From: GROL (Gro Laier)
Subject: Public consultation to implementation measures on Pharmacovigilance

Dear Sirs,

Novo Nordisk A/S have two comments additional to choose submitted via EFPIA and a remark to one of the EFPIA comments.

Both comments are related to Annex IV – Protocols, abstracts and final study reports for the post-authorisation safety studies
3. Format of the abstract of the final study report, item 10:
A full discussion may be too long to include in an abstract. However, a conclusion on the impact of the results on the risk-benefit of the product might be presented.

4. Format of the final study report, item 5: To include planned dates for all the named milestones in the final study report does not seem to add value and may be logistically problematic, if the plan has changed multiple times.

The remark concerns the definition on Medication Error:
Finally, we would like to stress the rational for a minor change to the proposed definition of "Medication error", in order to avoid confusion, we believe that the English meaning of the word error should be adhered to. An error mean something done by mistake. It may or make not be appropriate, normally it will be inappropriate. However, if someone decided to take an overdose that is not an error, it is an intentional drug misuse. Likewise, off-label use even if inappropriate may not be an error.

Best Regards,

Gro Laier, MD
Deputy QPPV
Global Safety

Novo Nordisk A/S
Krogshøjvej 55
DK-2880 Bagsværd
Denmark