EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2017
EMA/413091/2017
Inspections, Human Medicines, Pharmacovigilance and Committees Division

The new EudraVigilance System –Communications Plan for EMA and National Competent Authorities in the EEA

An overview of the planned communication milestones

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

1. Introduction

This communication plan sets out important milestones as part of the go-live of the new EudraVigilance System on 22 November 2017. It identifies the impacted stakeholders, their needs and interests and determines how to effectively communicate with these stakeholders and the date/frequency of the communication.

In the frame of this communication plan, the following stakeholders and stakeholder groups (SGs) have been identified:

- **EU regulators:** EU Regulatory network (SG1)
- **EMA:** European Medicines Agency (SG1)
- **HPs**: healthcare professionals (SG2)
- **MAHs:** Marketing Authorisation Holders (SG1)
- **NCAs:** National Competent Authorities in the European Economic Area (EEA) (SG1)
- **Non-EU regulators:** EU regulators outside the EEA (SG3)
- **Public:** general public (SG2)
- **Sponsors:** sponsors of clinical trials (SG4)
- **WHO:** World Health Organisation (SG5)

The document also proposes **communication channels** depending on the topic upon which stakeholders should be informed; these communication channels may not be exhaustive and each Member State may decide on the most appropriate format to inform their stakeholders.

ID	Topic	Target Audience	Purpose	Channel	Target Date	Owner	Comments
1.	NCA re-routing rules configuration	NCAs	Obtain the requirements for the re-routing rules from each NCA for configuration in the EudraVigilance production environment	E-mail	End Jul 17	EMA	EMA will set the initial re-routing rules for NCAs when the new EudraVigilance System goes live on 22 November 2017; thereafter NCAS can maintain the rerouting rules using the EVWEB application
2.	Update of EU ICSR Implementation Guide (revision 1)	SG1, SG3, SG4, SG5	Inform about the update of the EU ICSR Implementation Guide and associated business rules and code lists	WEB-document publication E-mail	Mid Jul 17	EMA	Inform that the EU ICSR Implementation Guide has been updated and will be effective with the date of publication
3.	Finalisation of revision 2 of GVP Module VI	SG1 and SG 5	Inform about the availability of the final version of GVP Module VI revision 2	WEB-document publication E-mail	End Jul 17	EMA	Inform that GVP Module VI revision 2 has been finalised and will become effective

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

ID	Topic	Target Audience	Purpose	Channel	Target Date	Owner	Comments
							as of 22 Nov 17
4.	Announcement of transitional arrangements for the implementation of the requirement for MAHs to monitor EV data based on feedback from the EC	SG1	Inform about transitional arrangements for MAHs to monitor EV data	WEB-announcement E-mail	Jul 17	EMA	Inform about the outcome of the consultation with the EC on the transitional arrangement for MAHs to monitor EV data
5.	Finalisation of revision 1 of GVP Module IX	SG1, SG3 SG5	Inform about the availability of the final version of GVP Module IX revision 1	WEB-document publication E-mail	Oct 17	EMA	Inform that GVP Module IX revision 1 has been finalised and will become effective as of 22 Nov 17
6.	Questions & Answers in support of the go-live of the new EudraVigilance System, the simplified reporting and the signal management process for MAHs	SG1 and SG4	Address frequently asked questions from stakeholders	WEB-document publication E-mail	Monthly as of Jul 17	EMA	Q&As will be reviewed with the PhV Business Team and where necessary input thought from NCAs as regards MS specific requirements or arrangements
7.	Targeted communication to sponsors of clinical trials	SG4	Targeted communication with main focus on the update of the EVWEB functionalities with emphasis that SUSAR	WEB-page E-mail Newsletter	Aug 17	EMA NCAs	Direct sponsors to specific areas of interest in relation to SUSAR reporting and the use of the new

ID	Topic	Target Audience	Purpose	Channel	Target Date	Owner	Comments
			reporting rules do not change until the Clinical Trial Regulation becomes applicable; inform about simplified training option				EVWEB functionalities
8.	Go-live plan	SG1, SG3, SG4, SG5	Remind about the switch to simplified reporting in 2 months' time and planned EV downtime; instruct what to do during the transition (downtime) from the current to new EV system; clarify process for switching from interim to simplified ADR reporting rules; define when new signal management for MAHs will apply	WEB-document publication E-mail	Sept 17	EMA NCAs	Inform about the go-live strategy in preparation of the launch of the new EudraVigilance System on 22 Nov 17 EMA to share email with NCAs via early notification system so communications can be aligned
9.	Go-live plan - NCA specific additions	MAHs and sponsors at national level	In addition to point 8: inform about NCA specific requirements (e.g. use of local language) and arrangements and preparations (local NCA contact points; local system changes; screening of local website	WEB-document publication E-mail	Sept 17	NCAs	Inform about NCA specific plans, arrangements and requirements

ID	Topic	Target Audience	Purpose	Channel	Target Date	Owner	Comments
			for ADR reports, sending of copies of literature articles locally etc)				
10.	Announce the launch of the new EudraVigilance System	SG1-SG5	Communicate on the launch of the new EV system and expected benefits	News item	22 Nov 17	EMA NCAs	EMA to share news item with NCAs via early notification system so communications can be aligned
11.	Announce the new functionalities of the adrreports.eu website	SG2	Communicate on the new functionalities available to query EudraVigilance data	News item	22 Nov 17	EMA	Inform about the new query functionalities and new data outputs such as line listings and individual case report forms