

A Guideline

ÚSKVBL/UST - 02 / 2006

Expert consultation by employees of the Institute for State Control of Veterinary Biologicals and Medicaments (ÚSKVBL)

Valid since:	March 3, 2006 (update of legislation 2009)
Valid to:	unlimited
Amends/Complements the guideline:	-
Repeals/Replaces the guideline:	ÚSKVBL/UST – 1/2004

The Institute for State Control of Veterinary Biologicals and Medicaments (ÚSKVBL) provides consultation services relating to the fields of its regulatory powers in areas of veterinary medicinal products, veterinary non – medicinal products and veterinary devices. The objective of consultation is to enable the enquiring party to deal with particular issues so as to inform them of the ÚSKVBL's view of the given matter. The output of the particular sessions is considered as confidential. They serve as the ÚSKVBL's tool for generalizing its stand-points and for providing for a similar procedure in similar cases. The ÚSKVBL will respect the conclusions of the consultation sessions which, however, are not legally binding for the enquiring parties – they can opt for a different solution that has been recommended which leads to the desired end. They can neither be considered as fully binding for the ÚSKVBL's staff. Despite there is an expectation that the session conclusions will be applicable for an acceptable period of time, it can not be ruled out that new findings can somewhat modify the application of some sessions. Subsequently, the date when the consultation has been provided will have to be seen in the perspective of the particular legislative, legal and expert driven changes that will have taken effect.

By implementing this procedure, the ÚSKVBL hopes to allow for the ÚSKVBL's staff to be prepared for the consultation session and thus to ensure that the information is comprehensive and accurate. Also, if need be, it aims to provide for the presence of third party experts and to limit unplanned for and unexpected interference with the ÚSKVBL staff's standard duties. Apart from this, the ÚSKVBL will try and reduce the need for individual consultation by monitoring the frequency of questions asking about the same issue for which cases it will be more suitable to make the information accessible to all public.

With respect to the introduction of fees to cover the costs of expert tasks of the ÚSKVBL (see the guideline USKVBL/UST–4/2008 entitled as *Administration fees and payment of costs for expert tasks on demand*), fees are also levied for some oral consultation. Payment of a fee is not required for oral consultation provided as part of the ÚSKVBL's expert tasks already in place under the guideline USKVBL/UST–4/2008. Also, consultation does not include meetings with the regulated party representatives to which they have been invited by the ÚSKVBL.

The procedure

- The enquiring party shall send a request in writing (also via email) to the expert or to the email address uskvbl@uskvbl.cz. The request shall contain concrete questions or areas for consultation, an estimate of time necessary for the consultation to take place, contact person and their address, telephone or e-mail details. If the consultation is subject to a fee payment, the commercial name of the company, the address and the tax ID shall be included, too.
- The expert shall propose a date of the session or shall request a specification of the session's topics.
- The session shall take place.
- If the consultation is subject to a fee payment, the ÚSKVBL shall send the enquiring party an invoice after the session, quoting the fee – the sum being 2200 CZK for every hour, billed in 1 hour increments, following the provisions of the USKVBL/UST-4/2008, code 0-01 (01) on *Providing hourly oral consultation on demand* (they are not connected with the already submitted application). The sum of money can also be paid in cash at the cash office of the ÚSKVBL immediately after the session.
- In order to record the conclusions, every consultation session shall be completed with a short conclusions summary in writing which answer the questions raised (in Czech or in English) which will be made available to the expert by the contact person on behalf of the enquiring party within 5 working days. The consultant shall amend the report if necessary, confirm its final version and send it to the enquiring party within 5 days in case of consultation sessions that have been charged for of the date that they receive a confirmation of the invoice payment being carried out (identification of the payment on the ÚSKVBL's account). The deadlines for writing the report can be negotiated otherwise during the session. The consultation conclusions which have not been confirmed by the ÚSKVBL in writing (report confirmation) shall not be deemed as its official view by the ÚSKVBL and they shall not be taken into account in its operation by the ÚSKVBL. In particular, making reference to the oral statements made by the ÚSKVBL's staff is unfounded.

Number of attachments: 2

Annex 1: Form for application

Annex 2: Form for consultation report