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. These requirements will also be applicable for the reporting to Croatia (HR) from 1 July 2013, date of accession of this country to the European Union.

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 (a)	15 days
		All non-serious	• Member State where suspected adverse reaction occurred, if required (b)	90 days
	Non-EU	All serious	• EudraVigilance database • Member States where suspected medicinal product is authorised, if required (b)	15 days

(a) Member States may request marketing authorisation holders to report serious EU ICSRs originating in their territory to them and/or to EudraVigilance. Those requirements are detailed in Table 2.

(b) Member States' reporting requirements during the interim period for non-serious EU ICSRs and for serious non-EU ICSRs are presented respectively in Table 3 and 4.

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

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

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

Marketing authorisation procedure	Member states who wish to receive non-serious cases of suspected adverse reactions occurring in their territory
• Centralised • Mutual recognition, decentralised or subject to referral • Purely national	AT, DE[1] DK, HR, PL, RO.

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.

Table 4. Reporting requirements applicable to marketing authorisation holders – Interim period – Member States' requirements for serious non-EU ICSRs

Marketing authorisation procedure	Member States who wish to receive non-EU serious cases of adverse reactions suspected to be related to a medicinal product authorised in their country
• Centralised • Mutual recognition, decentralised or subject to referral • Purely national	DE, UK.