# Country–specific requirements for LCPPV

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EEA Member States' Requirements on the Role of Local Contact Person for Pharmacovigilance (LCPPV)

# Contents

# Legislative Background

Article 104(4.) of Directive 2001/83/EC states that:

"…national competent authorities may request the nomination of a contact person for pharmacovigilance issues at national level reporting to the qualified person responsible for pharmacovigilance activities."

There are several EEA countries that indeed enforce this requirement with some other countries retaining the right to request an LCPPV but in practice never do.

## Our thoughts

Some countries do not have this requirement at all, and it is a sensible thing to do. The LCPPV role is a relic from the time before the centralized computerized database systems that make the LCPPV role practically obsolete. It is, however, still a legal requirement necessary to meet to be compliant with the law.

For marketing authorization holders and companies entering the European market, this requirement is one of those boxes to tick that makes very little common sense, brings no additional value to the monitoring of the safety profile of the product and, unfortunately, very frequently can be a big cost. Ticking this box is easy and that's why it is also one of the favorite points to check for inspectors and auditors.

Without doubt, your best shot at meeting these legal requirements with the most sensible approach at the lowest cost possible is Tepsivo and our unique Tepsivo Platform, removing all admin overhead and easily managing all EEA countries in one place.

EMA publishes regularly a document called "Information on the Member States requirement for the nomination of a pharmacovigilance (PhV) contact person at national level" which is based on Pharmacovigilance Inspectors Working group survey and captures the different requirements in each Member State. This document works as a good quick guide for those who are completely new to the topic. However, the document contains several inconsistencies, errors and is missing information. Also, in couple cases, the document does not reflect the practice in the country..

We have supplemented the information provided by EMA with details of the exact legal requirements from the national legislation and national competent authority websites and included instructions for nominating the LCPPV in those countries that require it. We have also included our own comments based on years of experience managing LCPPVs around EEA.

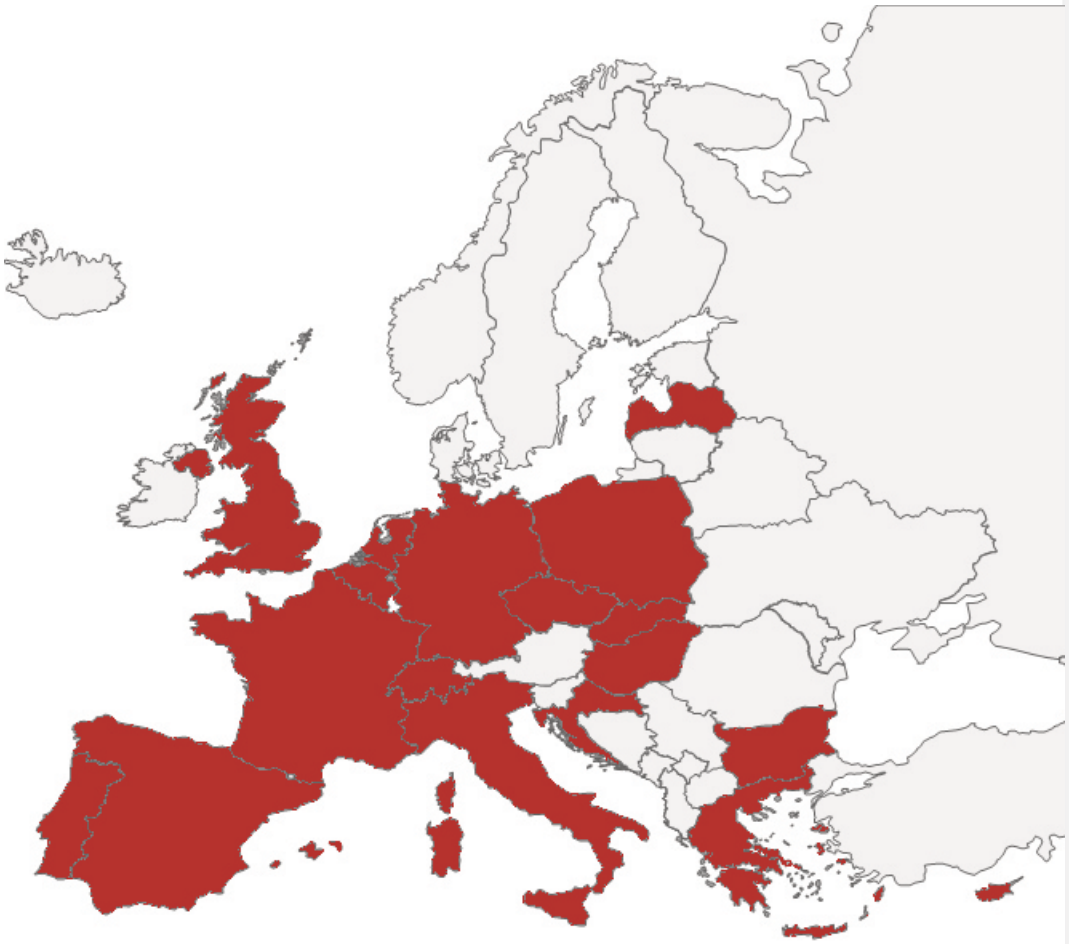
### General comments

- NCAs probably won't request an LCPPV appointment, if it's optional
- If there is no requirement to appoint an LCPPV, you never should
- This information here is valid for human medicinal products only

# Overview

## LCPPV required in:

Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
France
Germany
Greece
Hungary
Italy
Latvia
Luxembourg
Netherlands
Poland
Portugal
Slovakia
Spain
+ Switzerland
+ United Kingdom



# Austria

## LCPPV required?

NO

## Comments

- There is no legal requirement to appoint an LCPPV in Austria, however the Austrian competent authority (AGES) can require the nomination of LCPPV from the MAH.
- The EMA document says that "this has not been executed so far since most MAHs nominate contact persons on national level anyway".
- This is highly unlikely to be requested and most sensible thing to do is not to appoint an LCPPV.

## Legislation and Guidelines

**The local law § 75i(6) AMG states:**

§ 75i. (6) Unbeschadet des Abs. 5 kann das Bundesamt für Sicherheit im Gesundheitswesen die Benennung einer Kontaktperson für Pharmakovigilanzfragen in Österreich verlangen, die dem Pharmakovigilanzverantwortlichen Bericht erstattet.

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**Translation:**

Without prejudice to Paragraph 5, the Federal Office for Safety in Health Care can request the designation of a contact person for pharmacovigilance issues in Austria who will report to the pharmacovigilance officer.

## Registration

Not applicable

# Belgium

LCPPV required?

YES

## Comments

» Nomination of LCPPV is legally required in Belgium.

» The EMA document states that the requirement is based on article 66§2 of the Royal Decree 14/12/2066, however the correct legal reference is article 66§2 of the Royal Decree 14/12/2006 (published on 14th of December 2006) and amended on 10th of June 2013.

## Legislation and Guidelines

**According to article 12sexies§2 of the Law of 25 March 1964 concerning the medicinal products:**

Dans le cadre de ce système de pharmacovigilance, il prend notamment les mesures suivantes :

a) il a de façon permanente et continue à sa disposition une personne possédant les qualifications appropriées qui est responsable pour la pharmacovigilance, ainsi que, le cas échéant, une personne de contact en matière de pharmacovigilance au niveau belge qui est rattachée à cette personne qualifiée, et ce pour chaque dossier permanent du système de pharmacovigilance; le Roi fixe les conditions auxquelles la personne qualifiée et la personne de contact doivent répondre pour exercer leurs activités;

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**Translation:**

As part of this pharmacovigilance system, it takes the following measures in particular:

(a) he has permanently and continuously at his disposal a person with the appropriate qualifications who is responsible for pharmacovigilance, as well as, if applicable, a contact person for pharmacovigilance at the Belgian level which is attached to this qualified person, and this for each file permanent pharmacovigilance system; the King sets the conditions under which the qualified person and the contact person must meet to carry out their activities.

**The information about LCPPV requirements is described on the national competent authority FAMHP website. The information is based on Circular 600, annex I, annex II and QA document that give more regarding the LCPPV and the nomination process.**

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According to the circular, the local contact person should meet the following requirements:

- must be contactable 24 hours a day, 7 days a week
- must carry out activities in pharmacovigilance in Belgium
- 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.

## Registration

The format for the nomination letter to FAMHP is provided in the Circular 600, in annex I and annex II, which constitute the notification letter form.

According to the Circular 600, the form can be submitted as PDF to phvinsp@fagg-afmps.be and it needs to be signed by a representative of the MAH.

# Bulgaria

LCPPV required?

YES

## Comments

» LCPPV is required, unless the EU QPPV is located in Bulgaria.

## Legislation and Guidelines

**The LCPPV requirement is described in the law for medicinal products in human medicine, Article 191.**

Art. 191.(amend. – SG, 102/2012,in force from 21.12.2012)

- The marketing authorisation holder shall select a qualified person with an appropriate qualification, responsible for vigilance of the medicinal safety.
- The person under Para. 1 shall be established on the territory of a Member State and shall be permanently at disposal of the marketing authorisation holder.
- In order to assist the activity of the qualified person, the marketing authorisation holder shall select a person, established on the territory of the Republic of Bulgaria. The appointment of such a person shall not liberate the qualified person under Para. 1 from his/her responsibilities under this Chapter

## Registration

An LCPPV nomination letter should be sent via email to BDA or delivered as a paper copy in order to receive a confirmation number.

# Croatia

LCPPV required?

YES

## Comments

» MAH has to appoint an LCPPV residing in Croatia.

» HALMED's requirements are some of the strictest in Europe.

## Legislation and Guidelines

Ordinance on Pharmacovigilance (Official Gazette 83/13)p.7

"proof that the future authorisation holder has a person approved by the Agency for pharmacovigilance with residence in the Republic of Croatia, or proof of a submitted request to the Agency for authorisation of a person responsible for pharmacovigilance with residence in the Republic of Croatia"

Ordinance on Pharmacovigilance (Official Gazette 83/13)Article 32

The authorisation holder is obliged without delay to submit to the Agency the request for the approval of a change in the person responsible for pharmacovigilance seated in the Republic of Croatia, pursuant to Articles 26 and 27 of this Ordinance.

Medicinal Product Act (official gazette no. 76/13)Article 3 Point 58

Person of the marketing authorisation holder qualified for pharmacovigilance in the Republic of Croatia shall mean a doctor of medical science specialised in clinical pharmacology, or a doctor of medical science, or a doctor of dental medicine, or a graduate pharmacist, or a master of medical biochemistry, or a doctor of veterinary medicine with two years of experience in pharmacovigilance or two years of experience in his/her profession with appropriately documented training in pharmacovigilance

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# Registration

Detailed list of national requirements:

Proof that the future MAH has responsible person for Pharmacovigilance seated in Croatia authorised by the Agency or proof that application for their approval has been submitted to HALMED. This submission should be separate from the submission for marketing authorisation.

Documents to be submitted in electronic form:

- Proof of the legal entity's seat, if the future marketing authorisation holder is a natural or legal person than the applicant, proof that the seat of the future marketing authorisation holder is in the EU, valid no longer than six months from the submission date
- Written statement of the marketing authorisation holder not having seat in the Republic of Croatia about the appointment of a local representative with the seat in the Republic of Croatia with his contacts

Request for approval of LCPPV should contain:

- original statement of the qualified person of the MAH for appointing local QPPV
- signed CV of the local qualified person
- copy of diploma proving completed education, copy of specialist training completion certificate (clinical pharmacology), or if the QPPV isn't a clinical pharmacology specialist proof of two-year work experience in Pharmacovigilance, i.e. proof that the person has undergone Pharmacovigilance terms, spontaneous and solicited adverse reactions reporting, adverse reaction reporting procedure, adverse reaction report grading, Individual Case Safety Report (ICSR-a), Periodic Safety Update Report (PSUR), Risk Management Plan (RMP) and Development Safety Update Report (DSUR) training
- proof of residence of the QPPV
- 24-hour contact information on QPPV
- proof of employment of the QPPV at the MAH or a contracted legal person that has a registered activity for adverse reaction tracking, i.e. Pharmacovigilance activities in the Republic of Croatia, with whom the MAH has concluded an agreement on Pharmacovigilance
- copy of the agreement on appointing contractual local QPPV
- EV code/codes (PSMF Location EV Code)

If the local QPPV is an employee of the MAH belonging to the same authorization holder group as the holder submitting the request, instead of copy of the agreement appointing contractual local QPPV/deputy, a statement signed by QPPV of the MAH stating that the company in which the local QPPV/deputy is employed is part of the same MAH group will be accepted.

If MAH has authorized a third legal party to conclude agreements for Pharmacovigilance with a legal entity that has a registered activity for adverse reaction tracking, i.e. Pharmacovigilance activities in the Republic of Croatia, instead of a copy of the agreement of appointing contractual local QPPV/deputy, a copy of the authorization given to the third legal entity as well as a copy of the contract that the third legal entity concluded on behalf the MAH with the contractual legal entity for Pharmacovigilance in which local QPPV/deputy is employed.

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MAH appoints one local qualified person for each Pharmacovigilance system regarding medicinal products that have marketing authorization in the Republic of Croatia.

MAH can submit a request for approval of additional local QPPV, aside from the already appointed one by HALMED, only if the request addresses a new pharmacovigilance system of the MAH. In the request for local QPPV approval and deputy of local QPPV, as well as in all the submitted documents containing signatures, by each signature should be printed name, last name and function of the signatory.

Information on the approval procedure of local qualified person / deputy responsible for pharmacovigilance: lqppv@halmed.hr

# Cyprus

## LCPPV required?

**YES**

## Comments

» For the LCPPV in Cyprus requirement, the EMA document states "Yes" and the comment says "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."

## Legislation and Guidelines

The Drugs for Human Use (Quality Control, Supply and Prices) Law of 2001(70 (I) /2001) states:

(3)(α) Το ειδικευμένο άτομο που αναφέρεται στην παράγραφο (α) του εδαφίου (2) διαμένει και δραστηριοποιείται στην Ευρωπαϊκή Ένωση και είναι υπεύθυνο για τη δημιουργία και τη διαχείριση του συστήματος φαρμακοεπαγρύπνησης.

(β) Ο κάτοχος της άδειας κυκλοφορίας υποβάλλει το ονοματεπώνυμο και τα στοιχεία επικοινωνίας του ειδικευμένου ατόμου στην αρμόδια αρχή και στον ΕυρωπαϊκόΟργανισμό Φαρμάκων.

(4) Με την επιφύλαξη των διατάξεων του εδαφίου (3), το Συμβούλιο Φαρμάκων μπορεί να ζητήσει το διορισμό αρμοδίου επικοινωνίας για θέματα φαρμακοεπαγρύπνησης ο οποίος θα αναφέρεται στο ειδικευμένο άτομο υπεύθυνο για δραστηριότητες φαρμακοεπαγρύπνησης.

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**Translation:**

(3) (a) The qualified person referred to in paragraph (a) of subsection (2) resides and operates in the European Union and is responsible for the establishment and management of the pharmacovigilance system.

(b) The marketing authorization holder shall submit the name and contact details of the qualified person to the competent authority and to the European Medicines Agency.

(4) Without prejudice to the provisions of subsection (3), the Medicines Board may request the appointment of a pharmacovigilance liaison officer to report to the qualified person responsible for pharmacovigilance activities.

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**The Cypriot Ministry of Health has published a circular on requirements for local contact persons. Unfortunately, the older circulars are no longer available on the website of the pharmaceutical services of the ministry of health.**

**The circular states:**

Θέμα: Απαιτήσεις για το Τοπικά Ειδικευμένο Άτομο για Φαρμακοεπαγρύπνηση (Local QPPV) / Υπεύθυνο Άτομο για Φαρμακοεπαγρύπνηση (Local RPPV) –Υπενθύμιση και διευκρινίσεις

Σε συνέχεια της εγκυκλίου των Φαρμακευτικών Υπηρεσιών ημερομηνίας 1 Σεπτεμβρίου 2008, το Συμβούλιο Φαρμάκων ενημερώνει τους ΚΑΚ για τις τοπικές απαιτήσεις σχετικά με το τοπικά Ειδικευμένο Άτομο για Φαρμακοεπαγρύπνηση (QPPV) και το τοπικά Υπεύθυνο Άτομο για Φαρμακοεπαγρύπνηση (RPPV). Υπενθυμίζονται οι ΚΑΚ για την υποχρέωση1 διορισμού ενός τοπικά QPPV/RPPV για την Κυπριακή αγορά εάν ο EU/EEA QPPV δεν διαμένει και δεν δραστηριοποιείται στην Κυπριακή Δημοκρατία. Σύμφωνα με το Συμβούλιο Φαρμάκων, ο τοπικά QPPV/RPPV, ο οποίος θα διαμένει στην Κύπρο, πρέπει να είναι επαγγελματίας υγείας, βιολόγος ή χημικός κατάλληλα εκπαιδευμένος στη φαρμακοεπαγρύπνηση. Πρέπει, επίσης, να κατέχει άπταιστα την ελληνική γλώσσα προκειμένου να εκτελέσει αποτελεσματικά τις δραστηριότητες της φαρμακοεπαγρύπνησης που έχουν ανατεθεί σε αυτόν / αυτήν από το EU/EEA QPPV του ΚΑΚ. Όσοι ΚΑΚ δεν έχουν ακόμη ορίσει ένα κατάλληλο τοπικά υπεύθυνο άτομο για τη φαρμακοεπαγρύπνηση, θα πρέπει να το πράξουν άμεσα και να ενημερώσουν το Συμβούλιο Φαρμάκων ως προς τα στοιχεία του προσώπου αυτού χρησιμοποιώντας το συνημμένο έντυπο κοινοποίησης. Οι ΚΑΚ που δεν έχουν κοινοποιήσει στο Συμβούλιο Φάρμακων τα απαιτούμενα στοιχειά του νυν τοπικού υπεύθυνου ατόμου για την φαρμακοεπαγρύπνηση πρέπει επίσης να ενημερώσουν το Συμβούλιο Φαρμάκων με τα επικαιροποιημένα στοιχεία χρησιμοποιώντας επίσης το συνημμένο έντυπο. Θα πρέπει να σημειωθεί ότι δημόσιοι υπάλληλοι ή άτομα τα οποία δεν μπορούν να είναι διαθέσιμοι συνεχώς δεν είναι εφικτό να οριστούν ως τοπικοί QPPV/RPPV. Είναι όμως επιτρεπτό για τον τοπικά QPPV/RPPV να διοριστεί σαν τοπικά QPPV/RPPV σε πέραν του ενός ΚΑΚ. Για οποιαδήποτε διευκρίνιση παρακαλείσθε όπως επικοινωνείτε με τη Μονάδα Φαρμακοεπαγρύπνησης των Φαρμακευτικών Υπηρεσιών.

**The English part of the circular states:**

Re: Requirements for local QPPV/RPPV – Reminder and Clarification

Further to the Circular of September 1 2008 concerning the QPPV and local contact persons, the Drugs Council wishes to remind Marketing Authorisation Holders of the requirement 2to nominate a local Qualified/Responsible Person for Pharmacovigilance for the Cyprus market, should the EU QPPV not reside and operate in the Republic of Cyprus.

The Drugs Council requires this local QPPV/RPPV, who will reside in Cyprus, to be a qualified healthcare professional or a biologist or chemist and to have been adequately trained in pharmacovigilance. Additionally, they must be fluent in written and spoken Greek, in order to effectively perform the pharmacovigilance activities delegated to him/her by the EU QPPV of the MAH.

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Any MAHs who have not yet nominated a suitable person, must do so immediately and will notifythe Drugs Council as to the particulars of the nominated person using the attached notification form. Other MAHs who may not have notified the change of their local QPPV/RPPV must also notify the Drugs Council of the updated details using the attached form.

It must be noted that a person currently employed in the public service, or a person who is unable to be available continuously, may not be nominated as local QPPV/RPPV.It is possible, however, for a local QPPV/RPPV to be appointed as QPPV/RPPV for more than one MAH.

Please do not hesitate to contact the pharmacovigilance department of the Pharmaceutical Services should you require any clarification.

2 Article 57 of The Medicines for Human Use (Control of Quality, Supply and Prices) Act of 2001(70(I) / 2001)and Article 104 of the Directive 2001/83/ECofthe European Parliament and of the Council of 6 November 2001on the Community code relating to medicinal products for human use, as amended.

## Registration

The above-mentioned circular contains notification form in Greek and in English. The form can be submitted by email to phscentral@phs.moh.gov.cy

The form contains the following information:

Name of the nominee (SURNAME, First name)

Contact Details: Address, 24 hour Telephone Number, Fax Number, Email address
Back-upArrangements : Name of Contact (deputy) should the above nominee not be available, Contact Details

Checklist of Enclosed/Attached Documents

- Curriculum vitae Evidence of adequate
- Training and Experience in Pharmacovigilance
- Summary of Responsibilities as outlined in the Pharmacovigilance Agreement/Contract between the local QPPV/RPPV and the EU/EEA QPPV
- List of Products for which the Local QPPV/RPPV is responsible
- Evidence/declaration of adequate knowledge of Modern Greek
- Other

I, the undersigned, declare that the above information and supporting documents are accurate and correct to the best of my knowledge. I will be continuously available to receive and respond to queries, reports and any other safety related data from the general public, health care professionals and the National Authorities. I undertake to maintain a pharmacovigilance training portfolio that will be made available to the Pharmaceutical Services of the Ministry of Health for review as and when requested.

Signture, Date, Print name

Additional details regarding the enclosed documents:

- The address must be within the Republic of Cyprus
- General enquiry mailboxes (e.g. info@MAH.com) will not be accepted
- Training and Experience in Pharmacovigilance should be analogous to the delegated responsibilities

# Czech Republic

LCPPV required?

YES

## Comments

» In practice, the national competent authority requests all marketing authorization holders to appoint an LCPPV, unless the EU QPPV speaks Czech or Slovak

» The LCPPV in the Czech Republic must:

- be able to communicate in Czech or Slovak
- be contactable on a telephone number with the Czech area code
- be established in the territory of the EU

» It is acceptable, and practical, to use the same LCPPV for both the Czech Republic as well as Slovakia

## Legislation and Guidelines

**The NCA instructs that according to the act on pharmaceuticals, section 91a(3):**

Kvalifikovaná osoba odpovědná za farmakovigilanci (§91a)

- Držitel rozhodnutí o registraci musí mít trvale a nepřetržitě k dispozici kvalifikovanou osobu odpovědnou za farmakovigilanci.
- Kvalifikovaná osoba odpovědná za farmakovigilanci odpovídá za vytvoření a správu farmakovigilančního systému a musí mít bydliště a plnit své úkoly v oblasti farmakovigilance na území Evropské unie. Držitel rozhodnutí o registraci sdělí jméno, příjmení a kontaktní údaje kvalifikované osoby odpovědné za farmakovigilanci Ústavu a agentuře.
- Ústav může požádat držitele rozhodnutí o registraci o jmenování kontaktní osoby pro otázky farmakovigilance v České republice, která bude podřízena kvalifikované osobě odpovědné za farmakovigilanci (upřesnění zde).
- Držitel rozhodnutí o registraci je povinen neprodleně informovat Ústav v případě změny kvalifikované osoby odpovědné za farmakovigilanci nebo změny jejích kontaktních údajů; obdobně informuje o změnách týkajících se kontaktní osoby.

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**Translation:**

Qualified person responsible for pharmacovigilance (§91a)

- The MAH must keep the qualified person responsible for pharmacovigilance available at all times.

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- The qualified person responsible for pharmacovigilance is responsible for the establishment and administration of the pharmacovigilance system and must be resident and perform his pharmacovigilance tasks in the European Union. The marketing authorization holder shall communicate the name, surname and contact details of the qualified person responsible for pharmacovigilance to the Institute and the Agency.
- The Institute may request the marketing authorization holder to appoint a contact person for pharmacovigilance issues in the Czech Republic, who will report to a qualified person responsible for pharmacovigilance (details here).
- The marketing authorization holder is obliged to immediately inform the Institute in the event of a change in the qualified person responsible for pharmacovigilance or a change in his contact details; similarly informs about changes concerning the contact person.

**Guideline PHV-6 SÚKL requirements for reporting changes in the PSMF, for appointing the qualified person for pharmacovigilance and for appointing the contact person for pharmacovigilance issues in the Czech Republic**

**SÚKL has requested the nomination of the contact person by all MAHs who have legal PV obligations in the country: https://www.sukl.cz/leciva/phv-6-verze-3**

**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 pharmacovigilance issues is to provide the contact between SÚKL and the QPPV.**

**The contact information in the body of the e-mail must include the e-mail address and telephone number of the contact person for pharmacovigilance issues and the name of the represented marketing authorization holder (all represented marketing authorization holders). The marketing authorization holder may also inform SÚKL of the contact person's deputy if one is appointed.**

## Registration

The marketing authorization holder is obliged to immediately inform the Institute in the event of a change in the qualified person responsible for pharmacovigilance or a change in his contact details; similarly informs about changes concerning the contact person.

If the marketing authorization holder meets the requirements set out above for the appointment of a contact person for pharmacovigilance issues in the Czech Republic, informs the pharmacovigilance department electronically by email to the address pharmacovigilance@sukl.cz.

# Denmark

## LCPPV required?

**NO**

(not in practice)

## Comments

» The Danish law allows the Danish national competent authority to request an LCPPV appointment but the authority does not enforce it.

» The EMA document states that DKMA has up until now not required of any MAH the appointment of LCPPV in Denmark.

## Legislation and Guidelines

**According to Medicines Act § 53, the Danish Health and Medicines Authority 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).**

Bivirkninger ved lægemidler
§ 53. Indehaveren af en markedsføringstilladelse til et lægemiddel skal råde over en sagkyndig inden for lægemiddelovervågning med bopæl i EU.
Stk. 2. Stk. 1, nr. 2, gælder ikke for lægemidler til dyr.
Stk. 3. Sundhedsstyrelsen kan, når lægemiddelovervågning gør det påkrævet, pålægge indehaveren af markedsføringstilladelsen til et lægemiddel til mennesker at udpege en kontaktperson i Danmark for den i stk. 1, nr. 7, nævnte sagkyndige.

**Translation:**

Side effects of drugs
§ 53. The holder of a marketing authorization for a medicinal product must have a pharmacovigilance expert resident in the EU.
PCS. 2. Stk. 1, no. 2, does not apply to medicinal products for animals.
PCS. 3. The Danish Health and Medicines Authority may, when pharmacovigilance so requires, require the holder of the marketing authorization for a medicinal product for humans to appoint a contact person in Denmark for the person referred to in subsection (1). 1, no. 7, mentioned experts.

## Registration

Not applicable

# Estonia

## LCPPV required?

NO

## Comments

» By default, LCPPV is not required, but an Estonian-speaking contact point may be required in cases where prescribers of the medicinal products are to be informed about the safety risks associated with the use of medicines (direct healthcare professional communication and materials for additional risk minimisation measures)

## Legislation and Guidelines

**According to regulation of the Minister of Social Affairs no. 26 (§ 4 section 4) 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.**

## Registration

Not applicable

# Finland

## LCPPV required?

**NO**

(not in practice)

## Comments

- 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 LCPPV, all ICSR related communication will be directed to the EU QPPV.
- Fimea does not request all MAHs to nominate a contact person. Seeing that all PV communication directed centrally to the EU QPPV or delegates is more practical, there is no good reason to appoint an LCPPV.

## Legislation and Guidelines

The medicines legislation 30 c § (3.5.2013/330) states:

Lääkealanturvallisuus-jakehittämiskeskusvoitarvittaessapyytäämyyntiluvan, rinnakkaistuontimyyntiluvan ja rekisteröinnin haltijaa nimeämään kansallisen tason lääketurvatoiminnasta vastaavan yhteyshenkilön, joka raportoi lääketurvatoiminnasta vastaavalle henkilölle.

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**Translation:**

Fimea can request the MAH to appoint a contact person responsible for national level pharmacovigilance activities who reports to the EU QPPV.

## Registration

There is a specific form available for the contact information of the LCPPV and the EU QPPV. The form can be sent via email to phvigi.contact@fimea.fi, by mail to Finnish Medicines Agency, Pharmacovigilance unit, P.O.Box 55, FI-00034 Fimea, Finland or by fax to +358 29 522 3006.

# France

LCPPV required?

YES

## Comments

» According to national law, nomination of LCPPV (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). The LCPPV is nominated to ANSM.

» For France, it is important to make the difference between the LCPPV (responsable de pharmacovigilance, RPV) and Responsible Pharmacist (Pharmacien Responsible, PR). They can be one and the same person, but they are not the same role.

## Legislation and Guidelines

**The ANSM website provides a comprehensive Q&A related to the French GVP and the LCPPV requirements.**

**Est-il possible de préciser l'échéance de désignation d'un responsable de pharmacovigilance (RPV) pour un exploitant n'ayant pas encore de produits sur le marché?**

Afin d'assurer les obligations et les responsabilités qui lui incombent en matière de pharmacovigilance, l'exploitant dispose, conformément aux dispositions de l'article R.5121-164 du CSP, des services d'une personne de référence en matière de pharmacovigilance sur le territoire national.

Cette personne de référence, médecin ou pharmacien, réside et exerce ses activités en France et doit justifier d'une expérience en matière de pharmacovigilance. Elle peut être distincte (ou non) de la personne qualifiée responsable en matière de pharmacovigilance dans l'union européenne (QPPV) et/ou du pharmacien responsable (PR).

La désignation d'un RPV doit se faire dès qu'une entreprise exploite un médicament, conformément aux dispositions de l'article R. 5121-164 du code de la santé publique (CSP) : « toute entreprise ou tout organisme exploitant un médicament ou un produit mentionné à l'article R. 5121-150 dispose des services d'une personne de référence en matière de pharmacovigilance.… ».

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**Translation:**

**Is it possible to specify the deadline for appointing a pharmacovigilance manager (RPV) for an operator that does not yet have any products on the market?**

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In order to fulfill its obligations and responsibilities in terms of pharmacovigilance, the operator has, in accordance with the provisions of article R.5121-164 of the CSP, the services of a reference person in terms of pharmacovigilance on the national territory.

This reference person, doctor or pharmacist, resides and exercises his activities in France and must demonstrate experience in pharmacovigilance. It may be separate (or not) from the qualified person responsible for pharmacovigilance in the European Union (QPPV) and/or the responsible pharmacist (PR).

The appointment of an RPV must be made as soon as a company uses a medicine, in accordance with the provisions of Article R. 5121-164 of the Public Health Code (CSP): "any company or organization using a medicine or a product mentioned in article R. 5121-150 has the services of a reference person in terms of pharmacovigilance.…".

**Le RPV doit-il avoir un suppléant?**

Il n'existe pas en tant que telle d'exigence de disposer d'un suppléant au RPV dans le code de la santé publique ou les BPPV. En revanche, il est nécessaire de prévoir un système de suppléance du RPV en cas d'absence de celui-ci (Good vigilance practices (GVP) Module I, CSP article R.5121-164, BPPV chapitre 4 point 4.6). Le RPV doit s'assurer que son suppléant dispose de toutes les informations nécessaires pour remplir son rôle.

Le suivi des dossiers (transmissions) entre le RPV et son remplaçant avant et après son absence doit être formalisé.

Il n'y a pas d'obligation de communiquer à l'ANSM le nom du remplaçant du RPV en cas d'absence.

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**Translation:**

**Should the RPV have a deputy?**

As such, there is no requirement to have a deputy RPV in the public health code or the BPPV. On the other hand, it is necessary to provide a backup system for the RPV in the event of its absence (Good vigilance practices (GVP) Module I, CSP article R.5121-164, BPPV chapter 4 point 4.6). The RPV must ensure that their deputy has all the information necessary to fulfill their role.

The follow-up of files (transmissions) between the RPV and their deputy before and after their absence must be formalized.

There is no obligation to communicate to the ANSM the name of the deputy of the RPV in the event of absence.

**Un EUQPPV (European qualified person for pharmacovigilance) installé en France peut-il être aussi RPV?**

Un EUQPPV peut être également RPV à condition qu'il réponde aux mêmes conditions que le RPV, soit :

- être médecin ou pharmacien ;
- résider et exercer en France ;
- justifier d'une expérience en matière de PV.

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**Translation:**

**Can an EU QPPV (European qualified person for pharmacovigilance) installed in France also be a RPV?**

An EUQPPV can also be a RPV provided that it meets the same conditions as the RPV, i.e.:

- be a doctor or pharmacist;
- reside and practice in France;
- justify experience in terms of PV.

**According to Code de la Santé Publique, article 5.5121-164:**

Toute entreprise ou tout organisme exploitant un médicament ou un produit mentionné à l'article R.5121-150disposeen permanence des services d'une personne responsable de la pharmacovigilance résidant et exerçant dans un Etat membre de l'Union européenne ou un Etat partie à l'accord sur l'Espace économique européen, et justifiant de qualifications appropriées en matière de pharmacovigilance. L'identité, la qualité et la fonction ainsi que les coordonnées de cette personne sont communiquées au directeur général de l'Agence nationale de sécurité du médicament et des produits de santé et à l'Agence européenne des médicaments dès sa nomination.

En outre, toute entreprise ou tout organisme exploitant un médicament ou un produit mentionné à l'article R. 5121-150disposedesservices d'une personne de référence en matière de pharmacovigilance rattachée à la personne qualifiée responsable pour les activités de pharmacovigilance. Cette personne de référence, médecin ou pharmacien, réside et exerce en France et doit justifier d'une expérience en matière de pharmacovigilance. L'identité et la qualité ainsi que les coordonnées de cette personne sont communiquées au directeur général de l'Agence nationale de sécurité du médicament et des produits de santé dès sa nomination.

Ces personnes collaborent en vue de :

1° Rassembler, traiter et rendre accessibles à toute personne habilitée les informations portées à la connaissance de l'entreprise ou de l'organisme exploitant le médicament ou le produit, ainsi qu'aux personnesmentionnéesà l'article L. 5122-11quifontdel'information par démarchage ou de la prospection pour des médicaments et des produits, et relatives aux effets indésirables suspectés d'être dus à des médicaments ou des produits qu'exploite l'entreprise ou l'organisme ;

2° Mettre en place et gérer le système de pharmacovigilance prévu à l'article R. 5121-162etlesystèmede gestion des risques prévu à l'article R. 5121-163;

3° Préparer et soumettre les déclarations et rapports mentionnés aux articles R. 5121-166,R.5121-168et R. 5121-170;

4° Assurerla miseen œuvre et le suivi des études de sécurité post-autorisationainsi que le suivi spécifique du risque, de ses complications et de sa prise en charge médico-sociale mentionnés aux articles R. 5121-36-1et R. 5121-37-3;

5° Assurer la mise en place des procédures et le recueil des informations mentionnés au premier alinéa de l'article R. 5121-167etenenvoyer les éléments nouveaux à la base de données européenne " Eudravigilance " ;

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6°Veiller à ce qu'il soit répondu, de manière complète et rapide, auxdemandes du directeur général de l'Agence nationale de sécurité du médicament et desproduitsde santé mentionnéesau troisièmealinéa du I de l'article R. 5121-155etauxdemandesdes centres régionaux de pharmacovigilance mentionnés à l'article R. 5121-158etdes centres d'évaluation et d'information sur la pharmacodépendance et d'addictovigilance mentionnés à l'article R. 5132-112;

7° Fournir au directeur général de l'Agence nationale de sécurité du médicament et des produits de santé toute autre information présentant un intérêt pour l'évaluation des risques et des bénéfices liés à un médicament ou à un produit, notamment les résultats tant positifs que négatifs des recherches biomédicales et des études de sécurité et d'efficacité pour toutes les indications et populations, qu'elles soient mentionnées ou non dans l'autorisation de mise sur le marché, ainsi que les données concernant toute utilisation du médicament non conforme aux termes de l'autorisation de mise sur le marché et toute information relative au volume des ventes et à la prescription pour le médicament ou le produit concerné.

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**Translation:**

Any company or organization operating a drug or a product mentioned in Article R. 5121-150 permanently has the services of a person responsible for pharmacovigilance residing and practicing in a Member State of the European Union or a State Party. to the Agreement on the European Economic Area, and justifying appropriate qualifications in pharmacovigilance. The identity, quality and function as well as the contact details of this person are communicated to the Director General of the National Agency for the Safety of Medicines and Health Products and to the European Medicines Agency upon appointment.

In addition, any company or organization operating a drug or a product mentioned in article R. 5121-150hastheservices of a pharmacovigilance reference person attached to the qualified person responsible for pharmacovigilance activities. This reference person, doctor or pharmacist, resides and practices in France and must prove that he has experience in pharmacovigilance. The identity and position as well as the contact details of this person are communicated to the Director General of the National Agency for the Safety of Medicines and Health Products upon appointment.

These people work together to:

1 ° Gather, process and make accessible to any authorized person the information brought to the attention of the company or body operating the drug or product, as well as to the persons mentioned in Article L. 5122-11whodo information by canvassing or prospecting for drugs and products, and relating to undesirable effects suspected to be due to drugs or products operated by the company or organization;

2 ° Set up and manage the pharmacovigilance system provided for in article R. 5121-162andtherisk management system provided for in article R. 5121-163;

3 ° Prepare and submit the declarations and reports mentioned in Articles R. 5121-166,R.5121-168 and R. 5121-170;

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4 ° Ensure the implementation and monitoring of post–authorization safety studies as well as the specific monitoring of the risk, its complications and its medico–social care mentioned in Articles R. 5121–36–1 and R. 5121–37–3;

5 ° Ensure the implementation of the procedures and the collection of the information mentioned in the first paragraph of article R. 5121–167 and send the new elements to the European database "Eudravigilance";

6 ° Ensure that requests from the Director General of the National Agency for the Safety of Medicines and Health Products mentioned in the third paragraph of I of Article R. 5121–155 and at the requests of the regional pharmacovigilance centers mentioned in article R. 5121–158 and the evaluation and information centers on drug dependence and addictovigilance mentioned in article R. 5132–112;

7 ° Provide the Director General of the National Agency for the Safety of Medicines and Health Products with any other information of interest for the assessment of the risks and benefits associated with a medicinal product or a product, in particular the results both positive and negative biomedical research and safety and efficacy studies for all indications and populations, whether or not they are mentioned in the marketing authorization, as well as the data concerning any use of the medicinal product that does not comply with the terms of the marketing authorization and any information relating to the volume of sales and the prescription for the drug or product concerned.

## Registration

The declaration of the LCPPV or reference person for pharmacovigilance in France (RPV) is submitted by using an online form.

Information about the submitted appointment can be asked by email declarationrpv@ansm.sante.fr or by phone 01 55 87 37 14.

# Germany

LCPPV required?

YES

## Comments

» The LCPPV in Germany is called "Stufenplanbeauftragter" or officer of the graduate plan (graduated plan officer).

» In Germany, it is worth noting that there are several regulatory authorities that might have to be notified of the appointment of the LCPPV. Two country-wide ones: BfArM ("traditional" medicinal products), Paul-Ehrlich-Institut, PEI (vaccines, blood preparations, gene therapeutics etc.). Then, the regional authorities of the states (Regierungspräsidium), which applies if the marketing authorization holder is located in Germany.

## Legislation and Guidelines

**The role of the LCPPV is defined in §63a of the German Drug Law (AMG) and their responsibility related to product complaints and recalls is described in §19 of the ordinance on GMP:**

### Graduated plan officer

(1) Anyone who, in his/her capacity as a pharmaceutical entrepreneur, places finished medicinal products that are medicinal products under the terms of section 2 (1) or subsection (2) no. 1 on the market, must appoint a qualified person who is resident in a Member State of the European Union, who has the required expert knowledge and the reliability necessary for exercising his/her function (graduated plan officer) to set up and manage a pharmacovigilance system and to collect and evaluate notifications on medicinal product risks that have become known and co-ordinate the necessary measures. Sentence 1 does not apply to persons who do not require a manufacturing authorisation pursuant to section 13 (2) sentence 1 nos. 1, 2, 3, 5 or subsection (2b). The graduated plan officer is responsible for meeting the obligations to notify insofar as they concern medicinal product risks. He/she must also ensure that additional information for the evaluation of the risk-benefit profile of a medicinal product, including his/her own evaluations, are sent immediately and in full, if requested by the competent higher federal authority. The details are stipulated by the Ordinance on the Manufacture of Medicinal Products and Active Substances. Persons other than those specified in sentence 1 are not authorised to perform the duties of the graduated plan officer.

(2) The graduated plan officer may be a qualified person pursuant to section 14 or a responsible person pursuant to section 20c at the same time.

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(3) The pharmaceutical entrepreneur must notify the competent authority and the competent higher federal authority about the identity of the graduated plan officer and must make notification of any change beforehand. In the case of an unforeseen change in the person of the graduated plan officer, notification is to be made immediately.

Product complaints and recalls

(1) The Graduated Plan Officer is responsible for ensuring that all reports of drug risks that have become known are collected according to a written or electronic procedure and that all complaints are systematically recorded. In this context, the immediate review of the reports must be initiated, and an assessmentthen made as to whether there is a drug risk, how serious it is and what measures are required to avert the risk. The necessary measures are to be coordinated and brought to the knowledge of the qualified person according to § 14 of the Medicines Act so that they can take the necessary measures, if necessary, especially if it could be a quality problem. The effectiveness of the procedures must be checked regularly.

(2) The person responsible for the graduated plan must inform the competent authority immediately of any defect that could lead to a recall or an unusual restriction on distribution and must also state the countries to which the medicinal product was shipped or exported. In addition, the authority must also be informed immediately of any suspicion of counterfeit medicinal products or active ingredients; in the case of medicinal products intended for human use, the marketing authorization holder must also be informed.

(3) The Graduated Plan Officer must fulfil the notification obligations under the Medicines Act insofar as they relate to drug risks. The reporting obligations according to § 14 of the GCP regulation in the version valid on the day before it expires according to Article 13 paragraph 4 of the Fourth Act amending pharmaceutical law and other regulations of December 20, 2016(Federal Law Gazette I p. 3048)remain unaffected.

(4) Paragraph 1 applies accordingly to investigational medicinal products. The phased plan officer is responsible for ensuring that, in cooperation with the sponsor, complaints are systematically recorded and checked and that effective systematic precautions are taken so that further use of the investigational medicinal products can be prevented if this is necessary. Any defect that could lead to a recall or an unusual restriction of distribution must be documented and investigated, and the competent authority must be informed immediately and at the same time it must be stated to which test centers within or outside the scope of the Medicines Act the investigational medicinal product was delivered. If the investigational medicinal product is an approved medicinal product,

(5) The Graduated Plan Officer must keep records of the content of the reports, the type of review and the knowledge gained, the result of the evaluation, the coordinated measures,and the notifications.

(6) The graduated plan representative should be independent of the sales or distribution units and can only be represented by persons who have the expertise under Section 63a paragraph 1 sentence 1 of the Medicines Act, and must be in the area of application of the Medicines Act or in another reside and operate in a Member State of the European Union.

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(7) Insofar as a pharmaceutical entrepreneur places products other than those mentioned in Section 63a(1) sentence 1 of the Medicines Act on the market, he/she must commission an appropriate person to carry out the duties of the Graduated Plan Officer. The correspondingly commissioned person is responsible for compliance with the obligations under paragraphs 1 to 5. Product complaints and recalls

(8) The pharmaceutical entrepreneur must ensure that all reports of medicinal product risks and complaints received by the company, as well as information for the assessment of the risk-benefit ratio of a medicinal product, are immediately communicated to the phased plan officer or the correspondingly authorized person pursuant to paragraph 7 sentence 1 will.

(9) Paragraphs 1 to 3 and 5 to 8 apply accordingly to auxiliary preparations within the meaning of Article 2 paragraph 2 numbers 8 and 10 of Regulation (EU) No. 536/2014.

BfArM Guidance on Stufenplanbeauftragter

The national competent authority provides information about the requirements and guidance on their website.

According to § 63a AMG, a Graduated Plan Officer (who is equivalent to the EU QPPV ) for national approvals and approvals from DCP or MRP procedures is responsible for the area of application of the AMG at the competent authority (state authority) and at the competent higher federal authority (Federal Institute for Drugs) and medical devices and/or to the Paul-Ehrlich-Institut if necessary).

The duties of the Graduated Plan Officer are defined in the AMG and in the Ordinance on the Production of Drugs and Active Substances (AMWHV). Due to the specifications in the AMWHV the tasks of the Graduated Plan Officer include additional obligations compared to the EU QPPV ( e.g. systematic recording of complaints and information of the competent authority about every defect that could lead to a recall or to an unusual restriction of sales).

Graduated Plan Officer must be sufficiently knowledgeable; a specific proof of knowledge is not (or no longer) required. The person must have sufficient professional qualifications to ensure compliance with the relevant regulations, in particular the company pharmacovigilance system.

This qualification can be acquired through professional training and practical experience. The professional qualification is assessed on a case-by-case basis and should be based on the product portfolio of the pharmaceutical company and the assessment of the possible drug risks associated with it (§ 19 Para. 1 AMWHV). Further details on this must be agreed with the competent state authorities.

There are no language requirements in the AMG. However, since communication with the authorities is predominantly in German, the Graduated Plan Officer, unless he speaks German himself, must have 24-hour access to a suitably qualified person.

Graduated Plan Officer can also be EU QPPV, an additional report by the phased plan officer is required.

The notification of the Graduated Plan Officer according to § 63a para. 3 AMG takes place via the PharmNet.Bund portal "Notification of the graduated plan officer".

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BfArM LCPPV FAQ

To see detailed answers from the national competent authority for questions related to the above legal requirements and guidance, see the FAQ on the Graduated Plan Officer.

## Registration

To appoint the LCPPV in Germany to BfArM, the company should register through the PharmNet.Bund registration site. The reporting portal is used to report graduated plan officers, deputies, change reports of persons or contact details, as well as deregister the named persons.

If the marketing authorization holder is located in Germany, they should find out what the requirements of the state authority are, and register the Stufenplanbeauftragter with them.

# Greece

LCPPV required?

YES

## Comments

» Referring to the below described legislation, the Greek national competent authority EOF has stated in the EMA document that 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.

## Legislation and Guidelines

Ministerial Decree no. ΔΥΓ3α/Γ.Π.32221ΦΕΚ 1049/29-04-2013:

ρθρου 11παράγραφος1. 1α.Ο κάτοχος της άδειας κυκλοφορίας είναι υπεύ-θυνος για την κυκλοφορία του φαρμάκου στην αγορά. Ο ορισμός αντιπροσώπου δεν απαλλάσσει τον κάτοχο της αδείας κυκλοφορίας από την κατά νόμο ευθύνη. Ο τοπικός αντιπρόσωπος ευθύνεται αυτοτελώς και παραλ-ήλως με τον κάτοχο της άδειας κυκλοφορίας. 2. Η άδεια που αναφέρεται στην παράγραφο 1 του παρόντος άρθρου, απαιτείται επίσης για τις γεννήτριες ραδιονουκλιδίων, kit και ραδιοφάρμακα, πρόδρομους ραδιονουκλιδίων, καθώς επίσης και για βιομηχανικώς παραγόμενα ραδιοφάρμακα.

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**Translation:**

1a. The Marketing Authorization Holder is responsible for the marketing of the medicinal product. The appointment of a representative does not relieve the holder of the marketing authorization from the statutory liability. The local representative is responsible independently and in parallel with the marketing authorization holder.
2. The authorization referred to in paragraph 1of of this Article is also required for generators radionuclides, kit and radiopharmaceuticals, precursors radionuclides, as well as for industrial radiopharmaceuticals produced.

## Registration

To appoint the LCPPV, their contact details are sent via email to adr@eof.gr. The nomination letter should include: Full name, Qualification (see Comments), Short CV, Telephone number for communication (company's and 24-hour availability), Fax number and Email.

# Hungary

LCPPV required?

YES

## Comments

» LCPPV must be appointed if the EU QPPV is located outside of Hungary.

» This contact person has to report to the EU QPPV. The LCPPV shall have a degree in life sciences, chemist or chemical engineering and has to be trained in pharmacovigilance.

## Legislation and Guidelines

**According to the NCA website, the Hungarian Decree 15/2012(VIII.22.)of the Ministry of Human Resources on the Pharmacovigilance of Medicinal Products for Human Use contains the following requirements for the LCPPV:**

- Appointment of a local pharmacovigilance contact is required if the EU QPPV does not reside in Hungary.
- The local pharmacovigilance contact reports to the EU QPPV.
- The local pharmacovigilance contact must meet the following requirements:
  - Holds a degree in life sciences, chemistry, or chemical engineering
  - Has been adequately trained on the reporting requirements to the EU-QPPV
  - This training is provided or acknowledged by the marketing authorisation holder

The marketing authorization holder must notify OGYÉI of the appointment or any changes of the EU QPPV and the local pharmacovigilance contact person, including their contact information.

**1. How should OGYÉI be notified on the person and contact details of the EU QPPV and the local pharmacovigilance contact? What documents should be submitted?**

MAHs must notify the Institute about the appointment or any changes of the EU QPPV and the local pharmacovigilance contact person, including their contact information via an electronic business portal (Cégkapu). The notification should be submitted on the day of launch of the activity, at latest, and copies of documents confirming qualification should be attached (latter requirement does not apply if the EU QPPV is residing/established outside Hungary). Compliance with all other requirements specified by the Decree is investigated by OGYÉI during pharmacovigilance inspections.

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### 2. When should the local pharmacovigilance contact be appointed?

As the scope of the Decree covers medicinal products used in the territory of Hungary; therefore, the local pharmacovigilance contact should generally start his/her activity simultaneously with the launch of the product to the Hungarian market. The local pharmacovigilance contact should be employed as long as the marketing authorisation(s) of the concerned medicinal product(s) is (are) valid in Hungary.

It may occur in certain instances that the medicinal product has not been launched in Hungary yet; nevertheless, patients have already been receiving it. Appointment of the local pharmacovigilance contact should be considered in this scenario on a case-by-case basis.

### 3. Should the local pharmacovigilance contact reside in Hungary?

Appointment of a local pharmacovigilance contact is required if the EU QPPV is not residing in Hungary. Consequently, the local pharmacovigilance contact should reside in Hungary.

### 4. Should the EU QPPV residing in Hungary or the local pharmacovigilance contact speak Hungarian?

A requirement placed by the Decree on the EU QPPV residing/established in Hungary is the knowledge on pharmacovigilance systems, and the ability to operate them. This obligation includes the handling of pharmacovigilance data originating from the territory of Hungary, i.e. collection, scientific assessment and management of such data in line with the rules of Hungarian public administration. To successfully comply with these requirements, a good command of the Hungarian language is essential. If the EU QPPV does not reside in Hungary, the local pharmacovigilance contact, as set out in the Decree, should assist the EU QPPV to comply with its legal obligations in terms of managing pharmacovigilance data originating from the territory of Hungary. Consequently, thorough command of the Hungarian language is expected also from the local pharmacovigilance contact.

### 5. What are the tasks of the local pharmacovigilance contact?

Tasks of the local pharmacovigilance contact are not specified item by item in the Decree; the pharmacovigilance legislation establishes tasks and obligations only for the MAH. Nevertheless, when specified in the Decree, the MAH should rely on the services of a local pharmacovigilance contact, in terms of fulfilment of pharmacovigilance activities (including communication with OGYÉI) concerning medicinal products used in Hungary. The delegation of tasks should be based on a formal agreement between the MAH and the local pharmacovigilance contact. Nevertheless, the responsibility for complying with legal obligations and tasks will always remain with the MAH.

### 6. Should the local pharmacovigilance contact be available in 24 hours/day and 7 days/week (24/7)?

The Decree does not establish such a requirement. Nevertheless, the MAH should operate its pharmacovigilance system in full compliance with all legal obligations. Availability of the local pharmacovigilance contact should be determined by the MAH in view of the above.

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**7. Should a deputy of the local pharmacovigilance contact be appointed? If yes, what requirements should he/she comply with?**

The Decree does not establish such a requirement. Nevertheless, the MAH should operate its pharmacovigilance system in full compliance with all legal obligations. Appointment of a deputy to the local pharmacovigilance contact should be considered by the MAH in view of the above.

## Registration

MAHs must notify the Institute about the appointment or any changes of the EU QPPV and the local pharmacovigilance contact person, including their contact information via an electronic business portal (Cégkapu).

# Iceland

LCPPV required?

NO

## Comments

» LCPPV is not required in Iceland.

## Legislation and Guidelines

**Not applicable in Iceland**

## Registration

Not applicable

# Ireland

LCPPV required?

NO

## Comments

» LCPPV is not required in Ireland.

## Legislation and Guidelines

**Not applicable in Ireland**

## Registration

Not applicable

# Italy

LCPPV required?

YES

## Comments

- In the EMA document, the requirement is "No".
- The comment from AIFA in the same document states that the appointment of LCPPV in Italy is not mandatory but someone must be registered to the national pharmacovigilance database in which all information is in Italian.
- If the EU QPPV knows Italian language it is not necessary to nominate a local contact person for pharmacovigilance for Italy.
- In practice, the LCPPV is indeed required, unless the EU QPPV speaks Italian.

## Legislation and Guidelines

On its website, the national competent authority AIFA provides guidance on their LCPPV requirements and how to appoint LCPPV and register them to the local safety system:

**2) For pharmaceutical companies**

- Connect to the Online Services website and fill in the registration form (see "Related Links").
- Connect to the Network and log in with the credentials received (new ID and password). After accessing, request the activation of the functionality "Pharmacovigilance" by filling in an electronic form similar to the previous one with the Company's data.
- Following registration of the electronic form, the company's legal officer shall transmit by fax to the number 06/59784142 or by email to the address: ReteFV@aifa.gov.it, an appointment note confirming the details of the appointed Person responsible for Pharmacovigilance, with attached documentation proving powers of the legal representative (e.g. copy of Company Registration Report).
- It is important to specify in the note whether the appointed Person responsible for Pharmacovigilance plays a role in the EU QPPV because in this case it is necessary to notify the EMA on the name by updating the European database provided for in Art. 57 of Regulation (EC) No 726/2004.
- The note shall specify if the registration relates to the function of "local contact" for Pharmacovigilance, indicating also the name of the EU QPPV (in this case it is not necessary to modify the Art. 57 database).

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**3) Request for the substitution of the Person responsible for Pharmacovigilance registered in the RNF**

In the case of a request for replacement of the previously registered Person responsible for Pharmacovigilance, the request for disabling the name must be included in the same note.

Once the documentation and the correct registration on the portal have been verified, AIFA enables the user who is required to access with his/her credentials and click on the link "pharmacovigilance" in order to complete the registration to the system.

In case the residence of the Person responsible for Pharmacovigilance is outside the Italian territory, considering that all the communications are presented exclusively in Italian, a "declaration" signed by the legal representative shall be attached, and with this declaration the MAH shall assume full responsibility for equipping itself with all those language interpretation resources that may be necessary in order to comply with regulatory obligations.

**4) For the Persons responsible for Pharmacovigilance already registered in the RNF**

In order to be able to associate an account in RNF to a second company, the responsible will have to access directly to the Network of Pharmacovigilance with his credentials (those of the already associated company), fill out a new registration form in the "new profile request" section and wait for endorsement.

## Registration

For registration follow the instructions described above under Legislation and Guidelines. For the nomination, the following documents are required:

- Nomination letter signed by the MAH representative
- Declaration letter signed by the EU QPPV
- Proof of signatory rights of the MAH representative
- Company register and copy of ID

# Latvia

LCPPV required?

YES

## Comments

» This is a requirement based in the Latvian law.

» LCPPV is mandatory unless the EU QPPV resides and works in Latvia.

## Legislation and Guidelines

Regulation No. 47 Pharmacovigilance Procedures states:

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;

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)

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)

## Registration

The LCPPV contact details are submitted to the Latvian NCA via email to info@zva.gov.lv.

# Liechtenstein

LCPPV required?

NO

## Comments

» LPPV is not required in Liechtenstein

## Legislation and Guidelines

The local legislation 1998.045812.103,article 13 states that:

3) Der Pharmakovigilanz-Verantwortliche muss im Europäischen Wirtschaftsraum ansässig und tätig sein und ist für die Einrichtung und die Führung des Pharmakovigilanz-Systems verantwortlich. Der Inhaber der Genehmigung für das Inverkehrbringen übermittelt dem Amt für Gesundheit und der Europäischen Arzneimittelagentur den Namen und die Kontaktangaben des Pharmakovigilanz-Verantwortlichen. Jede Änderung dieser Daten ist umgehend zu melden.

4) Unbeschadet des Abs. 3 kann das Amt für Gesundheit die Benennung einer Kontaktperson für Pharmakovigilanz-Fragen in Liechtenstein verlangen, die dem Pharmakovigilanz-Verantwortlichen Bericht erstattet.

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**Translation:**

3) The pharmacovigilance officer must be resident and active in the European Economic Area and is responsible for setting up and managing the pharmacovigilance system. The Marketing Authorization Holder shall provide the Health Office and the European Medicines Agency with the name and contact details of the Pharmacovigilance Officer. Any change to this data must be reported immediately.

4) Irrespective of paragraph 3, the Public Health Office may request the appointment of a contact person for pharmacovigilance issues in Liechtenstein, who will report to the pharmacovigilance officer.

## Registration

Further details would be shared by the national authorities, if the registration of LCPPV was ever requested by them.
In general, the Health Authorities in Liechtenstein can be reached at info.ag@llv.li

# Lithuania

LCPPV required?

NO

## Comments

» The EMA document states that according to the "local law on pharmacy" LCPPV may be requested by the Lithuanian NCA.

» However, during our review of the legislation, we have not found such statement in the text statement in the text.

## Legislation and Guidelines

**Not applicable in Lithuania**

## Registration

Not applicable

# Luxembourg

LCPPV required?

YES

## Comments

» The EMA document states that, according to national legislation, the nomination of an LCPPV is required in Luxembourg.

» The LCPPV should meet the following requirements:

- should reside and carry out his/her activities in the European Union
- should be reachable 24 hours a day, 7 days a week
- 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

» According to the EMA document and the LCPPV registration form, these requirements are from Grand-Ducal Regulation, as amended, of December 15, 1992 relating to the marketing of medicinal products, Article 45.-3, however the legislation does not mention the LCPPV.

» It makes sense to appoint the same person as in Belgium (if there is one already).

## Legislation and Guidelines

**The website of the national competent authority for Luxembourg contains a FAQ section that**

**Déclaration de la personne de référence en matière de pharmacovigilance (RPV) au niveau national**

Dans le cadre du système de pharmacovigilance, le titulaire de l'autorisation de mise sur le marché a de façon permanente et continue à sa disposition une personne possédant les qualifications appropriées, responsable pour la pharmacovigilance.La personne responsable pour la pharmacovigilance, réside et exerce ses activités dans l'Union Européenne.Le titulaire de l'autorisation de mise sur le marché communique à la direction de la Santé le nom et les coordonnées de la personne qualifiée, ainsi que de la personne de référence en matière de pharmacovigilance au niveau national rattachée à la personne qualifiée responsable pour les activités de pharmacovigilance.

- Formulaire de déclaration de la personne de référence en matière de pharmacovigilance (RPV) au niveau national (Notification of the contact person for pharmacovigilance at national level (or local person for pharmacovigilance/LPPV))

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**Translation:**

**Declaration of the reference person for pharmacovigilance (RPV) at national level**

Within the framework of the pharmacovigilance system, the marketing authorization holder has permanently and continuously at his disposal a person with the appropriate qualifications, responsible for pharmacovigilance. The person responsible for pharmacovigilance, resides and exercises its activities in the European Union The marketing authorization holder communicates to the Health Department the name and contact details of the qualified person, as well as of the reference person for pharmacovigilance at national level Reporting to the qualified person responsible for pharmacovigilance activities.

Reporting Form the person of pharmacovigilance reference (RPV) nationally (Notification of the Contact person for pharmacovigilance at national level (local or person for pharmacovigilance /LPPV).

# Registration

The LCPPV registration form is filled in and returned by email to pharmacovigilance@ms.etat.lu or by mail to Division de la pharmacie et des médicaments, 20, rue de Bitbourg, L-1273 Luxembourg Hamm, Grand Duchy of Luxembourg.

# Malta

LCPPV required?

NO

## Comments

» In the EMA document, the comment (from the NCA) is "No information available" but according to Guidance Notes from the Maltese Medicines Authority, "the Medicines Authority may request the nomination of a contact person for Pharmacovigilance issues at national level, reporting to the qualified person responsible for pharmacovigilance activities.

» If such a contact person is requested, this person may or may not be medically qualified. Unless specifically requested, it is the prerogative of each company to decide on the nomination of a person for pharmacovigilance."

## Legislation and Guidelines

Guidance Notes for Pharmaceutical Companies on Pharmacovigilance Obligations for Medicinal Products for Human Use, published in June 2020state:

The Medicines Authority may request the nomination of a contact person for Pharmacovigilance issues at national level, reporting to the qualified person responsible for pharmacovigilance activities. If such a contactpersonisrequested,thispersonmayormaynotbemedicallyqualified.Unlessspecificallyrequested, it is the prerogative of each company to decide on the nomination of a person for pharmacovigilance.

## Registration

The LCPPV can be nominated with a free text email notification to postlicensing.medicinesauthority@gov.mt

# Netherlands

LCPPV required?

YES

## Comments

» The EMA document states that the Netherlands requires a pharmacovigilance contact person at national level if the EU 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 LCPPV 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.

## Legislation and Guidelines

**As mentioned in the EMA document, the requirement of the LCPPV is not specified in the Dutch legislation, but Dutch regulatory authorities have outlined a general guidance for such a person.**

The national contact person for pharmacovigilance:

- acts as contact person with the authorities
- acts as contact person for patients and medical healthcare practitioners
- should be appointed at the moment that a marketing authorisation holder will market a product in the Netherlands.

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Guidelines for a national contact person

The MEB and the Health and Youth Care Inspectorate (IGJ) have compiled guidelines for a national contact person. This person:

- should have a thorough command of both spoken and written Dutch.
- should have knowledge of the relevant national legislation, guidelines and procedures.
- should have a medical qualification (university medical school graduate), or have access to someone with medical training. These arrangements must be clearly recorded.
- should maintain contact with the QPPV concerning the range of duties related to pharmacovigilance.
- should have a back–upprocedure in place in the event of absence.

## Registration

The LCPPV is notified to the MEB using a registration form.

# Norway

## LCPPV required?

**NO**

## Comments

» LCPPV is not required.

» NoMA has a Q&A on their website which states: The Norwegian Medicines Agency (NoMA) has not introduced any separate or additional Norwegian requirements. In particular, the MAH is not required to have a qualified person for pharmacovigilance (QPPV) residing in Norway.

## Legislation and Guidelines

**Not applicable**

## Registration

Not applicable

# Poland

LCPPV required?

YES

## Comments

» The EMA document comments from the NCA state that MAHs are required to designate an LCPPV, the LCPPV should speak Polish and that according to Polish legislation, the person shall fulfil the same requirements as the QPPV and shall live or have the office in Poland.

» Registration needs to be performed by sending a hard copy notification letter (specific NCA form) to the authority by mail.

## Legislation and Guidelines

**The Polish NCA website contains the following information:**

KOMUNIKAT

PREZESA URZĘDU REJESTRACJI PRODUKTÓW LECZNICZYCH, WYROBÓW MEDYCZNYCH I PRODUKTÓW BIOBÓJCZYCH z dnia 1 sierpnia 2014roku

w sprawie wskazania osoby do kontaktu w zakresie nadzoru nad bezpieczeństwem stosowania produktu leczniczego

Prezes Urzędu, w związku z przepisem art. 36g ust 3 ustawy Prawo farmaceutyczne (Dz. U. Nr 45 poz.271 z późn. zm.), prosi podmioty odpowiedzialne posiadające pozwolenia na dopuszczenie do obrotu produktów leczniczych o wskazanie osoby do kontaktu w zakresie nadzoru and bezpieczeństwem stosowania produktu leczniczego, która będzie posiadała miejsce zamieszkanialub siedzibę na terytorium Rzeczypospolitej Polskiej.

Osoba taka znająca język polski i pracująca w naszym kraju ułatwiłaby zgłaszanie działań niepożądanych przezpacjentów orazfachowych pracowników opieki zdrowotnej,w tymzbieranie wszystkichniezbędnych danych potrzebnych do oceny przypadku.

Wskazania osoby do kontaktu prosimy dokonywać w formie pisemnej, na formularzu stanowiącym załącznik do Komunikatu, Formularz zgłoszenia powinien zostać podpisany przez osoby upoważnione przez podmiot odpowiedzialny do reprezentowania.

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W przypadku posiadania lub wyznaczenia takiej osoby informację o tym fakcie prosimy przekazać do Urzędu Rejestracji najpóźniej do dnia 30 września 2014 roku. W przypadku wszelkich zmianach danych kontaktowych wskazanych osób prosimy o tym fakcie niezwłocznie informować Urząd.

Załączona do komunikatu tabela zawiera dane, o których wskazanie Urząd prosi.

Jednocześnie Prezes Urzędu, mając na względzie zdrowie publiczne, zwraca się z prośbą do podmiotów odpowiedzialnych o rozważenie możliwości umieszczenia danych ww. osoby na stronie internetowej podmiotów odpowiedzialnych lub przedstawicieli podmiotów odpowiedzialnych.

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**Translation:**

ANNOUNCEMENT

PRESIDENT OF THE MEDICAL PRODUCTS REGISTRATION OFFICE, MEDICAL DEVICES AND BIOCIDAL PRODUCTS of August 1, 2014

on the appointment of a contact person in the field of pharmacovigilance

The President of the Office, in connection with the provision of Art. 36g (3) of the Pharmaceutical Law (Journal of Laws No. 45, item 271, as amended), asks the marketing authorization holders for medicinal products to indicate a contact person for the supervision and safety of the medicinal product, which will be had the place of residence or seat in the territory of the Republic of Poland.

Such a person who knows the Polish language and works in our country would facilitate the reporting of adverse reactions by patients and healthcare professionals, including the collection of all necessary data needed for case assessment.

Please indicate the contact person in writing, on the form attached to the Communication, the application form should be signed by persons authorized by the responsible entity to represent.

If you have or appoint such a person, please provide information about this fact to the Registration Office by 30 September 2014 at the latest. In the event of any changes to the contact details of the indicated persons, please inform the Office immediately.

The table attached to the communication contains the data requested by the Office.

At the same time, the President of the Office, having regard to public health, asks the responsible entities to consider the possibility of placing the above-mentioned data. persons on the website of the responsible entities or the representatives of the responsible entities.

**The legislation referred to on the URPL website states:**

3. Prezes Urzędu może zwrócić się do podmiotu odpowiedzialnego z wnioskiem o wskazanie osoby do kontaktu w zakresie nadzoru nad bezpieczeństwem stosowania produktu leczniczego, posiadającej miejsce zamieszkania lub siedzibę na terytorium Rzeczypospolitej Polskiej, która podlega osobie, o której mowa w ust.

1 pkt 1. Osoba do kontaktu jest obowiązana spełniać wymagania określone w ust. 2 pkt 1.

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**Translation:**

3. The President of the Office may request the responsible entity to indicate a contact person in the field of safety oversight a medicinal product with a place of residence or seat in the territory of the Republic of Poland, which is subject to the person referred to in paragraph 1 point 1. The contact person is obliged to meet the requirements specified in sec. 2 point 1.

**Paragraph 1 point 1 states:**

1. Podmiot odpowiedzialny, który uzyskał pozwolenie na dopuszczenie do obrotu, jest obowiązany do:

1) wskazania osoby, do obowiązków której należeć będzie nadzór nad bezpieczeństwem stosowania produktów leczniczych;

**Translation:**

1. The MAH that has obtained a marketing authorization is obliged to:

1) indication of the person responsible for supervising the safety of medicinal products;

**And section 2 point 1 states:**

2. Osoba, o której mowa w ust. 1 pkt 1, jest obowiązana:

1) spełniać wymagania określone w art. 10 ust. 1 rozporządzenia wykonawczego Komisji (UE) nr 520/2012 z dnia 19 czerwca 2012 r. w sprawie działań związanych z nadzorem nad bezpieczeństwem farmakoterapii, o których mowa w rozporządzeniu (WE) nr 726/2004 Parlamentu Europejskiego i Rady i w dyrektywie 2001/83/WE Parlamentu Europejskiego i Rady;

**Translation:**

2. The person referred to in sec. 1, point 1, is obliged to:

1) meet the requirements set out in Art. 10 sec. 1 of the Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on pharmacovigilance activities referred to Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council;

## Registration

Send the completed registration form by mail to Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, Poland.

# Portugal

LCPPV required?

YES

## Comments

» The LCPPV in Portugal should meet the following requirements:

- be appointed by the marketing authorisation holder (MAH)
- located in Portugal
- perform its pharmacovigilance functions in a permanent and continuous way
- have appropriate training and experience in pharmacovigilance, knowledge of the Pharmacovigilance System in place and be fluent in Portuguese language

**The Excel table and the Appointment statement mentioned in the nomination process are currently not available on the Infarmed website. Here is a summary of the contents:**

**Statement:**

Dear <salutation>,

Marketing authorisation holder <MAH name>, here represented by the EU QPPV <EU QPPV name>, hereby notifies the INFARMED IP of the local contact person for pharmacovigilance (LCPPV) issues in accordance with Decree-law 176/2006, August 30th (current version) and CI n.º 145/CD/8.1.6, June 25th 2013.

Please find attached the signed declaration for your records

The EU QPPV contact details are the following:

- Name:
- Address:
- Landline/office telephone number:
- Mobile telephone (24/7):
- Fax:
- Email:

The LCPPV contact details to consider are the following:

- Name:
- Address:
- Landline/office telephone number:
- Mobile telephone (24/7):
- Fax:

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The new LCPPV is acting as such since <date> and for the following MAH medicinal products:

Excel column headers:

- MAH
- EU QPPV
- LCPPV
- Medicinal Product name
- Strength
- Pharmaceutical form
- Process number

# Legislation and Guidelines

**According to the National Legislation, Decree-Law n.º 176/2006, 30 August, in the present actualization, article n.º 170, number 5:**

O titular de uma autorização de introdução no mercado notifica previamente ao INFARMED toda e qualquer informação que pretenda transmitir ao público em geral, directamente ou através do responsável pela farmacovigilância, sobre questões de farmacovigilância.

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**Translation:**

The holder of a permit to enter the market notifies INFARMED in advance of any and all information it intends to transmit to the public in general, directly or through the person responsible for pharmacovigilance, on pharmacovigilance matters.

**The circular from Infarmed to marketing authorization holders on "Contact person for pharmacovigilance issues at national level" No. 145/CD/8.1.6 published on 25th June 2013 contains more information about the legal requirements, requirements for the LCPPV and for the appointment of LCPPV in Portugal.**

# Registration

The EU QPPV is responsible for the appropriate training and experience of the contact person and should declare it by issuing an appropriate statement.

To appoint the LCPPV the MAH should complete the Excel file that will be sent to each MAH by the email dam@infarmed.pt. The file should be sent along with the respective(s) statement(s) of the EU QPPV within 90 consecutive days to the email address dam@infarmed.pt

The contents of the file will be loaded directly into the Infarmed's database. Therefore, the information related to the EU QPPV and the LCPPV should be completed for each medicinal product, even in case of repeated information.

# Romania

## LCPPV required?

**NO**

(not in practice)

## Comments

- Romania is one of the countries where the EMA document's requirement does not seem to be aligned with the comment column and the national legislation and its practical implementation.
- The EMA document's comment says: "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."
- However, Article 815 is about advertising of medicinal products and the LCPPV requirement is described under Article 830.
- Either way, the NAMMD may request the appointment of an LCPPV, but it does not happen in practice.

## Legislation and Guidelines

The national Law 95/2006, Article 830, states:

(4) The qualified person referred to in under (3) a) shall reside and operate in the EU and should be responsible for the establishment and maintenance of the pharmacovigilance system. The marketing authorisation holder shall submit the name and contact details of the qualified person to the NAMMD and to the European Medicines Agency.

(5) Notwithstanding the provisions of paragraph (4), the NAMMD may require nomination of a contact person for pharmacovigilance issues at national level reporting to the qualified person responsible for pharmacovigilance activities.

## Registration

Not applicable

# Slovakia

## LCPPV required?

YES

## Comments

» The EMA document states that according to the national legislation (the act 362/2012,§68,art.13)SUKLcan require the MAH to nominate an LCPPV for Slovakia. It should be noted that the correct legislative reference is 362/2011,§68,art.14.

» Requirements for the LCPPV 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 outside of Slovakia, but pharmacovigilance activities have to be applied in Slovakia

» It makes sense to use the same contact person for both The Czech Republic and Slovakia.

## Legislation and Guidelines

According to the law on medicines and medical devices 362/2011,§68,art.14:

Kvalifikovaná osoba odpovědná za farmakovigilanci (§91a)

Držiteľ registrácie humánneho lieku je povinný určiť osobu zodpovednú za dohľad nad bezpečnosťou humánnych liekov s bydliskom v niektorom členskom štáte a kontaktnú osobu pre dohľad nad bezpečnosťou humánnych liekov v Slovenskej republike, ktorá je podriadená osobe zodpovednej za dohľad nad bezpečnosťou humánnych liekov. Držiteľ registrácie humánneho lieku oznámi štátnemu ústavu a agentúre meno, priezvisko a kontaktné údaje o týchto osobách.

**Translation:**

The holder of a marketing authorization for a medicinal product for human use is obliged to designate a person responsible for supervising the safety of medicinal products for human use residing in a Member State and a contact person for supervising the safety of medicinal products for human use in the Slovak Republic. The holder of the marketing authorization of a medicinal product for human use shall notify the state institute and the agency of the name, surname and contact details of these persons.

## Registration

Registration form is provided by SUKL (C. Nominated (contact) person for pharmacovigilance). The table should be completed in Slovak. The table should be filled in and sent as an attachment to an email with subject: "Oznámenie kontaktnej osoby pre farmakovigilanciu" or "Notification of nominated person for pharmacovigilance" to the email address: pharmacovigilance@sukl.sk

# Slovenia

## LCPPV required?

**NO**

(not in practice)

## Comments

» According to the EMA document, in the new Slovenian legislation which implements the new PhV regulation, it is written that it is possible but not obligatory to have an LCPPV in Slovenia.

» JAZMP has the possibility to require LCPPV for individual cases.

## Legislation and Guidelines

The Medicinal Products Act, Article 133 (duties of the marketing authorization holder), 6 states:

Če imetnik dovoljenja za promet z zdravilom nima sedeža v Republiki Sloveniji, lahko poleg odgovorne osebe določi tudi kontaktno osebo za farmakovigilanco v Republiki Sloveniji, ki ima izobrazbo medicinske, veterinarske ali farmacevtske smeri druge stopnje oziroma raven izobrazbe, ki v skladu z zakonom ustreza tej stopnji in je ustrezno usposobljena. Kontaktno osebo za farmakovigilanco imenuje tudi, če to zahteva JAZMP in o tem izda sklep. Kontaktna oseba je lahko poslovni s sedežem v Republiki Sloveniji ali posameznik s stalnim ali z začasnim prebivališčem v Republiki Sloveniji, ki izvaja farmakovigilančne dejavnosti za potrebe enega ali več poslovnih subjektov iz prvega in tretjega odstavka 20. Člena tega zakona oziroma enega ali več poslovnih subjektov, ki so imetniki dovoljenja za vnos oziroma uvoz zdravil.

Translation:

If the marketing authorization holder is not established in the Republic of Slovenia, they may, in addition to the responsible person, also designate a contact person for pharmacovigilance in the Republic of Slovenia who has a medical degree, veterinary or pharmaceutical courses of the second level or the level of education that corresponds to this level in accordance with the law and is suitably qualified. They also appoint a pharmacovigilance contact person if requested by the JAZMP and issues a decision to that effect. The contact person may be a business entity established in the Republic of Slovenia or an individual with permanent or temporary residence in the Republic of Slovenia performing pharmacovigilance activities for the needs of one or more business entities referred to in the first and third paragraphs of Article 20 of this Act or one or more business entities, who are holders of a permit for the import or import of medicinal products.

## Registration

Not applicable

# Spain

LCPPV required?

YES

## Comments

» LCPPV in Spain is required.

## Legislation and Guidelines

**LCPPV is required in Spain according to Royal Decree 577/2013, Article 14:**

Artículo 14. Persona de contacto de farmacovigilancia.

1. El titular de la autorización de comercialización deberá disponer en España, de manera permanente y continua, de una persona de contacto en materia de farmacovigilancia, y comunicará a la Agencia Española de Medicamentos y Productos Sanitarios los datos de contacto de la misma a través de un sistema electrónico que se proveerá a tal efecto. La persona designada deberá poseer la experiencia y formación adecuadas para la realización de sus funciones. La Agencia Española de Medicamentos y Productos Sanitarios mantendrá una base de datos de estas personas, que estará disponible para los órganos competentes de las comunidades autónomas.

2. La persona de contacto de farmacovigilancia asistirá a la persona cualificada responsable de farmacovigilancia europea referida en el artículo 8.3 en aquellas funciones que se le encomienden y colaborará en las siguientes funciones:

a) Recopilar, la información sobre todas las sospechas de reacciones adversas de las que tenga conocimiento el personal de la empresa, con el fin de que dicha información se incorpore en el registro referido en el apartado 1 del artículo 9, garantizando que:

1.º Se obtiene información exacta y verificable que permita la evaluación científica de las notificaciones de sospechas de reacciones adversas.

2.º Se recabe información de seguimiento sobre estas notificaciones.

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3.º En colaboración con el Sistema Español de Farmacovigilancia se detecten casos duplicados de sospechas de reacciones adversas.

4.º Se identifiquen adecuadamente las sospechas de reacciones adversas que el notificador haya informado que son consecuencia de un error de medicación.

b) Trasmitir a la persona responsable de farmacovigilancia de la Unión Europea referida en el artículo 8.3 cualquier solicitud de información adicional de la Agencia Española de Medicamentos y Productos Sanitarios necesaria para poder evaluar los beneficios y riesgos de un medicamento y dar respuesta a cualquier informaciónque la Agencia Española de Medicamentos y Productos Sanitarios le solicite relativa al volumen de ventas o de prescripciones del medicamento de que se trate en España.

c) Actuar como punto de contacto para proporcionar información a la Agencia Española de Medicamentos y Productos Sanitarios acerca de la ejecución en España de las medidas reguladoras adoptadas por razones de seguridad, así como de las acciones realizadas en España relativas a lo establecido en el plan de gestión de riesgos.

d) Establecer los procedimientos necesarios que garanticen el correcto funcionamiento de las actividades locales de farmacovigilancia.

e) Actuar como persona de contacto para las inspecciones de farmacovigilancia realizadas en España.

f) Cooperar con los centros autonómicos de farmacovigilancia facilitando toda la información de que disponga en relación con las notificaciones de sospechas de reacciones adversas a medicamentos.

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**Translation:**

Article 14.Pharmacovigilance contact person.

1.The marketing authorisation holder shall have in Spain, on a permanent and continuous basis, a contact person in the field of pharmacovigilance, and shall communicate to the Spanish Agency for Medicines and Health Products the contact details of the same through an electronic system that will be provided for this purpose.The designated person shall possess the appropriate experience and training for the performance of his or her duties. The Spanish Agency for Medicines and Health Products will maintain a database of these people, which will be available to the competent bodies of the autonomous communities.

2. The pharmacovigilance contact person shall assist the qualified person responsible for European pharmacovigilance referred to in Article 8.3 in those tasks entrusted to him or her and shall assist in the following tasks:

(a) Collect information on all suspected adverse reactions known to the staff of the undertaking, so that such information is entered in the register referred to in Article 9(1),ensuring that:

1º Accurate and verifiable information is obtained that allows the scientific evaluation of the reports of suspected adverse reactions.

2º Follow-up information is collected on these notifications

3º In collaboration with the Spanish Pharmacovigilance System, duplicate cases of suspected adverse reactions are detected.

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4º Suspicions of adverse reactions that the notifier has reported as a result of a medication error are adequately identified.

b) Transmitto the person responsible for pharmacovigilance of the European Union referred to in article 8.3 any request for additional information from the Spanish Agency for Medicines and Health Products necessary to be able to evaluate the benefits and risks of a medicine and respond to any information that the Spanish Agency for Medicines and Health Products requests regarding the volume of sales or prescriptions of the medicine in question in Spain.

c) Act as a point of contact to provide information to the Spanish Agency for Medicines and Health Products about the execution in Spain of the regulatory measures adopted for safety reasons, as well as the actions carried out in Spain related to the provisions of the risk management plan.

(d) Establish the necessary procedures to ensure the proper functioning of local pharmacovigilance activities.

e) Act as a contact person for pharmacovigilance inspections carried out in Spain.

f) Cooperate with the regional pharmacovigilance centres by providing all the information available to them in relation to the notifications of suspected adverse reactions to medicinal products.

## Registration

The appointment of the LCPPV in Spain is notified using an online form on the AEMPS website following the user manual for pharmaceutical industry.

# Sweden

LCPPV required?

NO

## Comments

» LCPPV is not required in Sweden.

## Legislation and Guidelines

**Not applicable in Sweden**

## Registration

Not applicable

# Non-EEA Countries

## Comments

» Outside of EEA, it's worth noting that contact persons are required in Switzerland and United Kingdom (or guidance, in case of MHRA).

# Any questions?

If you need local Pharmacovigilance expertise, we are here to support you, anywhere in the world.

Visit our website www.tepsivo.com to learn more about our unique approach to PV services, or contact us directly at contact@tepsivo.com

Thank you for reading!
Martti Ahtola, 2024

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