Part of
UK and EU transition: new rules for 2021 (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

- Notification of QPPV and PSMF details to XEVMPD
- Queries

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), including Great Britain MAs granted to allow unfettered access from Northern Ireland.

- 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 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. Where the QPPV is not in the UK, there will be a need for a national contact person for pharmacovigilance as set out below.

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.

Once the national contact person for pharmacovigilance has been appointed, their details should be notified to the MHRA via the MHRA Submissions Portal. You should follow the instructions for submitting these details. You should receive a confirmation by email immediately upon completion of the form.

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/registering-to-make-submissions-to-the-mhra-from-1-january-2021) 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 either applying for a new UK marketing authorisation or 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.

Guidance for applicants for UK marketing authorisations from 1 January 2021

The material to accompany an application for a UK marketing authorisation includes a summary of the applicant's pharmacovigilance system (SPS).

This must include the following elements:

1. proof that the applicant has at their disposal an appropriately qualified person responsible for pharmacovigilance who resides and operates in the EU or the UK,
2. the country (which must be either the UK or a Member State) in which the appropriately qualified person resides and carries out his or her tasks
3. the contact details of the appropriately qualified person
4. a statement signed by the applicant which says that they have the necessary means to fulfil the tasks and responsibilities listed in Part 11
5. a reference to the location where the pharmacovigilance system master file for the medicinal product can be accessed electronically, which must be in the UK

The SPS should also include the UK PSMF number.

The above is following HMR Schedule 8.

Guidance on the application process and on registering to make submissions via the MHRA Submissions Portal is available.

You should use Agency Activity Reference ID: G0001 – Initial Marketing Authorisation Application and Subactivity Text: H002 – "Original Submission".

Information on the QPPV and PSMF for UK authorised products should be entered in section 2.4.4 of the electronic application form (eAF). You should note the following:

- if the QPPV for UK authorised products resides and operates in the UK, the checkbox entitled "The above-mentioned qualified person resides and operates in the EEA" can remain unchecked.
- the UK location where the PSMF can be accessed from does not need to be registered in the Article 57 database, therefore the associated checkbox can remain unchecked.

Notification of QPPV and PSMF details to the MHRA by existing holders of UK marketing authorisations

You should submit Type IAIN variations related to the SPS to the MHRA and these submissions should cover all UK product licences (PL) under a unique pharmacovigilance system.

How to make your submission

All applications to update the SPS are required to be submitted as a Type IAIN - C.I.8 variation via the MHRA Submissions Portal. You should use Agency Activity Reference ID: G0098 – Variation Type IA - Establishing UK QPPV-PSMF and Subactivity Text: H002 – "Original Submission".

From 1 January 2021 we are expecting a large volume of regulatory submissions. You should submit your SPS updates as single changes and, to prevent delays, you should submit in collections of no more than 25 PLs.

You should submit no more than two collections in a single package or within a single week without prior notification.

You may contact the MHRA at IPUScientificValidation@mhra.gov.uk to discuss and agree the submission schedule and the processing timelines. Please include reference 'PSMFT1' in the email subject line.

Documentation you need to supply

You should supply the following documentation in a C.I.8 submission (Introduction of, or changes to, a summary of pharmacovigilance system for medical products for human use):

- Proof that the applicant has at their disposal a qualified person responsible for pharmacovigilance and a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Part 11
- The country (which must be either the UK or a Member State) in which the appropriately qualified person resides and carries out their tasks
- Contact details of the appropriately qualified person who resides and operates in the EU or the UK
- A reference to the location where the PSMF for the medicinal product can be accessed, which must be in the UK
- UK PSMF number

Failing to supply all required documentation and information may lead to a rejection of the submission, which will require you to make a resubmission addressing all discrepancies.

The requirements for various categories of variations are outlined in the guidelines published by the Commission under Article 4 of Regulation (EC) No 1234/2008.

Submission timeframes

From 1 January 2021, you must notify the MHRA of the details in the SPS following any changes to the QPPV responsible for UK authorised products from the baseline information held by the MHRA. The baseline information is the QPPV details that were registered in XEVMPD on 31 December 2020.

The submission of SPS details for licences that were authorised via the EU centralised procedure should be handled differently to UK national licences. Please refer to the Submission timeframe overview (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/929062/Submission_Timeframes_Overview_v6.pdf) (PDF, 12.3KB, 1 page) which has an overview of the timeframes for submitting SPS details to the MHRA. Further details for the different licence types are provided below.

Guidance relating to UK national licences (including those authorised via mutual recognition or decentralised procedures)

From 1 January 2021, if the identity, location and contact details of the QPPV responsible for UK authorised products are identical to that of the EU/EEA QPPV immediately prior to 1 January 2021 (as entered in XEVMPD), no immediate action is required to notify the MHRA.

Within two weeks of a change of identity, location or contact details of the QPPV responsible for UK authorised products, you should submit a single change Type IAIN - C.I.8 variation. This should cover all UK PLs under a unique pharmacovigilance system (in collections of no more than 25 PLs).

If you anticipate no changes to the QPPV details from those entered in XEVMPD by 30 June 2022, then these details for the QPPV, together with the UK location that the PSMF can be accessed from and UK PSMF number, should be submitted as a single change Type IAIN - C.I.8 variation by this deadline.

Licences authorised via the EU centralised procedure

All existing MAs authorised through the centrally authorised procedure will automatically be converted into UK MAs. These MAs will be issued with a UK MA number before the end of the transition period.

You will have a period of one year, starting on 1 January 2021, to submit the baseline initiating sequence data and related information in eCTD format.

At the point of submission of the baseline initiating eCTD sequence you should follow the following guidance:

If the identity, location or contact details of the QPPV responsible for UK authorised products are different to that of the EU/EEA QPPV immediately prior to 1 January 2021 (as entered in XEVMPD), you should simultaneously submit a Type IAIN - C.I.8 variation as a separate sequence in the same submission package. This variation will be processed once the baseline sequence is processed.

If the identity, location and contact details of the QPPV responsible for UK authorised products are identical to that of the EU/EEA QPPV immediately prior to 1 January 2021 (as entered in XEVMPD), no immediate action is required to notify the MHRA. Following receipt of the baseline sequence approval letter from the MHRA, you should take the following actions:

- Within two weeks of a change of identity, location or contact details of the QPPV responsible for UK authorised products, you should submit a single change Type IAIN - C.I.8 variation. This should cover all UK (ex-EU) PLs under a unique pharmacovigilance system (in collections of no more than 25 PLs).
- If you anticipate no changes to the QPPV details from those entered on XEVMPD by 30 June 2022, then the details of the QPPV and PSMF should be submitted by this deadline.

Notification of QPPV and PSMF details to XEVMPD

Prior to 1 January 2021, you must continue to submit QPPV and PSMF details for all UK authorised products to XEVMPD (also known as the Article 57 database), including any changes to these details.

From 1 January 2021, for products in respect of Northern Ireland (UK-wide and Northern Ireland-only MAs), in addition to notifying the QPPV and PSMF details to the MHRA, you must also continue to submit this information to the Article 57 database in accordance with Regulation (EC) No 726/2004 Article 57(2).

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

Queries relating to submission of Type IA variations should be sent to variationqueries@mhra.gov.uk

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1. 23 October 2020
   Added new section on Guidance for applicants for UK marketing authorisations from 1 January 2021.
2. 4 September 2020
   First published.

Transition period

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

Related content

- Renewing Marketing Authorisations for medicines from 1 January 2021 (https://www.gov.uk/guidance/renewing-marketing-authorisations-for-medicines-from-1-january-2021)
- How Marketing Authorisation Applications referred under Article 29 will be handled from 1 January 2021 (https://www.gov.uk/guidance/how-marketing-authorisation-applications-referred-under-article-29-will-be-handled-from-1-january-2021)
- Reference Medicinal Products (RMPs) from 1 January 2021 (https://www.gov.uk/guidance/reference-medicinal-products-rmps-from-1-january-2021)

- Converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs) from 1 January 2021, 'grandfathering' and managing lifecycle changes (https://www.gov.uk/guidance/converting-centrally-authorised-products-caps-to-uk-marketing-authorisations-mas-from-1-january-2021-grandfathering-and-managing-lifecycle-chan)
- Registering to make submissions to the MHRA from 1 January 2021 (https://www.gov.uk/guidance/registering-to-make-submissions-to-the-mhra-from-1-january-2021)

Collection

- MHRA post-transition period information (https://www.gov.uk/government/collections/mhra-post-transition-period-information)

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- Vigilance, safety alerts and guidance (https://www.gov.uk/topic/medicines-medical-devices-blood/vigilance-safety-alerts)