

## CTS WORKING GROUP

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### **BACKGROUND**

The Communication and Tracking System (CTS) is the system used by the National Competent Authorities (NCAs) involved in the licensing of human and veterinary medicinal products via the mutual recognition and decentralised procedures

CTS supports the co-ordination and tracking of marketing authorisation, post-licensing and work sharing procedures as monitored by the CMDs. The system serves as data provider for other applications.

Owned by the Heads of Medicines Agencies management responsibility for the CTS has been given to the Coordination Group for Mutual Recognition and Decentralised Procedures (CMD) for Human and Veterinary medicines. The CTS Working-Group has been established by the CMDs to elaborate the details for further development of the system, agree and monitor the level of service and deal with further aspects of communication between the NCAs.

### **MANDATE**

The CTS Working group has the following mandate:

- Review the performance of the service provider.
- Agree all changes to be carried out to the CTS application and liaise with the service provider on the implementation of these changes.
- Determine the priority of changes and updates to the system.
- Provide user requirements information in respect of legislative issues i.e. changes to the CTS resulting from changes in regulatory environment for consideration at the CTS User Group.
- Provide user requirements and agree on specifications for solutions concerning other systems built from or interacting with CTS (e.g. the Product-Index, interface to NCA system).
- Propose procedural/technical improvements for the electronic communication of data and documents between NCAs via CTS or other means (e.g. email).

- Review recommendations from the service provider with regard to additional or enhanced services.
- Agree timescale for introduction of changes; version, content and dates.
- Provide feedback to the CMDh and CMDv on all relevant issues.
- Identify any additional costs to be notified to the CMDh, CMDv and HMA for consideration.
- Liaison with the service provider, through the Chairperson. The chairperson will report back to the CTS Working group on any discussions/meetings held with the service provider.
- Collation of all requested amendments, through the Chairperson.
- The Chairperson of the CTS Working group is the chairperson of the CTS User-Group and will provide the subgroup with reports of meetings of the User group and meetings with the service provider.
- Develop/arrange and organise annual CTS training plan.
- Provide costing/recommendations with regard to CTS training for consideration by HMA.
- Liaise with the Telematics management group as the CTS- Telematics Implementation Group.

*Meetings: As required – minimum 4 per annum*

*Chairperson: The Chairperson of the CTS Working group is also the chairperson of the CTS user group. This chairperson is elected by the CMDh and CMDv for a period of two years (term is renewable)*