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recherche & développement

European Commission
Pharmaceuticals Unit
Att.: sanco-pharmaceuticals@ec.europa.eu

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Sanofi-aventis and Sanofi Pasteur response on the public consultation concept paper on the Revision of the 'Clinical Trials Directive' 2001/20/EC.

Sanofi-aventis and Sanofi Pasteur appreciate the opportunity to review and comment on the views about more concrete ideas on the issues previously presented during the 2009/10 public consultation on the Revision of the Clinical Trials Directive.

Enclosed you will find our response to this public consultation concept paper.

We consider that a key objective of the Clinical Trials Directive, the "protection of the health and safety of clinical participants" has been achieved. However we believe that the revision of the EU regulatory framework for clinical trials authorisation is now necessary and should be designed to streamline the procedure and optimise the exploitation and sharing of the knowledge generated during Clinical Trials implementation.

To reach these objectives, **sanofi-aventis and Sanofi Pasteur strongly support optional single submission with Central Assessment rather than a Coordinated Assessment Procedure. Central Assessment would facilitate the access to multicentre/multinational Clinical Trials in all Member States and guarantee harmonisation and transparency *via* a single portal. The procedure should be based on the existing expert network at the level of National Competent Authorities, without establishing a formal centralised committee**.

We wish to inform you that we have contributed to, and support, the comments submitted by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Yours faithfully,

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L'essentiel c'est la santé.

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