

Opinion of the Committee of the Regions on the 'Communication from the Commission, accompanied by a proposal for a European Parliament and Council Decision adopting a programme of Community action on rare diseases within the framework of action in the field of public health'

(98/C 64/17)

THE COMMITTEE OF THE REGIONS,

having regard to the Communication from the Commission concerning a programme of Community action on rare diseases within the framework for action in the field of public health [COM(97) 225 final — 97/0146 (COR)]⁽¹⁾;

having regard to the decision taken by the Council on 27 June 1997, under Article 129 and the first paragraph of Article 198c of the Treaty establishing the European Community, to consult the Committee of the Regions on the matter;

having regard to its decision on 8 March 1996 to direct Commission 8 'Economic and Social Cohesion, Social Policy and Public Health' to draw up the relevant opinion;

having regard to the draft opinion adopted by Commission 8 on 24 September 1997 (COR 246/97 rev.) (rapporteur: Mr Mollstedt);

adopted the following opinion at its 20th plenary session on 19 and 20 November 1997 (meeting of 20 November).

1. Introduction

The Commission has presented a proposal to classify, investigate, treat and provide information about 'rare diseases', defined as diseases with a prevalence of less than five per 10 000 inhabitants for the European Union as a whole. The proposal provides a logical explanation of the reasons for including such diseases under actions in the field of public health, and, in particular, draws attention to the fact that these rare diseases can be of considerable importance for individuals and for local and regional authorities from both a humanitarian and economic standpoint.

The Committee of the Regions has studied the proposal and attendant justification with great interest.

2. General comments

2.1. The COR shares the Commission's concern for promoting and backing cooperation among Member States to improve exchanges of information and the control of rare diseases and to enhance measures to help patient and family support groups. However, the COR would question the efficacy of a separate action programme to combat rare diseases. Instead, the work involved should be incorporated into the existing action programme on health promotion or into a new framework programme on public health.

2.2. It is very difficult to define 'rare diseases'. The proposed working definition is acceptable, but it may require some fine-tuning during the programme's life-time. A simple numerical or statistical definition should be treated with caution, as this may be too mechanical, and issues could arise around boundaries and thresholds. The Commission is urged to consider this further.

2.3. As rare diseases are extremely difficult to quantify in terms of incidence or prevalence and to study in terms of causes, triggering factors, progress, etc., it would be advisable to establish registers, surveys or other types of Community-wide studies in order to frame appropriate policies for primary and secondary prevention and treatment.

2.4. The proposal sheds no light on the contribution research into rare diseases can make to furthering knowledge of common illnesses. This is particularly true of genetic damage and diseases.

2.5. Consequently, the programme should provide for greater cooperation with the relevant research funds.

2.6. The Committee of the Regions welcomes the proposal's particular emphasis on the fact that rare diseases can have major implications for neighbouring local or regional areas, and expects such information to be included in the programme.

2.7. The Committee of the Regions would further emphasize the need to promote the development of

⁽¹⁾ OJ C 203, 3.7.1997, p. 6.

medicines for these diseases, since the return on these specific medicines can be very small.

2.8. The Committee of the Regions feels there is good reason for the EU to establish close liaison on these issues, but wishes to emphasize that the problems raised by many of these diseases often require cooperation on a global level. Duplication of effort must be avoided, via cooperation between the WHO and other international bodies, and with treatment centre networks, etc.

2.9. The proposal emphasizes the importance of cooperation with patient and parent support groups, etc. on rare diseases. The Committee of the Regions would insist on this point and underline the need for cooperation with local and regional health authorities.

3. Specific comments

3.1. The Committee of the Regions notes that the proposed budget of ECU 1,3 million only applies to the first year (1998). Subsequent appropriations must be dependent on an assessment of the results of the introductory year. A review mechanism could be put in

place to ensure that the programme offers value for money and is appropriately focused year on year.

3.2. The Committee wonders whether the programme really needs an advisory committee with representatives from all 15 Member States. It would probably be more efficient to appoint a small permanent advisory group of four or five qualified researchers, who could avail themselves of expert advice where necessary.

3.3. The Committee of the Regions has already pointed out the need to set up a 'health observatory'. Now that further public health programmes are being suggested, the need is all the more urgent. Both coordination benefits and improved quality could be expected.

4. Summary

The Committee of the Regions:

- endorses the programme in principle,
- would emphasize the importance of coordination with research funds,
- would point to the need to review the budget after the first year,
- reiterates its earlier conviction of the benefits of a joint, independent 'health observatory'.

Brussels, 20 November 1997.

The Chairman
of the Committee of the Regions
Pasqual MARAGALL i MIRA
