

Document Title:	Document Version: 1.0
NtA-TIGes Interlinking Group	Document Ref: interlinking-mandate-final.doc
Mandate and Working Methods	Document Status: Adopted

NtA-TIGes Interlinking Group

MANDATE AND WORKING METHODS

Document Control Cover

Change Record

Version	Date	Rapporteur	Comments
0.1	23-JUN-2003	Miguel Bley	1st draft for comment
0.2	26-JUN-2003	Miguel Bley	Revised in line with feedback from Interlinking Group at the Kick-off meeting 23 June 2003
0.3	22-JUL-2003	Miguel Bley	Changes adopted during the Interlinking Group meeting
0.4	23-SEP-2003	Miguel Bley	Comments received after the meeting
0.4	9-OCT-2003	Miguel Bley	Adoption by NtAWG without modifications

Review

Version	Name	Organisation
0.1	Attendees at the 23-JUN-2003 meeting	Interlinking Group
0.2	Attendees at the 22-JUL-2003 meeting	Interlinking Group
0.3	T.BUXTON-H.BOONE	Interlinking Group

Distribution

Version	Date	Group Name	Status
0.1	23-JUN-2003	Interlinking Group	Draft
0.2	26-JUN-2003	Interlinking Group	Draft
0.3	29-JUL-2003	Interlinking Group	Draft
0.3	11-SEP-2003	TIGes	Draft
0.4	23-SEP-2003	Interlinking Group/TIGes	Draft-Adopted
0.4	9-OCT-2003	NtAWG	Draft-Adopted
1.0	10-OCT-2003	NtAWG/TIGes	Final-Adopted

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MANDATE AND WORKING METHODS

BACKGROUND

The Notice to Applicants Working Group (NtAWG) is responsible for the regulatory guidelines that define the procedures for marketing authorisation and the presentation and content of the dossier as part of the rules governing medicinal products for human use in the European Community. It has representatives of all European competent authorities and is chaired by the European Commission. These guidelines are compiled in The Notice to Applicants which is published by the Commission on its website :

<http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm>

Volume 2B of the Notice to Applicants takes into account the international agreements on the structure and format of the **Common Technical Document (CTD)** which was agreed in November 2000 within the International Conference on Harmonisation (ICH) framework. The CTD is an internationally agreed upon format for the preparation of a well structured presentation for applications to be submitted to regulatory authorities in the three ICH regions of Europe, US and Japan. It is intended to save time and resources and to facilitate regulatory review and communication. The CTD gives no information about the content of a dossier and does not indicate which studies and data are required for a successful approval.

The Multidisciplinary Group 2 (M2) at ICH was given the responsibility to develop an electronic standard format for the CTD to be submitted in the three ICH regions. This standard has been called Electronic Common Technical Document (eCTD) and agreed in September 2002 within the ICH framework. The eCTD is the electronic version of the CTD. The eCTD specification describes the means to create and transport an electronic submission that meets the definitions of the Common Technical Document. It lists the criteria to consider an electronic submission as technically acceptable. eCTD includes Module 1 for regional information. Regional information refers to documents that have not been harmonised within the ICH framework. There are also some regional information required by the three ICH regions in other modules of the CTD.

The Telematics Implementation Group for electronic submission and ICH Implementation (TIGes) was set up in June 2000 by the Telematics Steering Committee (TSC) as part of a new structure for the management of European IT projects in the pharmaceutical regulatory area endorsed by the Pharmaceutical Committee. It is responsible for the development of eCTD regional standards and its implementation. All concerned European Competent Authorities are represented and the group is chaired by France. It works in close collaboration with the European delegation of the ICH M2 Expert Working Group responsible for the ICH eCTD Specification.

The TIGes and the NtAWG have agreed to set up a small NtA-TIGes Interlinking Group with representatives of the NtAWG and TIGes in order to prepare the guidelines for implementation of eCTD in Europe for publication in the Notice to Applicants. The NtAWG, MRFG and CPMP/EMEA will be informed of the outcomes of the group when appropriate.

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MANDATE

The ultimate objective of this group is the facilitation of implementation of eCTD in Europe through the publication of regional standards in the Notice to Applicants that meet the needs of both industry and Competent Authorities.

This Interlinking group has been set up as :

1. An interface of the TIGes with NtAWG representatives responsible for the content and structure of Marketing Authorisation Applications.
2. A forum for the explanation of the technical aspects of eCTD.
3. A forum for dialogue to ensure consistent approach between guidance for the CTD and its electronic implementation in the eCTD.
4. A forum to develop the wording to present the specifications of the regional standards for eCTD implementation to be published in the Notice to Applicants.
5. An interface to identify common answers to EU specific questions on eCTD.
6. A forum for discussion of impact on competent authorities and applicants of the electronic submission implementation and requests for changes to the eCTD and CTD.

WORKING METHODS

Harmonised general implementation guidelines on eCTD are published in the eCTD specification on the ICH website (www.ich.org).

The TIGes develops standards on regional implementation of eCTD.

Standards for electronic implementation of eCTD are highly technical documents. A statement on the status and purpose for users should introduce the standards placed in a new section in the Notice to Applicants. The Interlinking group is responsible for the wording of those statements to be proposed for adoption to the NtAWG together with the electronic standards.

Answers to questions on eCTD that apply to all ICH regions will be published in the ICH-M2 tracking document on the ICH website.

Questions on the implementation of the CTD are collected and answered in a Questions & Answers section in Notice to Applicants. A similar section will be introduced in Notice to Applicants for questions related to eCTD implementation in Europe.

The interlinking group will work on the basis of requests from either TIGes, NtAWG or both.

The interlinking group will meet whenever its members consider it necessary. It will do so in the margins either of the MRFG or the NtAWG meetings whenever possible.

Minutes of the Interlinking Group meetings will be drafted by members in turns.

The group will work by E-mail to make progress and update the produced documents wherever possible.

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Documents other than minutes will have a Document Control cover including change and approval record in order to facilitate their identification.

Draft documents will be circulated among members of the Interlinking Group for approval.

Relevant documents approved by the Interlinking Group will be circulated to members of TIGes, NtAWG.

Documents will have a rapporteur. The rapporteur will be designated by the group. In general it will be the member of the group most involved with the subject of discussion but it could be another member of the group.

Rapporteurs of proposals originated in any of the working groups : NtAWG, MRFG and TIGes, could be invited to participate and present the proposal at the Interlinking group meeting.

External experts could also participate if considered necessary by the group.

Changes in the European legislation could require changes in both CTD and eCTD guidelines.

When the NtAWG revises relevant documents to reflect for instance changes in the legislation, it will request the Interlinking Group to analyse and report on the impact of the change on eCTD implementation. The report will be discussed and agreed within the TIGes.

Where revisions require urgent implementation the Interlinking group will be consulted in parallel with the NtAWG.

The eCTD implementation could provide innovation in the procedures that add value to the authorisation process and have an impact on CTD guidelines. The TIGes will then communicate its proposals to the NtAWG through the Interlinking Group. The proposals will be discussed and agreed within the NtAWG.

It is proposed always to have an open point in the NtAWG and TIGes meetings agenda for presentation and discussion of guidelines on eCTD or CTD respectively. Members of the Interlinking group will be responsible for the presentation. The presentation from the Interlinking group should be announced to the chairman of the group with sufficient notice.

The Interlinking Group will explain the guidelines on regional implementation of CTD and eCTD to NtAWG, MRFG, TIGes and CPMP/EMEA as needed.