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Transition period (https://www.gov.uk/transition)
Guidance

Guidance on qualified person responsible for pharmacovigilance (QPPV) including pharmacovigilance system master files (PSMF) from 1 January 2021

Pharmacovigilance system requirements from 1 January 2021

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From:
Medicines and Healthcare products Regulatory Agency
(https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)

New rules for January 2021

The UK has left the EU, and the transition period after Brexit comes to an end this year.

This page tells you what you'll need to do from 1 January 2021. It will be updated if anything changes.

For current information, read: European Medicines Agency: Legal framework: Pharmacovigilance (https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance/legal-framework-pharmacovigilance)

You can also read about the transition period (https://www.gov.uk/transition).

Contents

From 1 January 2021, the following legal obligations will apply to holders of UK marketing authorisations (MA). These include those that cover the whole of the UK, or are specific to Northern Ireland or to Great Britain (England, Wales and Scotland):

- To operate a pharmacovigilance system for UK authorised products.

- To have an appropriately qualified person responsible for pharmacovigilance (QPPV) that resides and operates in the EU or the UK and is responsible for the establishment and maintenance of the pharmacovigilance system for UK authorised products.
- To maintain and make available upon request a pharmacovigilance system master file (PSMF) that describes the pharmacovigilance system for UK authorised products. The PSMF must be accessible electronically or physically from the UK at the same site at which reports of suspected adverse reaction may be accessed.

Guidance on the QPPV for UK authorised products

For all UK MAs, including those that cover the whole of the UK or are specific to Northern Ireland or to Great Britain, the marketing authorisation holder (MAH) must have permanently and continuously at its disposal a QPPV who resides and operates in the EU or the UK, and is responsible for the establishment and maintenance of the pharmacovigilance system.

This is provided for by regulation 182 of the Human Medicines Regulations 2012 (as amended) (HMR).

For MAs that cover the whole of the UK or are specific to Northern Ireland, the legal requirements concerning the qualifications and responsibilities of the QPPV that are outlined in Article 10 of the Commission Implementing Regulation (EU) No 520/2012 (CIR) will remain unchanged.

For MAs that are specific to Great Britain, legal requirements concerning the qualifications and responsibilities of the QPPV are outlined in paragraph 10 of HMR Schedule 12A (inserted by the EU Exit Regulations 2019), which mirrors Article 10 of CIR.

Statutory guidance concerning the QPPV for UK authorised products is described in the Good Pharmacovigilance Practices (GVP) Module I. This guidance will be supplemented by the ‘Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders’, which will be published in due course.

There will be no temporary exemption as to the requirement to have a QPPV who resides and operates in the EU or the UK and is responsible for the pharmacovigilance system for UK authorised products. This requirement applies from 1 January 2021.

National contact person for pharmacovigilance

If you choose to establish a QPPV who resides and operates in the EU, you must nominate a national contact person for pharmacovigilance who resides and operates in the UK and reports to the QPPV. This individual should have access to the reports of suspected adverse reactions referred to in regulation 187 of the HMRs and the PSMF for UK authorised products. The individual should be able to facilitate responses to pharmacovigilance queries raised by the MHRA, including via inspections.

There will be a temporary exemption in place which allows you 12 months from 1 January 2021 to appoint a national contact person for pharmacovigilance that resides and operates in the UK. Further guidance on the process for notifying the details of the national contact person for pharmacovigilance to the MHRA will be published in due course.

Guidance on the PSMF for UK authorised products

For all UK MAs, including those that cover the whole of the UK or are specific to Northern Ireland or to Great Britain, the MAH must maintain, and make available upon request of the MHRA, a PSMF that describes the pharmacovigilance system for UK authorised products.

PSMF location and accessibility

For MAs that cover the whole of the UK or are specific to Northern Ireland, the PSMF must be located either at the site in the European Union where the main pharmacovigilance activities are performed or at the site where the QPPV operates, in accordance with Article 7(1) of the CIR. The PSMF must be accessible electronically at the same point in the UK from which the reports of suspected adverse reactions referred to in regulation 187 of the HMRs are accessible.

For MAs that are specific to Great Britain, the PSMF must be accessible electronically at the same point in the UK from which the reports of suspected adverse reactions referred to in regulation 187 of the HMRs are accessible.

The PSMF needs to be permanently and immediately available for inspection at the stated location in the UK.

PSMF format, content and representation of pharmacovigilance systems

For MAs that cover the whole of the UK or are specific to Northern Ireland, the legal requirements concerning the format and content of the PSMF that are outlined in Chapter I of CIR will remain unchanged.

For MAs that are specific to Great Britain, legal requirements concerning the format and content of the PSMF are outlined in Part 1 of Schedule 12A of HMR, which mirrors Chapter I of CIR.

As the legal requirements concerning PSMF format and content are identical for MAs that cover the whole of the UK and Northern Ireland, and those that are specific to Great Britain, a single PSMF can be used for all UK authorised products. This is assuming that the pharmacovigilance system applied to all products is the same.

Statutory guidance concerning the PSMF for UK authorised products is described in GVP Module II. This guidance will be supplemented by the ‘Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders’, which will be published in due course.

The PSMF must describe the global pharmacovigilance system and reflect the global availability of safety information for UK authorised products.

As per GVP Module II, there are different approaches to establishing a pharmacovigilance system. For example:

- MAHs can establish more than one pharmacovigilance system
- A pharmacovigilance system can be shared by several MAHs

The PSMF should be an accurate representation of the pharmacovigilance system that has been established and you must make sure that every pharmacovigilance system covering UK authorised products has been assigned a unique PSMF number by the MHRA.

How to request a UK PSMF number

All PSMFs that cover UK authorised products should be registered with the MHRA. You should request a unique UK PSMF number from the MHRA for each pharmacovigilance system that you are operating for UK authorised products. Where the pharmacovigilance system is shared by several MAHs, a single request for a UK PSMF number should be submitted to the MHRA.

A UK PSMF number can be requested via the MHRA Submissions Portal (https://www.gov.uk/guidance/making-submissions-to-the-mhra-in-a-no-deal-scenario) from 1 January 2021. You should follow the online instructions for requesting a UK PSMF number and you should receive the number by email immediately upon completion of the form.

You are encouraged not to request the UK PSMF number until you are notifying the MHRA of a change in the details of the QPPV for UK authorised products from the baseline information held by the MHRA.

The baseline information will be the QPPV details that were registered in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) on 31 December 2020.

Further guidance regarding the notification of QPPV and PSMF details to the MHRA for new and existing holders of UK marketing authorisations will be published in due course.

Queries

General queries relating to the QPPV, PSMF and establishment of pharmacovigilance systems for UK authorised products should be sent to: gpvpinspectors@mhra.gov.uk

Queries relating to the UK PSMF number should be sent to: UKPSMFadmin@mhra.gov.uk

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Transition period

Find out what it means for you (https://www.gov.uk/transition)

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Collection

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