MEMO – A Recommendation on Rare Diseases

1. What is a Recommendation

A Recommendation is a legislative declaratory act on a given subject. It is usually proposed by the European Commission and adopted by the Council of the European Union, where the EU Member States seat. It engages them to act upon what it recommends. Although not legally binding, a Recommendation may bear a significant political weight. Recommendations are especially used for coordination actions, when action is required not only from the EU but also from the individual Member States.

2. A Recommendation on Rare Diseases

In certain policy areas, like public health, the EU cannot issue binding acts, such as Regulations or Directives, and Recommendations are the only legislative instruments that can be adopted by EU Institutions. A **Recommendation is therefore the best tool that is available to the EU to promote rare diseases as a public health priority**.

With the expected adoption of a Recommendation on Rare Diseases by the end of 2008, almost ten years after the adoption of the Regulation on Orphan Drugs, the European Union will achieve another milestone in the fight against rare diseases. The Recommendation will formulate coordinated objectives and strategies which the EU, on the one side, and the Member States, on the other, should implement. It will be accompanied by a Communication on Rare Diseases, a programmatic document which outlines the latest reflections and the envisaged actions in the field of rare diseases. When adopted jointly, the Communication often introduces the actions called for in the Recommendation.

Although the Recommendation on Rare Diseases is in the process of being drafted, we may expect that it will deal with the following important issues, which have a direct or indirect impact on the everyday life of patients:

- **The elaboration of National Plans on Rare Diseases**. Member States will be encouraged to structure their action in the field of rare diseases in the form of a National Plan, whereas common policy guidelines should ensure that consistency is achieved throughout the EU;
- **Pooling European expertise**, i.e. gathering at European level the limited and scattered expertise on rare diseases in order to provide the national level with expert opinions, while ensuring equal access to health and social care all over the EU;
- **Centres of Expertise and European Reference Networks**. Member States will be called upon to identify and support Centres of Expertise for rare diseases, their participation to European Reference Networks and to organise healthcare pathways for patients through the establishment of cooperation with all the experts within the country or from abroad when necessary;
- **Patients' empowerment**, notably the involvement of patients and their representatives at all stages of the policy and decision-making processes having direct consequences on their lives;
- **Research**. Member States should develop strategies to enhance research in the field of rare diseases, and ensure adequate means for sustaining on a long-term base research infrastructures and projects.

3. The crucial role of patient groups and national alliances in the next steps of the process

In mid-2008, the Commission should present a proposal for a Recommendation together with the proposal for the Communication on Rare Diseases, which will take into consideration the results of the successful public consultation. The adoption is expected in December 2008, under the French Presidency of the EU.

It is therefore in the second half of this year that Member States must find an agreement on the final text of the proposed Recommendation and its eventual modifications. In this phase, **National Alliances and patient organisations should maximise their efforts to persuade their governments to support a text which puts patients at the centre of policy action**, ensures equal access to quality healthcare throughout Europe and engages EU countries to mobilise adequate resources to implement those actions. Most of all, patient groups have a key role to play in **ensuring that their respective governments endorse at the Council level the recommendation to adopt National Plans on Rare Diseases**, ideally by a given date (or following a fixed agenda), and **consequently adopt such a Plan in their country**.

In order to support its members in their national advocacy efforts, EURORDIS will provide them in due time with a detailed analysis of the Recommendation text and guidance on the specific points which deserve support or, on the contrary, require modification.