Subject: BIA response to European Commission's consultation on orphan drug guideline

Dear Mr Arlett,

The BioIndustry Association (BIA) welcomes the opportunity to be able to respond to the European Commission's consultation on its revised Guideline on the format and content of applications for designation as orphan medicinal products and on the transfer of designations from one sponsor to another. The BIA is the trade association for innovative enterprises in the UK's bioscience sector. We represent over 350 members, the majority of which are involved in healthcare bioscience.

The BIA welcomes the update of the Guideline with respect to the participation of Norway and Iceland with the Member States of the European Union for the purposes of orphan designation process, thus enabling sponsors of orphan drugs in those countries to take benefit of Community incentives but also to be included in the population for the prevalence calculation of the condition.

The BIA also welcomes the update of the Guideline with respect to EU enlargement and cross-reference to the Commission Communication (2003/C 178/02). However, we would recommend an amendment to page 3, line 1 of the Guideline, referring to Directive 65/65/EEC which was repealed and replaced by Directive 2001/83/EC.

Finally, we request that the impact on small and medium-sized companies of the increased cost and bureacracy involved in meeting requirements to achieve orphan drug status is taken into account.

Yours sincerely

Dr Christiane Abouzeid
Regulatory Affairs Manager
BioIndustry Association