COUNCIL CONCLUSIONS

of 29 June 2000

on Medicinal Products and Public Health

(2000/C 218/04)

THE COUNCIL OF THE EUROPEAN UNION,

- (1) TAKES NOTE of the conclusions of the debates at the European Conference on Medicinal Products and Public Health held at Lisbon on 11 and 12 April 2000 on the future of the European System for Evaluation and Supervision of Medicinal Products, the relevance of the added therapeutic value of medicinal products, aspects determining innovation and research, the rational use of medicinal products, the importance and evolution trends for the information systems for medicinal products, the increasing use of generic medicines and the key issues on veterinary medicinal products.
- (2) UNDERLINES the continuing need for regulation, at the appropriate national or Community level, of the pharmaceutical sector to reconcile private supply and social objectives. Policy must ensure the widest possible access to appropriate medicines and respond to the challenges of dynamic pharmaceutical markets, taking into account the significance of the European pharmaceutical industry as an efficient leading technology sector with high creation of added value, providing qualified jobs. In this context the Community has an opportunity, within the powers provided for by the Treaty, to assist Member States in their efforts to pursue public health and industrial policy objectives. This is particularly important in the context of enlargement.
- (3) STRESSES the fact that the forthcoming review of the Community legislation on pharmaceuticals should take fully into account that the centralised and decentralised authorisation procedures are and must be based on the principle of cooperation and close involvement of Member States in the authorisation process.
- (4) UNDERLINES that identification of medicines with significant added therapeutic value is of great importance to promote innovation, which is vital not only from a health-protection perspective but also from an industrial policy viewpoint and that this requires relevant basic and applied research, both at national and Community level.

- (5) RECALLS the importance of actions in the framework of the strategy against antibiotic resistance as suggested in the resolutions adopted by the Council at its meeting on 8 June 1999 (Health) and 12 December 1999 (Agriculture).
- (6) POINTS OUT that given that the increasing demands on health care put great pressures on available resources, it is imperative that expenditure on medicines, like all other areas of health care is assessed to ensure that it provides a rational use of medicinal products, and considers that collaboration between Member States to share experience and develop evaluation methodologies can be of great value in this regard.
- (7) CONSIDERS it important to develop databases to provide industry-independent information on medicines to health professionals and also, as appropriate, to the public, for example on generic drugs. This should be done in parallel with the extension of existing information systems.
- (8) STRESSES that the promotion of the use of generics can have an important impact in reducing pharmaceutical expenditure by promoting cost-effective use. The use of generics also creates headroom in pharmaceutical expenditure to help pay for new innovative products.
- (9) POINTS OUT that issues in relation to quality, safety and efficacy arise in respect of medicinal products for use in the veterinary field, in the same way as for human medicines. Moreover the safety of the consumer of animal-derived products, the safe usage of veterinary medicinal products, policies on the eradication of certain infectious diseases, the possible diffusion into the environment and protection against some misuses, have also to be considered.
- (10) INVITES the Commission to take account of the abovementioned considerations where they are relevant to drawing up detailed plans and implementation strategies

for the new programme on public health and the forthcoming review of Community legislation on pharmaceuticals.

- (11) URGES the Commission in carrying forward its broad health strategy, to exploit the full potential for Community action in relation to medicinal products and public health, particularly action to promote cooperation
- and exchange of experience between Member States, using the full range of possibilities for action under the Treaty.
- (12) ENCOURAGES the Member States to provide their full support so such policies and facilitate their implementation at national and Community level.