EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Preparation of 'lines-to-take' documents for use within the EU regulatory network to answer external queries in a consistent manner		
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1. Purpose

The purpose of this standard operating procedure (SOP) is to detail the process for preparing lines-to-take (LTT) documents.

LTTs are prepared to enable press officers and other staff within the European Union (EU) regulatory network (European Medicines Agency [EMA], European Commission [EC] and National Competent Authorities [NCAs]) dealing with media or other enquiries to answer on a given issue in a consistent manner. LTTs are not public. They can be written at any time about any issue, and are not necessarily linked to a Committee for Medicinal Products for Human Use (CHMP) or other meeting.

LTTs are created when an issue is emerging for which enquiries are likely, but where an Agency press release or other proactive communication is not (yet) considered necessary or possible. This is:

- either because the issue is 'active' but the Agency does not have new information to communicate proactively, e.g. when there is a high level of media interest on a suspected adverse event or other issue, the marketing authorisation holder (MAH) is likely to communicate, or another regulatory agency has indicated it will communicate;
- or because the issue has made it into the public domain through a third party before the Agency has finalised its position, e.g. a 'leak' or the pre-publication of significant results, or problem at or closure of a manufacturing site.

2. Scope

This SOP applies to the Human Medicines Development and Evaluation Unit, the Patient Health and Protection Unit (P) and the Office of the Executive Director (D-ED).

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3. Responsibilities

It is the responsibility of each Head of Sector (HoS) to ensure that this procedure is adhered to within his or her sector. The responsibility for the execution of each step of this procedure is identified in the right-hand column of Heading **9. Procedure**.

4. Changes since last revision

New SOP.

5. Documents needed for this SOP

- The lines-to-take template is available in Microsoft Word under File/New and can be found on the X: drive: X:\Templates\Filenew\Press.
- Internal guidance for preparing 'lines-to-take' documents (EMEA/253251/2009 – internal working document).

6. Related documents

WIN/H/3210 - Sending of lines to take and safety-related information to the European Union regulatory network and international partners.

Communicating on product safety - Press releases, questions and answers documents, public statements and lines to take – how to decide (EMEA/152969/2007).

Policy on European Medicines Agency communication on (emerging) safety related issues for medicines for human use (EMA/170165/2010).

European Medicines Agency communication on (emerging) safety related issues for medicines for human use – practical arrangements (EMA/785792/2009).

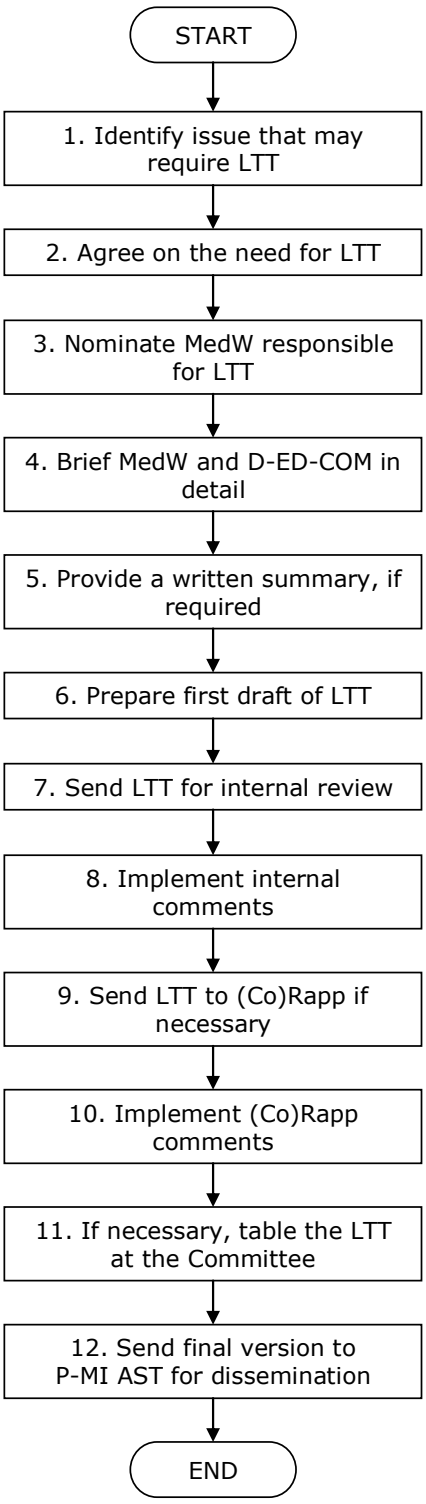
The European Union regulatory system incident management plan for medicines for human use (for use in the context of a pilot) (EMEA/579383/2008).

7. Definitions

CHMP:	Committee for Medicinal Products for Human Use
(Co)Rapp:	(Co)Rapporteur
D-ED:	Office of the Executive Director
D-ED-COM:	Communications and Media
EC:	European Commission
EDMS:	Electronic Document-Management System
EMA:	European Medicines Agency
EU:	European Union
HoS:	Head of Sector
HoU:	Head of Unit

LTT:	Lines to take
MAH:	Marketing authorisation holder
MedW:	Medical writer
NCA:	National Competent Authority
P:	Patient Health Protection Unit
P-MI:	Medical Information Sector
P-MI AST:	Assistant in the Medical Information Sector
P-MI-PIN:	Section for Public Information and Stakeholder Networking
P-PV:	Pharmacovigilance and Risk Management Sector
P-R:	Regulatory, Procedural and Committee Support Sector
PTL:	Product team leader
SH:	Section Head
SOP:	Standard operating procedure

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1	Identify an issue that may require the preparation of LTT. The need for LTT may also be identified by the Incidence Review Network (see SOP/EMA/0111). LTTs may be needed because of media interest in the product or issue; they may also be directly requested by a Committee, the press office or the EC.	PTL
2	Ensure, in collaboration with the SH, HoU P, HoS P-PV, HoS P-R and (Co)Rapp as appropriate, that a decision is made on whether LTT are necessary and the timelines for dissemination within the EU Regulatory Network, involving HoS P-MI and HoS D-ED-COM. LTTs should be finalised within two working days or earlier, unless they are being prepared in response to an expected publication. In this case, dissemination should be at the time of publication, and the LTT should include a footnote with a link to the published information.	PTL
3	Assign work to a MedW from P-MI-PIN and inform the PTL accordingly.	SH P-MI-PIN
4	Organise a meeting with MedW, D-ED-COM and other concerned staff to give background information on the issue, provide any supporting documentation, and determine the key messages. Clarify the interested parties who need to be included in the review of the LTT, and decide whether (Co)Rapp should be involved and, if so, whether the MedW or the PTL will liaise with the (Co)Rapp.	PTL
5	If required, provide MedW with a brief written summary of the issue.	PTL
6	Prepare first draft of the LTT.	MedW
7	Send first draft of the LTT for quick internal review to relevant EMA staff (PTL, PTM, P-MI and D-ED-COM), with a maximum deadline of 12 hours.	MedW
8	Implement internal comments as appropriate.	MedW
9	Send second draft LTT to the (Co)Rapp for comments if appropriate, with a maximum deadline of 12 hours.	MedW or PTL as decided in step 4
10	Implement comments from (Co)Rapp as appropriate and send updated version to D-ED-COM and PTL.	MedW
11	If the Committee is in session at the EMA at the time, and the issue is on the Committee agenda, table the LTT for information. If LTT have been prepared on the request of the Committee, they should be tabled for discussion.	PTL
12	Send final version to P-MI AST, copying in the PTL and the appropriate SH, PTM, and D-ED-COM, for dissemination within the EU Regulatory Network in accordance with WIN/H/3210.	MedW

10. Records

Original LTT and correspondence are filed in the Product Master File (when the LTT are related to a specific product or procedure) and in the Early Notification System (ENS) Master File in P-MI.

Electronic copies are saved in EDMS in the product folder if appropriate, as well as in Documentum\Docbases\EDMS\Operational Units\Human\Post\MIS\Early Notification System & LTT\Faxes, and Documentum\Docbases\EDMS\Operational Units\Human\Post\MIS\Medical Writing.

Copies of all correspondence are also saved in Chrono H-MIS.