



ELECTRONIC SUBMISSIONS FOR CENTRALLY AUTHORISED VETERINARY MEDICINAL PRODUCTS

Introduction

The initiative to create a veterinary sub-group of the Telematics Implementation Group on electronic submission (TIGesVet) came from the Heads of Medicines Agencies.

The TIGesVet is composed of representatives from Industry, National Competent Authorities and the EMEA. In order to comply with the requirement that all Agencies should be able to accept electronic submissions for marketing authorisations from 1 January 2010, the TIGesVet has developed guidance for those companies wishing to submit their dossiers electronically. It should be noted that e-submission is not mandatory.

Scope

Electronic submission is acceptable for all marketing authorisation applications, irrespective of whether they are centralised, national, mutual recognition or decentralised procedures.

Guidance available

The overall objective has been to develop a harmonised approach to the compilation and submission of regulatory documents in an efficient way, taking into account the specific nature and limited resources of the veterinary sector, both from an authority and an industry point of view. The approach has been to retain the current Notice to Applicants format and to allow the submission of dossiers via various media (PDF or Word on CD Rom, DVD or sent via Eudralink etc).

Good progress has been made by the TIGesVet and a [Guideline for the specifications of e-submission of veterinary medicinal products documents](#) was published at the end of 2007; this guidance is applicable for all types of application (mutual recognition, decentralised and centralised). Discussions continue in the TIGes Vet on practical issues. A web page relating to e-submission (<http://esubmission.emea.europa.eu/tiges/vetesub.htm>) has been created and a [Frequently Asked Questions](#) section is available.

For centrally authorised products, the EMEA will be pleased to provide information and guidance to Applicants to assist them in their submissions.

For all types of application a half-day Industry workshop with the TIGesVet in the Spring of 2009 is planned in order to facilitate submission for Applicants.

Timetable

TIGesVet first meeting:	July 2006
Publication of e-submission guidance	December 2007
Publication of Frequently Asked Questions	Summer 2008, updated Autumn 2008
Update on e-submission for centralised procedures:	December 2008
Workshop on e-submission in the Veterinary Sector	May 2009
Agencies to be “e-submission ready”	January 2010