**08 May 2008**

**Comments on "Public Consultation in Preparation of a Legal Proposal to combat Counterfeit Medicines for Human use: Key Ideas for Better Protection of Patients Against the Risk of Counterfeit Medicines"**

The EU Commission has accepted EQAC, a confederation of European Quality Assurance associations as an appropriate body to submit comments on proposed guidelines and legislation. We are very grateful for this opportunity to contribute to the development of regulations and guidelines. Our comments on the consultation document published in March 2008 follow:

EQAC obviously is concerned about counterfeit medicines and their potential impact on public health. However, the great majority of our members work in pharmaceutical development organisations, and as such are concerned that one of the proposed measures to improve the security of supply could have an unintended consequence for the conduct of clinical trials.

It is very common practice to repackage marketed medicinal products for use as comparators in blinded clinical trials; without this repackaging and relabelling blinding is impossible. The current proposal, under section 4.1.3, "Improving Product Integrity through a Unique Seal from the manufacturer to the retailer or wholesaler; using a risk based approach, supported by a ban on repackaging", would appear, as written, to forbid companies from repackaging in this way. This would seem to prevent the proper use of licensed comparators in clinical trials. It is suggested that the legislation be modified to include a phrase that would allow the opening of the unique seal and repackaging of a medicinal product for use in clinical trials. Under current legislation, if carried out in the EU this must be done at a facility holding a Manufacturing Authorisation for IMPs, and is therefore subject to inspection by the Competent Authority, as well as Qualified Person certification. Records at the clinical trial repackaging site could be amended to record the individual serial numbers of the packs of medicinal product, thus allowing compliance with the suggestion, under 4.1.5, for mass serialisation for pack-tracing.