# TIGes Vet Group for e-Submission in the Veterinary Sector:

# Terms of Reference


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# 1 Document Control

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## 1.2. Reviewers

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## 1.3. Distribution

| Version | Name | Company/Agency |
|---|---|---|
| 0.3 | Per Helboe | Denmark |
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# 3 Purpose of this Document

This document describes the Terms of Reference of the TIGes Vet Group concerning implementation of electronic submission standards for the veterinary sector. These Terms of Reference are to be adhered to and agreed by all members of the group as well as those in the associated wider framework of telematics groups (referenced here) responsible for the implementation of e-submission standards throughout the European pharmaceutical and regulatory community.

# 4 Background Information

A management structure for EU Pharmaceutical IT systems was set out by the European Commission in the Strategy Paper on Telematics in the Pharmaceutical sector, as amended by the decision of the Telematics Steering Committee (TSC) on 8th September, 2004 (Revised version 1.0) and the Implementation Plan for Telematics in the Pharmaceutical Sector, version 12.5.3 revised by TSC in November 2004.

The main objective of this Implementation Plan/IT strategy is the reinforcement of appropriate communication between stakeholders (general public, industry, Member States, European Commission and EMEA) to support pharmaceutical regulatory activities for both human and veterinary medicines.

Several implementation groups are mandated to ensure the continuing success of the Implementation Plan for Telematics. The Telematics Implementation Group for e-Submission (TIGes) is charged with the development of standard specifications for electronic data exchange of information submitted and exchanged in support of marketing authorisation applications in Europe, consistent with ICH standards. The TIGes is further responsible for the development of requirements for IT systems for implementation of standards that would permit the submission, validation and evaluation of applications for marketing authorisation using electronic standards, specifically the electronic Common Technical Document (eCTD). ICH standards for CTD and eCTD are developed for human medicinal products and a veterinary parallel has not been elaborated, i.e. the NtA format still applies to veterinary submissions.

In April 2005 a deadline of December 2009 was agreed by Heads of Medicines Agencies, by which the European Regulatory Network will have the infrastructure and processes in place to handle electronic submissions to successfully support the related decision-making processes for medicinal products within the European Union.

The work of the TIGes is focused on the continuing development and implementation of the eCTD and associated structured data formats (electronic application form, PIM) for the human sector. It is felt that the work of the TIGes with regard to the implementation of electronic submission formats for the veterinary sector should be appropriately scaled to the EU animal health market, which in 2003 reached only 3% of the size of the human pharmaceutical market. Whilst respecting and harnessing the extensive work already carried out in the implementation of electronic standards for human medicines, a pragmatic and appropriate solution for the veterinary sector is sought that takes into account the scale of the industry, adherence to current standards for harmonisation, amount of non-electronic legacy information, and available financial, technical and human resources.

It is with the objective of developing these veterinary standards and associated implementation guidance that the TIGes Vet Group of the TIGes for e-Submission in the veterinary sector was formed, and its creation is endorsed by the Telematics Steering Committee.

# 5 Scope

The TIGes Veterinary Sub-Group for e-Submission is seeking to progress the implementation of fully working business processes and supporting Telematics for the paperless submission and review of information in support of marketing authorisation applications in the European Union for human and veterinary medicinal products. This TIGes Vet Group assumed responsibility for delivering the objectives, listed in section 6, and the deliverables, listed in section 9, in July 2006. The Team will have completed its work when these objectives have been met and the deliverables have all been finalised. In scope is the submission of electronic information in accordance with a harmonised defined standard or standards, and the management of the lifecycle of such information for all procedure and application types relating to veterinary MAAs in the EU.

# 6 Objectives

The overall objectives of e-submission implementation in the veterinary sector can be found in the TIGes Vet Group Project Initiation Document (doc. ref. EMEA/522487/2006)

The detailed objectives of this TIGes Vet group are:

- To develop simple, useable and appropriate standards for the electronic submission and lifecycle management of information in support of a veterinary marketing authorisations in the EU, based on known technology and standards where possible, and with international consideration;
- To analyse and re-use existing standards where they are applicable to the veterinary sector;
- To provide a forum for exchange of views between NCAs, EMEA and industry and seek consensus on rationale, format, and timescale for implementation of e-submission in the veterinary sector;
- To define and implement the roadmap for agencies and industry for the implementation of the adopted electronic data exchange standards for veterinary medicines, obtaining approval and ratification from relevant bodies and in accordance with implicated groups;
- To develop and implement pragmatic and appropriate guidance for adoption of this standard in the veterinary sector;
- To develop requirements and specifications for systems and a suitable architecture for the electronic submission of veterinary information in the EU;
- To suppress further development from agencies that may lead to unilateral standards and requirements
- unilateral development at a national agency level in the arena of electronic submission in favour of a common approach;
- To define any funding and resources required for the implementation of the standards and systems;
- To resolve issues in a proactive manner;
- To actively communicate progress on the implementation across all stakeholders.

# 7 TIGes Vet Group Structure

The TIGes Vet Group will include representation from all of the required stakeholders, particularly industry and Competent Authorities. They will represent the user requirements of stakeholders from their detailed knowledge of the business processes and technical processes that stakeholders will need to follow and will help to ensure that full and complete analysis is carried out, and full and complete documentation are produced, by the Team.
The TIGes Vet Group consists of representatives from EMEA, the National Competent Authorities of EU Member States,, and industry organisations IFAH, AVC and EGGVP.

Representation from small and larger pharmaceutical companies manufacturing veterinary medicines should be assured, as well as EMEA and a wide range of regulatory agencies. Representation from the TIGes is further required as well as individuals with sound knowledge of existing e-submission standards and associated implementation issues for the veterinary pharmaceutical sector.

The number of representatives in the sub-group will be reviewed on a regular basis but will not exceed a maximum of 15 regular members. Where a change in the constitution or membership of the Sub Group is considered necessary by the Sub Group itself, it shall, by a simple majority decision, determine the representatives to be nominated. Such a change should be endorsed by the TIGes and TMC, particularly where there may be financial implications.

Vendors and software developers are not members of the Sub Group. However, they may be invited to participate with respect to specific issues.

The emphasis is on a shared vision and collaborative approach between industry and regulators.

# 8 Meeting Schedule, Roles and Reporting

The Veterinary sub-group is an ad hoc autonomous group that has a mandate from the TIGes to make practical and management decisions for the implementation of the submission in the veterinary sector, and is ultimately responsible for ensuring that the development of standards and implementation progresses and is completed. The Sub Group is also, crucially, responsible for the development and implementation of a communication strategy for e-submission in the veterinary sector.
Whilst discussion of related standards and developments that may impact e-submission in the veterinary sector may be important for implementation, technical development of these related standards and related work does not fall within the remit of the sub-group.

The group is responsible for the development, maintenance and evolution of suitable electronic submission standards for the veterinary sector, in line with existing standards for the exchange of similar information for human medicines where appropriate. It is responsible for resolution of issues related to the development of the standard, in line with legislative changes and also for the coordination of testing and evaluation of test results. The group is mandated to liaise with the TIGes, VICH and other standards development bodies (e.g. ISO) and working groups as appropriate to ensure open communication and the continuing alignment of the veterinary e-submission standard with other related standards.
It will further work in conjunction with Veterinary Standards Organisations and Electronic Submission Working groups as necessary for consideration of the technical and business impact of changes and the practical implementation these changes, in addition to re-defining business processes where necessary.

A clear programme of work is defined for the Sub Group and laid out in the Project Initiation Document (doc. ref. EMEA\522487/2006)

Delegates will be expected to and should agree to devote 5% of their time to the project (on average 1 day per month inclusive of all meetings and travelling time). This involvement may increase during key periods. EMEA shall host the meetings of the TIGes and subgroups and reimbursement of travel and accommodation costs for participation of delegates shall be covered as per EMEA's reimbursement rules, and industry members will not therefore be reimbursed for travel expenses incurred by attending meetings.

Meetings will be every quarter, and occasionally if necessary teleconferences may be held between face-to-face meetings. Membership is formed from individuals with a range of expertise in the regulatory management of veterinary submissions and the implementation of IT systems.

The Sub Group will be chaired by the Danish Medicines Agency, assisted by EMEA. It may define other ad hoc groups or specify consultation with other groups as necessary.

Operating decisions of the Sub Group shall be reached by consensus and shall, under normal circumstances, be unanimous. Under exceptional circumstances the Chairs may decide to proceed with a majority decision.

In order for a Sub Group meeting to be quorate, at least 2 industry organisations should be represented at each meeting. Furthermore, EMEA and 3 regulatory agencies must be represented in all meetings (replacements to normal team members may be sent if necessary).

All members of the Sub Group are expected to actively contribute to the development and documentation of standards, specifications, policies and guidance as appropriate, in consultation if necessary, as well as actively reviewing the work of all other Group members.

Representatives of the Sub Group should present the progress to the TIGes on completion of each phase related to the timelines and expected results. Members of the Sub Group should report on issues encountered during implementation and give recommendations to the TIGes at each TIGes meeting during the implementation period.

# 9 Deliverables

## 9.1. Already Delivered

1. Documentation from veterinary industry stating the business case for implementation of electronic submission standards in the veterinary sector and outlining the basic principles and recommended concepts underlying such an implementation of e-submission, sufficient to enable a pharmaceutical company or competent authority for veterinary medicinal products to adopt an electronic approach within an achievable timeframe. The following principles are laid out in this document:
    - Requirement for analysis of existing human medicine standards for re-usability potential and applicability
    - Development of a pragmatic and simple system, based on known technology and standards
    - Avoidance of disparate national initiatives

- Objective of introducing electronic submission in the veterinary sector in a flexible and measured manner
- Incorporation of lifecycle management principles
- Pragmatic solutions to those issues which have caused difficulties in the human sector for e-submission (electronic signatures etc)
- Implementation of a suitable architecture to support e-submission in the veterinary sector e.g. a common repository and review aid
- The importance of 'optionality': Flexibility and choice for industry in the implementation of electronic submission standards and systems

## 9.2. Deliverables of this Phase of the Project

1. A comprehensive Project Initiation Document, discussed and agreed by all EU HMA.
2. Agreement on the priorities and order of development/implementation for the electronic information hierarchies detailed in the Project Initiation Document (True electronic exchange of information which may be used to populate databases and then re-used e.g. the Application Form and Product Literature; Information which can be viewed, which can be cut & pasted and manipulated; and information which is reviewable, searchable, more accessible).
3. Assessment of the solutions suited to the defined priorities
4. Development of a suitable approach or approaches, in an appropriate order, towards electronic submission of MAA information for veterinary products, in accordance with the heirarchies
5. Agreed user requirements specifications for each of the 3 types of electronic information handling
6. Comprehensive implementation guidance, policy information and training material for the application of the approaches for all European procedures and application types
7. Definition of the implementation process for the information hierarchies, and monitoring of this implementation
8. Comprehensive and documented business processes and continued lifecycle support for the exchange and review of veterinary information submitted electronically via all procedures

# 10 Costs and Funding

The cost of this implementation (meetings, travel, external consultancy with relation to standards development and documentation) is assumed to be borne by EMEA and covered by the European Telematics budget. In accordance with the EMEA's reimbursement rules, industry members will not be reimbursed for travel expenses incurred by attending meetings

All decisions which will result in funds being committed, or spent, will be approved by the TSC. When commitments are directed towards NCAs the decision also needs to be approved by the HMA Veterinary.

Other management and responsibility for other costs incurred in the implementation of e-submission in the veterinary sector will be subject to further discussion and agreement by all parties.

# 11 Assumptions, Risks and Constraints

The risks and constraints for the work of the Sub Group are:

1. Availability of human resources and expertise to progress the work needed;
2. Availability of sufficient budget to support the necessary activities involved in implementation of a standard for e-submission in the veterinary sector;
3. Preparedness of European National Competent Authorities approach and engage in the implementation and refrain from activity that may lead to unilateral requirements development
4. Preparedness of Marketing Authorisation applicants to agree to and embrace the approach;
5. Preparedness of other stakeholders to embrace the approach and engage in the project, particularly high-level support and commitment from the European Commission;
6. Availability of appropriate software if necessary to support the developed standard and implementation policy

# 12 Outline Plan and Milestones

To be completed. Precise timelines should be agreed by the TIGes Vet Group.

Two key initial milestones exist:

- Agreement of the Project Initiation Document by HMA, and commitment to the objectives therein, including objectives to prioritise and potentially progress at different timelines the implementation of different heirarchies of electronic information;
- Agreement of the Project Initiation Document by TSC, and commitment to the objectives therein.

# 13 Confidentiality

A level of confidentiality is to be applied to each document that the TIGes Vet Sub Group produces. The levels of confidentiality are defined as follows:

Level 1 (Confidential) : Document is confidential to TIGes Vet Sub Group only (Narrow Circulation) Circulation should be limited to regulator members of the TIGes Vet Sub Group, limited circulation within regulator's agencies and no circulation beyond industry representatives on the TIGes Vet Sub Group. This may be a draft for comment or a final document that is not to be made public.

Level 2 (Restricted): Document is available for Limited Circulation. Circulation should be limited to members of the TIGes Vet Sub Group, circulation within regulator's agencies and working groups such as TIGes. Circulation to industry representative's groups (eg. IFAH, EGGVP, AVC) as necessary.

Level 3 (Consultation): Document is available for Wider Circulation. Documents may be cascaded widely for consulation eg. IFAH, EGGVP, AVC full membership, vendors etc. This is not a final document but one for which comments are being sought.

Level 4 (Public): Document is available for Public Dissemination A final document for publication, typically via the TIGes website.

All versions of all documents should be assigned one of these categories

# 14 Termination of this Phase of Implementation

## 14.1. Determination upon achievement of the project deliverables

Sub Group members will have no further obligations under these Terms of Reference once the TSC has agreed that all of the deliverables of the joint project set out in section 8.2 have been satisfactorily completed.

## 14.2. Completion

The implementation initiative will be complete once all the deliverables listed in section 9.2 have been made available.

# 15 Glossary

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| AVC | Association of Veterinary Consultants |
| CMD(v) | Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary |
| eCTD | Electronic Common Technical Document. The eCTD provides a common format for the electronic submission of information to regulatory authorities in the three ICH regions. |
| EGGVP | European Group for Generic Veterinary Products |
| EMEA | European Medicines Agency |
| ICH | International Conference for Harmonisation |
| IFAH | International Federation for Animal Health |
| MAA | Marketing Authorisation Application |
| National Competent Authority (NCA) | An authority established within the European Union by Community or national legislation, which is responsible for the authorisation and supervision of medicinal products. |
| PIM | Product Information Management - a joint project of EMEA and EFPIA to design, develop, pilot and implement secure electronic submission of product information (i.e. the Summary of Product Characteristics (SPC), Package Leaflet (PIL) and labelling text to the EMEA and to other regulatory authorities of the European Union. |
| TIGes | Telematics Implementation Group for eSubmission |
| TSC | Telematics Steering Committee |
| VICH | [Definition to be provided] |