**From:** Gro Wesenberg [mailto:gro.wesenberg@legemiddelverket.no]
**Sent:** Saturday, September 15, 2012 10:34 PM
**To:** SANCO FEES PHARMACOVIGILANCE
**Cc:** Karen Marie Ulshagen; Jan Petter Akselsen
**Subject:** PC 12/05 Public Consultation on pharmacovigilance fees

The Norwegian Medicines Agency has the following comments to the Public consultation on pharmacovigiliance fees:

"For consultation item 1-6 and 8-9, we agree with the proposed approaches.

Regarding consultation item 7, the proposal is to charge an annual service fee of maximum 1000 Euro per year per medicinal product. The suggested fee seems rather modest compared to the resource the MAHs will save by not having to monitor the literature for drug safety issues.

Regarding consultation item 10, on additional items and other comments, we would like to raise the following issues:

- A yearly pharmacovigilance service fee and fees for assessments of PSURs, PASSes and safety referrals are to be charged for CAPs as well as for non-CAPs.

The concept paper does not offer any clarity on who shall have the responsibility for charging the fees. For decentralized procedures, the charging of fees have so far been a purely national responsibility. How will this be handled in the new system?

- For CAPs the amount of financial resources redistributed to NCAs for the services of rapporteurs, co-rapporteurs and experts, is half of the fees received by the Agency for activities like full MAA, type II variations etc. Will the same principle be applied to the fees related to the new pharmacovigilance system?"

Sincerely yours
Norwegian Medicines Agency

Dr. Gro Ramsten Wesenberg
Director General