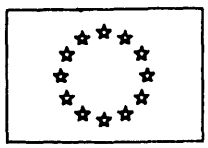

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.05.1997
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COMMUNICATION FROM THE COMMISSION

concerning a programme of Community action on rare diseases within the framework for action in the field of public health

Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DECISION

adopting a programme of Community action 1999-2003
on rare diseases in the context of the framework for action
in the field of public health

(presented by the Commission)

COMMUNICATION FROM THE COMMISSION

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I. INTRODUCTION

1 In its Communication of 24 November 1993 on the framework for action in the field of public health[1] the Commission defined objectives for protection of health as laid down in Article 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 diseases, particularly the 'major health scourges' and protecting health. Based upon criteria laid down in the Commission communication, rare diseases have been identified as a priority for Community action.

3 Public health is by definition addressed to the health needs of the entire population. This means that available health services and resources, particularly preventive measures, should be used for the benefit of as many people as possible. This principle applies just as much to those affected by rare diseases as it does to those affected by the 'major health scourges'. However, the very fact of the rareness of the low-prevalence diseases and conditions and the consequent lack of information about them can lead to many affected by these conditions not receiving the health resources and services they need. This is because there may be a particular shortage of relevant information and expertise and a lack of consensus about appropriate intervention for a specific rare disease.

4 The Commission's framework communication on public health presents several criteria for deciding on Community priorities. These are: a disease's impact on morbidity and mortality, a disease's socio-economic impact, how far a disease is amenable to effective preventive action and of particular importance, how far there is scope for Community actions to complement and add value to what is being done by the Member States.

5 Clearly rare diseases do not meet the criteria on a population level. However at the level of the individual and family they do cause significant premature morbidity, mortality or loss of disability-free life. With regard to whether they

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[1] COM(93) 559 final

are preventable, this varies between the thousands of rare diseases; some are now so, some may become so in the future. But the final criterion, that of providing added value at Community level has a particular relevance to rare diseases.

6 It is self-evident that rare or low-prevalence diseases have a limited impact on society as a whole and are responsible for relatively little morbidity and mortality. They cannot therefore be considered as being major health scourges. However, they are by no means unimportant economically, for providing effective advice, diagnosis and health interventions tends to cost disproportionately more than similar provision for more common conditions.

7 In this area there is much that the Community can offer. Work at Community level can confer a number of important benefits. In particular, because of the much larger population of the Community as a whole, individual cases can be aggregated to form a much larger group sharing the same characteristics. This provides the opportunity to undertake a much wider range of interventions and to initiate co-ordinated actions with patients who might otherwise be isolated or incorrectly diagnosed.

8 The public health importance of rare diseases can also be considered in another way. They can sometimes occur with greater frequency in particular regions and in specific population groups, such as ethnic communities, than in the national population as a whole. Thus the consequences at national level may be slight, but at regional or group level they may be very significant. This is particularly true for genetic diseases.

9 Moreover, one should not forget the wider issue of diseases which are rare in the European Community but common elsewhere in the world. We could use our expertise to provide assistance in the fight against tropical diseases which are rare in our lands but, can cause huge suffering and loss of life in the developing world.

10 In addition, some diseases with a low prevalence at present may in the future become major health scourges. This is for instance possible if the disease is caused by an unknown agent as was the case with HIV/AIDS or more recently with Bovine Spongiform Encephalopathy/Creutzfeldt-Jacob Disease (BSE/CJD). A similar effect can be caused by a newly introduced medicinal product, thalidomide being an obvious example. A co-ordinated Community approach offers an effective way to tackle these potentially large-scale health problems.

11 Some diseases and especially communicable diseases which were once very common, such as poliomyelitis, have become rare in the Community as a result of effective preventive measures, notably paediatric vaccinations. However, such diseases can and do re-emerge if for example population immunity falls. In this connection the sudden appearance of cases of such a disease in one country can provide an early warning to others that their vaccinations or other preventive measures may be becoming ineffective. Action at Community level can help individual Member States to recognise such problems at an early stage and to co-ordinate their response.

12 The aetiology of many diseases, and especially rare diseases, is unknown. Preventive measures are dependent upon this basic knowledge. The thousands of rare diseases or conditions, their low prevalence and the limited means and budgets for scientific research to unravel their aetiologies, make it less likely that swift progress in their treatment and cure will be made. Therefore collaboration between the Member States and work at Community level in this domain can provide added value to the actions of individual Member States.

13 The limited resources within health systems are primarily, and necessarily, directed at major health scourges, thus there is likely to be only limited attention given to low-prevalence diseases in individual Member States. It falls within the scope of the Community's public health policy to help the Member States achieve the most efficient use of resources in this respect. In the case of these conditions there may be real economies of scale by combining limited national expertise and resources at Community level.

14 It is for these reasons that the Commission has decided to give rare diseases priority within the public health framework.

II. IMPORTANT ASPECTS OF RARE DISEASES

INFORMATION

15 An unknown number of Europeans suffer from rare diseases. Many of these low-prevalence diseases have no specific patient support organisation or agency dedicated to research, prevention, diagnosis or treatment. Information of all kinds for patients and their families, physicians, researchers, health authorities and the general public is lacking or poorly disseminated.

16 For rare diseases the sources of appropriate detection, recognition and medical care are limited or even non-existent. Little or nothing is available for effective prevention and treatment; little may be known to inform the patient and his family about the future course of the disease, the possibilities of avoiding risks and the creation of environments and life-styles conducive to health.

17 The US National Commission on Orphan Diseases has undertaken a detailed study of the problems of people in the USA with these rare conditions. This found that it took between 1 and 5 years for one third of them to receive a proper diagnosis, and 15% went undiagnosed for six or more years. Moreover, the costs of these conditions, in monetary and human terms, are enormous. Half the patients said their illnesses caused great financial hardship for themselves and their families; and that their diseases prevented them from working or attending school.

PATIENT SUPPORT GROUPS

18 Patient help groups can play a key role in rare diseases. A number of such groups covering many rare diseases have been created in the past decades, sometimes in response to a feeling that the statutory authorities were not devoting sufficient attention to these conditions. Moreover, there is considerable collaboration between these groups at regional and national level and internationally, often related to the different groups of diseases. There are also several international umbrella organisations, such as the European Alliance of Genetic Support Groups (EAGS). These patient and parent organisations have a wealth of knowledge based upon their own experience with a disease. This is particularly valuable given the facts of frequent delay in establishing a diagnosis, the limited knowledge of health care providers, the lack of medicinal products, and health insurance problems.

CLUSTERS

19 In considering rare, low-prevalence diseases and conditions it is useful to address the issue of clusters. These can be defined as an aggregation in time and place of occurrences of a rare disease. Another way to put it is that in a defined area during a defined period, conspicuously more cases occurred of a rare disease than was predicted from the 'base-line' or the expected number of this condition. The need to deal effectively with clusters, (i.e. identifying a real increase, determining causal factors, assessing implications and assuaging public concern) is obvious: a specific local factor could have been the cause, or contributed to the cause, and this has to be identified.

20 In dealing with clusters the actions taken should follow a particular order: first, identification of a cluster by for example early warning systems; second, using monitoring and surveillance systems to establish a comparison with the established baselines for the relevant diseases, (however for rare diseases this process may not be possible because the necessary epidemiological data may not exist.); third there is the need to allay public concern by communicating as accurately as possible the risks involved. Handling clusters effectively has great benefits for public health. This is not merely because responding to a particular problem quickly and adequately can help avoid any possibility of a specific cluster developing into a wider problem, but more generally because it helps create public confidence in the ability of the authorities to safeguard health.

CLASSIFICATION OF RARE DISEASES

21 Improper classification of low-prevalence diseases and lack of official recognition pose problems in the recognition, detection, treatment and prevention of those diseases. Diagnoses identified in the WHO's International Classification of Diseases (ICD 10) are grouped into 23 major categories based on organ systems; these categories are subdivided into 470 diagnosis-related groups. In some instances, there is little emphasis on individual diseases in these groups.

22 Moreover, the validity and the usefulness of these classifications for low-prevalence diseases is limited. There are many instances in which these diseases are not included in conventional classification systems, such as the ICD and the British Paediatric Association classification for birth defects. In other instances, low-prevalence diseases are inappropriately or inadequately

classified: the ICD classification number assigned to Marfan syndrome, for instance, is shared by more than 20 other conditions.

23 The terms rare diseases or low-prevalence diseases relate to perhaps more than 5,000 different conditions or illnesses. There seems to be no common denominator to define the entity of a rare disease. Some are based upon syndromes (the combination of associated symptoms or defects), or single defects or non-associated conditions. Obviously, priorities have to be set when actions at a Community level have to be initiated.

III. DEFINITION OF RARE DISEASES

PROBLEMS WITH A NUMERICAL DEFINITION

24 It might seem that a definition of rare or low-prevalence diseases based upon numbers of cases would be straightforward. However, in the case of rare diseases these data either do not exist, or if they do, the figures produced on the basis of routine data collections will be broad estimates which are likely to understate the true rate.

25 Difficulties in establishing precise prevalence and incidence rates may arise for several reasons: differences in defining a disease; a lack of specific methods to monitor patients with these low-prevalence diseases; low diagnostic accuracy, particularly for the less serious diseases; and finally, distortion of information between data collection and analysis.

26 Well-known diseases may be classified and sub-classified repeatedly. For instance, cancers are often differentiated by pathologic classifications so that a number would fit numerical criteria for rare cancers. On the other hand, the classification of less-understood diseases is sometimes based upon symptoms which in fact group several diseases together. In this way specific low-prevalence diseases may be subsumed within larger entities.

DEFINITION BY FIXED NUMBER OR LIMIT

27 One way to overcome the problems inherent in using a fixed number for the definition of rare diseases is to establish limits. The Commission services have discussed this question with national experts. Several possibilities for fixing limits were discussed: a mortality rate not exceeding a given certain figure in a certain number of Community countries, or an incidence not exceeding a given certain value or a reported prevalence among Community inhabitants not exceeding a certain value. Another possibility might be the criterion that the condition is not among the 100 most common causes of morbidity and mortality in the European Community.

PROPOSED DEFINITION

28 For the purposes of this programme rare diseases will be defined as life-threatening or chronically debilitating diseases which are of such low prevalence that special combined efforts are needed. They are those diseases with a generally-accepted prevalence in the total Community population of less than 5 per 10,000. Moreover, the diseases to be specifically addressed by this programme will be those where special combined efforts are needed to ensure that there is no significant prenatal and premature morbidity or mortality, great loss of quality of life or socio-economic potential for the individual.

RELATED ISSUES

29 In considering actions on rare diseases we need also to take account of other related areas of Community work, such as research and the development and marketing of orphan products, including pharmaceuticals, which are mainly indicated for rare diseases. Given that rare diseases involve small numbers, there is a need to establish a population large enough for research purposes, such as clinical trials. The Community can take action in this regard. Similarly the commercial interest for the industrial sector in developing medicinal products for small numbers of potential patients is limited. There is therefore a need to encourage investment within the context of Community industry policy. Actions in these areas can complement well work in the public health domain.

30 Within the field of orphan medicinal products, a considerable amount of action has been taken at Community level. Recently, for example, the Commission has supported studies examining the issue with a view to formulating a

Community policy. An expert group was convened in February 1995 consisting of Commission officials and experts from both Member States and other countries to consider the findings of the studies and arrive at conclusions. During 1995 further consideration was given to this issue, and a Council Resolution on this was adopted on 20 December 1995, which invited the Commission to undertake further work, particularly on the development and marketing of orphan products.

IV. OVERVIEW OF PUBLIC HEALTH ACTIONS IN THE MEMBER STATES AND INTERNATIONALLY CONCERNING RARE DISEASES

MEMBER STATES

31 A number of Member States are pursuing work with regard to information, detection, recognition, intervention and prevention of particular rare diseases, including support for patient and parent groups. For example the United Kingdom has established a programme on Creutzfeldt-Jakob disease; France has set up a centre of information on genetic diseases and has some well-established centres for monitoring and surveillance of birth defects; and Portugal has a special interest in and is undertaking actions on paramyloidosis.

32 On the basis of information received from the Member States it would appear that only a few Member States, notably France, Sweden and Italy, which has set up a European School for Rare Diseases, are attempting to address rare diseases in a systematic way.

INTERNATIONAL ACTIONS

33 The country that is very much in the lead on this is the United States. In 1983 an Orphan Drug act was enacted to speed up the development and marketing of orphan products. Also in 1983 the National Organisation for Rare Disorders was set up; this brings together and assists the voluntary bodies which support people with rare diseases. A National Commission on Orphan Diseases was formed in 1985 to review national policy in this area. It reported in 1989. Its main recommendations were that there should be a central focal point to foster the development, research and marketing of orphan products. Furthermore an Office of Rare Diseases at the National Institutes of Health has been established.

Within the context of co-operation with third countries and following the recent Joint EU-US Action plan, the two parties have among others pledged to

establish a task force to develop and implement an effective global warning system and response network for communicable diseases, including rare diseases, while co-operating on respective programmes on health-related matters and in the research field.

V. OVERVIEW OF COMMUNITY ACTIONS RELEVANT TO RARE DISEASES

COUNCIL

34 In its Resolution of 20 December 1995[2] the Council and the Ministers for Health, meeting within the Council, invited the Commission, in close co-operation with the competent authorities of the Member States to take stock of the knowledge and experience available in the Member States, the Community and international organisations and to look into the situation of orphan drugs in Europe in relation to rare diseases.

EUROPEAN PARLIAMENT

35 In its Resolution A4-0311/95[3] on the Medium-Term Social Action Programme 1995-1997 the Parliament asked the Commission to present, under the proper procedures, the action programme for rare diseases foreseen in the Commission's framework communication on public health.

ECONOMIC AND SOCIAL COMMITTEE

36 In its wide-ranging Opinion of 6 July 1994 on the Commission's framework communication on public health it urged the Commission to adopt a broad approach to the subject and emphasised the importance of rare diseases.

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2 OJ C350 30.12.95 p.3

3 OJ C 032 05.02.96, p. 15-24

VI. COMMUNITY ACTION PLAN

EUROPEAN COMMUNITY INFORMATION ON RARE DISEASES

37 Accurate information is essential for ensuring effective interventions in rare diseases. The most immediate need of anyone with a rare disease is for an accurate diagnosis, followed closely by the need for treatment and support services. Once diagnosed, patients and their families are anxious to find out all there is to know about their disease and often become experts on it. They want information about the cause, prognosis, genetic basis (if any), and future manifestations of the disease, the availability of effective therapeutic interventions or, if none exists, how to cope with the disease, as well as information on current research. Patients want also information about support groups and treatment or focal centres.

38 All these kinds of information, where they exist at all, are widely dispersed. Moreover, available information may relate to a disease in general or a group of people, but it may be specific to an individual, which will necessitate appropriate safeguards for confidentiality. A further problem is that several different groups apart from those directly concerned in an individual case have a need for information at various levels of detail. These include physicians and researchers, governmental agencies, patient support groups and the pharmaceutical industry.

39 In the light of the major advances being made in genetics and of the current difficulties in obtaining up to date information on rare diseases, set out above, there is a pressing need for a Community information database on rare diseases and for a system for gathering and disseminating data.

40 In developing such a Community system, there must be close liaison with the Community's telematics programme. This might help define the technical requirements for the database and system and determine the most effective mechanisms for disseminating the information to the different interest groups and the relevant agencies in the Member States. A telematic network linking those working in the field would also provide a mechanism for the identification of relevant research and researchers and for the exchange of information.

41 The objective of Community action could be to provide a better information about rare diseases especially for patients, health professionals and researchers.

42 The actions to be taken to achieve this objective could include:

- encouragement and support for the establishment of a European rare diseases database, with entries listing the disease name, synonyms, a general description of the disorder, symptoms, causes, diagnostic tests available, affected population, standard treatments, investigational treatments (when available) and a list of resources that can be contacted for further information about the condition;
- promoting access to information and co-ordinating existing information systems and services by supporting the setting up and strengthening of networks at local, regional, national and community level; and
- organising consensus meetings among health professionals in order to improve the early detection, recognition, intervention and prevention of rare diseases.

PATIENT AND FAMILY SUPPORT GROUPS

43 These organisations have a wide-ranging role. They support the collection, dissemination and exchange of knowledge and experiences, foster public awareness and stimulate research and raise ethical issues. They also provide counselling for individuals and ensure that patients' interests are safeguarded, for example in terms of confidentially and informed consent to clinical procedures. There is a need to promote the development of these patient support groups so that all areas of the Community are properly covered and to encourage their co-operation at regional, national and European level. There is also a need to establish one or more umbrella organisations at Community level which can undertake a clearinghouse, linking and support role. There are already some organisations, such as the European Alliance of Genetic Support Groups (EAGS), that might be able to develop their activities in this way.

44 One of the objectives of Community action could be to establish, foster and strengthen voluntary organisations involved in supporting people directly or indirectly affected by rare diseases, such as various neurodegenerative conditions.

45 The actions to be taken to achieve this objective could include:

- promoting the establishment of groups of those persons with the same rare conditions or those professionally involved in order to disseminate their experience, to facilitate training and to co-ordinate their activities at national and Community level;
- promoting the groups' collaboration and networking and the setting up and fostering of umbrella bodies, focusing particularly on efforts to encourage the continuity of work and cross-national co-operation.

HANDLING OF RARE DISEASES CLUSTERS

46 Handling clusters of cases effectively involves analysing, assessing and managing the problem and communicating clearly to the public. Such action is both necessary and difficult. The necessity is clear since any local factor which might have been the causative or contributing agent has to be identified. But it is also difficult because there are many reasons for a cluster to be identified, and all possibilities need to be considered and investigated before a particular causal association is proposed. However, clusters occur only rarely in any particular region. This means that there is little opportunity for those involved in an individual case to gain the necessary experience.

47 In this situation there would be value in establishing within the Community 'Rare Disease Cluster Response Teams', involving those with appropriate expertise which would be available to give assistance to the local authorities concerned. The experience gained recently with Creutzfeldt Jacob disease indicates the need for such an approach enabling the best use to be made of scarce expertise in risk assessment and management.

48 In the case of clusters of rare diseases there is a need for the creation of networks of focal points for particular rare diseases or groups of related diseases, which would help in providing early warnings of potential problems, co-ordinating the investigation of clusters and provide relevant information, for example on expected prevalence levels, to the response teams. These focal points will need a high level of expertise in epidemiology and statistics, and the epidemiological information that is available on low-prevalence diseases from monitoring and surveillance programmes, both those at Community level and those undertaken nationally and regionally.

49 As mentioned above, epidemiological data for rare diseases are not currently comprehensive. Such data depend on effective monitoring and surveillance programmes. The majority of rare diseases are congenital disorders, and in this area a monitoring and surveillance programme has been set up: EUROCAT (European Registration of Congenital Anomalies). This is a concerted action with mainly participants from the Member States who locally and sometimes regionally study a population and investigate the number, type and possible causes of birth defects in order to prevent these congenital malformations. The Commission contributes financially to EUROCAT. Other birth defects monitoring programmes exist in the Member States, and collaboration with these programmes and with programmes that monitor other (groups of rare diseases) is necessary to permit an optimal use and analysis of the available data.

50 The objective of Community action would be to ensure an efficient handling of the problem of clusters, which is of key importance for rare diseases.

51 The actions to be taken to achieve this objective could include:

- supporting the monitoring (sentinel) of rare diseases, including birth defects, genetic disorders or diseases of different organ systems and the appropriate techniques for low-prevalence diseases, in order to meet on the one hand the demands of detection, treatment and research and on the other hand the demands of relevant statistical monitoring ;
- promoting the creation of rare diseases response teams and of specialised training courses for those investigating clusters ;
- establishing surveillance systems and detecting timely possible clusters; and
- encouraging the exchange of expertise in the evaluation, assessment, communication and management of clusters of rare diseases that are associated with exogenic causes.

ORPHAN PRODUCTS

52 In the context of the Community's work on the control and authorisation of pharmaceutical products, a legislative proposal is being prepared which has the aim of providing a legal framework for 'orphan medicinal products'. This will cover the following areas: designation of orphan medicinal products; support of research; market access; and monitoring, including pharmacovigilance.

As part of this proposal, the Commission intends to propose a definition for such products, along the following lines: any substance or combination of substances presented as proprietary medicinal product which is:

- used for the treatment, prevention or diagnosis of a life-threatening or chronically debilitating disease in human beings,
- where that disease indication affects not more than 5 per 10,000 people in the European Community, and
- where the commercial return is insufficient.

EUROPEAN COMMUNITY RESEARCH ON RARE DISEASES AND ORPHAN PRODUCTS

53 The Fourth Framework Programme (1994 - 1998) for Research and Technological Development[4] namely the Biomedecine and Health programme (Biomed2), area 1 "Pharmaceutical research" and area 4.6 "Research on rare diseases" covers the research activities on the development of orphan drugs and supports the basic and clinical research on rare diseases

54 Under the area of "Rare Diseases" the research tasks include the definition of diagnostic criteria, causes, genetic aspects, and methods of prevention, with emphasis on the establishment of European epidemiological observatories, information networks, and registries of patients with rare diseases in order to increase information available on rare diseases.

55 Under the area of "Pharmaceutical research" the aim is to support research on the treatment of rare diseases, including methodologies for fast-track schemes in the development of orphan drugs and repositories of available orphan drugs in Europe.

VII. CONSULTATION, ASSESSMENT AND REPORTS

CONSULTATION

56 The actions of this programme will be implemented in close collaboration with the Member States, particularly as regards co-ordination of their policies and programmes. To facilitate this, the Commission proposes the creation of an Advisory Committee of representatives of the Member States. Appropriate links will also be maintained with the WHO, other relevant international organisations and third countries in accordance with the requirements of the programme's actions.

EVALUATION REPORTS

57 Assessment of the programme will be provided in two reports:

- a mid-term report to the Council, the European Parliament, the Economic and Social Committee, and the Committee of the Regions. The

[4] Decision 94/1110/EC of 26..04.1994, OJ L126, 18.05.94, p.1, as amended by Decision 96/616/EC of 25.03.1996, OJ L86, 04.04.96, p.69

purpose of the mid-term report is to ensure that the Community Institutions and, through them, all the parties concerned, are kept fully informed on the progress of the actions undertaken. It will include information on the projects supported under the different actions.

- a final report on the implementation of the programme, which will include an evaluation of the actions undertaken, will be submitted to the above-mentioned institutions by the Commission after the completion of the programme.

GENERAL INFORMATION ACTIVITIES

58 The Commission will ensure that reports on the activities undertaken are made available to concerned parties and the general public.

59 Future Community public health action on rare diseases must take account of the existing large body of work, in particular that undertaken under Articles 129 and 130f of the EC Treaty. In accordance with Article 129 of the Treaty, the Community shall contribute towards ensuring a high level of human health protection by encouraging co-operation between Member States, lending support to their actions and promoting, in close contact with them, co-ordination of their policies and programmes, and fostering co-operation with third countries and international organisations competent in the sphere of public health.

Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DECISION

adopting a programme of Community action 1999-2003 on rare diseases in the context of the framework for action in the field of public health

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EXPLANATORY MEMORANDUM

1 In its Communication COM(93) 559 final of 24 November 1993 on the framework for action in the field of public health, the Commission outlined the principles and strategy to be followed in undertaking Community activities directed towards the attainment of the objectives on health protection laid down in Articles 3(o) and 129 of the Treaty establishing the European Community.

2 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 the target the best results already obtained in a given area anywhere in the Community.

3 In accordance with Article 129, the Commission presents proposals for the adoption by the European Parliament and the Council of incentive measures intended to contribute towards ensuring a high-level of human health protection.

4 The aforementioned Commission communication sets out criteria on which to determine priority areas for Community action programmes. In accordance with these criteria, rare diseases were identified as such a priority area.

5 The present Commission proposal, based on Article 129 and already announced in the Commission programme of work for 1996, comes under the principle of shared competence between the Community and the Member States, and seeks to improve information on rare diseases, support for patient groups and risk analysis and risk management in case of clusters of rare diseases. This Community action will follow the principles of subsidiarity and proportionality.

6 According to the principle of subsidiarity, action on matters not under the exclusive competence of the Community, such as action on rare diseases, must be undertaken by the Community only if and in so far as, by reason of its scale or effects, it may be better achieved at Community level.

7 Rare diseases are those diseases with a generally-accepted prevalence in the total Community population of less than 5 per 10,000. The diseases to be

specifically addressed by this programme will be those where special combined efforts are needed to ensure that there is no significant prenatal and premature morbidity or mortality, great loss of quality of life or socio-economic potential for the individual.

8 The proposed 5-year action programme seeks to complement ongoing work in the Member States by actions addressed to the public, health professionals, and the authorities.

9 With the limited resources available it would be impractical for a Community public health programme to address all the approximately 5,000 rare diseases and all aspects of rare diseases.

10 In selecting objectives and defining actions to be included in the programme, account has been taken of the situation currently existing in the Member States and at Community level in the field covered by the programme. The programme aims at bringing about an accelerated and effective sharing of information, support for patient groups and umbrella organisations, and the efficient establishment of cluster response teams, and increased co-operation of Member States. This will avoid unnecessary duplication of work and speed up the adoption of the best solution to problems common to all the Member States concerning such diseases.

11 Finally, the criterion of providing added value at Community level has a particular relevance to rare diseases, all of the activities involved being of such unique scale and effect as to provide added value to all Member States.

12 This programme is undertaken on the basis of a European Parliament and Council decision pursuant to Article 129. It does not come under the exclusive competence of the Community, and does not require the harmonisation of national provisions in the field covered.

13 An evaluation of the actions implemented under the programme will be provided in two reports: a mid-term report reviewing progress and a final report on the implementation of the programme. These reports will incorporate information on Community financing in the various fields of action as well as the results of evaluations. They will be transmitted to the Council and the European Parliament, as well as to the Economic and Social Committee and the Committee of the Regions.

Proposal for a
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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

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

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

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

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

Acting in accordance with the procedure referred to in Article 189b of the Treaty,

1. Whereas, the very fact of the rareness of the low-prevalence diseases and conditions and the consequent lack of information about them can lead to people affected by these conditions not receiving the health resources and services they need;

2. Whereas, for the purposes of this programme rare diseases will be defined as life-threatening or chronically debilitating diseases which are of such low prevalence that special combined efforts are needed to address them;.

3. Whereas, in accordance with point (o) of Article 3 of the Treaty, Community action shall include contribution towards the attainment of a high level of health protection;

4. Whereas Article 129 expressly provides for Community competence in this field in so far as the Community contributes to it by encouraging co-operation

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1 OJ -n°
2 OJ n°
3 OJ n°

between the Member States and, if necessary, lending support to their action; promoting co-ordination of their policies and programmes, and fostering co-operation with third countries and international organisations competent in the sphere of public health; whereas Community action should be directed towards the prevention of diseases, and the promotion of health education and information;

5. Whereas rare diseases have been identified as a priority area for Community action within the framework for action in the field of public health[4];

6. Whereas in its Resolution (A4-0311/95) on the Medium-Term Social Action Programme 1995-1997[5] the Parliament asked the Commission to present, under the proper procedures, the action programme for rare diseases foreseen in the Commission's framework communication on public health;

7. Whereas, in accordance with the principle of subsidiarity, action on matters not under the exclusive competence of the Community, such as action on rare diseases, must be undertaken by the Community only if and in so far as, by reason of its scale or effects, it may be better achieved at Community level;

8. Whereas, the Community can provide added value to the actions of Member States concerning rare diseases. through the co-ordination of national measures, the dissemination of information and experiences, the joint establishment of priorities, the development of networking as appropriate, selection of European Community-wide projects and the motivation and mobilisation of all involved;

9. Whereas co-operation with the international organisations competent in the field of public health and with third countries should be fostered;

10. Whereas, by providing support for acquiring better knowledge and understanding of, and wider dissemination of information about rare diseases and by developing actions complementary to existing Community programmes and actions, while avoiding unnecessary duplication, the programme will contribute to the achievement of the Community objectives set out in Article 129;

11. Whereas, in order to increase the value and impact of the programme, a continuous assessment of the actions undertaken should be carried out, with

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4 COM (93) 559 final

5 OJ N° C 32 05.02.96, p. 15-24

particular regard to their effectiveness and the achievement of the objectives set and, with a view where appropriate, to making the necessary adjustments;

12. Whereas this programme should be of five-year duration in order to allow sufficient time for actions to be implemented to achieve the objectives set;

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

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

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

16. Whereas this decision lays down, a financial framework constituting the principal point of reference, within the meaning of point 1 of the Declaration of the European Parliament, the Council and the Commission of 6 March 1995, for the budgetary authority during the annual budgetary procedure;

17. Whereas the Community's financial perspective is valid up until 1999 and will have to be revised for the period beyond that date;

18. Whereas the financial framework for the last four years of the programme (2000-2003) shall be determined after the establishment of the future financial perspectives;

HAVE DECIDED AS FOLLOWS:

Article 1

Establishment of the programme

1. A programme of Community action on rare diseases hereinafter referred to as "this programme", is hereby adopted for the period 1 January 1999 to 31 December 2003 in the context of the framework for action in the field of public health.

2. The aim of this programme is to contribute towards ensuring a high level of health protection in relation to rare diseases by providing knowledge about these diseases by promoting and strengthening patient support groups and by fostering the setting up of cluster response teams.

3. The actions to be implemented under this programme and their specific objectives are set out in the Annex under the headings:

   1) Actions on Community information on rare diseases
   2) Actions in support of patient and family support groups
   3) Actions on handling rare diseases clusters

Article 2

Implementation

1. The Commission shall ensure implementation, in close co-operation with the Member States, of the actions set out in the Annex.

2. The Commission shall co-operate with institutions and organisations active in the field of rare diseases.

Article 3

Budget

1. The financial framework for the implementation of the programme for the year 1999 shall be ECU 1,3 Million, in keeping with current financial perspectives.The financial framework for the final four years of the programme (2000-2003) shall be determined in detail after the establishment of the future financial perspectives.

2. The annual appropriations shall be established by the Budgetary Authority in accordance with the financial perspectives.

Article 4

Consistency and complementarity

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 actions.

Article 5

Committee

1. In implementing this action plan, the Commission shall be assisted by an advisory committee, hereinafter referred to as "the Committee", consisting of two representatives from each Member State, and chaired by the Commission representative.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken concerning, in particular:
   (a) the criteria, and procedures for selecting and financing projects under this programme;
   (b) the evaluation procedure.

   The Committee shall deliver its opinion on the draft, within a time limit which the chairperson 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.
The representative of the Commission shall keep the Committee regularly informed about Commission proposals or Community initiatives and the implementation of programmes in other policy areas which are relevant to the achievement of the objectives of this programme.

Article 6

International co-operation

1. In the course of implementing this programme, co-operation with third countries and with international organisations competent in the field of public health shall be fostered.

2. This programme shall be open to participation by the associated countries of Central Europe (CEC), in accordance with the conditions laid down in the Association Agreements or Additional Protocols related thereto concerning participation in Community programmes. This programme shall be open to participation by Cyprus and Malta on the basis of additional appropriations in accordance with the same rules as those applied to the EFTA countries, in accordance with procedures to be agreed with those countries.

Article 7

Monitoring and evaluation

1 In the implementation of this Decision, the Commission shall take the necessary measures to ensure the monitoring and continuous evaluation of the programme taking account of the general and specific objectives referred to in Article 1 and in the Annex.

2 During the third year of this programme, the Commission shall present to the European Parliament and to the Council an evaluation report

3 The Commission shall submit to the European Parliament and the Council a final report on completion of this programme.

4 The Commission shall incorporate into these two reports information on Community financing in the various fields of action and on complementarity with the other actions referred to in Article 4, as well as the results of the evaluations. It shall also send them to the Economic and Social Committee and the Committee of the Regions.

Done at Brussels,

For the European Parliament
The President

For the Council
The President.

ANNEX

SPECIFIC OBJECTIVES AND ACTIONS

I. ACTIONS ON COMMUNITY INFORMATION ON RARE DISEASES

Objective: to provide knowledge about rare diseases especially for patients, health professionals and researchers.

1. Encouragement and support for the establishment of a European rare diseases database, with entries listing the disease name, synonyms, a general description of the disorder, symptoms, causes, affected population, standard treatments, investigational treatments (when available) and a list of resources that can be contacted for further information about the condition.

2. Promoting access to information and co-ordinating existing information systems and services by supporting the setting up and strengthening of networks at local, regional, national and community level.

3. Organising consensus meetings among health professionals in order to improve the early detection, recognition, intervention and prevention of rare diseases.

II. ACTIONS IN SUPPORT OF PATIENT AND FAMILY SUPPORT GROUPS

Objective: to establish, foster and strengthen voluntary organisations involved in supporting people directly or indirectly affected by rare diseases.

4. Promoting the establishment of groups of persons with the same rare conditions or those professionally involved in order to disseminate their experience, to facilitate training and to co-ordinate their activities at national and Community level.

5. Promoting the groups' collaboration and networking and the setting up and fostering of umbrella bodies, focusing particularly on efforts to encourage the continuity of work and cross-national co-operation.

III. ACTIONS ON HANDLING RARE DISEASES CLUSTERS

Objective: to ensure an efficient handling of the problem of clusters, which is of key importance for rare diseases.

6. Supporting the monitoring (sentinel) of rare diseases, including birth defects, genetic disorders or diseases of different organ systems and the appropriate techniques for low-prevalence diseases, in order to meet on the one hand the demands of detection, treatment and research and on the other hand the demands of relevant statistical monitoring.

7. Promoting the creation of rare diseases response teams and of specialised training courses for those investigating clusters.

8. Supporting surveillance and early warning systems for clusters.

9. Encouraging the exchange of expertise in the evaluation, assessment, communication and management of clusters of rare diseases that are associated with exogenic causes.

FINANCIAL STATEMENT

1 TITLE OF OPERATION

Proposal for a European Parliament and Council Decision adopting a programme of Community action on rare diseases in the context of the framework for action in the field of public health

2 BUDGET HEADING INVOLVED

B3-.....

3 LEGAL BASIS

Article 3(o) and Article 129 of the Treaty establishing the European Community.

4 DESCRIPTION OF OPERATION

4.1 General objective

To contribute to achieving the objectives laid down by the Treaty:

- under Article 3 (o), the Community is required to make a contribution to the attainment of a high level of health protection;
- Article 129 requires the Community to contribute towards ensuring a high-level of human health protection, in particular by encouraging co-operation between the Member States, and if necessary lending support to their action, promoting co-ordination of their policies and programmes, and fostering co-operation with third countries and the competent international organisations in the sphere of public health. Community action is directed towards the prevention of diseases, in particular major health scourges, by promoting research into their causes and their transmission, as well as health information and education.

The general objective of the action programme is to contribute towards ensuring a high level of health protection on rare diseases.

The method for achieving this objective consists of undertaking actions which:

- provide the opportunity to undertake a much wider range of interventions and to initiate co-ordinated actions with patients who might otherwise be isolated or incorrectly diagnosed.
- provide information on rare diseases
- strengthen the organisation and setting up of patient and family support groups
- enforce the setting up of response teams involved in handling clusters of rare diseases.

4.2 Period covered and arrangements for renewal or extension

- 5 years: 01.01.1999 to 31.12.2003
- Report on implementation to be transmitted to the Council and European Parliament during the third year of the programme
- Report to the Council and European Parliament after completion of the programme together with the results of evaluations.

5 CLASSIFICATION OF EXPENDITURE OR REVENUE

- Non-compulsory expenditure
- Differentiated appropriations

6 TYPE OF EXPENDITURE OR REVENUE

Subsidy for joint financing with other sources in the public and/or private sector (not exceeding a certain percentage of the total cost of the proposed projects).
The level of funding granted depends on the scope of the measure to be financed and on the extent to which the action programme is reflected in the various activities planned. Such funding will not exceed 70% of the total budget earmarked for the proposed projects except in the case of networks and work ordered and of direct use to the Commission, where the subsidy may amount to 100% .

7 FINANCIAL IMPACT

7.1 Method of calculating the total cost of operation (definition of unit cost)

The method of calculation is the result of experience acquired in previous activities related to environmental health. This encompasses the various types of Community action listed in Table 4 of Commission Communication COM(93) 559 final of 24 November 1993, and represents 10 years of know-how in financing cooperative efforts with the Member States and NGO's of collection, analysis and dissemination of information, setting up of networks, survey of the quality of campaigns such as European weeks, establishment of mechanisms and procedures of consultation and cooperation for setting common objectives and for policy coordination and for the formulation and development of strategies at the Community level. The specific cost estimates are based on the assumption that half of the activities to be undertaken under this programme will require 100 percent funding while the other half will require 50 percent funding and that the activities to be undertaken will involve most or all of the Member States. An amount of ECU 1.3 million is deemed necessary for the implementation of these activities for the year 1999. The new budget framework for the final four years will be established in the year 2000 taking into account the future Community's financial perspectives. The annual allocations will be decided in accordance with the normal budgetary procedures.

7.1.1 Data base about rare disease for patients, health professionnals and researchers

Establishment of european rare diseases data base, with entries listing the disease name, synonyms, a general description of the disorder, symptoms, causes, affected population, standard treatments, investigational treatments (when available) and a list of resources that can be contacted for further information about the condition. The setting up of this data base in 1999 is calculated as 600.000 Ecus.
Organising consensus meetings on rare diseases among health professionals in 1999 will cost 100.000 Ecus.

7.1.2 Establishment of volontary organisations on rare diseases

Meetings in order to promote the establishment of volontary organisations involved in supporting people affected by rare diseases in 1999 : 200.000 Ecus.

7.1.3 Efficient handling of clusters of rare diseases

Setting up monitoring facilities of (sentinel) rare diseases will cost 300.000 Ecus in 1999.

The creation of rare diseases "response teams" and setting up training courses to investigate clusters will cost 100.000 Ecus in 1999.

7.2 **Itemised breakdown of cost (in ECU million)** - indicative programming

OBJECTIVE	ACTION AREA	YEARS					
		1999	2000	2001	2002	2003	TOTAL
To provide knowledge about rare diseases especially for patients, health professionals and researchers	Encouragement and support for the establishment of a European rare diseases database, with entries listing the disease name, synonyms, a general description of the disorder, symptoms, causes, affected population, standard treatments, investigational treatments (when available) and a list of resources that can be contacted for further information about the condition.	0.6	-	-	-	-	0.6
	Promoting access to information and co-ordinating existing information systems and services by supporting the setting up and strengthening of networks at local, regional, national and community level.	-	-	-	-	-	-
	Organising consensus meetings among health professionals in order to improve the early detection, recognition, intervention and prevention of rare diseases.	0.1	-	-	-	-	0.1

OBJECTIVE	ACTION AREA	YEARS					
		1999	2000	2001	2002	2003	TOTAL
To establish, foster and strengthen voluntary organisations involved in supporting people directly and indirectly affected by rare diseases.	Promoting the establishment of groups of those persons with the same rare conditions or those professionally involved in order to disseminate their experience, to facilitate training and to co-ordinate their activities at national and Community level.	-	-	-	-	-	-
	Promoting the groups' collaboration and networking and the setting up and fostering of umbrella bodies, focusing particularly on efforts to promote the continuity of work and cross-national co-operation.	0.2	-	-	-	-	0.2

OBJECTIVE	ACTION AREA	YEARS					
		1999	2000	2001	2002	2003	TOTAL
To ensure an efficient handling of the problem of clusters, which is of key importance for rare diseases.	Supporting the monitoring (sentinel) of rare diseases, including birth defects, genetic disorders or diseases of different organ systems and the appropriate techniques for low-prevalence diseases, in order to meet on the one hand the demands of detection, treatment and research and on the other hand the demands of relevant statistical monitoring	0.3	-	-	-	-	0.3
	Promoting the creation of rare diseases response teams and of specialised training courses for those investigating clusters.	0.1	-	-	-	-	0.1
	Supporting surveillance and early warning systems for clusters.		-	-	-	-	-
	Encouraging the exchange of expertise in the evaluation, assessment, communication and management of clusters of rare diseases that are associated with exogenic causes.		-	-	-	-	-
	TOTAL	1.3	p.m.	p.m.	p.m.	p.m.	1.3

7.3 Indicative schedule of appropriations (in ECU million)

	1999	2000	2001	2002	2003	TOTAL
Commitment appropriations	1.3	-	-	-	-	1.3
Payment appropriations						
1999	0.78					0.78
2000	0.52	-				0.52
2001	-	-	-			-
2002		-	-	-		-
2003			-	-	-	-
Subsequent years				-	-	-
TOTAL	**1.3**	**p.m.**	**p.m.**	**p.m.**	**p.m.**	**1.3**

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 other public health budget lines in relation to the financial years 1991 to 1995 and have shown their effectiveness.

9 ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1 Specific and quantifiable objectives

The Community measures aim at contributing towards ensuring a high level of health protection on rare diseases by providing knowledge about rare diseases especially for patients, health professionals and researchers, and to establish, foster and strengthen voluntary organisations involved in supporting people directly and indirectly affected by rare diseases, and by ensuring an efficient handling of the problem of clusters, which is of key importance for rare diseases : by the accomplishment of the following specific objectives:

The indicators showing whether or not these objectives are achieved will include measures of the following kinds:

- dissemination of information on rare diseases to patients, health professionals and researchers;
- establishment of a European rare diseases data base;
- availability of consensus documents about the detection, recognition, intervention and prevention of rare diseases;
- presence and functioning of local, regional, national and Community patient organisations active in the field of rare diseases;
- presence of umbrella bodies at Community level for the promotion of collaboration on different rare diseases;
- existence of rare diseases response teams and of specialised trading, surveillance, early warning systems related to clusters of rare diseases.

Target Population

1. Competent health authorities of the Member States, at national, regional and local level and competent international organisations in the sphere of public health;
2. Patient support groups, health professionals, health and medical associations, academic institutions etc.;
3. NGO's and other bodies interested in health matters, and the public in general.

9.2 Grounds for the operation

In initiating action under Article 129, the Community has to address itself to preventing diseases and protecting health. The Commission's communication on the framework for action in the field for public health[1] sets out criteria on which to determine priority areas for Community programmes. In accordance with these criteria the framework Communication evaluated the different options for addressing diseases, in particular major scourges and their underlying causes, by various types of community actions and retained on the basis of criteria listed in that communication, eight priority areas of which rare diseases was one.

For the purposes of this programme rare diseases are defined as life-threatening or chronically debilitating diseases which are of such low prevalence that special combined efforts are needed as shown on the basis of an ex-ante evaluation .

The programme aims at bringing about an accelerated and effective sharing of information and experience, Community wide understanding of key issues and questions on tackling rare diseases, and increased co-operation of Member States so as to avoid unnecessary duplication of work and speed up the adoption of best solution to problems common to Member States concerning such diseases. This input envisaged for the Community and the Commission by Article 129 of the Treaty provides a clear common framework of rules.

As regards the intervention methods and the allocation of funds, the following will apply:

- specific application of the principle of subsidiarity when identifying measures to be undertaken and co-financed;
- identification and selection of projects for co-financing in the fields of rare diseases

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the concept of added Community value, which will continue to be realised in particular through the co-ordination of national measures, the dissemination of information and experiences, the establishment of priorities, the development of networking as appropriate, selection of European projects and the motivation and mobilisation of all involved.

Two methods will be employed to implement the programme. One is to support projects carried out in Member States and at the Community level. The selection of priority projects is based largely on general and intermediate objectives, and implementation of the measures themselves depends on the quality and effectiveness of projects submitted to the competent department during the course of the year. The other is to undertake specific activities necessary to achieve the objectives of the programme, which will be fully financed by the programme.

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;
- Relevance of selected methodology;
- Organisational competence and experience;
- Suitability of budget for objectives;
- Support for projects from national partners;
- Objective assessment;
- Opinion of the advisory committee involved.

The budget proposed of 1.3 MECU for the first year of this programme matches that proposed at the same time for the Community action programmes on injury prevention and pollution-related diseases. This reflects the equal priority attached to these fields for action determined by the Commission communication on the framework for action in the field of public health (1993), an evaluation which remains valid today. The amount proposed represents the bare minimum required to start the programme.

9.3 Monitoring and evaluation of the operation

9.3.1 Monitoring of the operation

Monitoring at the Community level is to be carried out by the Commission, which will submit a report half-way through the implementation of the programme, and a final report after its completion to the Council, the European Parliament, the Economic and Social Committee, and the Committee of the Regions, drawing from national reports as well as evaluations of the actions under the programme and of individuals projects.

9.3.2 Evaluation

Evaluation will be by means of:

- An evaluation of the main measures and of subsidised projects involving, where necessary, the participation of independent experts;
- An evaluation report during the third year;
- An overall report on the quality and effectiveness of projects implemented under the action plan, to be submitted by the Commission to the other Community institutions after completion of the programme.

Performance indicators selected for this evaluation:

- Evaluation of projects by Commission officials and/or those co-operating 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 organisers;
- Suitability of the budget for the objectives;
- Skills and experience of bodies;
- Dissemination of results;

Evaluation procedures 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.

10 ADMINISTRATIVE EXPENDITURE (PART A OF THE BUDGET)

Actual mobilisation of the necessary administrative resources will be conditioned by the Commission's annual decision on the allocation of resources, having regard in particular to additional staff and funds provided by the budgetary authority.

10.1 Impact on the number of employees

Types of employees		staff carrying out action		source of employee		duration
		permanent employees	temporary employees	from within DG or service	supplementary staff	
Officials or temporary agents	A	1	0	1	0	
	B	1	0	1	0	
	C	1	0	1	0	
Other resources						
Total		3	0	3	0	

10.2 Financial impact of supplementary staff

10.3 Increase in other running costs arising from the action

Budget line	Amounts	Method of calculation
Meetings A2510	104,250 ECU's	2 meetings of advisory committee/year , 1 representative/Member State = 2 meetings/year x 15 representatives x 695 ECU/representatives x 5 years = 104,250 ECU's

The resources necessary to cover the expenditure below for the 5-year period will be obtained by re-deployment of existing financial resources and the use of supplementary resources will not be required.

a) Personnel Expenses (Title A1, A2 and A5)
3 x 100,000 ECU's x 5 years = 1,500,000 ECU's

b) Operational Expenses
Expenses for meetings (A-250)
2 meetings/year x 15 experts x 825 ECU's/expert x 5 years = 123,750 ECU's
Expenses for travel (A-130)
24 missions/year Brussels-Luxembourg x 200 ECU's/mission x 5 years = 24,000 ECU's
60 missions/year to Member States x 1000 ECU's/mission x 5 years = 300,000 ECU's

c) Total: 1,947,750 ECU's

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