

Marketing Authorisation Holders



Lyffastofnun

Icelandic Medicines Control Agency

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Reporting of Adverse Reactions

Dear Madam, Dear Sir

In accordance with the Community legislation, marketing authorisation holders (MAHs) have to send all suspected serious adverse reactions occurring in Iceland and all suspected unexpected serious adverse reactions occurring in the territory of a third country to the Competent Authority of Iceland, the Icelandic Medicines Control Agency (IMCA).

In order to facilitate at the national level the technical implementation of the electronic transmission of individual case safety reports (ICSRs) by the MAHs, Iceland has agreed with the EMEA that the Agency will provide Iceland with access to EudraVigilance. In view of that agreement, please proceed as follows:

1. Send all serious ICSRs of cases occurring in Iceland electronically to both EudraVigilance with the message receiver identifier EVHUMAN and to the IMCA with the message receiver identifier ADALIMCA01.
2. When a local representative of a MAH in Iceland receives a report directly from a healthcare professional, in addition to submitting it to the MAH, the report should also be sent to the IMCA.
3. Third country (non-EEA) suspected unexpected serious adverse reactions should be sent to EudraVigilance only, with the message receiver identifier EVHUMAN.

Please also note that MAHs, which are not yet able to report electronically, must perform paper-based reporting to the IMCA until they have successfully implemented electronic reporting to EudraVigilance.

Yours sincerely

Rannveig Gunnarsdóttir

Executive Director of the Icelandic Medicines Control Agency

