

## Pharmathen S.A.

**From:** Dimitris Antoniadis <dantoniadis@pharmathen.com>  
**Sent:** 13 September 2012 10:27  
**To:** SANCO FEES PHARMACOVIGILANCE  
**Subject:** PC/12/05 - Public Consultation on pharmacovigilance-Consultation item n°2

Dear Sir / Madam,

Regarding Consultation item 2, we endorse the idea of grouping. However, we want to comment upon the 500 euro per party involved in the group. Since one company shall take over the compilation, submission and handling of each group's PSUR, then the EMA could invoice this party for the entire project (i.e. the 80.300 euro PSUR fee). This party in turn could distribute to each member of the group, its portion of the fee. This way the EMA shall be relieved from a considerable amount of administrative work, related to the additional MAH's. We therefore ask for the complete elimination of this fee, or a substantial decrease.

KR,

Dimitris Antoniadis

**Dr. Dimitrios M. Antoniadis**

**QP/QPPV**

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