Dear Sir/Madam,

Scleroderma is a life threatening rare disease for which is no cure. Early diagnose will prevent irreversable organ damage in many cases. Until now the diagnose is usually made when the damage is clearly detectable.

Herewith I like to inform you about the formation of a European federation of scleroderma associations, named FESCA.
FESCA is an umbrella organization of 16 European national scleroderma patient organizations from 13 different countries, founded on June 23rd 2006 in Amsterdam and officially registered in Belgium.

We are very pleased that you give us the opportunity by your public consultation to give you our views and ideas. Please find below our answers to your questions seen from a scleroderma patient's perspective.

Question 1:
We endorse the suggestion printed below the question.

Question 2:
We endorse your suggestion on this subject; we see amongst the countries of our member organizations huge differences in accepted figures of incidence and prevalence of scleroderma. Therefore we endorse a regularly updated and accepted list of rare diseases with a binding character not only to regulatory institutions but also to f.i. insurance companies throughout Europe.

Question 3:
We fully endorse your ideas in this field and like to inform you that EUSTAR (EULAR Scleroderma Trials and Research group) is on the brink of setting up such a database for scleroderma in connection with a bio-bank in which samples of scleroderma patients are stored. This activity deserves support from the European Commission.

Question 4:
We are in full agreement with your views.

Question 5:
These tools should be implemented and used throughout the EU with built-in safeguards that the data can only be used for medical purposes and not for commercial purposes. Bridging the differences of regulations in the EU member states is one of the first items to be addressed in order to set-up a good working and safe database for any RD.

Question 6:
The medical science in the field of scleroderma is (not yet) developed enough to be able to carry out neonatal screening on scleroderma.

Question 7:
However we feel that this is too far ahead for scleroderma, but in general any reasonable effective screening we will support. Many early scleroderma symptoms

are apparently trivial, such as cold blue fingers in winter (called Raynaud's Syndrome).

Question 8:
As a European umbrella organization of scleroderma patients we see huge differences in accessibility to orphan drugs, devices and diagnostics. A uniform and easy access will be highly appreciated by us.

Question 9:
As in the previous question/answer mentioned we would encourage any financial support for the social well-being of scleroderma patients by means of support to self-help groups who offer information/education and psychological support.

Question 10:
We are in full agreement with your views 4.3.

Question 11:
We endorse your suggestions printed below the question.

Question 12:
We endorse your view 4.4. As numbers of patients of rare diseases are per definition small we believe that a European approach is the only effective approach. Initiatives from member-states should be encouraged by but coordinated by the EC.

Question 13:
Any action to improve the outcome of RD is highly appreciated. This should be encouraged by the EC, but as per our answer to the previous question be coordinated and financed by the EC.
We see the creation of the EU Advisory Committee on RD as a good precursor of the establishment of a new Community Agency for RD.

Question 14:
As FESCA is a young organization and has not yet sufficient knowledge of the organogramm of the EU we are not yet able to give you our views on this subject.

Peter Bakker
for and on behalf of the board, as
delegated administrator of FESCA