



Work instructions

Title: Sending of lines to take and safety-related information to the European Union regulatory network and international partners		
Applies to: Medical Information Sector		
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Lead Author	Approver	Effective Date: 12-APR-11
Name: Malika Holleyman	Name: Noël Wathion	Review Date: 12-APR-14
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1. Changes since last revision

New work instructions (WIN).

2. Records

The templates needed for these WIN can be found on the X: drive: X:\templates\Others\H - Early notification templates folder.

The list of contacts (EU regulatory network and international partners) is saved in Documentum\Docbases\EDMS\Operational Units\Human\Post\MIS\Early Notification System & LTT>Contact lists.

3. Instructions

CHMP: Committee for Medicinal Products for Human Use

EC: European Commission

ECD: Eudra Common Directory

EDMS: Electronic Document Management System

EEA: European Economic Area

ENS: Early Notification System



EU: European Union

HMA-H: Heads of EU Human Medicines Agencies

LTT: Lines to take

P-HoU: Head of Patient Health Protection Unit

PhVWP: Pharmacovigilance Working Party

P-MI AST: Assistant in the Medical Information Sector

P-MI-HoS: Head of Medical Information Sector

PR: Press release

PTL: Product team leader

Q&A: Question-and-answer document

SH: Section Head

SOP: Standard operating procedure

WIN: Work instructions

Step	Action	Responsibility
1.	<p>Once the completed documents for dissemination to the European Union regulatory network and international partners (i.e. PRs, Q&As, LTTs and ENS table) have been received in accordance with SOP/H/3346, SOP/H/3347 and SOP/EMA/0111, finalise the relevant documents from the locators as follows:</p> <ul style="list-style-type: none">• Verify that all tracked changes have been accepted and comments removed;• Turn off the track changes option;• Check that there are no mark-ups in the document;• Add the appropriate watermark (i.e. "embargo" for Q&As and PRs and "do not publish" for LTTs);• Add the embargo day and time in red to Q&As and PRs.	P-MI AST
2.	<p>Prepare and provide P-HoU with a sign-off folder which includes the documents to be disseminated and an explanatory cover note prepared by P-MI HoS. The explanatory cover note is intended to be sent to the EU regulatory network only.</p> <p>Templates can be found on the X: drive: X:\Templates\Others\H - Early notification templates folder.</p>	P-MI AST
3.	<p>Once signed by P-HoU, send the communication material (i.e. safety-related Q&As and PRs, LTT and/or the ENS table) together with the explanatory cover note via Eudralink to the HMA-H, Observers (EEA), EC, CHMP and PhVWP.</p> <p>The list of contacts for HMA-H + Observers (EEA), CHMP and PhVWP can be found in ECD. Always download the list from ECD</p>	P-MI AST

Step	Action	Responsibility
	<p>as it is constantly being updated.</p> <p>The list of recipients at the EC is saved in Documentum\Docbases\EDMS\Operational Units\Human\Post\MIS\ Early Notification System & LTT>Contact lists.</p>	
4.	<p>Send the communication material (i.e. safety-related Q&As and PRs, and the ENS table) via Eudralink to international partners. LTTs are intended for use within the EU regulatory network and are not sent to international partners.</p> <p>The list of contacts for international partners is provided and updated regularly by the International Liaison Officer and is saved under documentum\Docbases\EDMS\Operational Units\Human\Post\MIS\ Early Notification System & LTT>Contact lists. Request for update confirmation of contacts are done every 2 months.</p>	P-MI AST
5.	<p>Once the communication material has been sent, inform relevant EMA staff by email, copying Chrono-P-MI. The list of recipients for this e-mail is saved on the X: drive: X:\Templates\Others\H - Early notification templates folder. The SH and PTL for the product(s) concerned should also be added as recipients of the e-mail.</p>	P-MI AST
6.	<p>Archive the following documents in the ENS master file:</p> <ul style="list-style-type: none"> • original signed explanatory note • communication material (i.e. safety-related Q&As, PRs, LTT and/or the ENS table) • print outs of the eudralink sent message showing the list of recipients and documents included. • Outlook e-mail notifying that a eudralink message has been sent by P-MI AST to the EU regulatory network attaching the word file of the relevant communication material (i.e. safety-related Q&As, PRs, LTT and/or the ENS table) and the eudralink message. • Outlook e-mail notifying that a eudralink message has been sent by P-MI AST to each international partner attaching the word file of the relevant communication material (i.e. safety-related Q&As, PRs, and/or the ENS table) and the eudralink message. 	P-MI AST
	<p>Make two copies of the above set of documents: give one copy to P-HoU and the other one to P-MI-HoS.</p>	P-MI AST