

## Santen Oy (Finland)

**From:** piia.tirila@santen.fi  
**Sent:** 14 September 2012 15:22  
**To:** SANCO FEES PHARMACOVIGILANCE  
**Cc:** Tapio.Kerttula@santen.fi  
**Subject:** PC/12/05 - Public Consultation on pharmacovigilance fees

Dear Recipient,

please find below our comment on Introduction of Fees to be charged by the EMA for Pharmacovigilance.

### 3.1. Fee for assessments of Periodic Safety Update Reports

#### Consultation item number 1:

*The PSUR assessment fee should somehow take into account the small products for which the yearly Gross Sales may be even lower than the proposed fee.*

*These are often so-called service products which are used by the medical society professionals' e.g. as diagnostic products. These products do not often generate any revenues for the providers, but are considered to be valuable in terms of co-operation/service. If it is set in the EURD list, that a MAH is required to submit PSURs for the given products and, if assessments are provided and charged by EMA for these PSURs, it is very likely that the profitability would drastically worsen and break even could not be met during the reporting cycle. Hence, providers would likely be forced to delist such goods from the market. This in turn might have a significant impact into the medical society.*

*One way to avoid such negative impact might be quittance procedure for products under pre-defined value sales or similar.*

Best regards,

Tapio Kerttula (QPPV) and Piia Tirilä (Drug Safety Specialist)  
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