Notification under the Services Directive IMI 374010.1 (SWEDEN) on the Medical Products Agency's regulations on the handling of samples of veterinary medicinal products.

Commission comment

The Commission would like to thank the Swedish authorities for the above-mentioned notification and would like to ask the following clarification:

The Commission notes that Section 4 of the Swedish Regulation of the Medical Products Agency on handling samples of veterinary medicinal products provides that samples of medicinal products shall be distributed only to recipients who have ordered them in advance. The order may be placed digitally or on paper.

Could the Swedish authorities explain whether such order of samples of veterinary medicinal products takes place within the context of Article 119(10) of Regulation (EU) 2019/6, which requires that the samples of veterinary medicinal products shall be given directly to veterinarians or other persons allowed to supply such veterinary medicinal products during sponsored events or by sales representatives during their visits?

In case the order of samples, as envisaged in Section 4 of the above mentioned Swedish Regulation, does not take place directly to veterinarians or other persons allowed to supply such veterinary medicinal products during sponsored events or by sales representatives during their visits, the Commission invites the Swedish authorities to align this provision with the requirements of Article 119(10) of Regulation (EU) 2019/6.

The Commission would like to thank in advance the Swedish authorities for their co-operation.