EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Reporting requirements of Individual Case Safety Reports (ICSRs) applicable to marketing authorisation holders during the interim period

During the interim period, in accordance with the transitional provisions set out in Article 2(4) and Article 2(5) of Directive 2010/84/EU, the reporting requirements detailed in Table 1 shall apply to valid ICSRs reported by healthcare professionals and non-healthcare professionals. This is independent of the conditions of use of the suspected medicinal products and of the expectedness of the adverse reactions.

Member States may request marketing authorisation holders to report electronically to EudraVigilance serious EU ICSRs originating in their territory. Those requirements are detailed in Table 2.

Member States reporting requirements during the interim period for serious non-EU ICSRs and for non-serious EU ICSRs are presented in Table 3.

Table 1. Reporting requirements applicable to marketing authorisation holders - Interim period

Marketing authorisation procedure	Origin	Adverse reaction type	Destination	Time frame
• Centralised • Mutual recognition, decentralised or subject to referral • Purely national	EU	All serious	• Member State where suspected adverse reaction occurred (See Table 2)	15 days
		All non-serious	• Member State where suspected adverse reaction occurred, if required (See Table 3)	90 days
	Non-EU	All serious	• EudraVigilance database • Member States where suspected medicinal product is authorised, if required (See Table 3)	15 days

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Table 2. Reporting requirements applicable to marketing authorisation holders – Interim period – Serious cases originating in the territory of a Member State

Marketing authorisation procedure	Origin	Adverse reaction type	Destination	YES
• Centralised • Mutual recognition, decentralised or subject to referral • Purely national	EU	All serious	Member State where suspected adverse reaction occurred only	AT, CZ, DE, DK, ES, FI, IE, IT, LT, LV, NO, PT, RO, SI, SK, UK
			EudraVigilance only	BE, CY, EE, FR[1], GR, IS, LI, LU, MT, NL, PL, SE
			Member State where suspected adverse reaction occurred & EudraVigilance	BG, HU

FR[1]: Marketing authorisation holders already submitting ICSRs electronically directly to France can continue to do so during the interim period (France retransmits these ICSRs electronically to EudraVigilance), or can switch to direct electronic transmission to EudraVigilance.

Table 3. Reporting requirements applicable to marketing authorisation holders – Interim period – Member States requirements for serious non-EU ICSRs and for non-serious EU ICSRs

Marketing authorisation procedure	Origin	Adverse reaction type	Destination	YES	NO
• Centralised • Mutual recognition, decentralised or subject to referral • Purely national	EU	All non-serious	Member State where suspected adverse reaction occurred	AT, DE[1] DK, IS, PL, RO	BE, BG, CY, CZ, DE, EE, ES, FI, FR, GR, HU, IE, IT, LI, LT, LU, LV, MT, NL, NO, PT, SE, SI, SK, UK
	Non-EU	All serious	Member States where suspected medicinal product is authorised	DE, UK	AT, BE, BG, CY, CZ, DK, EE, ES, FI, FR, GR, HU, IE, IS, IT, LI, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK

DE[1]: Only for non-serious cases related to vaccines reportable to the Paul-Ehrlich-Institut. Reporting of other non-serious cases related to non-vaccines medicinal products will only be requested individually in case of safety concerns.