SUBMISSION OF COMMENTS ON LEGISLATIVE PROPOSALS TO STRENGTHEN AND RATIONALISE THE EU SYSTEM OF PHARMACOVIGILANCE (5 DECEMBER 2007)

COMMENTS FROM NV Organon, a part of Schering-Plough Corporation
LIST OF MOST IMPORTANT ISSUES (UP TO 10) IN A DECREASING PRIORITY ORDER

COMMENTS ON TEXT

Precise Reference and page of consultation document	**Comment and Rationale**	**Proposed change**
Section 3.2.3; page 5	The venue to inspect (supervisory authority) should not be associated with the Member State the Qualified Person resides in, but rather the country where main EU Pharmacovigilance activities reside (which may not necessarily be the same location).	The Market Application Holder should be able to indicate the most suitable and practical point (MS) in the community for inspection of their PV system.
Section 3.2.4; page 5	The spirit of section 3.2.4 is good, though the current text is too vague to satisfy reasonable requirements to specify when RMPs are needed. As currently proposed, it is unlikely to result in a reduction and therefore will not likely be cost-neutral.	
Section 3.2.6; page 7	The wording of section 3.2.6 on expedited reporting is unclear and may lead to the requirements of non-serious ADRs. There is insufficient guidance on the basis for which a product would be put on the list of	

	medicines under intensive monitoring and under what criteria to lift the monitoring. Further clarification is needed.	
Section 3.2.8; page 9	The roles and timing of communications should be clarified as well as the content, accessibility of the information and tools to be used. It is important to agree on the role the website will have in this respect. Please explain in more detail what is meant by "timing" in this section. Will the message issue at the same point in time in all member states? Also, when will a safety issue rise to the level that a communication is needed? The urgency and consistency of communications is a crucial component of transparency. Under today's situation, some countries issue warnings (e.g., dear doctor letters) while others do not. Please clarify what is intended by the first sentence of the second paragraph ". . . legal base would be clarified . . ."	
Section 3.2.9; page 9	Although the principle of highlighting key safety information seems a good improvement, the question that arises is how to determine what is key and what is not. Liability issues may arise for not including a safety warning in the section whereas the warning is included in other parts of the labeling. A new section of "key safety information" is not favored at this time, however, if such a section is included there should be clear and unambiguous guidelines on what qualifies as such.	

Please feel free to add more rows if needed.