DECLARATION OF SOUTH EASTERN EUROPEAN AND LITHUANIAN CYSTIC FIBROSIS PATIENT ASSOCIATIONS AND CYSTIC FIBROSIS EUROPE:
”TOWARDS HARMONIZATION OF CYSTIC FIBROSIS DIAGNOSIS AND CARE FOR ALL PATIENTS IN EUROPE“

The participants of the South Eastern European Cystic Fibrosis Conference (www.cisticna-fibroza.hr/dubrovnik2010/en), including our colleagues from Lithuania, hereby urge all European countries to implement “*Standards of care for patients with CF: a European consensus*” as the guideline for CF care at their respective national level (Journal of Cystic Fibrosis 2005 Mar;4/1/:7-26). This is particularly relevant for the participants of this meeting, given the recently substantiated marked disparities in the quality of care, resulting quality of life and thus patient survival in South-Eastern Europe (Lancet 2010 Mar 20;375/9719/ :1007-1013).

Cystic Fibrosis (CF) is the most common life threatening inherited disorder in European-derived populations. Although current treatments merely delay or relieve disease symptoms, people with CF who have access to adequate care, according to the European standards cited above, mostly live longer and better lives. Moreover, it has been clearly shown that early diagnosis facilitates proper multidisciplinary interventions which positively influence the overall course of the disease. However, in South Eastern Europe and Lithuania, access to proper diagnosis and/or care is generally inadequate, whereby too many children with CF are diagnosed late and/or are treated under different diagnoses, which leads to decreased quality of life, including premature death in childhood or adolescence. Given lower awareness of medical professionals in the cited region milder adult CF cases are usually not recognised.

We very much welcome scientific progress which promises causative treatment of CF! Therefore, it is of our prime responsibility to ensure that all patients have equal access to current treatment modalities now which will enable them to benefit from upcoming therapies.

Representatives of South Eastern European and Lithuanian CF patient associations endorse the recent European and Eurordis communication / recommendations for rare diseases, for which CF is often cited as a paradigm disorder: a) “Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions on Rare Diseases: Europe's challenges” /SEC(2008)2713; SEC(2008)2712/ (ec.europa.eu/health/ph_threats/non_com/docs/rare_com_en.pdf); b) EU Council „Recommendation of 8 June 2009 on an action in the field of rare diseases“ 2009/C 151/02V (eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0007:0010:EN:PDF) and the Eurordis guideline for „Centres of Expertise and European Reference Networks for Rare Diseases“(www.eurordis.org/IMG/pdf/position-paper-EURORDIS-centres-excellence-networksFeb08.pdf), including the c) Council of Europe „Oviedo Convention“ for the „Protection of Human Rights and Dignity of the Human Beings with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine“ (conventions.coe.int/Treaty/en/Treaties/Html/164.htm). Moreover, we wellcome the EU Council provision in its Recommendation which suggests that national plans or strategies for rare disease be adopted. Although, this is *de iure* relevant to current EU members, it is *de facto* applicable to countries which are still not part of the European Union. In this regard evaluation of decades of national and/or European epidemiologic registries demonstrate that care provided by multidisciplinary teams of qualified health professionals

within dedicated CF centres, operating in accordance with Eurordis reference centre guidelines, is essential for optimal management and improved disease outcome in CF patients.

In accordance with the EU Council recommendation successful care for any rare disease requires close cooperation and continuous feedback from patient support organisations. Hereby, CF patient association representatives present at the Conference endorse these provisions and will aim at their implementation within their national health care systems, including all stakeholders (government, medical professionals and the public at large). We will also foster establishment of national plans for rare diseases in our countries in accordance with the Europlan project recommendations (www.eurordis.org/content/europlan-joint-action-national-strategies-and-plans-rare-diseases-all-eu-member-states).

The conference co-organiser "Cystic Fibrosis Europe" (CF Europe; www.cfeurope.org), which is a federation of national CF patient associations, representing more than 40.000 patients in 38 countries, urges all European countries to ensure that CF care, according to the European standards, be implemented in all children and adults with this disease. This organisation also endorses EU Council and Eurordis position statements. CF Europe was a model patient organisation for important Eurordis surveys published in the recent publication "The Voice of 12,000 Patients" (www.eurordis.org/publication/voice-12000-patients).

In summary, participants of the South Eastern European CF conference recognise and endorse the following issues as being crucial for establishing adequate care in CF:

- "*Standards of care for patients with CF: a European consensus "* should be accepted as the official guideline for CF care in all countries
- Multidisciplinary reference centres for CF should be established in accordance with European Commission, EU Council and Eurordis guidelines
- All CF children and CF adults should have equal and full access to medication and treatments recommended in the "*Standards of care for patients with CF: a European consensus*" and these should be covered by national health insurance
- Measures improving early and equal diagnosis of CF, such as neonatal screening, should be available to all newborns and infants at a nation-wide level, albeit neonatal screening should be followed by adequate care as stipulated above
- Each country should establish a national CF registry and participate in the European ECFS registry in order to benchmark national results and foster exchange of best practices
- Efforts fostering awareness and knowledge on CF in health care professionals and in the general public should receive full support
- CF families, including CF adults, should receive sufficient social support which will facilitate their quality of life and prevent discriminatory social barriers

We are convinced that the implementation of measures stipulated above will result in better care, substantially improved quality of life and longer survival in CF.

In summary, this Conference is thus an important step forward in the fight against Cystic Fibrosis in South Eastern Europe, and beyond.

Dubrovnik, October 2, 2010

CF Associations or representatives and professionals present at the Conference:

Croatian Cystic Fibrosis Association – Ms. Anja Kladar

Macedonian Cystic Fibrosis Association – Ms. Snežana Bojčin

Cystic Fibrosis Association for Republic of Srpska – Ms. Biljana Kotur

Cystic Fibrosis Association "Zehra Kalajdžić" Bosnia and Hercegovina – Mr. Elvis Bilalagić

Republic Serbia Association for help and support to people with CF – Mr. Dragan Đurović

Association "Mucoviscidosis" Bulgaria – Ms. Svetlana Atanasova

National Alliance of People with Rare Diseases Bulgaria – Mr. Vladimir Tomov

Lithuanian Cystic Fibrosis Association – Ms. Lijana Kazlauskienė

Cystic Fibrosis Europe – President Ms. Karleen De Rijcke

Croatian Society for Rare Diseases – Prof. Ingeborg Barišić, MD, PhD

European Cystic Fibrosis Society Board Member (www.ecfs.eu) - Prof. Milan Macek, MD, DSc

Parent and allied health professional, Montenegro - Ms. Lidija Kijanović