

National Agency for Medicines and Medical Devices of Romania (NAMMDR) may request the appointment of a contact person for pharmacovigilance issues at national level, who will report to the qualified person responsible for pharmacovigilance (EU QPPV), as per the current legislation [Romanian Law 95/2006, art 830 (5)].

Currently, the nomination by the MAH of a local contact person responsible for pharmacovigilance in Romania is not mandatory.

To facilitate communication in the pharmacovigilance area, the MAH is recommended to nominate such a local contact person. It is also recommended that the contact person resides in Romania and is medically qualified or has access to a medically qualified person. It is necessary for the local contact person to be trained in Pharmacovigilance by the MAH.

In case a person is nominated, the details of the local contact person for Pharmacovigilance in Romania should be sent to the NAMMDR, through an official address, in written or electronic format (email addresses: [registratura@anm.ro](mailto:registratura@anm.ro) and [farmacovigilenta@anm.ro](mailto:farmacovigilenta@anm.ro)), to the attention of the Pharmacovigilance and Risk Management Unit.

The Pharmacovigilance System Master File is managed by the EU QPPV who resides and operates in the European Union and who is responsible for the establishment and maintenance of the pharmacovigilance system.

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