## COMMISSION OF THE EUROPEAN COMMUNITIES

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#### COMMUNICATION FROM THE COMMISSION

concerning a Community action programme on the prevention of AIDS and certain other communicable diseases in the context of the framework for action in the field of public health

# Proposal for a EUROPEAN PARLIAMENT AND COUNCIL DECISION

94/0222 (COD)

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

(presented by the Commission)

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#### I. INTRODUCTION

#### BACKGROUND

- In its communication of 24 November 1993 on the framework for action in the field of public health<sup>(1)</sup> the Commission defined a framework for Community action in order to attain the objectives on health protection laid down in Articles 3(o) and 129 of the Treaty establishing the European Community. The role of the Community is identified as underpinning the efforts of the Member States in the public health field, assisting in the formulation and implementation of objectives and strategies, and contributing to the provision of health protection across the Community, setting as a target the best results already obtained in a given area anywhere in the Community.
- 2. In initiating action under Article 129, the Community has to address itself to preventing disease and protecting health. Based on the criteria laid down in the Commission communication, AIDS and other communicable diseases have been identified as a priority for Community action.
- 3. These are diseases which have the following characteristics:
  - they cause or are likely to cause in the absence of intervention, significant premature death and/or overall high death rates;
  - they cause or are likely to cause in the absence of intervention, significant ill health including high morbidity and/or disability;
  - they have significant implications for the quality of life as well as major socio-economic effects, such as high health care and treatment costs, and considerable absenteeism and unfitness for work;

## and for which:

- practicable measures of prevention exist;
- there would be added value from the Community undertaking actions, particularly through economies of scale.
- Furthermore, AIDS has been singled out by the Council, the European Parliament, the Economic and Social Committee, and the Committee of the Regions, as a major scourge which deserves special attention by the Community. A long series of resolutions, conclusions and opinions by these institutions culminated in June 1994 in the adoption of a common position<sup>(2)</sup> by the Council, following favourable opinions by the other bodies, concerning the prolongation in 1994-1995 of the "Europe against AIDS" programme along the lines proposed by the Commission.

<sup>(1)</sup> COM(93) 559 final.

<sup>(2)</sup> OJ No

The AIDS crisis has aroused interest, from the public health point of view, in all the other diseases in this category. This applies first and foremost to the other sexually transmitted diseases (STDs) which can often accompany the HIV (human immunodeficiency virus) infection which leads to AIDS. The occurrence of certain STDs alongside HIV infection has caused the infectious disease experts to re-think many of their ideas, obliging them to adapt to a new, complex and constantly evolving reality. The renewed interest applies also to those infectious diseases which accompany the onset of AIDS proper, and which are known as opportunistic infections. Some of these, which have been known about for a very long time, now need to be monitored more vigilantly, such as for example tuberculosis.

## 2. BASIC CHARACTERISTICS OF COMMUNICABLE DISEASES

- 6. At various stages in our history there have been epidemics which have affected and even decimated whole populations. The plague of the Middle Ages wiped out a quarter of the population of western Europe in a mere four years, and the Spanish flu, which ravaged every continent at the start of this century, killed more than 20 million people in the space of a few months. But medical advances such as the development of vaccines and new drugs, combined with substantial improvements in living conditions and public hygiene, have considerably reduced the threat from infectious diseases to the citizens of the European Union. Worldwide, however, infectious diseases are still a major cause of death, and in the least-developed countries they represent more than 70% of the global burden of disease.
- 7. A remarkable success has recently been achieved in the fight against communicable disease by the eradication of smallpox. Through a combination of active monitoring and an effective, easy-to-use vaccine, the health authorities managed first to stem the spread of the smallpox virus and then cause it to disappear altogether, thus eradicating this disease from the surface of the Earth. In the same period, however, infectious diseases which were thought to have disappeared or to be on the way out have begun to re-appear, and have reached epidemic proportions in certain places.
- 8. Examples are diphtheria, which is rampant again in eastern Europe, and, to a lesser degree, poliomyelitis, which was thought to be on the point of extinction. Another example is tuberculosis, the resurgence of which results from a combination of factors, such as the slackening of vaccination programmes, the inability of certain drugs to cope with resistant new strains, and poor living conditions all factors about which something could be done.
- 9. Moreover, new diseases are appearing on the scene, ranging from Lyme borreliosis, transmitted by ticks and becoming increasingly prevalent, to chlamydiosis, a sexually transmitted bacterial disease which has serious implications for female fertility.

- Of particular importance has been the appearance of HIV infection, which has become pandemic since its appearance at the start of the 1980s and which leads to AIDS. It has rightly given great cause for concern because it is fatal in the long term and because there is at yet no serum, vaccine or effective treatment available. Its nature is such that it has forced the public authorities to take measures guided by the circumstances to try to halt its progression and this explains why so much attention is being paid to it. If the weapons deployed so far against it appear ineffective, there can be no doubt that they have nonetheless borne some fruit, both in terms of checking somewhat its spread in certain countries and among particular groups, and also in terms of the beneficial impact they have had on the fight against sexually transmitted diseases in general.
- All communicable diseases are caused by a transmissible agent, such as a bacterium, a virus, a parasite, a worm or a fungus. To combat these infectious diseases as effectively as possible, it is therefore necessary to find ways of preventing these agents from causing disease.
- 12. The modes of transmission of infectious agents include: water (cholera, hepatitis A, etc.); animals which transmit various zoonoses to man (brucellosis, trichinosis, echinococcosis, rabies, tuberculosis, etc.); food (salmonellosis, listeriosis, etc.); the environment (legionellosis, etc.); human contact (tuberculosis, influenza, etc.); the iatrogenic route (blood transfusions which can transmit the HIV virus, the hepatitis C virus, etc.).
- 13. A distinction needs to be made between infection, i.e. the fact that one of these agents takes up residence in the body of an individual and multiplies within it, very often with no obvious clinical manifestations, and the disease itself, i.e. it produces symptoms and signs which, in most cases, is the only aspect which the general public worries about. Many more people carry an infection, all too often without realising it, or are exposed to a source of infection, than actually contract a disease and become ill. Controlling or reducing the spread of any communicable disease is usually restricted to measures aimed at containing the transmission of the infection by the causal agent. For example, chronic carriers of the hepatitis B virus or the HIV virus are not necessarily ill but may, in certain circumstances, transmit the infection to other unaffected persons. In this respect, such carriers are a potential risk to public health.
- 14. The severity of a communicable disease depends not only on the intrinsic danger constituted by the causal agent but also on whether it is able or not to spread easily in the environment and at some stage to affect the state of health of any individual contracting it. Furthermore, in the case of some communicable diseases the infection process is due to toxins produced by the causal agents. This is the case with the agents responsible for botulism and tetanus, for example. Finally, certain agents responsible for communicable diseases are able to trigger an allergic process within man, such as Ascaris Suum and Candida Albicans.
- 15. Communicable diseases may affect the general population, or be more prevalent in certain risk groups or in some types of situations. A distinction is therefore made between the following:
  - communicable diseases affecting the general public, such as HIV, hepatitis (A, B and C especially), tuberculosis, sexually transmitted diseases, gastrointestinal diseases, communicable diseases (other than tuberculosis and hepatitis) preventable through vaccination, and zoonoses;

- those affecting, more particularly, certain categories of the population classifiable as being "at-risk"; these communicable diseases can become dangerous when they affect certain constitutionally or physiologically fragile categories of the population:
  - Among pregnant women these are rubella (German measles), toxoplasmosis, listeriosis and rickettsioses.
  - Among children these are diseases which can be tackled through vaccination such as diphtheria, whooping cough, poliomyelitis and tuberculosis, but also hyperacute communicable diseases which have an adverse effect on survival prognosis (such as certain meningococcal infections).
    - Among old people this is influenza, which although preventable, in particular through vaccination can assume serious dimensions, thus adversely affecting survival prognosis.
  - Among fragile individuals, such as the immunodepressed, alcoholics, the disabled, but also excluded individuals living in adverse or precarious socio-economic conditions, often far below the poverty line, such as the homeless or migrant communities, certain mycotic or parasitic infections, anaerobic germ infections and opportunistic infections.
- And, finally, those whose transmissibility is increased in certain situations:
  - this is particularly the case for hospitals where nosocomial infections are causing an increasing prevention problem;
  - in communities (nurseries, armed forces, holiday camps, schools) where gastrointestinal diseases, hepatitis and infections preventable through vaccination are occurring more and more often;
  - in prisons, where there is a clear rise in the number of sexually transmitted diseases and HIV infection.
  - 3. SELECTION OF CERTAIN COMMUNICABLE DISEASES FOR COMMUNITY ACTIONS
- 16. In this Communication the Commission sets out the measures it proposes to undertake to prevent communicable diseases, drawing on the knowledge and experience acquired in the course of its previous actions. The Community cannot tackle all communicable diseases in one go since there are so many of them. Nor is it possible to cover all communicable diseases in this Communication, since there are far too many of them and their repercussions on public health are so variable.

- 17. In view of the limited resources available to the Community, a selection has to be made among the communicable diseases in order to identify those which would be the object of action yielding the highest Community added value; moreover, preference will have to be given to actions which can also benefit the fight against the greatest possible number of such diseases. Community actions must primarily encourage cooperation between the Member States, and aim, where appropriate, at coordinating health policies and programmes. In this context, the fact, for example, that many communicable diseases can be treated effectively with chemotherapy or can be contained through tried-and-tested vaccination programmes has been followed up more assiduously by some Member States than by others, and has thus resulted in a widely contrasting situation which merits closer, case-by-case analysis. Finally, the communicable diseases to be selected must include those for which the Member States themselves and the Community institutions have expressed an interest or preference for a contribution by the Community primarily on the basis of the perceived risks to individuals as well as to the society as a whole.
- 18. Applying this approach to communicable diseases involves selecting those diseases which are to be the main focus of this action, viz.:
  - 1. HIV infection, AIDS and sexually transmitted diseases;
  - 2. diseases which can be prevented through vaccination; and
  - 3. diseases which can be tackled through certain specific Community measures.

## II. THE SITUATION AS REGARDS COMMUNICABLE DISEASES AT COMMUNITY LEVEL

#### 1. ZOONOSIS

- 19. Zoonoses, i.e. infectious diseases carried by animals and liable to be transmitted to man, have been the subject of close attention for more than three decades. The Community has endeavoured to contribute to safeguarding public health in general by adopting and implementing a series of specific programmes involving substantial funds (for instance, over MECU 125 for the 1987-1992 period) and aimed at combatting or eradicating certain zoonoses.
- 20. Since 1964 Community programmes have focused on monitoring and eradication of bovine tuberculosis, as a result of which many herds in the Community have been declared clear of this disease. The same applies to bovine brucellosis (B. abortus) and, more recently, sheep and goat brucellosis, while the fight against B. melitensis continues. Since 1989 the battle against rabies, in wild animals especially, has made good progress thanks to vaccination by means of aerial dropping of bait. Trichinosis is now under better control thanks to improved processing of fresh meat, especially horse meat. As for salmonellosis, this has received special attention over and above that stipulated by legislation including efforts to improve the quality of livestock, hygiene in abattoirs and undertakings processing and transforming products of animal origin into foods for human consumption. In this respect, significant progress has been achieved through the establishment of microbiological criteria designed to ensure the absence of salmonella or related contaminants, plus checks on application thereof in the case of minced meat, meat-based products, shellfish, milk and egg products.

#### 2. HIV INFECTION, AIDS AND SEXUALLY TRANSMITTED DISEASES

- 21. By 31 March 1994, a cumulative total of 105 446 AIDS cases, including 1 920 paediatric cases, had been reported in the twelve countries of the European Community (EC) and 6 476 (including 6 386 adults/adolescents and 86 paediatric cases) in the six COST<sup>(3)</sup> countries. The cumulative number of cases reported by country ranges from 79 in Luxembourg to 30 003 in France. Three countries (France, Italy, and Spain) have reported over 20 000 cases and account for 72% of the cases reported in the EC. In 1993 over 20 000 new cases were reported, and 6 000 for the first three months of 1994.
- 22. The analysis of adult/adolescent cases by transmission group from 1990 to 1993 shows an increase in the proportion of cases attributed to heterosexual contact (from 10.8% to 15.3%) and among intravenous drug users (IDUs) (from 40.0% to 41.8%). In the same period, there were gradual decreases in the proportions of homo/bisexual males (from 39.3% to 32.2%), haemophiliacs (from 1.7% to 1.1%) and transfusion recipients (from 2.2% to 1.5%).
- 23. A preliminary breakdown of the transmission category "heterosexual contact" shows an increase, from 1990 to 1993, in the proportion of cases in several groups: persons originating from countries where heterosexual transmission is common (from 2.9% to 3.7% of all adult/adolescent cases), persons with an IDU partner (from 2.5% to 3.5%), and persons with an HIV-positive partner without a known risk factor (from 1.2% to 2.9%).
- 24. The proportion of infected females is 15.2% among adult/adolescent cases but 46.7% among paediatric cases. This proportion varies according to the transmission group: among adult/adolescent cases, it is highest in the transfusion recipient group (46.1% females) and in the heterosexual contact group (43.0% females). Among cases in the heterosexual contact group, 67.0% of persons with an IDU partner are females.
- 25. The analysis of cases by period of diagnosis, from 1990 to 1993, shows an increase in the proportion of females among adult/adolescent cases (from 14.9% to 18.3%). This increase is largely correlated to the decrease in the proportion of homo/bisexual cases, but also reflects an increase (from 40.8% to 45.4%) in the proportion of female cases in the heterosexual contact group. This latter increase is observed particularly among persons originating from countries where heterosexual transmission is common (36.8% to 46.0%) and among persons with an IDU partner (61.9% to 68.4%).
- 26. The total number of people in the Community infected with HIV is unknown. Nevertheless, application of certain mathematical models makes it possible to estimate the number of people who are currently seropositive at something in the region of half a million throughout the Community, with major variations from one country to another. Thus, there are thought to be some 200 000 seropositives in France and under 50 000 in the United Kingdom. If, as the present state of knowledge indicates, all seropositive individuals eventually develop full-blown AIDS, this provides some idea of the extent of the public health problem faced, all the more so given that prevention by vaccination or effective chemotherapy are not yet possible.

<sup>(3)</sup> Cooperation in Scientific and Technical Research.

27. In each Community country one or more national surveillance systems cover certain sexually transmitted diseases: gonorrhoea and syphilis are monitored in all Member States, but this is not so for genital herpes. Furthermore, case definitions vary from one Member State to another depending on the type of disease monitored. This means that given the relatively low prevalence of the most common sexually transmitted diseases - such as gonorrhoea, syphilis, chlamydiosis, Condylomata A infection, genital herpes, soft chancre, granuloma inguinale and lymphogranuloma venereum - we currently have no accurate epidemiological data at Community level.

#### 3. COMMUNICABLE DISEASES PREVENTABLE BY VACCINATION

- 28. Many communicable diseases can be contained through tried-and-tested vaccination programmes. Public health programmes to eliminate certain communicable infectious diseases have often based themselves on vaccination, which is the most effective means of prevention for many of them. However, the resurgence of certain communicable diseases lends weight to the need for a re-examination of vaccination policies used by Member States to assist in improving their control.
- Vaccination policies may differ in their aims, from eradication to elimination or to control of the disease. Eradication means bringing about the total and definitive disappearance of the causal agent and the disease, but it can only be successful if there is a global strategy at international level. Elimination means bringing about a situation in which the causal agent continues to exist but the incidence of the disease is extremely low; this is costly for the public health sector, since it involves regular and long-term expenditure on vaccination programmes, permanent monitoring, and intervention whenever an epidemic flares up. On the other hand, control aims merely to bring about a situation where the existence of the disease does not constitute a major health problem: the vaccination policy is directed towards certain groups of the population considered to be at high risk.
- 30. Member States' vaccination policies differ, ranging between compulsory vaccination, either for everyone or for certain groups, and voluntary vaccination, with or without incentives such as free vaccines. The countries with the most similar vaccination policies are France, Luxembourg and the United Kingdom. All Member States vaccinate against diphtheria, tetanus and poliomyelitis, and most vaccinate against whooping cough, measles, mumps and rubella. Increasingly vaccination is also offered against haemophilus influenza B. As concerns hepatitis B, Italy is the only country which has introduced compulsory vaccination for the entire population, since the incidence there is higher than in any other country.

- 31. This diversity is borne out by WHO statistics (1991). They show that more than 90% of children in the European Community are vaccinated against diphtheria and tetanus, except in Ireland (65%) and Spain (86%). Similarly more than 90% are vaccinated against whooping cough, except in Greece (84%) and in Italy and Ireland (40%). Child vaccination against measles ranges from 86% to 96% in the Member States, with the exceptions of Ireland and Italy (50%) and France (77%). Finally, the child vaccination level for poliomyelitis ranges between 88% and 99% in the European Community, with the exception of Ireland (63%) and Greece (77%). However, caution must be used in interpreting these statistics as the levels of vaccination cover are calculated differently from one Member State to another, since no common criteria are applied and the figures are often merely estimates rather than accurate calculations. To some extent, low percentage can be explained by the absence of incentive measures when immunization was not compulsory.
- Pursuing an effective vaccination policy at national level over a sufficiently long period clearly pays off. For example, in the case of very high initial incidence rates of tetanus, it has been possible to reduce them considerably. Thus, the rate per 100 000 dropped from 2.21 to 0.4 in Portugal between 1974 and 1991 as the corresponding vaccination cover rose from 53% to over 94%; it went from 1.33 to 0.14 in Spain between 1980 and 1990; from 0.35 to 0.16 in Greece between 1974 and 1990; and from 0.53 to 0.06 in France between 1974 and 1990 where vaccination coverage grew from 79% to 92%. Where incidence rates were very low to begin with, a sustained vaccination effort has made it possible either to keep the rate very low, as in Great Britain where it remained at 0.03 between 1974 and 1989 or in the Netherlands where it decreased from 0.05 to 0.01 between 1974 and 1990, or to reduce it to virtually zero as in Denmark and Luxembourg. The results are even more spectacular for poliomyelitis, where maintenance of extensive vaccination cover during a sufficiently long period at least two decades has led to extremely low, even zero, incidence rates in the European Community nowadays, which is more or less tantamount to eradication of the disease.
- 33. The characteristic epidemiological features of influenza include the occurrence of frequent, but unpredictable epidemics and periodic worldwide pandemics. Outbreaks of influenza A or B infection are reported nearly every winter and vary in severity. Influenza surveillance provides important information on the timing and potential of an influenza outbreak. This information is used to coordinate an appropriate public health response, including issuing guidelines on vaccination and antiviral treatment and assessing the need for additional medical resources. Vaccination plays an important role in reducing mortality and morbidity from influenza, particulary in groups at risk. It is most effective when the influenza strain which is likely to cause an outbreak is identified beforehand.
- 34. Mortality from influenza increases dramatically with age and the presence of underlying medical conditions. For instance, the 1989-90 epidemic in England and Wales was the worst since 1976 and was thought to be responsible for over 29 000 excess deaths. Increased numbers of deaths from cerebrovascular or cardiac disease were also recorded during the epidemic, and it is probable that influenza played a part in these excess deaths.

#### 4. COMMUNICABLE DISEASES WHICH REQUIRE SPECIFIC MEASURES

## (a) Hepatitis

- 35. Hepatitis is a condition characterised by inflammation of the liver of a toxic or infectious origin, provoking a change in the hepatic cells and consequently a change in normal liver functions. Viral hepatitis is an infectious disease common throughout the world which on account of its frequency, severity of certain forms (acute, chronic, cancerous) and cost of treatment constitutes a serious public health problem. Several viruses (A, B, C, D, E and others, as yet unidentified) may cause hepatitis, two of which call for special attention.
- 36. Hepatitis B is one of the major human diseases against which safe and effective vaccines have been available since 1982 in the Community. A preliminary analysis of a survey, conducted by the WHO Regional Office for Europe, estimates that 900 000 to 1 000 000 people in Europe are infected by hepatitis B every year. Of these, 24 000 will die from the effects of the chronic disease, cirrhosis and liver cancer, and 90 000 will become chronic hepatitis B carriers. About 85 000 cases of acute hepatitis B are reported every year to the WHO Regional Office for Europe. The carriers also represent a large reservoir of infection which serves to perpetuate the infection through various modes of transmission.
- Among the types of viral hepatitis, hepatitis C the virus causing it having been identified in 1989 warrants special attention since its public health consequences are dire. There is no vaccine against it in contrast to A and B hepatitis and one of its special features is that people infected by the C virus are unaware of it for most of the time, with the disease developing quietly over one or two decades, without any obvious clinical signs in almost 95% of cases.
- 38. The specialists acknowledge that in the natural course now being mapped out of this disease 10% of those who have the C virus will suffer cirrhosis several years after the initial infection, and of those, 10 to 20% will develop cancer of the liver unless secondary prevention measures are taken. Recent epidemiological studies, undertaken after improvements in screening tests, have shown that some 16 million people are infected by the C virus in the Community. This gives an idea of the size of the problem the public health authorities are facing or will face, all the more so given the fact that at present although the transfusion risk, i.e. of infection from donated blood, has been substantially reduced there seems to be no plausible explanation for 50% of infections.

## (b) <u>Tuberculosis</u>

- 39. Tuberculosis has been a major affliction of man since ancient times. In Britain during the industrial revolution of the eighteenth century, a tuberculosis epidemic claimed so many lives that it became known as "the white plague". Subsequently the disease declined steadily, probably due to a combination of several factors.
- 40. The persistence of a high level of tuberculosis in Europe can be attributed to several factors such as poor living conditions in certain regions of the world, changing eating and migratory patterns and resistance to some strains of tuberculosis bacteria to standard treatments. Tuberculosis is a disease which can be prevented by vaccination, yet there is less than 100% coverage by current vaccination programmes.

- 41. A retrospective WHO survey in 1992 indicates that 50 000 new cases were registered in the Community in 1991, half as many as in 1974, and that the decline in tuberculosis has halted in most Member States of the Community. There was a steady decline in the number of cases reported in Germany, Belgium and France between 1974 and 1991. The situation had stabilised in Portugal and the United Kingdom, while increases had been observed recently in Denmark, Spain, Ireland, Italy and the Netherlands. There has been a 5% annual increase in France and the United Kingdom since 1992. These figures must be interpreted with caution, since the revival of interest in this communicable disease could have led to more diligent reporting of cases. Also, the definitions used are not always the same.
- 42. In some countries of northern Europe, immigration from countries where tuberculosis is endemic seems to be a key factor. For example, in Germany the number of cases of tuberculosis reported in nationals continued to decline between 1986 and 1989, while the number of cases reported among people coming from countries where tuberculosis is endemic rose by an average of 7% each year during this period. Similarly, in the Netherlands there was a 5% annual decrease in the number of cases reported among Dutch nationals between 1984 and 1990, accompanied by an annual increase of 13% among the foreign population. The rise in cases among the immigrant population does not, however, seem to have created new outbreaks of tuberculosis infection elsewhere.
- 43. As regards possible links between the AIDS epidemic (and, more widely, HIV infection) on the one hand, and the resurgence of tuberculosis on the other, there is no clear evidence of absolute or systematic links. The proportion of AIDS patients with tuberculosis varies from 2.3% in the United Kingdom to 23.9% in Portugal. This proportion is also higher among drug addicts and among those infected via heterosexual transmission.

#### (c) Nosocomial infections

- 44. Among all the categories of communicable disease there is one category which has been known about for some time, but of which the general public is often unaware. This is the category of nosocomial infections, i.e. infections which patients contract in hospitals and other health-care establishments.
- 45. Their importance is now recognised and preventive measures, which are considered a priority in all health establishments, are underway. This is essential because the costs of nosocomial infections are considerable both in human terms (morbidity and mortality rates) and in economic terms (they cost the Community tens of billions of ecus each year). The rate of prevalence of nosocomial infections, i.e. the ratio between the number of infections and the number of persons present in health care establishments varies but averages from 8 to 10% in the European Community as a whole.
- 46. The occurrence of these infections is often associated with invasive procedures during hospitalisation, such as surgery, catheter insertion or the use of artificial pulmonary ventilation. But it is also facilitated by a patient's advanced age or reduced resistance to infection (immunodepression). This explains, for example, the recent occurrence of nosocomial tuberculoses among patients with HIV infection.

47. In order of frequency, nosocomial infections occur most frequently in the urinary area (roughly a half of all cases), then in the pulmonary area and in operation wounds. The germs most often isolated are Escherichia coli, staphylococci and Pseudomonas, and these have developed a much greater multi-resistance to traditional antibiotics.

## III. OVERVIEW OF ACTIVITIES ALREADY UNDERTAKEN IN THE MEMBER STATES AND AT COMMUNITY LEVEL

#### THE COUNCIL

- 48. Council Directive 92/117/EEC 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<sup>(4)</sup> provides among other things for the collection of data on the incidence of zoonoses and the presence of zoonotic agents in the human population, in domestic animals, in animal feeding stuffs and in wildlife. A corresponding Community system has been set up to ensure optimum implementation of actions to combat and prevent such diseases.
- As regards other communicable diseases taking into consideration the existence of the single 49. market and the free movement of persons and foodstuffs, the Council specifically addressed the need to take more account at Community level of the risks of the spread of communicable diseases (including food-borne diseases) by adopting on 13 November 1992 a Resolution on the monitoring and surveillance of communicable diseases<sup>(5)</sup> which invited the Commission to report on the existing transnational surveillance networks in this field and to submit proposals for improving and extending such networks where this would prove useful. Moreover, the Council in its conclusions of 13 December 1993<sup>(6)</sup>, stressed the need for setting up an epidemiological network in the Community, which, whilst it should cover all diseases whether communicable or not, should as a priority collect data on communicable diseases with a view to acquiring better knowledge of their causes and their epidemiological context. This emphasis on epidemiological surveillance, analysis, and training was also shared by the European Parliament which in its resolution on public health policy after Maastricht<sup>(7)</sup>, called on the Commission to set up an epidemiological investigation service and to collect, analyse and disseminate data on notifiable diseases and to encourage the setting-up and operation of exchange schemes for health professionals.
- 50. On 3 May 1989 the Council adopted a Directive extending the scope of Directives 65/65/EEC and 75/319/EEC<sup>(8)</sup>, which establishes a number of specific provisions governing the placing of vaccines on the Community market.

<sup>(4)</sup> OJ No L 62, 15.3.1993, p. 38.

<sup>&</sup>lt;sup>(5)</sup> OJ No C 326, 11.12.1992, p. 1.

<sup>&</sup>lt;sup>(6)</sup> OJ No C 15, 18.1.1994, p. 6.

<sup>(7)</sup> OJ No

<sup>&</sup>lt;sup>(8)</sup> OJ No L 142, 25.5.1989, p. 14.

- 51. Active medicinal products against HIV are categorised as "high technology medicinal products", and as such qualify to be dealt with under the centralised procedure, which facilitates and speeds up the process of obtaining authorisations for such products to be placed on the market at Community level. Since 1987, high technology or biotechnology-derived vaccines have been covered by EC pharmaceutical legislation by virtue of Directive 87/22/EEC. Other vaccines were brought into the scope of EC pharmaceutical legislation by Directive 89/342/EEC. A future anti-AIDS vaccine would be covered by the same legislation and would benefit, through the centralised procedure, from provisions controlling its placing on the market at Community level.
- 52. Council Directive 89/381/EEC covers stable industrially prepared blood derivatives intended for a large number of patients, such as albumin, coagulation factors and immunoglobulins, but does not apply to whole blood, plasma and blood cells of human origin. These products are also subject to general provisions regarding manufacturing and marketing authorisation. The principles of good manufacturing practice laid down in Directive 91/356/EEC, as well as the quality, safety and efficacy of the tests referred to in Directive 91/507/EEC, are thus applicable to these products.
- 53. In addition to these general provisions, which are applicable to all medicinal products, Directive 89/381/EEC contains several elements which relate more specifically to medicinal products derived from human blood or plasma. The measures for selection and control of blood donors recommended by the Council of Europe and the World Health Organization have become compulsory as a result of this Directive. Moreover, for these particularly sensitive products, the Council has demanded the application of validated manufacturing and purification processes in order to guarantee, insofar as the state of technology permits, the absence of specific viral contamination (notably by HIV).
- 54. In response to a request from the Council which had expressed concerns about the quality, safety and supply of blood and plasma products in the Community following the adoption of Council Directive 89/381/EEC on medicinal products derived from human blood or plasma in June 1989, the Commission submitted a Communication on "Blood Self-sufficiency in the European Community". This Communication identified key issues of concern to Member States and specific actions for consideration.
- 55. On 13 December 1993, following approval of the Commission's Communication on blood self-sufficiency, the Council adopted Conclusions on self-sufficiency in the European Community which called <u>inter alia</u> for continued promotion of the quality and safety of blood collection and of blood-derivative production<sup>(9)</sup>.
- 56. Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs<sup>(10)</sup> establishes a complete legal context for taking any appropriate measure to combat health risks inherent in foodstuffs. In dealing with every practical stage in the chain of use of foodstuffs, from storage conditions to transport to supply to the consumer, this directive highlights the importance of food hygiene and, in use, should contribute significantly to ensuring that the requirement of a high level of health is met.

<sup>&</sup>lt;sup>(9)</sup> OJ No C 15, 18.1.1994, p. 6.

<sup>(10)</sup> OJ No L 175, 19.7.1993, p. 1.

- 57. In its Resolution of 29 May 1986, the Council and the Ministers for Health of the Member States, meeting within the Council, requested the Commission to organize an exchange of information and experience on AIDS<sup>(11)</sup>. As a result, on 11 February 1987 the Commission presented a Communication to the Council<sup>(12)</sup> laying down certain areas of action concerning AIDS prevention, information and education.
- In the following years the Council and the Ministers for Health of the Member States, meeting within the Council, adopted a number of texts dealing with the health problems posed by AIDS, the most important of which was the Decision of 4 June 1991 establishing the "Europe against AIDS" programme.
- This health programme, scheduled to run from 1991 to 1993, focused principally on preventive actions such as information and education. As required by the Decision, the Commission sent to the Council on 10 March 1993 a report on the implementation of the plan of action in 1991-1992. In this the Commission reported on the means deployed to achieve the objectives laid down in the Council Decision and commented on the early results obtained as well as on the relative weight and pertinence of the activities undertaken or requiring to be undertaken to give full effect to the aims of the Decision, set against the backcloth of the spread of the epidemic. The Commission also stated its view that there would be value in further actions on the public health aspects of HIV and AIDS being undertaken by the Community after the plan of action expired at the end of 1993.
- 60. Following consideration of the Commission's report, the Council and the Ministers for Health, at their meeting of 27 May 1993, agreed to invite the Commission to take the initiatives necessary for continuation of the actions of the "Europe against AIDS" programme in 1994, in anticipation of the entry into force of the Treaty on European Union, which provides in its Article 129 for Community action in the field of public health.
- 61. The subsequent evaluation in the Council of the effectiveness of the work undertaken concluded that the broad structure of the areas of action contained in the Council Decision could be maintained, but with a number of modifications in the objectives pursued, the introduction of new areas, and the deletion of others in order to reflect the changing needs of the Member States, increased knowledge of the problems posed by the disease, as well as its evolution and trends.
- 62. In order to avoid any break in the actions under the "Europe against AIDS" programme, and in order to respond to the wishes of the Council, the Commission submitted to the Council on 29 September 1993 a Proposal for a Decision concerning the extension to the end of 1994 of the 1991-1993 plan of action in the framework of the "Europe against AIDS" programme<sup>(13)</sup>.

<sup>(11)</sup> OJ No C 184, 23.7.1986.

<sup>(12)</sup> COM(87) 63.

<sup>(13)</sup> COM(93) 453 final.

63. Subsequent to the entry into force on 1 November 1993 of the Treaty on European Union, the Council adopted on 13 December 1993 a Resolution concerning the extension to the end of 1994 of the 1991-1993 plan of action in the framework of the "Europe against AIDS" programme<sup>(14)</sup>.

#### 2. THE EUROPEAN PARLIAMENT

- 64. As long ago as 1984 the European Parliament, in adopting a number of Resolutions concerning the fight against AIDS, revealed its growing concern at the inexorable spread of the epidemic and stressed the need for Community intervention.
- 65. The European Parliament has long taken interest in the frequency and incidence of various communicable infectious diseases, as reflected by the numerous written and oral questions addressed to the Commission by MEPs. Two areas in particular have received attention and have been the subject of reports by the European Parliament Office for Scientific and Technological Options Assessment (STOA).
- 66. The first of these reports, published in 1992, concerns the protection of public health by vaccination. The conclusions emphasise the need for more information on the levels of vaccination cover in all Member States, advocate the establishment of a European programme for the surveillance of diseases preventable by vaccination and call for an aid policy to help European vaccine manufacturers in the face of international competition. Comprehensive, and sensitive to all aspects of the problem, this balanced and reasonable report constitutes an important contribution to the public health debate, and one from which the Community could usefully draw inspiration.
- 67. The second report, at present in the course of being published, addressed the problems related to the resurgence of tuberculosis in Europe, and particularly its links with the AIDS epidemic and the movements of populations emigrating from places where tuberculosis is endemic and living in precarious socio-economic circumstances. The STOA's conclusions focus on the need to facilitate the collection, analysis and regular dissemination of epidemiological data concerning tuberculosis cases and setting up a network of laboratories for monitoring strains of bacillus tuberculosis which are multi-resistant to antibiotics.
- 68. The European Parliament adopted two Resolutions during the July December 1993 session dealing with self-sufficiency and the safety of blood and its derivatives. The first requested the Commission and Council to approve an action plan designed to improve safety and promote self-sufficiency through voluntary unpaid donations. The second called for the strengthening of controls to ensure the safety of blood and blood products and for the drawing-up of an instrument which would guarantee the monitoring of the safety of blood from donation to use, and the setting up of a European blood safety authority.

<sup>(14)</sup> OJ No C 15, 18.1.1994, p. 4.

#### IV. COMMUNITY APPROACH

## 1. Objectives and means

- As indicated in the Commission's Communication on the framework for action in the field of public health, Community action will, in particular, focus on encouraging cooperation between Member States, lending support to their action and promoting, in close contact with the Member States, coordination of their policies and programmes. In practice, this will involve the development and implementation of networks, joint actions and information exchange systems.
- 70. Future Community action in the public health field must take account, inter alia, of the principle of subsidiarity and the considerations set out in paragraph 27 of the Commission's Communication. Activities should be selected on the basis of prior appraisal and should yield a Community added value while achieving maximum cost-efficiency.
- As stated in the introduction, the criteria listed in paragraph 54 of the Commission's Communication are satisfied from a public health perspective since AIDS and other communicable diseases undoubtedly can cause significant premature death, have a significant morbidity and potential to devastate unprotected populations, constitute a significant risk for each individual and for the society as a whole, have major socio-economic impacts, especially as regards intervention and treatment costs, and moreover practicable measures of prevention exist. The lessons of the first AIDS plan, as established in the evaluation process, show that there is substantial scope for added value from Community actions, both from economies of scale and from dissemination of the results of projects.
- 72. The Commission proposes, in paragraph 50 of its public health Communication, four objectives which should form the basis of Community action:
  - (i) to prevent premature death which particularly affects the young and working population;
  - (ii) to increase life expectancy without disability or sickness;
  - (iii) to promote the quality of life by improving general health status and the avoidance of chronic and disabling conditions;
  - (iv) to promote the general well-being of the population particularly by minimizing the economic and social consequences of ill health.

This programme has to address all of these objectives.

- 73. The following criteria in particular will be used in future in selecting projects for Community support in this field:
  - activities on a scale which Member States themselves could not, or could only with difficulty, implement;
  - activities, the joint implementation of which would offer obvious benefits even after taking account of the extra costs involved;
  - activity which, because of the complementary nature of work being done at national level, enables significant results to be obtained in the Community as a whole;
  - activity which leads, where the need is recognised, to the establishment of best practice norms and standards;

- activities which contribute to the strengthening of solidarity and social cohesion in the Community, and promote its overall harmonious development.
  - 2. The Public Health Framework and the Community action programme on AIDS and other communicable diseases
- 74. In drawing up the proposed Community programme the Commission has taken fully into account the substantial programmes that Member States already have. In accordance with the principles developed in the Commission's Communication on the public health framework, the proposed Community programme is intended to complement and enhance the effectiveness of Member States' actions and to avoid any duplication of work.
- 75. The Commission seeks to ensure with its proposals that actions on the prevention of AIDS and other communicable diseases enjoy maximum priority and adequate funding and are given precise objectives. Priority will be given to large-scale wide-impact projects involving as far as possible the participation of governmental and non-governmental organizations with a proven record in this field.
- 76. The Community approach must be designed to ensure the coherence and continuity of preventive actions. The programme of activities has to address every stage of the prevention process, including information and data, education, specific preventive interventions, counselling and support. It must also include all parties and settings involved in these activities, in order to promote the development of the necessary skills, enhance cooperation between those undertaking actions, and foster coordination between those initiating preventive actions and the competent authorities. To achieve the maximum effect, the Commission will give particular support to the creation of networks of organizations in the different fields and to strengthening cooperation between existing networks.
- 77. As regards health education, health promotion, training, information, and actions in relation to communicable diseases, these are to be conducted partly under the programme on health promotion, education and training and partly under the proposed programme focusing on two particular areas, namely:
  - sexually transmitted diseases (STDs), with special emphasis on health education initiatives for young persons. These could take the form, for example, of education/information campaigns, using appropriate communication techniques, either for the general public or for particular groups in particular environments;
  - diseases which can be prevented by vaccination. Information on vaccination campaigns for certain diseases such as tuberculosis or the triple combination measles/mumps/rubella, aimed at parents or health professionals, especially family doctors, is deemed to be an area in which the Community can make a substantial contribution.

## 3. Other instruments of Community action

- 78. Special attention will be paid to the obligation contained in Article 129 which states that health protection requirements shall form a constituent part of the Community's other policies. Many aspects of Community policy impinge on the prevention of communicable diseases and the Commission undertakes in its Communication on public health to ensure that full account is taken of health protection and communicable disease prevention issues. The Commission has established appropriate procedures to ensure that this commitment is respected through adequate coordination and consultation in the development of relevant policies. In addition, the Commission will submit on a yearly basis a report on the health protection aspects of policies which will form part of the Commission's Annual Report.
- 79. The following are examples of other Community policies and instruments likely to have an impact on the prevention of communicable diseases:
  - certain instruments concerning the completion of the single market and consumer policy, particularly as regards drug precursors, pharmaceutical products in particular vaccines, medicinal products;
  - social affairs policies and instruments, particularly concerning migrants, poverty, employment, protection of workers' health and safety and the European Social Fund;
  - education and training for young people and health professionals, and activities targeted at young people in the field of culture, communication and information;
  - instruments designed to protect citizens' rights and ensure free movement of information such as personal data protection measures.
- 80. The specific programme of research and technological development in the field of biomedicine and health (1994-1998) lays stress on the integration of basic and clinical research and includes the following:
  - viro-immunological research, genetics, and the molecular and structural Jiology of HIV and its variability;
  - research towards the development of a safe and effective vaccine against AIDS, and of markers to evaluate its effectiveness and to monitor the evolution of the disease;
  - the identification, synthesis and evaluation of anti-viral components and of drugs designed to combat AIDS;
  - clinical research centred on clinical trials, the treatment of AIDS and its opportunistic diseases, including research on the prognosis and progression of these diseases and the impact of treatment;
  - studies of host response, pathogenesis, experimental models and new pathologies, and of resistance to conventional forms of therapy, taking into account the problem of hospital infections.
- 81. Significant progress has been achieved in the fight against AIDS thanks to AIDS research supported and coordinated by the Community.

- 82. The establishment of the biomedicine and health research programme (BIOMED 1) under the third Framework Programme has enabled more than 6 000 research teams to collaborate with each other within 400 networks set up to encourage cooperation between research teams throughout the European Union and the European Economic Area and between complementary disciplines, with a view to tackling health problems which would be difficult to resolve in a more limited context.
- As regards medical and biomedical research specifically into communicable diseases other than AIDS, the Commission has focused on a certain number among them under its BIOMED 1 programme and intends to do the same in the following phase, BIOMED 2. Even though the research did not relate particularly to public health, some special efforts were undertaken by the European teams, for example in the field of tertiary prevention in the case of hepatitis C, this being a communicable infectious disease which often develops into liver cancer or exposes those infected to the risk of Lyme borreliosis. Also worth mentioning is the study concerning specific genetic markers in connection with the molecular epidemiology of tuberculosis, a new discipline which needs to be developed much further but is clearly of significance for public health and the serious problem of the tuberculosis bacterium's multiple resistance to antibiotics.

## 4. Cooperation between Member States

- 84. On the basis of previous work, potential priority fields for cooperation between Member States have already been identified. These include:
  - exchanges of information on management regimes for people with HIV and AIDS, including external maintenance and care in the community;
  - cooperation on improving the methodology for evaluating care and therapeutic regimes, e.g. drug utilisation;
  - consideration of access to treatment and care and how to meet the needs of particular groups, such as children, pregnant women and migrants.
- Where appropriate, the Community will encourage cooperation between Member States in these fields by supporting exchanges of information and experience and dissemination of best practice. Cooperation will also be encouraged through the development of networks and support for programmes or pilot projects addressing objectives shared by the Member States.
  - 5. Cooperation with International Organizations and Third Countries
- 86. The activities of the Community programme should both add to the effectiveness of the global fight against AIDS and profit from relevant experiences gained in non-Community states and the work of international organizations. The activities of the Council of Europe such as on ethical questions and the World Health Organization's (WHO) work in many areas of public health has to be taken into account in the implementation of the programme. Equally, actions should go hand-in-hand with those taken by non-Community states and international organizations. Cooperation in this field is therefore necessary, leading, where appropriate, to joint action.

#### 87. The Commission intends to:

- build upon existing cooperation with the WHO, the Council of Europe and other international bodies by, for example, developing joint actions and employing their expertise in specific tasks;
- strengthen cooperation with third countries where possible, by promoting joint actions, involving them in Community projects and providing assistance for their programmes;
- contribute to the WHO's objective of eradicating the following diseases: measles, mumps, congenital rubella, neonatal tetanus, diphtheria and poliomyelitis. To this end, the Commission intends to establish an effective partnership with the WHO Expanded Programme on Immunization (EPI), which includes those responsible for implementation of the EPI in each Member State;
- set up consultation and cooperation with the WHO for the joint production of an information instrument based on the diverse surveillance data collected, for dissemination to specialists.
- 88. The PHARE programme, set up in 1990, provides financial and technical support for reform in the countries of Central and Eastern Europe. In this context it provides support for the restructuring of health systems intended to improve their quality and effectiveness. Activities against AIDS can be supported where they are included in priority action areas such as the development of training, health promotion and prevention measures. Similarly, assistance may be available under the TACIS programme for the newly independent states of the former Soviet Union.
- 89. The European Community has initiated AIDS activities for developing countries under its development programme, on the basis of resolutions by Parliament and the Council of Ministers<sup>(15)</sup>. Drawing on the lessons of 7 years experience of support programmes in developing countries the Commission has presented to the Council a Communication (COM(93) 479) defining main policy principles and priority strategies for the Community and the Member States in the field of HIV/AIDS in developing countries. The Communication was endorsed by a resolution of the Council in May 1994. The Commission has also submitted a more general communication entitled "The Community and Member States' policy on cooperation with the developing countries in the field of health" (COM(94) 77).
- 90. Under the Lomé Conventions, very significative efforts have been, and are being, implemented to support ACP countries in developing health care systems which could contribute to efficiently reduce the burden of communicable diseases. Special attention is given to the development of preventive activities at peripheral level, the improvement of the physical and financial accessibility to basic health care and essential drugs, particularly antibiotics. The EC/ACP AIDS programme was launched in 1987, with the collaboration of the ACP countries (the African, Caribbean and Pacific countries linked by the Lomé Convention). A year later, in 1988, the Community's AIDS programme was extended to cover all developing countries, and the accent was placed specifically on prevention. The Commission's total financial contribution for the period 1987-1992 was ECU 74.8 million, excluding funds allocated for

Parliament Resolution on AIDS, OJ No C 88, 14.4.1986, and Council Resolution, OJ No C 184, 23.7.1986.

research. The Member States contributed ECU 156.4 million over the same period, bringing the Twelve's total contribution to ECU 231.2 million.

91. Since 1988 the European Community's research programme in the field of life sciences and technologies for developing countries (EC-STD) has also focused on specific aspects of the AIDS epidemic in developing countries. This programme contributes towards improving the balance between biomedical research and research on programmes, promoting socio-economic research, developing the research capacities of national and regional research institutes in developing countries, and making more use of research results in order to ensure that the findings are rapidly put into practice.

#### V. COMMUNITY ACTION PLAN

- 92. In many respects the Community's involvement in public health activities for the prevention of communicable infectious diseases other than AIDS is relatively new. The Community's contribution complements ongoing work in this field by the Member States and various international organizations competent in the sphere of public health, notably WHO. The priority actions described here are based on the emerging needs in the Member States and for which there is value in undertaking activity at Community level.
- 93. The general objectives are:
  - to contribute to improving the prevention of communicable diseases in the Community by developing appropriate tools for the timely sharing of information and for ensuring prior consultation on communicable diseases and counter-measures, taking account of the existing situation;
  - to develop and improve existing practical measures aimed at preventing the emergence or resurgence of such diseases.
- 94. As regards the HIV/AIDS epidemic, the following three broad aims are involved in particular:
  - to contribute towards reducing the spread of HIV/AIDS in the Community;
  - to contribute towards minimizing the adverse consequences of the epidemic for individuals and for society; and
  - to cooperate with the efforts to combat AIDS and HIV outside the Community.

## A. Actions on HIV/AIDS and sexually transmitted diseases

- 1. Data collection
- 95. National epidemiological data are currently transmitted to the European Centre for the Epidemiological Monitoring of AIDS in Paris which produces statistics for the Community. The data available for the Community as a whole are, however, confined to AIDS. Owing to differences in Member States' approaches to HIV testing for epidemiological purposes, data on the prevalence and incidence of HIV infection in the Community are not available. Moreover, differences in Member States' collection systems and in the application of definitions can delay transmission of the data to the Paris Centre and cause difficulties in interpreting data from different sources.

- 96. In addition to epidemiological data, accurate information on people's knowledge, attitudes and behaviour in respect of HIV/AIDS is also important for developing policies and assessing preventive action. Member States' information varies, and that which is available is not always directly comparable.
- 97. Finally, the measures taken to combat AIDS and HIV in the Member States consume substantial resources of finance and personnel, and these are likely to increase. The development and promotion of objective parameters to assess the effectiveness of prevention measures is important, as is the exchange of information and experience which enables Member States to compare actions, utilise the best practices developed so far and learn from each other about what has proved effective.
- 98. The objectives of Community actions could be:
  - to improve the collection, analysis and dissemination of epidemiological and other data on AIDS, and increase the amount of data available on HIV infection while ensuring, insofar as identifiable personal data are concerned, that suitable safeguards are in place to protect the privacy of individuals;
  - to improve the available information on AIDS-related knowledge, attitudes and behaviour of the general public and target groups;
  - to improve the quality of information on preventive measures and their effectiveness and promote its diffusion.
- 99. The actions to be taken to achieve these objectives could be:
  - to strengthen cooperation and exchanges between Member States in order to improve the quality, comparability and accessibility of AIDS data and to explore how more data on HIV could be obtained, in this context the establishment of equivalent levels of protection for personal data at Member State level is clearly a priority; support for the European Centre for the Epidemiological Monitoring of AIDS to enable its work to be further developed;
  - to collect, analyse and disseminate existing information on the knowledge, attitudes and behaviour of the general public and specific target groups and about preventive measures undertaken in the European Community: development of further Eurobarometer surveys of the general public's knowledge and attitudes concerning AIDS;
  - to promote the development and use of assessment parameters to assess the effectiveness
    of the preventive measures, including the number and subject-matter of helpline calls,
    level and kind of media coverage, and trends in the incidence of sexually transmitted
    diseases.
    - 2. Measures for children and young people
- 100. Children and young people are best informed about the diseases at an appropriate time as part of the process of growing sexual awareness and personal development. Information about HIV/AIDS and STDs provided to young people who may be tempted to experiment with high-risk activities relating to sex and drug abuse helps them to minimize the risks of infection and to comprehend the impact of the diseases. Such information can be provided both within a formal educational setting and elsewhere, whether in youth and sports clubs, during organized holiday activities or at entertainment venues.

- 101. Wherever the information is provided, it must take account of age, level of maturity and cultural, religious and social background. Moreover, there are a number of specific settings, such as penal and military institutions, orphanages and residential homes for which tailor-made information would be useful, and also specific groups such as children from disrupted backgrounds, those with learning difficulties, and drop-outs and 'streetkids' for whom special initiatives need to be developed.
- 102. General health and sex education programmes, which cover physical, mental and social development and personal relationships, and also training for teachers and others involved are dealt with in the proposed programme on health promotion, education and training.
- 103. The objectives to be pursued could be:
  - to promote the provision of information on HIV/AIDS and STDs to specific groups of children and young people in specific settings;
  - to strengthen cooperation and exchanges between the national authorities and other organizations engaged in such work in order to improve the consistency of information provided in the different Member States.
- 104. The actions to be taken to achieve these objectives could be:
  - promotion of initiatives to provide information relevant to specific groups of children and young people on their knowledge, perceptions, behaviour and needs in specific settings in relation to HIV/AIDS and STDs and to exchange educational and training materials and promotion of pilot projects;
  - encouragement of studies and exchanges analysing current provision of HIV/AIDS and STD information to children and young people especially outside the educational setting, including issues arising in specific settings and for specific groups, and promotion of pilot projects.
    - 3. Prevention of HIV and STD transmission
- 105. Information aimed at reducing sexual transmission of HIV and STDs among the general population must be complemented by specific preventive initiatives targetted at particular groups other than children and young people who may be at higher risk or at settings where particular problems arise. Experience indicates that such measures would be of value to prostitutes and their clients, injecting drug users, travellers and tourists, for penal institutions and for health service professionals.
- 106. The European Community has already taken steps to ensure that condoms are manufactured to the highest standards. But there are also other issues to address, such as ensuring that people use condoms properly and the need to develop and promote new methods of protection.
- 107. The objectives to be followed could be:
  - to reduce mother-to-child transmission of HIV;
  - to reduce HIV and STD transmission in specific settings, such as penal institutions and hospitals, where there are particular problems;

- to reduce HIV and STD transmission among groups whose members may engage in high-risk behaviour, notably injecting drug users and sex workers;
- to ensure that condoms available in the Community are as safe as possible when used correctly and to promote other methods of protection for use by women.

#### 108. The actions to be undertaken could include:

- information on transnational tourism and travel between the Community and non-Community states and promotion of appropriate pilot projects eg. in tourist resorts or frontier areas;
- information for pregnant women, in particular drug users, who may be at risk of transmitting HIV infection to their children;
- information for people with HIV/AIDS and STDs in penal institutions, including information for prisoners and the existence of harm-reduction measures such as the provision of syringes for injecting drug users;
- evaluation of the HIV/AIDS related knowledge, attitudes and behaviour of drug users and of HIV prevention strategies for them; exchange of information on supplying safe injecting equipment and methadone programmes;
- exchanges of information on the situation of those at particular risk of HIV and STD infection, including sex workers and women involved with drugs, and on the actions being undertaken;
- exchange of information on the development and promotion of new methods of protection.

## 4. Safety of blood and blood products

- 109. The administration of HIV-contaminated blood and blood products to haemophilia and thalassaemia sufferers and others requiring transfusions in recent years and the ensuing tragic consequences have underlined the potential hazards of blood transfusion and highlighted the importance of ensuring the safety of blood and its derivatives, and the need to achieve Community self-sufficiency in blood as source material for products covered under Directive 89/381/EEC, based on voluntary non-remunerated donations.
- 110. The control of blood and blood products to ensure that they are safe for use is a matter which is currently being examined by the Commission in close collaboration with the Member States, with a view to identifying what further common rules will be required. The results of this examination will be made available in a Communication which the Commission intends to transmit to Council and the other Community institutions in due course. In addition, the Commission is pursuing work in close contact with the Member States, concerning the assessment of the situation in the Community as regards self-sufficiency, survey of attitudes, behaviour and practices as regards donation and its promotion, optimal use of blood and blood products, and assistance in creating networks so as to ensure exchange of information and facilitate transfers of blood and blood products.

## 5. Social and psychological support

- 111. The social and psychological needs of the rising numbers of people directly affected by HIV/AIDS are putting pressure on Member States' service provision. A particular problem is that of families where one or more parents and children are infected. Such families face enormous difficulties, often including stigmatisation and discrimination.
- 112. In response to these problems one significant trend throughout the Community is for non-governmental bodies to play an increasing role in providing information, care and social and psychological support. An accompanying trend has been the growth of self-help groups for people with HIV. Areas of non-medical support can profitably be addressed at the Community level with a view to assisting national efforts.

#### 113. The objectives in this field could be:

- to assist Member States to improve the effectiveness of their provision for social and psychological support
- to support the activities of non-governmental bodies, including self-help groups, and strengthen their capabilities.

#### 114. The actions to be carried out could include:

- exchanges of experience about models of assistance and support, the promotion of pilot projects and of studies on the psycho-social aspects of the disease
- exchanges on the needs of families with members infected with HIV;
- elaboration of manuals, bulletins and directories providing information on transmission of HIV, care and therapy, including organizations providing advice and support;
- encouragement of networks of organizations, particularly in the voluntary sector, in these areas.

## 6. Combatting discrimination

- 115. Discrimination against people with HIV and AIDS and those close to them by, for example, excluding them from obtaining certain kinds of employment, housing, insurance, education or health care is both morally objectionable and undermines public health measures. In the face of prejudice and stigma HIV-infected individuals are more likely to conceal their seropositivity or even be deterred from discovering their sero-status and less likely to maintain contact with health and social services which could assist them.
- 116. Unless people voluntarily come forward for such contacts, and unless people's confidentiality and fundamental freedoms are protected, the disease will go undetected, making it harder to combat. Moreover, when such discrimination is combined with prejudice against people in marginalised groups and minorities, such as homosexuals and immigrants, severe social tensions and disruptions can result.

- 117. Another form of discrimination is that of forcing certain groups to be screened for HIV for reasons unrelated to public health needs. Practices such as the mandatory testing of certain groups or individuals, such as prisoners, the armed services, people seeking or holding particular jobs or people immigrating to or entering a country, exist in various countries throughout the world. Discrimination may also occur in the areas of HIV-testing without consent, the violation of confidentiality about someone's infection and the compulsory tracing of sexual contacts.
- 118. In the light of this the objectives could be:
  - to increase people's understanding of AIDS and HIV and its effects and reduce the fears and prejudices which can provoke discrimination;
  - to assist Member States' efforts to combat discrimination, and to complement these by Community action, where appropriate.
- 119. The actions to be undertaken could be:
  - revision with Member States of the provisions on discrimination in the Resolution of the Council and the Ministers for Health of the Member States of 22 December 1989<sup>(16)</sup>, and the measures taken in the Community to avoid or reduce discrimination;
  - analysis of actual and potential discriminatory situations in the Community, such as in the fields of employment, insurance, housing, education and health care and at frontiers and on compulsory screening for groups such as immigrants, prisoners, employment seekers, patients and the armed forces.
    - B. Specific Community measures for certain communicable diseases
    - 1. Actions related to vaccination
- 120. One of the most effective methods of protecting an individual against certain communicable diseases is vaccination, provided an effective vaccine exists, which unfortunately is not always the case. Additionally, vaccination is one of the most cost-effective health protection measures available for both populations and individuals.
- 121. In public health terms the risks of an epidemic are lowest when a sufficient number of persons have been vaccinated against a disease; this is also referred to as the level of vaccination cover, the ideal, of course, being 100% cover. Obviously, the level of transmission of an infectious agent responsible for a disease within a given population depends on the level of vaccination cover within that population.

<sup>&</sup>lt;sup>(16)</sup> OJ No C 10, 16.1.1990, p. 3.

- 122. Consequently, an effective public health policy in this field involves defining, perfecting and implementing as effective a vaccination programme as possible, and it is for the Member States to carry out such a programme. Any national immunisation programme against a particular disease will necessarily comprise two stages. The first is to build up stocks of the appropriate vaccine, provide personnel to perform the vaccinations, and encourage people to be vaccinated. The second is to verify the effectiveness of the programme: this involves determining the level of vaccination cover and changes in this level over time and by geographical area, monitoring the disease, and developing reference laboratory services for identifying the strains responsible for the disease.
- 123. Coherent and reliable data on levels of vaccination cover for particular diseases or on surveillance of such diseases do not generally exist. Additionally, the sources of information differ widely from Member State to Member State, and the reliability of the information concerning immunisation schemes and the application of such schemes is uncertain. These schemes are reflected in the vaccination schedules, which differ in terms of dose, age of first injection, successive recalls, etc. The upshot is that there is no clear indication of the level of protection of populations, and this poses a potential risk when imported cases of a disease appear in the population.
- 124. To meet the requirement of a high level of health protection, a vaccination policy at Community level could have the following public health objectives:
  - to ascertain as accurately as possible the levels of vaccination cover for particular diseases in each Member State, so as to provide a picture of the overall state of immunisation in the European Community;
  - to contribute towards improving vaccination cover wherever necessary, disease by disease, by assisting in the launching of catch-up vaccination campaigns with a view to achieving a sufficiently high level of vaccination cover to prevent the circulation of the infectious agents responsible for the disease.
- 125. In this regard, the following actions could be envisaged:
  - publication of a document showing all the vaccination schedules at present available and in force in the Member States;
  - definition and development of a standard methodology for assessing levels of vaccination cover;
  - assessment of levels of vaccination cover in certain groups of the population such as children.
    - 2. Creation and development of networks
    - (a) Surveillance
- 126. Involving as it does the collection, recording and analysis of data on communicable diseases, and then communication of the findings to the public health authorities, surveillance takes a number of forms, depending on the type of communicable disease under investigation.

- 127. It can be carried out on the basis of clinical and/or biological criteria (the data being furnished by general practitioners and test laboratories) or on the basis of surveys (either exhaustive or via sampling, depending on the type of disease under investigation: rare and serious diseases require exhaustive surveys, e.g. obligatory notifications or morbidity registers, whereas common and less serious diseases require sample surveys of networks of doctors or laboratories). Additionally, 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).
- 128. Surveillance also depends on the administrative level involved (i.e. local, national or international), and the medium selected must be the most appropriate for the requirements (particularly as regards speed), e.g. written questionnaire, telephone or electronic data transmission. Additionally, a truly rigorous surveillance operation should feature 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. It requires adequate resources in order to ensure a satisfactory level of operation and effectiveness.
- 129. All observations indicate that there is a need to improve, at Community level, the availability, quality, relevance and dissemination of data on certain communicable diseases.
- 130. The diseases subject to such surveillance can be grouped by category:
  - diseases in which interest has been revived, tuberculosis (resistance to antibiotics) and blood transmission (hepatitis);
  - diseases which can be prevented by vaccination, which justify a particular approach;
  - nosocomial infections;
  - gastrointestinal diseases (entero-haemorrhagic E. Coli, salmonellosis, etc.) and certain other diseases (legionellosis, etc.).
- 131. The objectives of such surveillance can be stated as follows:
  - the early detection of epidemic outbreaks;
  - the establishment of guidelines for epidemiological intervention to contain such outbreaks;
  - identification of the medium and long-term trends with regard to individual diseases;
  - identification of at-risk groups;
  - study of changes in modes of transmission;
  - evaluation of prevention strategies and corresponding measures;
  - establishment of hypotheses for subsequent research and the formulation of a public health plan.

- 132. In the light of these objectives at European Community level, the following actions could be proposed:
  - interlink Member States' surveillance systems, with the emphasis on types of system: obligatory notification of certain agreed diseases; reporting on nosocomial diseases; computer-linked networks of doctors and laboratories; one-off studies; surveys on a given day;
  - establish a consensus for the adoption of a case definition common to all Member States, as well as on data collection frequency and the nature of the variables to be collected:
  - improve the quality of these systems by providing appropriate financial aid, to be jointly agreed with a group comprising servers and users of these systems;
  - offer assistance to Member States requesting it, through development of a network structure based on pooled resources.
- 133. In addition, as regards nosocomial diseases, the objectives of a Community policy could be:
  - to improve awareness of the existence of nosocomial infections, which are often masked by the patient's weakened state of health, through establishing consultation and coordination between the few existing national or regional surveillance networks in this field, with a view to achieving a minimum level of comparability of results recorded at local level and identifying the role and distribution of risk factors;
  - to promote exchanges of experience on the ways in which surveillance results are analyzed, processed and used by the players in the field, with a view to preventing nosocomial infections and reducing the related hospitalisation costs;
  - to promote and support the gradual creation of new surveillance networks so as to make the national public health authorities more aware of the problem and begin to include data on nosocomial infections in their routine data surveys concerning hospital conditions.
- 134. To achieve these objectives, the Commission could carry out the following specific actions:
  - production of standard protocols for nosocomial infection surveillance, to include infection definition criteria, inclusion criteria and infection coding conventions;
  - creation of a reference database usable by all health care establishments in the network, showing the incidence of certain important nosocomial infections by reference to types of risk factor and types of prevention practices used; by highlighting regional differences in prevention and treatment practices, the database will also make it possible to identify real problems which the aggregated national results tend not to reveal.
    - (b) <u>Dissemination of epidemiological information</u>
- The data collected in the surveillance of communicable infectious diseases must, of course, after being validated and interpreted, be disseminated in a suitably processed form to the public health authorities, so that they can define and adopt appropriate preventive measures, and to the players in the field, such as general practitioners, who are often the original sources of the information.

- 136. The information in question may serve one of two purposes: it may relate to an emergency situation where outbreaks or epidemics of a communicable infectious disease have been observed, in which case the public health authorities need to be alerted so that swift action can be taken, or it may relate to a routine situation, i.e. be no more than a periodic transmission of the harmonised surveillance data produced by the national surveillance systems or networks.
- 137. In the first case, succinct and validated information must be communicated rapidly using communication systems such as electronic data transmission. In the second case, the information is more elaborate in nature and transmitted to the health professionals and health authorities in the form of a specialist bulletin with a suitable, but not excessively long time-lag. In both cases there is a requirement for the existence of a combination of a network of surveillance systems with validated information available on an appropriate communication medium.
- 138. In the light of the above, the Community's objectives in this area could be:
  - improved knowledge and wider dissemination (i.e. beyond the Member State of origin) of existing national epidemiological bulletins containing both routine surveillance data (quantitative information) and specific original articles (qualitative information);
  - creation of an epidemiological information service open to health specialists and players in the public health field throughout the Community, the information being disseminated at intervals compatible with the requirements of public health action in the field.
- 139. In order to achieve these objectives the Commission could carry out the following actions:
  - a pilot study to establish the added value of a weekly notice, to be available to all existing national communicable disease surveillance networks electronically;
  - a pilot study for the production of a two-monthly or three-monthly European Community bulletin of four to six pages, designed for the same public as above and comprising processed data.
    - 3. Information, education and training
- 140. Increasing the population's knowledge and understanding about communicable diseases and their implications is needed to prevent transmission and reinforce preventive efforts. The development and implementation of information campaigns, whether aimed at the general public or at specific groups, are a key instrument in prevention. They must, however, essentially be undertaken by each Member State and what is appropriate and effective in each State varies according to their different traditions and to the different patterns of disease. Nonetheless, the Community can help Member States to draw on the results of experience elsewhere as coordinating campaigns across the Community can boost the overall visibility and impact of national activities.
- 141. There is also an increasing need for information activities to respond to the growing mobility of the Community population and for specific measures to be targetted at groups such as tourists, migrants, refugees and occupational travellers. Moreover, information is needed by those working in the media to ensure accurate reporting in relation to HIV/AIDS and certain other communicable diseases. Activities at the Community level can help to supplement national measures in this area.

- 142. Individuals with particular personal concerns need access to specific information and advice with proper respect for their privacy and confidentiality. Together with specialised advice centres, telephone helplines and other response mechanisms using modern technology play a valuable role. However, such facilities do not exist everywhere in the Community, nor do they all provide the same high level of service.
- 143. Those involved in communicable disease prevention, care and support activities and professionals whose work may bring them into contact with infected people with, for example, HIV and AIDS or hepatitis, such as the emergency services and prison staff, need relevant information and training about the disease, basic preventive techniques, but also how to provide advice and counselling. Initiatives to improve relevant training will help ensure that the resources available are used to the best effect in the whole Community.
- 144. Because of a shortage of manpower in the field of epidemiology, particularly as regards surveillance methodologies, and of the wide diversity of methods used to assess the extent of infectious diseases and control them, the use of comparative evaluation methods is at present difficult. Any attempt to improve this situation has also to take account of the international dimension, and in particular the European Community dimension. This is particularly true with regard to grouping cases of a disease of unknown aetiology.
- 145. Field epidemiology involves the application of epidemiological methods to the surveillance, data production, public health action and control of communicable diseases, so that all measures are taken to stop the spread of an epidemic outbreak and eventually extinguish it.
- 146. At present the information emanating from Member States is not comparable because of the wide diversity of their surveillance systems. Added to this is the fact that few epidemic outbreaks are detected and properly investigated. It is rare, when a public health problem of this nature arises, for a case investigation to be carried out and appropriate recommendations to be drafted, often because there is a lack of epidemiological training which would enable those serving the surveillance systems to deal with this type of situation.
- 147. There is therefore a need to provide specific training which would involve not only a basic academic element but also practical experience of approximately two years in several Member States. This is a model which has proved its worth in the USA and Canada but which cannot be found anywhere in Europe. The aim is to train a limited number of specialists who would then be capable of investigating outbreaks of epidemics, controlling them and preventing communicable infectious diseases.
- 148. Against this background, the Community's aim could be to improve public health practices with regard to the routine surveillance of infectious diseases and epidemic outbreaks whenever and wherever these occur in the Community.
- 149. The objectives in this area could be:
  - to increase the level of knowledge and understanding of the general public and specific groups about certain communicable diseases and their impact;
  - to maximise the effectiveness of Member States' campaigns by coordinating activities, where feasible, and by complementing them with Community initiatives;

- to extend the existing telephone and other response mechanisms and improve their effectiveness and cooperation;
- to improve the skills and knowledge of those directly involved or whose work may bring them into contact with communicable diseases;
- to monitor, and help to improve existing training courses and materials;
- to ensure appropriate awareness of communicable disease prevention and other issues;
- to foster a multi-sectoral and multi-disciplinary approach to prevention.

## 150. With a view to achieving these objectives the Commission could:

- encourage exchanges between Member States and improve cooperation on information campaigns aimed at the general public and specific groups, including the development of ways to reinforce and link information campaigns by using Community media and producing specific materials to give campaigns a Community dimension;
- promote the provision of information for use in the workplace and in the framework of health screening and surveillance;
- investigate the provision of telephone and other response mechanisms, and of centres providing information, and encourage the formation of networks and exchanges of personnel and expertise, and develop pilot projects;
- facilitate an examination of the training programmes currently in use for health and other professionals coming into contact with communicable diseases in order to identify gaps and help to devise further-training programmes;
- promote new training opportunities for those directly involved with communicable diseases and the exchange of materials, experience and personnel, and of trainers and students; development of pilot programmes involving exchanges between specific kinds of statutory bodies and voluntary organizations and implementation of pilot further-training programmes for people whose work brings them into contact with HIV/AIDS, such as personnel in the emergency services and penal institutions;
- facilitate an assessment of staff training in non-governmental organizations and promote interchanges for the dissemination of expertise and best practice;
- create a steering group, comprising representatives from the Member States, to examine how to improve the training for field epidemiologists specializing in communicable diseases:
- help develop a network of public health epidemiologists with a view to defining action objectives and common methods.

#### 4. Early detection and systematic screening

- 151. Systematic and early screening for communicable diseases is an important element, both to limit the spread of such diseases within the population and also to improve the prognosis for affected individuals, by making it possible to start effective treatment as soon as possible.
- 152. Some communicable diseases give a clear and rapid indication of their presence, thus making superfluous any approach involving systematic and early screening for them. The situation is different for the communicable diseases which develop quietly in a more or less chronic manner (hepatitis C, certain parasitoses), for particular forms of communicable disease (tuberculosis), or, finally, for those with specific consequences among certain at-risk categories of the population (toxoplasmosis in pregnant women). Due to the hidden nature of these communicable diseases, early screening for them must include supplementary targeted

examinations: specific serological analyses for hepatitis C and toxoplasmosis, lung X-rays for tuberculosis, parasitological examination of stools for certain helminthiases, etc.

- Analysis of the situation in the Member States shows that the methods of early and systematic screening for such communicable diseases often vary and that it would be beneficial to promote exchanges of information and experience in this field. Such exchanges could lead to the start of pilot projects and the drawing-up of recommendations at Community level. The experience gathered from early and systematic screening for an initial number of specific communicable diseases could be applied to other diseases if the associated feasibility studies and cost/benefit analyses showed this to be useful.
- 154. The objectives could be as follows:
  - to contribute to the development and establishment of early detection and effective screening systems for communicable diseases;
  - to spread the use of appropriate practices based on guidelines to be drawn up at European level in the quality assurance protocols for the screening and early diagnosis of communicable diseases;
  - to improve the quality of communicable disease screening through the development of continuing training of health personnel.
- 155. The strategy could include the following key elements:
  - the promotion of investigations on the effectiveness and feasibility of screening for certain types of communicable disease (tuberculosis, hepatitis, etc);
  - support for the training of health personnel, in particular in the context of early detection and systematic screening of communicable diseases;
  - cost-benefit analysis of screening for different types of communicable disease, in particular among pregnant women.

#### VI. CONSULTATION, ASSESSMENT AND REPORTS

- 1. CONSULTATION AND PARTICIPATION MECHANISMS
- (a) Advisory Committee
- 156. The experience of the "Europe against AIDS" programme between 1991 and 1993 has shown the value of having an appropriate consultation and coordination structure. In order to permit the fullest possible integration of the various partners involved in the Programme, the Commission will propose the creation of an Advisory Committee composed of representatives from each Member State and chaired by the Commission. The composition of the Committee should ensure optimum representation of the interests and expertise of the national authorities, the health professionals and the NGOs competent in the field of AIDS and other communicable diseases. The Committee will assist the Commission in all policy questions relating to AIDS and other communicable diseases, and in particular relating to the programme's development and approach.

## (b) Other participants

- 157. The Commission will encourage the Member States to set up national coordination committees for the programme on AIDS and other communicable diseases in order to enhance the motivation and involvement of the national players. These national committees, the composition and functions of which will be determined locally, have already proven their worth, in other programmes, in improving the coherence of actions undertaken at national level and in helping the national partners involved to work together more closely.
- 158. In the past few years of the Community AIDS programme, the NGOs involved have contributed generously to the realisation of Community actions, both in funds and in expertise. In view of the instrumental role in prevention, care and research played by these organizations, the Commission will maintain and strengthen its links with them, both through the Advisory Committee described above and through direct links with them.
- 159. The Commission will seek, in particular, to involve other partners, as justified by the extent of its action on AIDS and communicable diseases and by the implications for other fields of action in the area of public health. In this context, the Commission will ensure that its action on AIDS and other communicable diseases is consistent with "horizontal" actions and with actions under specific action programmes addressing other diseases.

## 2. ASSESSMENT AND REPORTS

- 160. The assessment of the action plan will comprise three main elements:
  - a mid-term report on the execution of the Programme to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions;
  - an independent peer review evaluation of the major actions and studies funded;
  - a global report on the efficiency and effectiveness of projects undertaken under the action plan to be submitted to the relevant Institutions by the Commission at the end of the execution of the Programme.
- 161. Mid-term and global reports on the execution of the action plan

The purpose of the mid-term report is to ensure that the institutions, and through them all the parties concerned, are kept fully informed of the progress of the actions undertaken in the context of this action plan. It will include an analysis of projects supported under the different actions and a detailed examination of activities in other sectors relevant to AIDS and other communicable diseases. The Commission will also submit a final global report at the end of the action plan.

162. Independent peer review evaluation of the major actions and studies funded

Experience acquired in the actions between 1991 and 1993 under the "Europe against AIDS" programme has highlighted the need for more effective evaluations of the Programme, both nationally and at European level. Such evaluations would facilitate the transferability of results of pilot projects from one country to another and hence increase the European added value of the Programme. In order to introduce effective evaluations of this type, the Commission may consult national authorities and other experts in the field in order to establish appropriate criteria and protocols.

#### 3. GENERAL INFORMATION ACTIVITIES

163. In addition to the information activities contained in the Programme, the Commission will ensure that the general public and all parties concerned have access to the results of the most important actions, studies and assessments undertaken.

# Proposal for a EUROPEAN PARLIAMENT AND COUNCIL DECISION

94/0222 (COD)

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

#### **EXPLANATORY MEMORANDUM**

- In its Communication of 24 November 1993 on the framework for action in the field of public health, the Commission defined a framework for future Community action in order to attain the objectives on health protection laid down in Articles 3(o) and 129 of the Treaty establishing the European Community. The role of the Community is identified as underpinning the efforts of the Member States in the public health field, assisting in the formulation and implementation of objectives and strategies, and contributing to the provision of health protection across the Community, setting as a target the best results already obtained in a given area anywhere in the Community. Community action is directed to the prevention of diseases and the provision of health information and education. Health protection requirements must also be part of other Community policies.
- 2. Future Community action in the public health field must take into account, inter alia, the principle of subsidiarity and the requirement of proportionality. It is worth noting in this context, that the diversity observed within and between the Member States in respect of geography, climate, lifestyles, culture, socio-economic conditions and the environment is such that, generally speaking, no detailed requirements can be proposed by the Community. Activities must be selected on the basis of prior appraisal and should yield a Community added value while achieving maximum cost efficiency.
- 3. The present proposal sets out the objectives and action areas for a programme on AIDS and certain other communicable diseases which is intended to run during the period 1995 1999. The Community's role will primarily be to promote cooperation between Member States, support their actions promote co-ordination between their policies and programmes in close collaboration with the Member States themselves, complement their actions, where appropriate, with measures at the Community level and ensure that Community policies in other areas such as education, social policy and the implementation of the single market support the prevention of these diseases.
- 4. The aims of the programme are to reduce as far as possible the spread of certain communicable diseases, including HIV and AIDS, in the Community, to minimize the adverse consequences for individuals and for society and to cooperate with efforts to combat them outside the Community. In the light of these aims, the Community approach must be designed to ensure the coherence and continuity of preventive action and thus must address every stage of the prevention process including information and data, education, specific preventive interventions, such as screening and vaccination where feasible and appropriate, counselling and support, and cover all parties and settings involved at the various stages.
- 5. A wide range of preventive measures will be needed to pursue these aims, and some of these will have to be implemented in close liaison with other existing Community programmes such as those on research and development assistance, or those currently being developed, such as those on drug dependency; health promotion, education and training; and health data and indicators, and monitoring and surveillance of diseases.

- 6. The previous action programmes on AIDS emphasised a number of fields of activity. It is proposed to continue these actions whilst extending the programme to include certain other communicable diseases. The fields of activity identified in the communication on the framework for action in the field of public health are: epidemiological data; provision of information to the public and specific target groups; health education; training; early detection and screening; research; and cooperation with international organizations and third countries. Other priority areas identified are gathering and disseminating various kinds of information on the spread of the diseases and the measures taken in response, measures for children and young people, specifically targeted preventive interventions, blood transfusion transmitted diseases, social and psychological support, combating discrimination and screening tests.
- 7. The Commission will transmit a mid-term and a final global report on the implementation of the programme to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. Moreover an independant peer review evaluation will be conducted of the major actions and studies funded. These will enable the institutions to assess the progress and impact of the work, and of the actions undertaken and the methods of implementation could then be modified, if required.

### Proposal for a EUROPEAN PARLIAMENT AND COUNCIL DECISION

94/0222 (COD)

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

#### 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<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Having regard to the opinion of the Committee of the Regions<sup>(3)</sup>,

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

Whereas AIDS is at present an incurable disease which, given its modes of transmission, can only be effectively combated by preventive measures;

Whereas the plan of action adopted by Decision 91/317/EEC of the Council and the Ministers for Health of the Member States, meeting within the Council<sup>(4)</sup>, in the framework of the "Europe against AIDS" programme expired at the end of 1993;

Whereas, in their conclusions of 27 May 1993<sup>(5)</sup>, the Council and the Ministers for Health, meeting within the Council, emphasised the need to continue the activities of the "Europe against AIDS" programme;

<sup>(1)</sup> OJ No

<sup>(2)</sup> OJ No

<sup>(3)</sup> OJ No

<sup>(4)</sup> OJ No L 175, 4.7.1991, p. 26.

<sup>(5)</sup> Doc. 6946/93 SAN 36.

Whereas, in consequence, the Commission submitted to the Council on 29 September 1993 a Proposal for a Decision concerning the extension to the end of 1994 of the 1991-1993 plan of action adopted in the framework of the "Europe against AIDS" programme<sup>(6)</sup>, to ensure continuation of the Community actions to combat AIDS pending the adoption of a multiannual action programme; whereas the Council adopted on 2 June 1994 a common position concerning that proposal<sup>(7)</sup>, with a view to extending the "Europe against AIDS" programme to the period 1994-1995;

Whereas, in its conclusions of 13 December 1993<sup>(8)</sup>, the Council agreed that it was necessary for the Community as a whole to acquire a better knowledge of diseases on the basis of their causes and their epidemiological context;

Whereas, in the same conclusions, the Council emphasized that all smooth running of a network for gathering epidemiological data requires that theoretical training in epidemiology and practical preparation in epidemiology in the field be developed for the teams participating in the network;

Whereas in their resolution of 13 November 1992<sup>(9)</sup>, the Council and the Ministers for Health meeting within the Council invited the Commission to consider the existing arrangements which provide for cooperation between Member States in the field of monitoring and control of communicable diseases;

Whereas the actions undertaken at Community level in the field of AIDS need to be continued and extended to cover certain other communicable diseases, and also to be consolidated within the framework of the action in the field of public health set out by the Commission<sup>(10)</sup>;

Whereas the actions must take into account, as the Council requested in its Resolution of 27 May 1993<sup>(11)</sup>, other actions undertaken by the Community in the field of public health or having an impact on public health;

Whereas in its Resolution of 2 June 1994 concerning the framework for Community action in the field of public health<sup>(12)</sup>, the Council agreed that priority should be given at present to AIDS and other communicable diseases;

Whereas, in accordance with the principle of subsidiarity, actions on matters not within the exclusive competence of the Community, such as action on HIV/AIDS and communicable diseases, should be undertaken by the Community only when, by reason of its scale or effects, its objectives can be better achieved at Community level;

<sup>(6)</sup> COM(93) 453 final of 29.9.1993.

<sup>&</sup>lt;sup>(7)</sup> OJ No C 213, 3.8.1994, p. 220.

<sup>&</sup>lt;sup>(8)</sup> OJ No C 15, 18.1.1994, p. 6.

<sup>&</sup>lt;sup>(9)</sup> OJ No C 326, 11.12.1992, p. 1.

<sup>(10)</sup> COM(93) 559 final of 24.11.1993.

<sup>(11)</sup> OJ No C 174, 25.6.1993, p. 1.

<sup>&</sup>lt;sup>(12)</sup> OJ No C 165, 17.6.1994, p. 1.

Whereas cooperation with the competent international organizations and with non-member countries should be strengthened;

Whereas a multiannual programme is required, defining the objectives of Community action, the priority actions for the prevenion of AIDS and other communicable diseases, and the appropriate evaluation mechanisms;

Whereas the objectives of this programme must be to contribute towards improving knowledge concerning the prevalence and patterns of HIV/AIDS and other communicable diseases, improving recognition of risk situations and improving early detection and social and medical support, with a view to preventing the transmission of communicable diseases and thus reducing the associated mortality and morbidity;

Whereas, from an operational point of view, past actions to establish European networks of non-governmental organizations and to mobilize resources should be maintained and developed;

Whereas possible duplication of effort should be avoided by the promotion of exchanges of experience and by the development of information material for the public, health educators and those who train the health professions;

Whereas this programme should be of five-year duration in order to allow sufficient time for the various actions to be implemented and to achieve the objectives set,

#### HAVE DECIDED AS FOLLOWS:

#### Article 1

A Community action programme on AIDS and certain other communicable diseases is adopted for a five-year period.

#### Article 2

The Commission shall ensure implementation of the actions set out in the Annex in accordance with Article 5 and in close cooperation and partnership with the Member States. The institutions and organizations active in the field of the prevention of AIDS and other communicable diseases shall take part in them as well.

#### Article 3

The budgetary authority shall determine the appropriations available for each financial year.

#### Article 4

The Commission shall ensure that there is consistency and complementarity between the Community actions to be implemented under this programme and those implemented under other relevant Community programmes and initiatives.

#### Article 5

For the implementation of the programme the Commission shall be assisted by an Advisory Committee, hereinafter referred to as "the Committee", comprising two representatives from each Member State and chaired by a Commission representative.

The representative of the Comission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee on the manner in which its opinion has been taken into account.

#### Article 6

- 1. The Community will encourage cooperation with third countries and with international public health organizations, in particular the World Health Organization.
- 2. The EFTA countries, in the framework of the EEA Agreement and the countries from Central and Eastern Europe with whom the Community has concluded association agreements may be associated with the activities described in the Annex, according to the provisions of those agreements.

#### Article 7

- 1. The Commission will regularly publish information on the actions undertaken and opportunities for Community support in the various fields of action.
- 2. The Commission will submit to the European Parliament, the Council, the Economic and Social Committee, and the Committee of the Regions a mid-term report on the actions undertaken, as well as an overall report at the end of the programme.

Done at Brussels,

For the European Parliament The President

For the Council The President

#### **ANNEX**

## COMMUNITY ACTION PROGRAMME CONCERNING THE PREVENTION OF AIDS AND OTHER COMMUNICABLE DISEASES

#### I. ACTIONS ON HIV/AIDS AND SEXUALLY TRANSMITTED DISEASES

#### A. Data collection

- 1. Exploration with Member States of ways to increase and improve AIDS and HIV data at the Community level, and provide support to strengthen the work of the national epidemiological surveillance systems and the European Centre for the Epidemiological Monitoring of AIDS.
- 2. Gather, analysis and dissemination information concerning preventive measures and the knowledge, attitudes and behaviour of the general public and target groups; promotion of the development and use of measures for assessing effectiveness and new surveys where existing information is inadequate, including Eurobarometer surveys.

#### B. Measures for children and young people

3. Encouragement of initiatives to ascertain and disseminate information about children's and young people's knowledge, attitudes and behaviour in relation to HIV/AIDS and STDs, to examine current practice in providing them with information both within and outside formal settings such as schools and training institutions and to promote the exchange of educational and training material, and the setting up of pilot projects and networks.

#### C. Prevention of HIV and STD transmission

- 4. Examination and exchanges of information on problems and situations related to groups at risk (drug users, sex workers, homosexuals and bisexuals), risk situations (mobile populations and border areas, penal institutions); and modes of transmission; exchange of experience on harm-reduction measures and preventive actions; and promotion of appropriate preventive measures and of pilot projects.
- 5. Promotion of information, advice and counselling to pregnant women who may be at risk of transmitting HIV to their babies, exchange of views and experience on screening pregnant women; and co-ordination of research on minimizing mother-child transmission.

#### D. Social and psychological support and combatting discrimination

6. Exchanges of experience and information concerning models of assistance and support, including the particular difficulties facing families with infected members, and concerning policies and practices on screening and discriminatory situations, promotion of analysies and pilot projects on the psycho-social aspects of the disease, and the setting up of networks of organizations providing information and assistance.

### II. SPECIFIC COMMUNITY MEASURES FOR CERTAIN COMMUNICABLE DISEASES

#### A. Actions related to vaccination

7. Support for initiatives designed to produce information on levels of vaccination cover in the Community, especially among children, at-risk groups and persons living in certain risk situations, against communicable diseases preventable by vaccination; promotion of initiatives designed to improve the vaccination cover of the general public, and especially of at-risk groups and persons living in certain risk situations; encouragement of measures designed to match vaccination schedules to the epidemiological context.

#### B. Creation and development of networks

#### 1°. Surveillance

- 8. Contribute to improving the quality of Member States' surveillance systems, taking into account the views of servers and users, and assist in the development of networks, based on agreed methodologies and conditions of transmission of information, prior consultation and coordination of responses.
- 9. Promote knowledge and exchanges of experience on the ways in which surveillance results of nosocomial infections are analysed, processed and used by the actors in the field, and encourage actions to increase awareness of the problems and inclusion of comparable and reliable data on nosocomial infections in routine surveys concerning hospital conditions, and support the creation of new surveillance networks for such infections.

#### 2°. Dissemination of epidemiological information

10. Contribute, in particular by the provision of the logistical support necessary, to the production and dissemination of a regular information notice and of a European Community bulletin on communicable diseases surveillance, comprising both routine surveillance data and reports on specific investigations.

#### C. Information, education and training

- 11. Encouragement of exchanges between Member States on information campaigns at all levels, development of ways of linking and reinforcing campaigns, such as provision of specific materials; and utilisation of telephone and other response mechanisms, and development and promotion of activities to complement national efforts, including the setting up of networks and the exchange of experience and expertise.
- 12. Examination of current training programmes for health and other professionals, and for those whose work brings them into contact with certain communicable diseases; identification of weaknesses and gaps, and devising and promotion of new further training opportunities and programmes.
- 13. Improvement of public health practices with regard to the routine surveillance of infectious diseases and epidemic outbreaks whenever and wherever these occur in the Community; development of a Community network of public health epidemiologists with a view to defining common methods and tools and enhancing the capacity for coordinated response.

#### D. Early detection and systematic screening

- 14. Promotion of investigations on the effectiveness and feasibility of screening for certain types of communicable diseases (tuberculosis, hepatitis, etc).
- 15. Support for the training of health personnel, in particular in the context of early detection and systematic screening of communicable diseases; cost-benefit analysis of screening for different types of communicable disease, in particular among pregnant women.

#### FINANCIAL STATEMENT

#### 1 TITLE OF OPERATION

Proposal for a European Parliament and Council Decision 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

#### 2 BUDGET HEADING INVOLVED

B3-4305 (former item B3-4301): Combating AIDS and other communicable diseases.

#### 3 LEGAL BASIS

#### (a) Actual legal basis

Article 3(0) and Article 129 of the Treaty on European Union.

#### (b) References

Resolutions of the European Parliament on measures to combat AIDS (OJ No C 46, 20.2.1984 and OJ No C 88, 14.4.1986).

Resolution of the representatives of the Governments of the Member States, meeting within the Council of 29 May 1986, on AIDS (OJ No C 184, 23.7.1986, p. 21).

Communication from the Commission of 11 February 1987 on the fight against AIDS (COM(87) 63 final).

Conclusions of the Council and of the representatives of the Governments of the Member States, meeting within the Council of 15 May 1987, concerning AIDS (OJ No C 178, 7.7.1987, p. 1).

Conclusions of the Council and of the representatives of the Governments of the Member States, meeting within the Council of 31 May 1988, concerning AIDS (OJ No C 197, 27.7.1988, p. 8).

Conclusions of the Council and the Ministers for Health of the Member States, meeting within the Council of 15 December 1988, concerning AIDS (OJ No C 28, 3.2.1989, p. 1).

Conclusions of the Council and the Ministers for Health of the Member States, meeting within the Council of 15 December 1988, concerning AIDS and the place of work (OJ No C 28, 3.2.1989, p. 2).

Resolution of the European Parliament of 30 March 1989 on the fight against AIDS (OJ No C 158, 26.6.1989, p. 477).

Conclusions of the Council and the Ministers for Health of the Member States, meeting within the Council of 16 May 1989, regarding the prevention of AIDS in intravenous drug users (OJ No C 185, 22.7.1989, p. 3).

Conclusions of the Council and the Ministers for Health of the Member States, meeting within the Council of 16 May 1989, on awareness measures for health care personnel (OJ No C 185, 22.7.1989, p. 6).

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).

Conclusions of the Council and the Ministers for Health of the Member States, meeting within the Council of 16 May 1989, regarding future activities on AIDS prevention and control at Community level (OJ No C 185, 22.7.1989, p. 8).

Resolution of the Council and the Ministers for Health of the Member States, meeting within the Council of 22 December 1989, on the fight against AIDS (OJ No C 10, 16.1.1990, p. 3).

Conclusions of the Council and the Ministers for Health, meeting within the Council of 17 May 1990, concerning medical and psychosocial support for persons affected by the AIDS epidemic (Doc. 7264/90 SAN 45).

Conclusions of the Council and of the Ministers for Health, meeting within the Council of 3 December 1990, on AIDS (OJ No C 329, 31.12.1990, p. 21).

Decision 91/317/EEC of the Council and the Ministers for Health of the Member States, meeting within the Council of 4 June 1991, adopting a plan of action in the framework of the 1991 to 1993 "Europe against AIDS" programme (OJ No L 175, 4.7.1991, p. 26).

Resolution of the Council and the Ministers for Health, 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).

Report from the Commission on the implementation of the plan of action (Europe Against AIDS) in 1991-1992 (COM(93) 42 final, 10.3.1993).

Conclusions of the Council and the Ministers for Health, meeting within the Council of 27 May 1993, on the implementation and continuation of the "Europe Against AIDS" programme (Doc. 6946/93 SAN 36).

Proposal for a Decision of the Council and the Ministers for Health of the Member States, meeting within the Council, concerning the extension to the end of 1994 of the 1991-1993 plan of action in the framework of the Europe Against AIDS programme (COM(93) 453 final, 29.9.1993).

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

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

Council Resolution of 13 December 1993 concerning the extension to the end of 1994 of the 1991 to 1993 plan of action in the framework of the "Europe Against AIDS" programme (OJ No C 15, 18.1.1994, p. 4).

Council Resolution of 2 June 1994 on the framework for Community action in the field of public health (OJ No .....).

#### 4 DESCRIPTION OF OPERATION

#### 4.1 General objective

Implementation of a programme of Community operations to prevent AIDS and other communicable diseases. Parliament, the Council and the Ministers for Health of the Member States meeting within the Council have, since the beginning of the epidemic, adopted a number of texts dealing with the public health problems posed by AIDS (see list above), the most important of which is the Decision of 4 June 1991 establishing the "Europe Against AIDS" programme.

The aim of this communication is to establish the necessary basis for extending Community operations against AIDS and expand them to cover other communicable diseases while taking into account the entry into force of the Treaty on European Union, particularly Article 129, which makes provision for Community action in the field of public health and, in particular, against the major health scourges.

The aim of this programme is to encourage cooperation between Member States, support their operations and promote coordination between their policies and programmes within the framework of the prevention of HIV/AIDS and other communicable diseases.

<u>Intermediate objectives</u>: these include reducing mortality and morbidity due to communicable diseases and reducing the risk of infection by the AIDS virus or other infectious agents.

Methods for achieving this objective: stimulating Member States to develop their own resources for the prevention of AIDS and other communicable diseases, prevention strategies and intra-Community cooperation, particularly through support for exchanges, identification and dissemination of best practice and the creation of networks; development of guidelines and financial assistance for programmes or pilot projects aimed at improving the effectiveness of prevention both among professionals in the social and health fields and among the general public.

#### 4.2 Period covered and arrangements for renewal or extension

- 5 years: 1995-1999

- Report on implementation to be transmitted to the Council and European Parliament during the third year of the programme: any modifications necessary

Report to the Council and European Parliament at the end of the programme: renewal or adaptation procedures.

#### 5 CLASSIFICATION OF EXPENDITURE OR REVENUE

Non-compulsory expenditure

Differentiated appropriations

#### 6 TYPE OF EXPENDITURE OR REVENUE

Subsidies for co-financing with other public and/or private sector bodies (not exceeding a certain percentage of the total cost of such projects).

#### 7 FINANCIAL IMPACT

#### 7.1 Method of calculating total cost of operation (definition of unit costs)

The method of calculation is the result of experience acquired in implementing operations to combat AIDS and other communicable diseases (items B3/4301, later B3-4305) over recent years, taking into account medium-term prospects set out in the Commission communication on the framework for action in the field of public health. A total amount rounded off to ECU 50 million during the period 1995-1999 appears to be necessary for these activities. The yearly allocation will be decided in accordance with the normal budgetary procedures.

### 7.2 Itemized breakdown of cost (in ECU million)

DISEASES	ACTION AREA	YEARS						
		PDB 1995	1996	1997	1998	1999	TOTAL 1995-1999	
		Indicative break- down	Indicative programming					
HIV/AIDS AND OTHER COMMUNI- CABLE DISEASES	Collection of epidemiological data; establishment of networks	0.2	0.3	0.3	0.3	0.3	1.4	
	Specific prevention measures (vaccination, safety of blood and blood products)	2	2.2	2.3	2.4	2.6	11.5	
	Information and awareness-raising for general public and target groups	0.5	0.5	0.5	0.6	0.6	2.7	
	Training and promotion of human resources	1,6	1.7	1.7	1.8	1.9	8.7	
HIV/AIDS	Measures for children and young people	1.3	1.3	1.4	1.5	1.5	7	
	Health and social support and assistance	1.7	1.7	1.8	1.9	2	9.1	
	Measures to combat discrimination	0.4	0.4	0.5	0.5	0.5	2.3	
OTHER COMMUNI- CABLE DISEASES	Early detection and systematic screening	4.3	1.3	1.4	1.4	1.5	6.9	
	TOTAL	9	9.4	9.9	10.4	10.9	49.6	

% variation 1.05 (see communication on public health)

#### 7.3 Indicative schedule of appropriations

	1995	1996	1997	1998	1999	TOTAL
Commitment appropriations	9	9.4	9.9	10.4	10.9	49.6
Payment appropriations						
50% 1995	3.2					3.2
35% 1996	4.3	4.7				9.0
15% 1997	1.5	3.3	5			9.8
1998		1.4	3.4	5.2		10
1999			1.5	3.7	5.4	10.6
Subsequent years				1.5	5.5	<b>7</b>
TOTAL	9	9.4	9.9	10.4	10.9	49.6

#### 8 FRAUD PREVENTION MEASURES; RESULTS OF MEASURES TAKEN

The grant application forms will require information on the identity and nature of potential beneficiaries so that their reliability can be assessed in advance.

Fraud prevention measures (checks, intermediate reports, final report) are included in the agreements or contracts between the Commission and beneficiaries. The Commission will check reports and ensure that work has been properly carried out before intermediate and final payments are made.

In addition, spot checks are carried out by the Commission to verify how funds have been used. Checks have already been carried out in relation to the financial years 1991, 1992 and 1993 and have shown their effectiveness.

#### 9 ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

#### 9.1 Specific and quantifiable objectives; target population

The Community measures are intended to encourage:

- improved knowledge of communicable diseases, including HIV infection, among the general public and risk groups;
- prevention of communicable diseases and HIV/AIDS among the general public and risk groups;
- guidance and advice: professionals in the social and health fields;

 social and health care: professionals in the social and health fields, work environment, risk groups (drug abusers, homosexuals, prostitutes, risk situations).

#### 9.2 Grounds for the operation

Rational use of budget provision based on:

- (a) specific application of the principle of subsidiarity when identifying measures to be undertaken and co-financed;
- (b) identification and selection of projects for co-financing in the fields of health education, improving knowledge among the public and certain risk groups, training and stimulation of cooperation between Member States in the field of prevention. These projects will be selected and implemented, where necessary, with national coordinating committees to be established at the request of Member States, with participation by all those involved in the prevention of HIV/AIDS and other communicable diseases;
- (c) the concept of added Community value, which will continue to be realised through the coordination of national measures, the dissemination of information and experiences, the establishment of priorities, the extension of existing European networks, selection of European projects and the motivation and mobilisation of all involved.

The main method of implementation for the programme is to support projects carried out in Member States. The selection of priority projects is based largely on general and intermediate objectives, and implementation of the measures themselves depends on the quality and reliability of projects submitted to the competent department during the course of the year.

The selection criteria for projects are as follows:

- Compatibility with the objectives and conformity with at least one of the established objectives;
- Examination of the "added Community value" of the projects (transnational participation, development of a model applicable in other Member States, information usable in other Member States, etc.);
- Presumed effectiveness and profitability;
- Clarity and justification of requirements;
- Population targeted or affected by the measure;
- Relevance of the selected methodology;
- Organizational competence and experience;
- Suitability of budget for objectives;
- Support for projects from national partners;
- Objective assessment;
- Opinion of the advisory committee involved.

#### 9.3 Monitoring and evaluation of the operation

#### 9.3.1 Monitoring of the operation:

Monitoring at Community level is by the Commission, which will submit an annual report on the operation of the programme to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, and at national level by national coordinating committees, if Member States choose to establish such committees, by the ministries with responsibility for the prevention of AIDS and other communicable diseases, NGOs and those responsible for the implementation and conduct of specific projects.

#### 9.3.2 Evaluation

#### Evaluation will be by means of:

- An annual report on the execution of the programme to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions;
- An independent evaluation of the main measures and of subsidised studies;
- An overall report on the reliability and effectiveness of projects implemented under the action plan, to be submitted by the Commission to the competent institutions during the second half of 1997.

#### Performance indicators selected for this evaluation:

- Estimate of the target population reached and any media coverage;
- Evaluation of projects by Commission officials and/or those cooperating with them;
- Analysis of intermediate reports on measures scheduled and financed, allowing a shifting of emphasis where possible;
- Impact studies by external bodies;
- Relevance of the methodology used by organizers;
- Suitability of the budget for the objectives;
- Clarity of original objectives;
- Skills and ence of bodies:
- Dissemin of results.

#### Evaluation, ocedures and intervals:

- Drawing up of intermediate and final reports on the various measures undertaken in the field;
- Development of a "standard" evaluation form for the measure, to be forwarded by the beneficiaries with their final reports, and checking of these documents by officials either at the Commission or in the field.

#### 9.4 Coherence with financial programming

Is the operation incorporated in the DG's financial programming for the relevant years? Yes.

To which broader objectives defined in the DG's financial programming does the objective of the proposed operation correspond?

"To contribute towards ensuring a high level of human health protection" - Article 129 of the Treaty.

#### 10 ADMINISTRATIVE EXPENDITURE (PART A OF THE BUDGET)

- The new action programme referred to in this financial statement comes under the new responsibilities of the Community in the field of public health following entry into force of the Maastricht Treaty (Article 129). In addition to the staff currently carrying out similar and preparatory work, implementation of the programme will necessitate the following additional staff: one grade A official, one grade B official and one grade C official subject to the outcome of the 1995 budget procedure and the Commission Decision on the allocation of funds. This additional personnel could be made available either by internal deployment of staff within the Commission or as part of the decision on the allocation of human resources to be taken by the Commission in 1995.
- The following meetings and missions are planned for 1995 in conjunction with the launching and implementation of the new action programme (the budget headings relating to meetings and missions are A 2500 and A 1300 respectively):

#### Meetings:

- 2 meetings of the Advisory Committee (two representatives per Member State)

 $(2 \times 24 \times 658 = 31584)$ 

32 000

- 4 meetings of experts

 $(4 \times 6 \times 658 = 15.792)$ 16 000

- Conferences and seminars for presentation and implementation  $(4 \times 48 \times 658 = 126 \ 336)$ 

126 000

TOTAL MEETINGS:

ECU 174 000

#### Missions:

- Luxembourg-Brussels (5 missions per month) (60 x 200 = 12 000)

Other missions (Member States)  $(25 \times 1000 = 25000)$ 

TOTAL MISSIONS:

ECU 37 000

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# **DOCUMENTS**

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