Dear Colleagues,

As you know, the European Commission has published a consultation document on the revision of the IVD Directive. The IVD Directive sets out the regulations which govern the safety and efficacy of diagnostic tests marketed in Europe and creates a single market for *in vitro* diagnostic devices across the EU.

The current IVD Directive has been criticized for being too inflexible and somewhat arbitrary in the way it classified tests. The blanket exemption for tests produced in health institution laboratories was also criticized for being too broad and poorly defined. EuroGentest produced a position paper on the revision of the Directive which was adopted as EuroGentest policy. This new consultation opened by the Commission gives us an important opportunity to make our views known and to influence the revision of the Directive.

A central proposal in the EuroGentest policy document was that the exemption from CE-marking for in-house tests manufactured in public health service laboratories should be retained, but that it should be restricted to laboratories accredited to ISO 15189 or equivalent. This provides a balance of test availability and patient safety. There have been calls for the abolition of the in-house exemption, which, if it happened, would severely limit the scope of testing available, especially for rare diseases. Our response to the consultation robustly supports the retention of the exemption, while emphasising that patient safety should be ensured by restricting it to accredited laboratories.

It is very important that the Commission receives the messages contained in this document from as many stakeholders as possible. Multiple labs and other bodies supporting the EuroGentest position will greatly increase the impact of our submission. We encourage all interested parties to make individual responses to the consultation and to disseminate the attached EuroGentest response to laboratory networks and rare disease organizations within their countries, encouraging them in turn to submit responses. If those submitting responses can **add data on the numbers of genetic tests carried out in their country/region/ laboratory which would not be available without the in-house exemption**, that would strengthen the case even more. We feel it is important to emphasise, whenever we support the retention of the exemption, to also mention that it should be restricted to accredited laboratories, in the interests of patient safety.

David E Barton, PhD
Chief Scientist & Associate Professor
National Centre for Medical Genetics
Our Lady's Children's Hospital, Crumlin
Dublin 12, Ireland.
Tel +3531 409 6749 Fax +3531 409 6971
www.genetics.ie