EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Health Systems and Products **Pharmaceuticals**
Brussels,SANCO

**PUBLIC CONSULTATION PAPER**

**REVIEW OF THE VARIATIONS REGULATION**
**REVIEW OF COMMISSION REGULATION (EC) No 1234/2008**

**Deadline for Public Consultation: 22 October 2011**

---

## CONSULTATION TOPICS RESPONSES

**Member state:**
Czech Republic

**Date:**
22/10/2011

**On behalf of:**
Institute for State Control of Veterinary Biologicals and Medicaments
Section of the marketing authorisation
Hudcova 56 a, 621 00 Brno
Czech Republic

---

**Consultation item no. 1:**
**Do you agree that where dossiers are not harmonised difficulties could raise for worksharing when accepting the assessment carried out by one member state by other member states?**

**We agree on the fact that theoretically the difficulties could raise in that case.**

**According to our practical experiences we can say that no difficulties /no problems related to non harmonised dossier have been identified till now in CZ. Dossier of all submitted applications has been harmonised.**

**Consultation item no. 2:**
**Which option a) or b) mentioned above do you consider that should be adopted to allow worksharing ?**

**We support option b).**

**Consultation item no. 3:**
**Do you agree with the principle that the deadline for adoption of Commission Decisions amending marketing authorisations must be driven by public health considerations?**

**Yes,we agree on that principle.**

**Consultation item no. 4:**
**Which category of variations do you consider that should be adopted within shorter deadlines?**

**Our opinion is that within shorter deadlines should be adopted variations connected with safety and efficacy risk concerns (including residua/WP,dosage schedule, pharmacovigilance/PSUR concerns…)**

**Consultation item no. 5:**
**Do you agree to extent the current system that allows holders to implement certain variations prior to the adoption of the Commission Decision (to the exclusion of those changes with most impact for public health)?**

**No,we do not agree to extent the current system,we do not support the extension of the actual variations list.**

**Yes,we agree on the exclusion of those changes with most impact for public health.**

**Consultation item no. 6:**
**Do you consider appropriate to introduce a deadline for the implementation of changes to product information significant from a public health standpoint?**

**Yes, we consider it as appropriate.**

**Consultation item no. 7:**
**Do you agree with the above analysis?**

**Yes,we agree on the above analysis.**

**Consultation item no. 8:**
**Do you consider appropriate to extend the time limits for assessment of complex grouped applications to enable a larger amount of cases where grouping under one single application could be agreed by the competent authority?**

**Yes,we consider appropriate to extend the time limits for assessment of complex grouped applications to enable a larger amount of cases where grouping under one single application could be agreed by the competent autority.**

**Consultation item no. 9:**
**Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?**

**Not applicable in VET area.**