Orphan medicinal products

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‘The Council of the European Union, having regard to the Treaty establishing the European Community; whereas, in its Resolution of 30 November 1995 on the integration of health protection requirements in Community policies, the Council considers that the Community must pay particular attention to the impact on health of action proposed in a number of areas, including free movement of goods; whereas action to improve understanding of and address the impact on human health of the free movement of goods, in particular the free movement of medicinal products, should form part of the Community’s overall strategy for action in the field of public health; whereas there are many diseases from which small numbers of people suffer in the Member States and across the Community as a whole; whereas steps are needed to make it easier for patients suffering from those diseases to have access to treatments, in particular by means of so--called ‘orphan’ drugs, meeting the same criteria as all medicines; whereas, despite the relative infrequency of such diseases, the nature of their treatment and their particular health, economic and social effects are such as to make it advisable to consider them in a European context; whereas the Commission, in its communication of 24 November 1993 on the framework for action in the field for public health, singled out rare diseases as one of eight priority areas for Community action; whereas, in its Decision of 15 December 1994 adopting a specific programme of research and technological development, including demonstration, in the field of biomedicine and health (1994 to 1998), the Council specified rare diseases and orphan drugs as a specific research area (area 4.6), with actions including an inventory of rare disorders; whereas the Commission in its communication of 2 March 1994 on the outlines of an industrial policy for the pharmaceutical sector in the European Community referred to the work to be undertaken, within the field of research on biomedicine and health, on orphan drugs, where research may not be commercially viable; whereas there are certain drugs which are already marketed and have low commercial interest but are of major importance for the treatment of some rare diseases; whereas a common European approach to rare diseases and orphan drugs holds out advantages in epidemiological, public health and economic terms, CALLS ON the Commission, in close cooperation with the Member States and in the light of the guidelines in the Annex, to look into the situation of orphan drugs in Europe and, if necessary, make appropriate proposals with a view to improving access to medicinal products intended particularly for people suffering from rare diseases. Annex Aspects to be considered 1) The definition of an ‘orphan drug’; 2) The definition of a ‘rare disease’, having regard to its prevalence; 3) The criteria for obtaining ‘orphan drug’ status in Europe, establishing conditions for drugs’ inclusion or exclusion, in the light of any changes in the conditions on the basis of which they were classified; 4) Measures using regulatory provisions (including intellectual property aspects) and financial incentives to promote research, development, marketing authorisation and distribution of orphan drugs; 5) Examination of the health impact of a European policy on orphan drugs in the Member States and its economic impact for European industry.’