

March, 2010

Dear Sir or Madam,

For an overall assessment of pharmacovigilance data of an active substance the <NCA> synchronises the submission schemes for Periodic Safety Update Reports (PSURs) on Veterinary Medicinal Products (VMPs) containing the same active substance. This approach is based on the agreed Data Lock Points (DLPs) for PSURs fixed in the context of the PSUR Work Share Project.

The Work Share Project for PSURs is an initiative of the Heads of Medicinal Agencies Vet (HMAvet), supported by IFAH Europe and EGGVP. All Member States of the European Economic Area agreed to participate in the consolidation phase of this initiative beginning in January 2010. For more information regarding the project and the DLPs see the HMA-homepage (www.hma.eu).

If your company has already synchronised the submission of PSURs of VMPs containing the same active substances within the EU, this synchronisation remains unchanged. Just DLPs will change (see list of DLPs on HMA-homepage). We apologise for causing any inconvenience.

If no harmonised DLP exists for an active substance contained in one of your VMPs, you may participate as originator in the PSUR Work Share Project and suggest a DLP, if applicable (for information [lj.v.hooft@cbg-meb.nl](mailto:l.j.v.hooft@cbg-meb.nl)). The DLP is agreed on by the PSUR Synchronisation Sub Group (PSSG). As long as there is no harmonised DLP for a VMP agreed on the existing submission scheme for PSURs remains unchanged. In all cases the period between two DLPs must not exceed three years time.

Contact point for clarification:

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