Part I Chapter 4: Requirements for Expedited Reporting of Individual Case Safety Reports – Requirements by Reporting Source – *Reports from Patients and Other Consumers*

Reference number	Questions	Answers
ID: 010	How should a MAH handle a case when there is partial confirmation of a consumer case by a health care professional (HCP) .i.e. a consumer reported 5 events but the HCP only confirms 2 of those reported?	Cases initially reported e.g. by a consumer or a lawyer, where at least one adverse event has been medically confirmed should be reported as medically confirmed. The data element ICH E2B(R2) A.1.14 *'Was report medically confirmed if not initially from health care professional'* should be set to 'Yes'. In the data element ICH E2B(R2) B.5.1 *'Case narrative including clinical course, therapeutic measures, outcome and additional relevant information'* any relevant information on the medical confirmation of the case should be also included.
ID: 021	EudraLex - Volume 9A, chapter I.4 Section 3.5 'Reports from Patients and Other Consumers' states that medically unconfirmed adverse reactions should not be reported to the Agency/EudraVigilance on an expedited basis. However, sending of reports from patients and other consumers which occurred in Liechtenstein to EudraVigilance is a requirement in EudraLex - Volume 9A.	To facilitate at national level the technical implementation of the electronic transmission of ICSRs by marketing authorisation holders, Liechtenstein has agreed with the EMA that the Agency will provide Liechtenstein with access to EudraVigilance. In view of this agreement, reports from patients and other consumers that are medically unconfirmed and that refer to adverse reactions, which occurred in Liechtenstein, should be reported to the EudraVigilance Post-Authorisation Module in line with the requirements laid down in EudraLex - Volume 9A. As regards the reporting of these ICSRs, the data element ICH E2B(R2) A.2.1.4 Primary Source *'Qualification'* should be populated with 'Consumer or other non health professional' and the data element ICH E2B(R2) A.1.14 *'Was the case medically confirmed, if not initially from a health professional?'* should be populated with 'No'.
ID: 029	How should reports from consumers be handled when they include medical documentation?	When a consumer submits medical documentation that supports the occurrence of a suspected serious adverse drug reaction to an identifiable patient and which indicates that an identifiable healthcare professional suspects a causal relationship between a medicinal product and the reported serious adverse drug reaction, this should be considered as a medically confirmed report which fulfils expedited reporting requirements. In addition, attempt should be made to obtain additional information from the healthcare professional. The ICSR should be reported electronically in an expedited manner no later than 15 calendar days

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		of receipt of the initial information from the consumer. The data element ICH E2B(R2) A.1.14 *'Was the case medically confirmed, if not initially from a health professional?'* should be populated with the value '1' (yes). Other guidance reported in EudraLex - Volume 9A, Chapter I.4 Section 3.5 'Reports from Patients and Other Consumers' applies. For some reactions, the documentation in laboratory data or tests supports the suspicion and does not require additional medical clarification.
ID: 035	Should a follow-up report received from a non-health care professional be submitted to EudraVigilance if the initial serious case has originally been received from a health care professional?	If the initial serious case has been originally medically confirmed, a follow-up report received from a non-health care professional should be submitted on an expedited basis. Effort should be made to obtain medical confirmation of the new information. The MAH should state in the ICH E2B(R2) data element B.5.1 '*Case narrative including clinical course, therapeutic measures, outcome and additional relevant information*' that information in this follow-up report has been reported by a non-health care professional.