EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 October 2024
EMA/INS/PhV/129721/2024, Rev 3
Quality and Safety of Medicines Department

Information on the Member States requirement for the nomination of a pharmacovigilance (PhV) contact person at national level – Human medicines requirements

Based on Pharmacovigilance Inspectors Working group survey, updated when new information available.

This revision applies only to human medicinal products. The requirements for veterinary medicinal products were updated by the application of REGULATION (EU) 2019/6, Article 77(3) and they are the same for all Member States.

Member State	Yes/ Mandatory	No/ Not mandatory	Comments
Austria		X	No legal standard requirement, but according to local law (§ 75i (6) AMG) the Austrian competent authority has the option to require the nomination of a PhV contact person at national level from the MAH (this has not been executed so far since most MAHs nominate contact persons on national level anyway).
Belgium	X		Legal obligation according to article 66§2 of the Royal Decree 14/12/2006 (obligation of local contact person with the following requirements is included since May 2013). The local contact person should meet the following requirements: • he/she must be contactable 24 hours a day, 7 days a week. • he/she must carry out activities in pharmacovigilance in Belgium. • he/she must have adequate qualifications to carry out his/her activities in pharmacovigilance, particularly the necessary language skills to talk to partners in the national language of their choice and to communicate with the qualified person

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			responsible for pharmacovigilance.
Bulgaria	X		Local Bulgarian law for medicinal products in human medicine in force from April 2007, last amendment from 22.12.2012, Article 191, Point 3. MAH to nominate local PhV person on national level with a view to give assistance to QPPV activity.
Croatia	X		According to Medicinal Products Act (Official Gazette No. 76/13 and 90/14; Article 3, Item 58) and Ordinance on Pharmacovigilance (Official Gazette 83/13), MAH must appoint a contact person at national level residing in Croatia. All other requirements and responsibilities of contact person are laid down in Articles 19 to 24 of the Ordinance. English versions of the Medicinal Products Act and Ordinance on Pharmacovigilance can be found on HALMED's website.
Cyprus	X		The pharmaceutical services request the appointment of a local responsible person for pharmacovigilance if the EU QPPV is not in Cyprus. The requirements for the local RPPV in CY: healthcare professionals, biologists or chemists adequately trained in pharmacovigilance. Resident in Cyprus and fluent in both written and spoken Greek.
Czech Republic	X		For human medicinal products, pursuant to Sec. 91a (3) of the Act on Pharmaceuticals and PHV-6 Guideline, the State Institute for Drug Control (SÚKL) requests the marketing authorisation holders to appoint a contact person for pharmacovigilance issues in the Czech Republic. The contact person for pharmacovigilance issues shall fulfil the following: • be able to communicate in Czech or Slovak language, • be contactable on a phone number with the Czech country code, • reside in the EU. The QPPV and the contact person for pharmacovigilance issues may be the same person. The contact person for pharmacovigilance issues is a part of the marketing authorization holder's pharmacovigilance system, whose responsibilities are set out and listed in the PSMF. The minimum responsibility of the contact person for

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			pharmacovigilance issues is to provide the contact between the State Institute for Drug Control and the QPPV. Note: The appointment of contact person for pharmacovigilance issues is an obligation which is imposed on all marketing authorization holders in the Czech Republic regardless of marketing status of their products.
Denmark		X	According to national legislation (Medicines Act § 53), the Danish Health and Medicines Authority (DHMA) may require the MAH of a medicinal product for human use to nominate a contact person in Denmark to represent the qualified person referred to in subsection (1)(vii). Up until now this has not yet been required of any MAH.
Estonia	X (only regarding RMMs)		According to national legislation it is not required that the qualified person responsible for pharmacovigilance (EU-QPPV) should reside in Estonia (according to Medicinal Products Act, paragraph 78 section 3, the qualified person responsible for pharmacovigilance must reside in the European Economic Area) However, according to the Regulation of the Minister of Social Affairs no. 26 (§ 4 section 4)''*Procedure for providing safety information about a medicinal product and the calculation of fee payable for safety and quality surveillance of a medicinal product*'', Estonian speaking contact person is required. It is assumed that the Estonian-speaking pharmacovigilance contact person appointed by the MAH has overview of the additional risk minimisation measures implemented for the medicinal product (including the content of the topic, the target group of the recipients, training of the recipients), ensures the dissemination of the materials to the recipients, has overview of the method of dissemination, content of the topic, the target group of the recipients and ensures the dissemination of the DHPC to the recipients, is able to answer requests of HCPs and regulatory authority. Further information in the guidance for aRMM: https://ravimiamet.ee/en/legislation-and-

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			supervision/marketing-authorisations?view_instance=1&current_page=1 https://www.ravimiamet.ee/sites/default/files/documents/2023-10/DHPC%202023-09_27_eng_0.pdf
Finland		X	According to national legislation (Medicines Act 30 c §), the Finnish Medicines Agency (Fimea) may request the nomination of pharmacovigilance contact person at national level. Fimea recommends the MAH to nominate a contact person for pharmacovigilance issues at national level. The contact person does not need to hold a specific medical degree, but a good knowledge of pharmacovigilance practices and regulatory requirements would be beneficial. If the MAH does not nominate the contact person, all individual case safety report (ICSR) related communication will be directed to the EU QPPV.
France	X		According to national law, nomination of a local PhV responsible person (physician or pharmacist) who lives and works in France, is required for each company that promotes and distributes human medicinal product(s) (MAH or not). This local responsible person for PhV must be nominated to the ''Agence Nationale de Sécurité du Médicament et des Produits de Santé'' (ANSM) *(French: National Security Agency of Medicines and Health Products)* for human medicinal products. Code de la Santé Publique, article R.5121-164.
Germany	X		''Stufenplanbeauftragte'' (Officer of the graduate plan), defined in § 63a of the German Drug Law (AMG), should be reported to PharmNet.Bund via https://www.pharmnet-bund.de/static/de/unternehmen/stufenplanbeauftragter/ It is important to note that this ''Stufenplanbeauftragte'' has further responsibilities regarding GMP non-compliance and recalls. The German''Stufenplanbeauftragte'' is often already required prior to marketing, for details see Q&A.

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Greece	X		According to the Ministerial Decree no. Δ.ΥΓ3α/Γ.Π. 32221 ΦΕΚ 1049/29-04-2013: A local qualified person for pharmacovigilance in Greece is appointed by the EU QPPV, for human medicinal products. This person should have an excellent knowledge of English, a degree in Pharmacy, Medicine, Biochemistry, Biology, Chemistry, Dentistry or Nursing, 2 years of experience in pharmacovigilance and they should not be related to the marketing or promotion departments.
Hungary	X		According to 15/2012 Regulation of Ministry of Human Resources on pharmacovigilance of human medicinal products the marketing authorisation holders should appoint a national contact person in case the residence of responsible person for pharmacovigilance (EU QPPV) is outside of Hungary. This contact person must report to the EU QPPV. He /she must have a degree in life sciences, chemist or chemical engineering and must be trained in pharmacovigilance.
Iceland		x	The Icelandic Medicines Agency (IMA) requires the nomination of a pharmacovigilance contact person within the EEA.
Ireland		X	A local contact person is not a legal requirement.
Italy		X	"According to the national legislation, AIFA may request the appointment of a pharmacovigilance contact person at national level who shall refer to the QPPV. The local national contact person for pharmacovigilance shall register to the national pharmacovigilance database (RNF)".
Latvia	X		Regulation No 47, Procedure for pharmacovigilance states: The marketing authorisation holder shall: • 15.4. nominate a contact person for pharmacovigilance issues at national level (hereinafter - national level contact person), who resides and works in Latvia, if the responsible person does not reside and work in Latvia. Shall immediately submit the contact details of the national level contact person - given name, surname, address of site of operation, electronic

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			mail address, phone number and fax number (if such exists), also for communication outside of working hours, as well as changes in the contact details (if any) to the State Agency of Medicines. • Point 16. The contact person at national level about pharmacovigilance activities shall report to the qualified person and shall act in accordance with the instructions of the qualified person. (Amended by the 30.09.2014. CM Regulation No. 590) • Point 71. The requirement referred to in the Article 15.4. of this Regulation for the national level contact person to reside and operate in Latvia shall come into force on 1 July 2015. (As formulated in the 30.09.2014. CM Regulation No. 590)
Lithuania		x	According to local Law on Pharmacy the State Medicines Control Agency (SMCA) may request the nomination of pharmacovigilance contact person at national level.
Luxembourg	X		According to national legislation, Grand-Ducal Regulation of 10 September 2012 amending the Grand-Ducal Regulation of 15 December 1992 relating to the marketing of medicinal products, Article 45.-3, the marketing authorisation holder shall notify to the Directorate of Health and the Agency the name and contact details of the qualified person, as well as the reference person for pharmacovigilance at national level attached to the qualified person responsible for pharmacovigilance activities. As the requirements for this pharmacovigilance contact person at national level are not specified in the national legislation, the Directorate of Health, Division Pharmacy and Medicinal products has outlined a general guidance. The local contact person should meet the following requirements: He/she reports to the European qualified person responsible for pharmacovigilance (EU-QPPV). He/she should reside and carry out his/her activities in the European Union. He/she should be reachable 24 hours a day, 7 days a week.

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			He/she should have documented experience in all aspects of pharmacovigilance to fulfil the responsibilities and tasks of the position. He/she should have the appropriate knowledge of languages to communicate at national level with different stakeholders: English and/or one of the official national languages (French, German, Luxembourgish) is strongly recommended.
Malta		X	No national requirements to designate a PhV contact person to human medicinal products.
Netherlands	X		The Netherlands requires a pharmacovigilance contact person at national level if the QPPV resides outside the Netherlands or if the QPPV does not master the Dutch language in speech and writing and should be appointed now that a marketing authorisation holder will market a product in the Netherlands. As the requirement for this pharmacovigilance contact person at national level is not specified in the Dutch legislation, the Health Care Inspectorate and Dutch Medicines Evaluation Board have outlined a general guidance for such a person. The pharmacovigilance contact person at national level shall: • report to the QPPV (reporting in this context relates to pharmacovigilance tasks and responsibilities and not necessarily to line management). • master Dutch language in speech and writing (this local contact person should not only act as contact person for the national competent authorities but may also have contact with patients and health care professionals). • be knowledgeable with the relevant Dutch legislation, guidelines, and procedures. • be medically qualified (basic medical training at academic level) or have access to a person with medical training. This access shall be duly documented. • have a good back up procedure in place in case of absence.
Norway		X	No national requirements to designate a PhV contact person to human medicinal products

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Poland	X		President of the Office1 requires of MAHs to designate a pharmacovigilance contact person at national level only applicable to human products. According to the announcement by the President of the Office of 1st August 2014, the person should speak Polish. According to Polish legislation, the person shall fulfil the same requirements as the QPPV and shall live or have the office in Poland. No national requirements to designate a PhV contact person to veterinary products.
Portugal	X		According to the National Legislation, Decree-Law n.º 176/2006, 30 August, in the present actualization, article n.º 170, number 5, Portugal must identify a contact person that will be responsible for reporting to the EU QPPV.
Romania		X	According to national legislation (Law no. 95/2006 on healthcare reform, as republished with subsequent amendments, art. 830 alin (5)) the National Agency for Medicines and Medical Devices (NAMMD) may request the nomination of pharmacovigilance contact person at national level for national pharmacovigilance aspects who should report the activity to EU QPPV level.
Slovakia	X		According to the national legislation (the act 362/2012, §68, art.14) the State Institute for Drug Control (SIDC) requires from MAH to nominate a contact person responsible for pharmacovigilance. Based on that fact the SIDC requires nomination of a contact person responsible for pharmacovigilance issues at national level which is subject to EU-QPPV. Requirements for pharmacovigilance contact person in Slovakia: • good knowledge and skills of pharmacovigilance issues. • knowledge of relevant legislation and guidelines. • ability to communicate in Slovak or Czech language. The premises for this person can be out of Slovakia, but pharmacovigilance activities must be applied in Slovakia. The notification of the local contact person nomination shall be sent to the SIDC in accordance

[1] President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

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			with Guidance No MP 139**.**
Slovenia		X	In our Medicinal products act, it is written that it is possible but not obligatory to have pharmacovigilance contact person in Slovenia (for human and veterinary medicinal products). The Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (JAZMP) has the possibility to require contact person for individual cases.
Spain	X		According to the national legislation, article 14 of Royal Decree 577/2013 of 26 July, regulating pharmacovigilance with medicinal products, only for human products. The Spanish Agency of Medicines and Medical Devices (AEMPS) request the nomination of contact person for pharmacovigilance who should support the activity of EU QPPV regarding national pharmacovigilance aspects.
Sweden		X	No national requirement for the nomination of a local pharmacovigilance contact person.