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Information and Communications Technology

Telematics Implementation Subgroup Group for electronic submission – Veterinary Subgroup (TIGes vet)

Terms of reference

Background

The Terms of Reference of the Telematics Implementation Group (TIG) for electronic submission – Veterinary Subgroup ("TIGes vet") derive from the Management Structure for EU Pharmaceutical IT systems as set out by the European Commission (letter of P. Brunet 22 Dec 1999), as amended by the decision of the Telematics Steering Committee (TSC) on 7 September, 2004. The generic terms of reference for a Telematics Implementation Group (TIG) state:

> "These technical groups will regroup Information Technology experts from all Member States as well as User representatives. Their precise composition will be determined by the Telematics Implementation Group, on a case by case approach, in order to ensure a high level of expertise and an adequate representation of users.
>
> Under the control and coordination of the Telematics Management Committee (TMC), the TIGs will have to deal with the practical and technical implementation of the decisions and strategies as determined by the TSC and report back on the progress being made. In particular they will be in charge of the definition of requirements for the specific IT projects"[1].

These generic terms of reference were refined[2] to include the following:

1. To agree on common user requirement specifications;
2. To review and comment on the technical specifications;
3. To participate in the testing of software deliverables;
4. To introduce and review change requests;
5. To enable Member States and stakeholders to provide input into a European user requirement specification;
6. To represent the Member State Competent Authorities in the final acceptance of the specifications, standards and systems and their documentation;
7. To act as conduits for the flow of project information back to the Member State Competent Authorities and stakeholders.

The Management Board Telematics Committee (MBTC) met for the first time on 9 December 2009, assuming from that point on the responsibility for directing the EU Telematics Programme previously exercised by the TSC. In taking on this role, the MBTC has initiated a review of the governance of EU

[1] European Commission – DG ENTR: Doc TSC-NL 4/04 (09/Dec/99, updated 26 June 2004)
[2] TSC/05/2005/012 Role Description: Telematics Implementation Group Chair

Telematics. These terms of reference are a revision of those in place in December 2009, and have been prepared in accordance with a revised template. These terms of reference remain valid following approval by the MBTC pending completion of the review of EU Telematics governance structures.

The TIGes vet was set up in September 2006 with the objective of developing and implementing specifications and standards for the e-submission of electronic information in the context of European veterinary medicines approval and surveillance procedures. As the TIGes vet is a subgroup of the TIGes, the terms of reference (ToR) of the TIGes vet should be in line with the "main" TIGes, and endorsed by the latter.

Composition

The TIGes vet shall be composed of representatives of the Member States Competent Authorities (EEA, dealing with medicines for veterinary use), the European Medicines Agency, and other stakeholders. Representatives should have a wide range of expertise in the regulatory management of veterinary submissions and/or the implementation of IT systems to ensure that full and complete analysis and documentation is carried out.

The subgroup members represent the stakeholders' user requirements based on their detailed knowledge of the regulatory (business) processes and technical processes. The emphasis is on a shared vision and collaborative approach between regulators and industry.

The composition of the subgroup is as follows:

- A Chair, appointed by the MBTC;
- 1 representative of each EEA Member State's competent agency: Member State representatives have to represent the veterinary interests;
- 1 representative of the European Medicines Agency (EMA)
- Representatives from industry organisations: 1 per organisation, namely, IFAH–Europe, AVC and EGGVP
- 1 observer per non-EEA country (e.g. Swissmedic)

The composition of the subgroup will be reviewed on a regular basis. The countries or bodies above may propose additional representatives to meetings of the TIGes vet with the consent of the Chair. Such additional representatives shall usually not be reimbursed by the EMA.

.Where a change in the constitution or membership of the subgroup is considered necessary by the subgroup itself, it shall, by a simple majority decision, determine the representatives to be nominated. Such a change should be endorsed by the TIGes, particularly where there may be financial implications.

Organisations other than those described above shall not be members of the TIGes vet, and may only attend sections of meetings of the TIGes vet when specifically invited so to do. Vendors and commercial software developers are not members of the subgroup. However, they may be invited to participate with respect to specific issues.

EMA shall host the meetings of the TIGes vet.

Role

Mission statement

The main mission is to enable applicants to submit applications for veterinary medicinal products electronically, and EEA regulatory authorities to process such submissions accordingly.

This will be supported by the following strategy:

- Defining the specifications for the exchange, archiving and review of electronic marketing authorization documentation, in close collaboration with the stakeholders. Supporting the implementation of these specifications by Member States.
- Promoting and facilitating the implementation of electronic exchange specifications and/or standards by stakeholders through:
  - Drafting and adopting guidance in close collaboration with other relevant regulatory working groups and users,
  - Communicating the specifications and/or standard together with implementation guidance to all stakeholders,
  - Implementing a sound change control process,
  - Exchanging on national experiences to ensure alignment with the EU specifications.
- Defining the specifications of the tools useful for the exchange, archiving and review of electronic marketing authorization documentation, in close collaboration with the stakeholders.
- Considering other EU Telematics working groups activities that may be of relevance for the implementation of veterinary e-submissions.

Ongoing responsibilities

The TIGes vet should make practical and management decisions for the implementation of the e-submission requirements in the veterinary sector, and is responsible for ensuring that the development of specifications, standards and implementation is completed.

The TIGes vet is also, crucially, responsible for the communication of e-submission requirements in the veterinary sector.

Whilst discussion of relevant standards and developments that may impact e-submission in the veterinary sector may be important for implementation, technical development of these standards and related work does not fall within the remit of the TIGes vet.

The TIGes vet is responsible for the development, maintenance and evolution of suitable e-submission specifications and/or 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 resolving 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 scope is the submission of electronic information in accordance with harmonised standards for all procedures relating to veterinary medicinal products in the EEA.

The TIGes vet is seeking to progress the implementation of fully working and harmonized business processes and supporting Telematics for the paperless submission, as well as for the review of

information in support of marketing authorization applications in the European Union for veterinary medicinal products.

Vision

To put in place an e-submission process for veterinary medicinal products between agencies and marketing authorization holders within the EEA; a process that is cost-effective, secure and easy to implement for all stakeholders

Currently, e-submission for veterinary dossiers is still optional. The aim of the TIGes vet is to obtain the following:

- The development, maintenance and use of simple and pragmatic e-submission formats for marketing authorizations for veterinary medicinal products (pre- and post-authorisation processes).
- The alignment of the requirements, working procedures and e-submission formats as well as archive formats, where possible.
- Effective harmonization of electronic submissions between applicants and agencies.
- Work towards compatibility of electronic submissions with other regions.
- The evolution of the guideline is driven by business needs aiming at cost effectiveness, sense of realism which means performance, flexibility and stability of the formats.

Meetings

The TIGes vet meets four times per year. Meetings will routinely be of one day's duration, and occasionally if necessary teleconferences may be held between face-to-face meetings.

Each member of the TIGes vet will be reimbursed for travel and per-diem by the Agency in accordance with the Agency's reimbursement rules, i.e. representatives from industry representations or observers will usually not be reimbursed.

All documentation relating to the meeting will normally be circulated a minimum of 5 working days in advance of the meeting date. Any ad-hoc documentation provided at the meeting, for example presentations, will normally be circulated to all members of the subgroup within 2 weeks prior to the meeting date.

Minutes of the meeting will be taken by the Agency's secretariat and will normally be circulated to all members of the subgroup for comment within 2 weeks after the meeting date. Minutes may be approved by written procedure.

The quorum for decisions at TIGes vet meetings is 50% plus one. In order for a meeting to be quorate, representatives from at least one industry organisation should be present. Furthermore, EMA and at least 3 regulatory agencies must be represented in all meetings (replacements to normal team members may be sent, if necessary).

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

Working methods

Responsibilities

All members of the subgroup are expected to actively contribute to the development and documentation of standards, specifications, policies and guidance as appropriate, in consultation with experts from the organisation they represent if necessary, as well as actively reviewing the work of all other group members.

As such, subgroup members 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.

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

Liaisons and interactions

Regular meetings of the chairs of the different TIGes subgroups are scheduled.

The TIGes vet is mandated to liaise with the TIGes, VICH and other standards development bodies (e.g. ISO, HL7) 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 the relevant Standards Development Organizations and e-submission Working groups, as necessary for consideration of the technical and business impact of changes, and the practical implementation of these changes.

The TIGes vet may define other ad hoc groups or specify consultation with other groups as necessary.

Sub-groups

Change control group (CCG)

At its June 2010 meeting, the TIGes vet put together a change control group (CCG) to communicate, discuss and execute changes to the European e-submission specifications and standards. The CCG has its own terms of references, under auspices of the TIGes vet. The CCG usually holds up to 4 (virtual) meetings per year. The result of the discussions and the CCG recommendations are presented by the chair of the CCG and/or other members of the CCG to the plenary TIGes vet for final decisions.

The stability of e-submission requirements is important both for stakeholders and agencies. Therefore, the following strategy for implementing new or amended specifications is being followed:

- Minor non-urgent updates are combined within a single update of the e-submission guidance, maximum once per year. Publishing of changes on a shorter timeframe should be restricted to the correction of errors or emergency releases.
  (Examples: Corrections of errors. Changes to the folder structure which are backwards compatible, meaning dossiers under preparation for submission do not have to be reformatted).
- Major updates of existing specifications should be announced at least 6 months in advance (Example: Changes which need reformatting of dossiers under preparation for submission).

- Major changes introducing fundamental changes of requirements should be announced at least 2 years before coming into effect.
  (Example: Implementation of a completely new specification, as in the case of VNeeS).

Term

The TIGes vet shall be dissolved on the day following the elapsing of three years from the date on which the MBTC has approved these terms of reference unless a further term is approved by the MBTC prior to the date of dissolution, or dissolution is proposed to and approved by the MBTC prior to the date of dissolution.

The terms of reference of the TIGes vet shall be reviewed at its first meeting each year. Any changes shall be proposed to the MBTC for approval, and should no changes be proposed, the MBTC shall be informed that the review has taken place and that no changes are proposed.