From: Carolyn Keats <ckeats@tendercorp.com>

Sent: 28 June 2012 19:31

To: SANCO FEES PHARMACOVIGILANCE

Subject: Fees Payable to the EMA

Tender Corporation is a manufacturer of over the counter pharmaceutical preparations. Currently we have one medicinal product on the market in the EU.

Already we find the regulatory fees to be exceedingly high and the proposed fees for pharmacovigilance to be charged by the EMA are prohibitive. This will be **crippling** for the industry. Moreover it is not clear how these are justifiable. We strongly object to the imposition of these fees on industry. **We hope the EMA will re-consider its position.** Certainly it should be clear that the regulatory burden being placed on industry by the European Commission is chasing business off-shore.

Sincerely,
Carolyn Keats
Director, International Business
Tender Corporation

Email: ckeats@tendercorp.com