Article 129 and already announced in the Commission's programme of work for 1995, comes under the principle of shared competence between the Community and the Member States and seeks to create a network for the epidemiological surveillance and control of communicable diseases in the European Community. Full participation by the Member States in the organisation and implementation of the network should help to ensure coordination and mutual cooperation in the collection, processing and exchange of information necessary for the prevention and control of communicable diseases. This Community action is therefore geared towards disease prevention and will follow the principles of subsidiarity and proportionality.

3 Infectious diseases caused by various microbial agents tend to spread through populations and through space, essentially as a result of the movements of people and, to a lesser extent, the movement of goods and the distribution of drinking water and foodstuffs. Additional factors include climatic change (global warming), increased resistance to antibiotics, the immunological status of individuals, and living conditions (socio-economic problems). The more that people travel about, and the further they travel, the greater the risks of these diseases spreading in the form of epidemics and, as a corollary, the greater the health risks to populations. From Asian flu and cholera, to the HIV virus responsible for AIDS, examples abound both in history and in the present day. The agents responsible for communicable infectious diseases know no geographical frontiers. And despite substantial progress in the field of public health protection, the exposure of populations to the risk of contracting these diseases is increasing all the time.

4 In order to take the appropriate measures necessary to block the progression of these infectious diseases or prevent their appearance, national health authorities clearly need to have as precise a picture as possible of the epidemiological situation. This can only be achieved through the systematic collection, analysis and interpretation of data on these diseases, followed by dissemination of the data to those responsible for public health. Taken together these activities amount to epidemiological surveillance, an essentially practical process the aim of which is to produce information so that swift action can be taken. In the case of communicable diseases all the specialists agree that the cornerstone is surveillance, with the results being used in order to control and prevent these diseases. Epidemiological surveillance has proved its worth over and over again, the outlay required being amply repaid by the savings made in terms of disease avoidance.

5 In this general context, if we look at the European area as a single entity it is obviously essential to standardise communicable disease surveillance. In this respect the Council and the Ministers for Health of the Member States meeting within the Council adopted on 13 November 1992 a Resolution, No 92/C 326/1[1], inviting the Commission to report briefly on the existing arrangements established between the Member States or by the World Health Organisation (WHO) for the surveillance of communicable diseases, including food-borne diseases; to identify needs and shortcomings; and to put forward proposals for improvements. And the European Parliament, in its Resolution on public health policy after Maastricht[2], invited the Commission to set up a trans-frontier network to devise working definitions of notifiable diseases, to collect, update, analyze and disseminate Member State data on notifiable diseases and to work with national and international agencies on these matters. Additionally, in its Conclusions No 94/C 15/04 of 13 December 1993[3], the Council requested the Commission to put forward proposals for the setting up of an epidemiological network in the Community. In its Communication COM(93) 559 of 24 November 1993 on the framework for action in the field of public health and its Communication COM(94) 413 of 9 November 1994 on AIDS and certain other communicable diseases, the Commission proposed specific Community measures in this respect, notably the creation and development of surveillance networks. To this end, the Commission proceeded to consult outside experts, including both national experts competent in the surveillance and control of communicable diseases and senior officials of the national Health Ministries sitting on the High Level Committee on Health, and has taken their comments fully into account.

6 Consequently, this proposal seeks to establish a system of close cooperation and effective coordination between Member States in the field of surveillance, both routine and emergency, with a view to improving the prevention and control of a certain number of serious communicable diseases which necessitate the

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1 OJ of 11.12.1992

2 OJ No C 329, 6.12.1993, p. 375

3 OJ of 18.1.1994

introduction of measures for the protection of populations. The proposal is modelled on Community instruments already adopted in similar areas for the accomplishment of similar objectives. The data in question will be collected in aggregated form and will and will in no case enable individuals to be identified. Thus, they will not conflict with existing or forthcoming Community instruments concerning the protection of personal data, such as Council Directive C 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data[4]. They will however comply with the Community provisions concerning systems of information exchange between administrations. In addition, the Decision contains specific provisions aimed at ensuring cohesion with other relevant Community policies, namely the Common Agricultural Policy, freedom of movement of goods and persons, and exchanges of data between administrations.

7 The setting up of this network for the surveillance of communicable diseases takes account of, and is based on, the situation already existing in this field at European level. It also aims to avoid unnecessary duplication of work by ensuring that all Member States have the same conception of surveillance, as a result of defining with them the type of information required and the arrangements appropriate for each group of communicable diseases. Finally, other parties will be associated with the network, under arrangements yet to be worked out. These will include the competent international organisations, non-member countries (such as the United States of America, with whom cooperation is already planned), and the surveillance networks to which Member States already belong.

8 The implementation of the decision will yield added value in a number of ways:

a) It will ensure the setting up of a system of continuous, well-structured, reliable and effective communication at Community level between national communicable disease surveillance authorities, something which is lacking at present;

b) It will facilitate the rapid, reliable and commonly agreed identification of cases of communicable diseases occurring inside the Community, or occurring outside and therefore being imported or likely to be imported;

c) It will give the competent authorities the opportunity and the means to consult together on the preventive measures to be taken, and it will help them in the coordinated introduction of such measures and the evaluation of their effectiveness;

d) It will give the authorities the support they need for analysing and interpreting data and for deploying the necessary measures to stop communicable diseases from spreading.

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4 OJ No L 281, 23.11.1995, p.31

9 The action envisaged can only be undertaken on the basis of a European Parliament and Council decision adopting the measures proposed for the setting up of a Community system needed to ensure cooperation between Member States and coordination of their respective systems in this area. It does not require the harmonisation of national laws and regulations.

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DECISION

creating a network for the epidemiological surveillance
and control of communicable diseases
in the European Community

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 129 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

1 Whereas the prevention of diseases, and in particular of the major health scourges, is a priority for Community action, requiring a global and coordinated approach between Member States,

2 Whereas the European Parliament, in its Resolution on public health policy after Maastricht[4], invited the Commission to set up a trans-frontier network to devise working definitions of notifiable diseases, to collect, update, analyze and disseminate Member State data on notifiable diseases and to work with national and international agencies on these matters,

3 Whereas in its resolution of 2 June 1994 on the framework for Community action in the field of public health[5] the Council agreed that priority should be given at present to communicable diseases in particular;

4 Whereas in its conclusions of 13 December 1993[6], the Council considers that there is a need to develop at Community level a network for the surveillance and control of communicable diseases, the main purpose of which would be to collect and coordinate information from monitoring networks in the Member States;

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1 OJ No ...
2 OJ No ...
3 OJ No ...
4 OJ No C 329, 6.12.1993, p. 375
5 OJ No C 165, 17.6.1994, p.1.
6 OJ No C 15, 18.1.1994, p. 6.

5 Whereas in these same conclusions the Council requests the Commission to devote special attention, in its proposals relating to the framework for action in the field of public health[7], to setting up an epidemiological network in the Community, taking account of current proceedings and mechanisms existing at Community level and that of Member States, and ensuring the comparability and compatibility of data;

6 Whereas in their resolution of 13 November 1992[8], the Council and the Ministers for Health meeting within the Council underline the desirability of improving, within the Community, the coverage and effectiveness of existing networks between Member States (including data-processing networks), and of maintaining, establishing or strengthening coordination between them for monitoring outbreaks of communicable diseases, where such action could add to the value of existing measures;

7 Whereas in this same resolution, the Council and the Ministers for Health meeting within the Council underline the value of collecting data from the Member States on a limited number of rare and serious diseases which require large samples for epidemiological study;

8 Whereas in this same resolution, the Council and the Ministers for Health meeting within the Council invite the Commission to examine the desirability of giving priority to certain suitable proposals relating to the control and surveillance of communicable diseases, in the light, *inter alia*, of their estimated cost-effectiveness;

9 Whereas, in accordance with the principle of subsidiarity, any new measure taken in an area which does not fall within the exclusive competence of the Community, such as the epidemiological surveillance and control of communicable diseases, may be taken by the Community only if, by reason of the scale or effects of the proposed action, the objectives of the proposed action can be better achieved by the Community than by one or more Member States;

10 Whereas measures in the health field must take into account other actions undertaken by the Community in the field of public health or which have an impact on public health;

11 Whereas European Parliament and Council Decision .../.../EC adopting a programme of Community action on the prevention of AIDS and certain other communicable diseases within the framework for action in the field of public health[9] envisages a number of Community actions for the creation and development of networks for the control and surveillance of certain communicable

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7 COM(93) 559 final, 24.11.1993.

8 OJ No C 326, 11.12.1992, p. 1.

9 OJ No ...

diseases, the early detection of such diseases, and promotion of the training of field epidemiologists;

12 Whereas cooperation with the competent international organisations, notably with regard to disease classification, must be fostered;

13 Whereas cooperation with third countries, notably in the case of the emergence or resurgence of serious communicable diseases, must be supported;

14 Whereas the emergence or recent resurgence of serious communicable diseases has demonstrated that when an emergency situation occurs all relevant information must be communicated swiftly to the Commission in an agreed form of presentation;

15 Whereas the introduction of specific Community arrangements will help to ensure that all Member States are swiftly informed in the event of such an emergency situation, so that the protection of the population can be ensured;

16 Whereas the provisions of Council Directive 92/117/EEC[10] concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications apply equally to information concerning zoonoses which affect human beings, and whereas the same directive provides for a system for collecting and transmitting information on specified zoonoses and zoonotic agents,

17 Whereas the setting up of a network for the epidemiological surveillance and control of communicable diseases at Community level necessarily presupposes observance of the legal provisions concerning the protection of individuals with regard to the processing of personal data and the introduction of arrangements to guarantee the confidentiality and security of such data and information; whereas in this connection the European Parliament and the Council adopted Directive 95/46/EC on 24 October 1995,

18 Whereas the Community projects in the field of the telematic interchange of data between administrations (IDA)[11] and the G7 projects should be closely coordinated with the implementation of the Community actions relating to the epidemiological surveillance and control of communicable diseases;

19 Whereas it is important, in an emergency situation, that the competent national structures should strengthen their cooperation, notably with regard to the identification of biological samples;

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10 OJ No L 62, 15.03.93, p. 38.

11 OJ No L 269, 11.11.1995, p.23.

20 Whereas these Community arrangements for the rapid exchange of information do not affect the Member States' rights and obligations under Treaties or bilateral and multilateral conventions;

21 Whereas it is important that the Commission should implement the Community network in close cooperation with the Member States; whereas a procedure therefore needs to be established to ensure the Member States' full participation in this implementation;

22 Whereas an agreement on a *modus vivendi* between the European Parliament, the Council and the Commission concerning measures for the implementation of acts adopted under the procedure laid down in Article 189b of the Treaty was reached on 20 December 1994;

HAVE DECIDED AS FOLLOWS:

Article 1

A general network for the epidemiological surveillance and control of communicable diseases shall be set up in the European Community.

This Community network shall be formed by putting into permanent communication with one another, through all appropriate technical means, structures which, at the level of each member State and under the responsibility of the Member State, are charged with collecting information relating to epidemiological surveillance and coordinating control measures.

Article 2

For the purposes of this decision the following terms shall have the following meanings:

1 - *epidemiological surveillance:* the ongoing systematic collection, analysis, interpretation and dissemination of health data concerning communicable diseases, for the purpose of enabling appropriate counter-measures to be taken;

2 - *control of communicable diseases:* the range of measures taken by the competent public health authorities to stop the spread of communicable diseases, as well as epidemiological studies, in particular of the pattern of spread of such diseases over time and space and analysis of the risk factors for contracting such diseases, the results of which enable appropriate preventive measures to be devised.

Article 3

For every Member State, the epidemiological surveillance and control of communicable diseases at Community level shall apply to:

a) the appearance or resurgence on its territory of cases of serious and/or rare communicable diseases as listed in the Annex;

b) the importation onto its territory, from another Member State or a non-Community country, of cases of serious and/or rare communicable diseases as listed in the Annex.

Article 4

For the purposes of implementing this decision the Commission shall be assisted by a committee consisting of representatives from the Member States and chaired by a representative of the Commission.

The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on this draft within a time limit which the chairman shall lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion has been delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall act by a qualified majority.

If, within three months of the matter being referred to it, the Council has not adopted measures, the Commission shall adopt the measures proposed and implement them immediately.

Article 5

The measures referred to in Article 4 concern in particular:

- case definitions, in particular the clinical definition and, where appropriate, the microbiological characterisation of the agent responsible;

- the nature and type of data and information to be collected by the structures referred to in Article 1 in the field of epidemiological surveillance;

- the epidemiological and microbiological surveillance methods;

- the protective measures to be taken, in particular at ports and airports, notably in emergency situations;

- information, recommendations and guides to good practice for the public;

Article 6

Each structure referred to in Article 1 shall communicate to the Community network and the Commission:

- information on the communicable diseases referred to in Article 2, together with information on control measures applied;
- any useful information concerning the progression of epidemic situations in the Member State to which the institution belongs;
- any evaluation element which will aid cooperation between Member States for the purpose of the control of communicable diseases, in particular the conservation of biological samples taken from patients for transmission to specialist laboratories linked to the Community network.

Article 7

Each Member State shall appoint, within six months following the entry into force of this decision, the structure or structures referred to in Article 1, and shall notify the Commission thereof.

Article 8

The Commission may amend or supplement the Annex in accordance with the procedure provided for in Article 4.

Article 9

This decision shall apply without prejudice to Council Directive 92/117/EC concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications, and shall take account of the information collection and transmission procedure provided for in that directive.

Article 10

This decision shall apply without prejudice to European Parliament and Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and to Council Decision 95/468/EC on a Community contribution for telematic interchange of data between administrations in the Community (IDA).

Article 11

This decision shall not affect Member States' reciprocal rights and obligations deriving from existing or future bilateral or multilateral agreements or conventions in the domain covered by the decision, and which are in line with the decision's subject, methods of implementation and objectives.

Article 12

This decision is addressed to the Member States and shall enter into force three months after the date of its publication in the Official Journal of the European Communities.

Done at Brussels

For the European Parliament
The President

For the Council
The President

ANNEX

The communicable diseases referred to in Article 3 are divided into groups of serious and/or rare disorders, namely:

- concerning paragraph a):

diseases requiring measures to be taken at local level and reported on periodically to the Member States' public health authorities in accordance with arrangements specific to each of these diseases and defined in accordance with Article 5, notably:

- diseases preventable by vaccination (tuberculosis, tetanus, poliomyelitis, diphtheria, meningitis, measles, mumps, rubella, influenza and influenza syndromes, etc.),
- sexually-transmitted diseases (hepatitis B, AIDS/HIV, chlamydiasis, etc.),
- viral hepatitis (including hepatitis C and other as yet unclassified categories of hepatitis),
- food-borne diseases (listeriosis, salmonellosis, etc.),
- water-borne diseases and diseases of environmental origin (legionellosis, etc.),
- nosocomial infections,
- other diseases transmissible by non-conventional agents (including Creutzfeldt-Jakob disease, etc.).

- concerning paragraph b):

the same diseases as under paragraph a), plus diseases requiring exceptional measures to be taken at national and international levels, such as:

- diseases covered by the International Health Regulations (yellow fever, cholera, plague)
- other diseases (rabies, typhus fever, African haemorrhagic fevers, malaria and any other as yet unclassified serious epidemic disease, etc.).

FINANCIAL STATEMENT

1 TITLE OF OPERATION

Proposal for a European Parliament and Council decision creating a network for the epidemiological surveillance and control of communicable diseases in the European Community.

2 BUDGET HEADING INVOLVED

Part A of the budget.

3 LEGAL BASIS

a) Actual legal basis:

Article 3(o) and Article 129 of the Treaty on European Union.

b) References:

Conclusions of the Council and the Ministers for Health of the Member States meeting within the Council of 16 May 1989 on the improvement of the general system for collecting epidemiological data, including the application of the new definition of AIDS cases (OJ No C 185, 22.7.1989, p. 7).

Resolution of the Council and the Ministers for Health of the Member States meeting within the Council of 13 November 1992 on the monitoring and surveillance of communicable diseases (OJ No C 326, 11.12.1992, p. 1).

Commission communication on the framework for action in the field of public health (COM (93) 559 final, 24 November 1993).

Council conclusions of 13 December 1993 on the setting up of an epidemiological network in the European Community (OJ No C 15, 18.1.1994, p. 6).

4 DESCRIPTION OF OPERATION

4.1 General objective

Implementation at Community level of a system of epidemiological surveillance in the field of communicable diseases, to meet the following objectives:

– firstly, to ascertain the incidence and the characteristics of a particular infectious disease or group of diseases, and to study the pattern of spread of the disease through time, space and social categories, so as to be able to take appropriate counter-measures;

– secondly, to detect disease clusters or epidemics, or even abnormal health incidents, so that measures can be taken to break the specific transmission chain;

– thirdly, to describe and measure the risk factors for contracting a communicable infection, so as to be able to select and implement the most appropriate preventive measures and recommendations.

4.2 Method employed for attaining these objectives

The setting up and running of a system for the surveillance and control of communicable diseases at Community level, requiring the exchange, at appropriate moments, of accurate and reliable information concerning diseases for which specific case definitions, identifications and verifications are required. It is proposed to set up this system on the basis of a European Parliament and Council decision, and to exploit the infrastructure set up by the IDA programme.

4.3 Period covered

– Open-ended.
– Implementation report to be transmitted to the Council and the European Parliament following the creation of the network, and further reports to be transmitted following any adaptations to the system.

5 CLASSIFICATION OF EXPENDITURE OR REVENUE

Non-differentiated appropriations.

6 TYPE OF EXPENDITURE OR REVENUE

Nil

7 FINANCIAL IMPACT

No financial impact in Part B of the budget.

8 ANTI-FRAUD MEASURES PLANNED

Measures in the rules on the reimbursement of travelling and subsistence costs of experts convened.

9 ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1 Specific and quantifiable objectives:

The aim is to establish a Community network for the epidemiological surveillance and control of communicable diseases, by achieving the following objectives:

– setting up of a system of close cooperation and effective coordination between Member States in the field of surveillance, both routine and emergency, with a view to improving the prevention and control in Europe of a certain number of serious communicable diseases which necessitate the introduction of measures for the protection of populations;

– list of diseases and/or groups of diseases kept under surveillance at Community level;

– case definitions, in particular the clinical definition and, where appropriate, the microbiological characterisation of the agent responsible;

– the nature and type of data and information to be collected in the context of epidemiological surveillance;

– epidemiological and microbiological surveillance methods;

– protective measures to be taken, in particular at ports and airports, notably in emergency situations;

– information, recommendations and guides to good practice for the public;

– designation of the structure responsible for coordination for particular diseases and/or groups of diseases.

9.2 Players concerned

1. The Member States' competent health authorities at national, regional and local levels, and competent international organisations.

2. Health professionals, institutions, laboratories and epidemiological health services.

9.3 Grounds for the operation

As regards the setting up of a system for the surveillance and control of communicable diseases at Community level, the Commission, in its communication of 24 November 1993 on the framework for action in the field of public health, outlined the principles and strategies to be followed in implementing Community activities directed towards the attainment of the health protection objectives laid down by Articles 3(o) and 129 of the Treaty establishing the European Community. The role of the Community is to underpin the efforts of the Member States in the public health field, to assist in the formulation and implementation of objectives and strategies, and to contribute to the continuity of health protection provision across the Community, setting as a target the best results already obtained in a given area anywhere in the Community.

The Commission's proposal for the creation of such a network advocates that the Member States should participate fully in its organisation and implementation. The network's task will be to ensure coordination in the collection, processing and exchange of information necessary for the prevention and control of communicable diseases. Focusing on disease prevention, and following the principles of subsidiarity and proportionality, this Community operation is designed to enable the authorities responsible for public health to take, at national level, measures to block the progression of these infectious diseases or to prevent their appearance.

An operation as extensive as the creation and development of a network which will link the competent authorities of all Member States can only be undertaken on a Community scale.

9.4 Monitoring and evaluation of the operation

9.4.1 Monitoring of the operation

The setting up and functioning of the network will be monitored by the Commission, which will submit reports to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. The Commission will base its reports on the national reports and on any evaluations carried out.

9.4.2 Evaluation

* Evaluation will take the form of:

– an evaluation of the effective establishment of the network, with the participation of independent experts;

– reports on the quality and effectiveness of the network's functioning, to be submitted by the Commission to the other Community institutions.

* Evaluation methods and intervals:

– establishment of regular reports on any adaptations which may be introduced.

10 ADMINISTRATIVE EXPENDITURE (PART A OF THE BUDGET)

The effective mobilisation of the administrative resources required will result from the Commission's annual decision on the allocation of resources, taking account of any additional staff and funds allocated by the budgetary authority.

10.1 Effect on the number of workers

Types of workers		Staff running the operation		Source of the workers		Duration
		Permanent workers	Temporary workers	DG or service	Additional personnel	
Officials, or temporary staff	A	1	0	1	0	
	B	1		1	0	
	C	1		1	0	
Other resources						
Total		3	0	3	0	

10.2 Financial impact of employing additional staff

Nil

10.3 Increase in other administrative expenditure resulting from the operation

Budget heading	Amount	Method of work
Meetings A2510	92 650	* 4 meetings of the committee, 2 representatives/Member State, 4 x 30 x 770 Ecus

The resources needed to cover the expenditure described below will be obtained by redeploying existing financial resources; no additional resources will be required.

Staff expenditure (Titles A1, A2 and A5)

3 x 100 000 Ecus = 300 000 Ecus

Administrative expenditure:

– Cost of meetings (A-250)
3 meetings x 15 experts x 879 Ecus = 39.555 Ecus

– Mission costs (A-130)
24 Brussels-Luxembourg missions x 200 Ecus = 4 800 Ecus
30 Member States missions x 750 Ecus = 22 500 Ecus

Total: 366 855 Ecus

ISSN 0254-1475

COM(96) 78 final

DOCUMENTS

EN 05

Catalogue number : CB-CO-96-087-EN-C

ISBN 92-78-00943-1

Office for Official Publications of the European Communities

L-2985 Luxembourg