EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Quality and Safety of Medicines Department

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

Based on Pharmacovigilance Inspectors Working group survey (to be updated when new information available)

Member State	Yes	No	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 14/12/2066 (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 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 has to 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 aforementioned Ordinance. English

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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			versions of the Medicinal Products Act and Ordinance on Pharmacovigilance can be found on HALMED's website.
Cyprus	X		Human: The pharmaceutical services request the appointment of a local responsible person for pharmacovigilance residing in Cyprus. The requirements for the local RPPV in CY: healthcare professionals, biologists or chemists adequately trained.
Czech Republic	X		For human medicinal products, pursuant to Sec. 91a (3) of the Act on Pharmaceuticals, the Czech agency requests the MAHs: • represented by a QPPV not mastering Czech or Slovak language and therewithal; • on whom the decision on marketing authorisation of a medicinal product imposed an obligation to collect pharmacovigilance data, or; • on whom the decision on marketing authorisation of a medicinal product imposed an obligation to perform PASS in Czech Republic or to participate in funding of patient support programs in Czech Republic etc.; • to appoint a contact person for pharmacovigilance in Czech Republic. Requirements for the contact person for pharmacovigilance in Czech Republic: Only ability to communicate in Czech or Slovak language.
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	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) But according to 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. The contact person is required for the cases where the prescribers of the medicinal products are to be informed about the safety risks associated with the use of medicines (that means both direct healthcare professional communication and materials associated with additional risk minimisation measures).
Finland		X	According to national legislation (Medicines Act 30 c §), the Finnish Medicines Agency (Fimea) may request the nomination of

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			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 (Vet)	X		According to Article R5141 -108 of Public Health Code (Amended by Decree No. 2011-385 of 11 April 2011 - Art. 1) (n*o official translation):* A MAH "exploitant" with veterinary drugs has permanently, the services of a person, pharmacist or veterinarian in charge of veterinary pharmacovigilance residing in the European Community. The name of this person, its quality and its coordinates are communicated to the Director General of the National Agency for Food, environment and occupational Safety. This person is responsible to: • gather, process and make available to any person entitled to know the information about all suspected adverse reactions that have been reported. This information is kept for a period of at least five years from the date of receipt; • prepare the reports referred to in Article R. 5141-105 (SAE report and PSUR) for their transmission to the director general of the agency; • ensure that answers fully and promptly, requests from the director general of the agency seeking to obtain additional information necessary for the veterinary drug, including information on post marketing surveillance studies on the market, the volume of sales or prescriptions of the veterinary medicinal product concerned.
France (Human)	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 5.5121-164.
Germany (BfArM)	X		"Stufenplanbeauftragter" (Officer of the graduate plan), defined in § 63a of the German Drug Law (AMG), human and vet.
Greece	X		According to the Ministerial Decree no. Δ.ΥΓ3α/Γ.Π. 32221 ΦΕΚ 1049/29-04-2013:

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			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 (Vet)	X		No legal requirement, but NCA requests for a pharmacovigilance contact person who can give the detailed information about the vet cases which occurred in Hungary. Through this person the NCA have connections with global QPPV, too.
Hungary (Human)	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 has to report to the EU QPPV. He /she has to have a degree in life sciences, chemist or chemical engineering and has to be trained in pharmacovigilance.
Iceland		X	The Icelandic Medicines Agency (IMA) requires the nomination of a pharmacovigilance contact person within the EEA, applicable to both human and vet products.
Ireland		X	No. A local contact person is not a legal requirement.
Italy		X	Italy doesn't require us mandatory the nomination of a local national contact person for pharmacovigilance (LNCPP). Anyway, the European QPPV or the LNCPP must to register to the national pharmacovigilance database (NPhVD) and all information in the NPhVD are in Italian language. If the European QPPV knows the Italian language it is not necessary to nominate a local contact person for pharmacovigilance for Italy.
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 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.

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			(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 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, as amended, of December 15, 1992 relating to the marketing of medicinal products, Article 45.-3, the nomination of a local contact person for pharmacovigilance is a requirement in Luxembourg. He/she should be nominated by the MAH and notified to the national competent authority (Directorate of Health, Division Pharmacy and Medicinal products). The local contact person should meet the following requirements: • 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. • He/she should be at a minimum with documented experience in all aspects of pharmacovigilance in order to fulfil the responsibilities and tasks of the position. • Knowledge of languages allowing to communicate with national stakeholders is strongly recommended: French, German, English and/or Luxembourgish.
Malta		X	No information available.
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. 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

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			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	The Norwegian Medicines Agency (NOMA) requires nomination of a pharmacovigilance contact person within the EEA, applicable to both human and veterinary products.
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 (Human)	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 has to identify a contact person that will be responsible for reporting to the EU QPPV.
Portugal (Vet)		X	No national requirement for the nomination of a local pharmacovigilance contact person but must be part of the Portuguese Veterinary professional college.
Romania	X		According to national legislation (Law 95/2006 with subsequent amendments, art.815 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.13) the State Institute for Drug Control can require from MAH to nominate a contact person responsible for pharmacovigilance. Based on that fact the State Institute for Drug Control in Slovakia 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 have to be applied in Slovakia.

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

Member State	Yes	No	Comments
Slovenia		X	In our new law on drugs, which implements the new PhV regulation, 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		National responsible for pharmacovigilance (contact person for pharmacovigilance as per our Royal Decree) is required according Royal Decree 577/2013 only for human products.
Sweden		X	No national requirement for the nomination of a local pharmacovigilance contact person.