Austrian
Federal Office for
Safety in Health Care
BASG

FAQ pharmacovigilance NEW

Periodic Safety Update Reports (PSUR) NEW

For which kinds of medicinal products should PSURs be submitted?

1. for all active substances and combinations of active substances which are according to the EURD list required to submit a PSUR. These PSURs are part of the PSUSA process (PSUR Single assessment).
2. For all pure NAP procedures, not listed on the EURD list

A submission for full and hybrid applications is mandatory.

Generics, bibliographic ("well established use") authorisations as well as traditional herbal medicinal products, homeopathic products and officinal formulations are exempted from the submission of a PSUR. Nevertheless these products must submit PSURs if:

- such an obligation was issued as a condition or requirement for granting an authorization or registration
- the Austrian Federal Office for Safety in Health Care requests a submission due to safety concerns

Marketing authorisation holders of homeopathic human medicinal products are informed that since 01.01.2020 [i.e. from the Data Lock Point: 30.09.2019] no further PSUR submissions are necessary, unless they are ordered by the BASG on a case-by-case basis.

Are amendments to the EURD-list possible?

Yes – the marketing authorisation holder can submit requests for amendment on one of the following grounds:

- for reasons relating to public health;
- in order to avoid a duplication of the assessment;
- in order to achieve international harmonisation.

Requests for amendments should be submitted using the template (available on the EMA-homepage) and sent to eurdlist@ema.europa.eu.

Do herbal medicinal products require a PSUR?

Traditional herbal medicinal products registered under Austrian Medicinal Products Act §12 are exempt from submitting a PSUR.

If the herbal active substance or combinations of active substances **is listed on the EURD list**, the submission of a PSUR is required as laid out by the list.
If the active substance or combination of active substances in herbal medicinal product is **not listed on the EURD list**, products that have been approved

according to 10(1) and 10(a), do not have to submit PSURs, unless otherwise specified in the marketing authorisation.

If specific safety monitoring measures (eg. cumulative reviews of specific suspected adverse events) have been imposed on a reference product, do these measure also apply to generic medicinal products? Do these reviews have to be submitted to the Austrian Federal Office for Safety in Health Care (BASG)?

Independent of the type of authorisation procedure, all MAH are obliged by law (AMG §75i(1)) to submit pharmacovigilance data, in order to determine whether

- new risks have been identified,
- known risks have changed, or
- the risk-benefit balance for the medicinal product has changed,

necessitating the implementation of additional surveillance measures. Measures such as “close monitoring” or “cumulative review” can be part of this obligation.

Although medicinal products authorised under Articles 10a of Directive 2001/83/EC are exempted from routine submission of PSURs. However, PSURs may become obligatory, if pharmacovigilance data raise concerns about the risk-benefit balance of the product (see §75m AMG)

Which submission intervals apply?

If the active substance or combinations of active substances are listed on the EURD list, the submission of a PSUR is mandatory for all mentioned MAHs as laid out by the list. PSURs have to be submitted exclusively in accordance with the specified data lock points and submission dates.

If an active substance is not listed on the EURD list, a PSUR must be submitted with the conditions specified in the marketing authorisation by the BASG.

Medicinal products that have been authorized according to 10(1) and 10(a) do not have to submit a PSUR if the active substance or the combination of active substances is not listed on the EURD list, unless otherwise specified in the marketing authorisation.

The Austrian Federal Office for Safety in Health Care (BASG) specifies the frequency of submission of PSURs in the marketing authorisation documentation.

The due date for submission is calculated based on the PSUR frequency specified in the marketing authorisation documentation, starting on the date the marketing authorisation comes into force.

If the intervals for submission have not been specified in the marketing authorisation documentation (applicable to products authorised before Austrian federal law BGBl. I Nr. 110/2012 came into force), PSURs should be submitted in according with the following:

- If the medicinal product has not been marketed: minimum of 6-monthly intervals after authorisation;
- If the product has been marketed: minimum of 6-monthly intervals for the first 2 years after authorisation, followed by yearly submissions for the next 2 years, followed by 3-yearly intervals;
- Immediately upon request by the Austrian Federal Office for Safety in Health Care (BASG)

The specifications outlined above are valid unless other intervals for submission are specified in the conditions of the marketing authorisation other deadlines for submission are defined or the active substance/the combination of active substances is included to the EURD list.

How are changes to the frequency of submission of PSURs announced and how can amendments be requested?

For medicinal products, whose active substances or combinations of active substances are listed in the EURP-list, the frequency of submission of PSURs and date for submission is determined by the Data Lock Point (DLP) given in the EURD-list.

Normally, notifications of changes to the PSUR submission are not necessary as long as these changes are in line with the DLP of the EURD-list. If, however, other intervals for submission are specified in the conditions of the marketing authorisation or a pre-existing risk management plan, changes to the frequency of submission have to be announced.

The MAH is obliged to keep up to date with potential changes to the EURD-list on a monthly basis.

For medicinal products, whose active substances or combinations of active substances are not listed in the EURP-list, but are mandatory for PSUR submission, changes to the frequency of submission of PSURs can be requested from the department of pharmacovigilance by using the form F_B23 PSUR Zyklus Änderung in accordance with Austrian Medicinal Products Act §75k.

What about medicinal products (generic, hybrid or well-established use) containing active substances or combinations of active substances not listed in the EURD-list?

A PSUR for an active substance or a combination, which is not on the EURD list, should generally be submitted nationally (at the PSUR repository as "non-EU single assessment") if a PSUR submission is mandatory (see above),However, if the active substance / combination is authorised in more than one country and it is a full application/hybrid application the EMA should be informed.(eurdlist@ema.europa.eu)

How to submit the PSUR?

PSUR submission to the PSUR repository became mandatory on June 13, 2016. The PSUR Repository offers a secure electronic submission point for Marketing Authorisation Holders (MAH) and acts as a common storage place for PSURs, PSUR Assessment Reports (ARs), comments and final outcomes.

Both PSURs for PSUSA-procedures ("EU-single assessments") and PSURs for national PSUR submissions ("non-EU single assessments") have to be uploaded in the PSUR repository. CESP-Submissions, CD-ROMs etc. are considered as not submitted.

For more detailed information and help for electronical submission please refer to PSUR Repository website, numerous trainings, webinars and MAH user guide.

Which requirements apply to the content and format of a PSUR?

The format and content of the PSUR, is described in the Guideline on good pharmacovigilance practices (GVP) Module VII – Periodic safety update report.

PSUR submission and eCTD

MAH, who have not yet submitted their documents in eCTD format, but in NeeS format, should prepare the next PSUR submission in the following way:

- Create a baseline in eCTD with the sequence 0000, which includes at least the documents of module 3.
- Submit the PSUR to the PSUR repository. In eCTD the PSUR will then be assigned to the next available sequence (0001 in this case).

Fees for PSUR submission - please refer to Fee Regulation

PSUR Repository NEW

What is the PSUR Repository?

The PSUR Repository is a common storage place for the PSURs, the regulators' PSUR Assessment Reports (ARs), comments, responses from the MAHs and final outcomes. National Competent Authorities (NCAs) have direct, secure access to the Repository. More information on the PSUR Repository can be found here.

How are PSUR submissions changing?

Since 13 June 2016, it is mandatory for all MAHs in the EU to submit PSURs for human medicines directly to the PSUR Repository. The PSUR repository is mandatory for both centrally and nationally authorised medicines whether they follow the EU single assessment or a purely national assessment procedure. The PSUR Repository is intended for PSURs for human medicines only.

After 13 June 2016, what happens if a PSUR is not submitted to the PSUR Repository?

PSURs that have not been sent to the PSUR Repository are considered as not submitted and will not be assessed. PSURs not sent to the PSUR repository will not fulfil the MAH's legal obligation to submit PSURs.

How do I submit a PSUR?

All PSURs are submitted to EMA's PSUR Repository using the eSubmission Gateway/ Web Client: http://esubmission.ema.europa.eu/esubmission.html

In order to submit a PSUR to the PSUR Repository via the eSubmission Gateway / Web Client all users must register using the registration functionality. PSURs must be submitted exclusively as an Electronic Common Technical Document (eCTD)). PSURs submitted in any other electronic format cannot be uploaded into the PSUR Repository and will be rejected.

Information on the Repository, guidance on how to register and multimedia tutorials for MAHs on how to submit a PSUR, as well as on the correct structured electronic formats, can be found on the EMA's PSUR Repository web pages here.

What steps do I have to take before I can submit a PSUR to the PSUR Repository?

Prior to submission to the PSUR Repository, MAHs must ensure that the information on their authorised medicines is entered correctly in the extended EudraVigilance medicinal product dictionary (XEVMPD), also named Article 57 database. This is a legally binding requirement from the EU pharmaceutical legislation.

The PSUR Repository product selection is connected to the Article 57 database. If a product has not been correctly included in this database, it will not be or not correct displayed in the PSUR Repository.
More information about the submission of information on medicines in the Article 57 database is available on the EMA website here.

Who can I contact to help me with my queries on PSUR Repository?

Users should directly contact the EMA to send their questions or report any issues they have with the PSUR repository and/or the eSubmission Gateway/ Web Client to the EMA Service Desk portal.

Which cover letter should be used for the PSUR submission to the PSUR repository? What should be observed using the cover letter?

For PSUSA procedures: The previously used formatted letter template is now no longer supported by the EMA (no longer available on the EMA homepage), but may continue to be used. The essential submission data are now contained in the XML delivery files.

To avoid problems when creating delivery files via the eSubmission Gateway XML delivery file User Interface, it is recommended to delete cookies and update the browser.

Purely national procedures (non-EU single assessments): The previously used formatted letter template is now no longer supported by the EMA (no longer available on the EMA homepage), but may continue to be used. The essential submission data are now contained in the XML delivery files.

In the PSUR repository, it is essential to uncheck "Subject to or related to a single assessment" when creating the file at Submission type.

For more information on submission, see the following website: PSUR Repository user guide for MAH submissions (europa.eu)

Further information about the PSUR repository can be found here: esubmission.ema.europa.eu/psur/psur_repository.html

Please pay attention to the „MAH PSUR repository User Guidance document".https://esubmission.ema.europa.eu/psur/docs/PSUR%20Repository%20user%20guide%20for%20MAH%20submissions.pdf

Can delivery files be re-used?

The delivery file describes the meta data of a PSUR submission (e.g. the respective product). As the PSUSA number is part of this information and future format changes of the delivery file cannot be excluded, **delivery files should not be re-used.**

Could EMA inform, how many MAHs are going to participate in a starting PSUSA procedure?

No, not at the moment. Only information about chargeable units for the respective marketing authorisation holder will be sent out.

PHV documents for renewal procedure NEW

Requirements for PHV renewal documents:

Irrespective of the "CMDh BEST PRACTICE GUIDE ON THE PROCESSING OF RENEWALS IN THE MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES" submission of the following data is required for a renewal procedure in Austria:

AT=RMS: An "Addendum to the clinical overview" should be submitted
AT=CMS: An "Addendum to the clinical overview" is currently only required if requested by the RMS.
Nationally approved:
An addendum is required, irrespective of a full, hybrid, generic, well-established use, traditional herbal or homeopathic application.

The "Addendum to the clinical overview " should cover the period from the date of approval to the date of submission of the renewal.

Sales data (post marketing exposure data) for Austria should be provided in the addendum.

„Apothekeneigene Zulassungen"are exempted from PSUR submission. However, identification of safety relevant aspects requires the submission of pharmacovigilance data.

Consultants tracking PSUR-procedure

Who can view the status of a PSUR-procedure on the eService platform "Marketing Authorisation & Lifecycle Management of Medicines"?

The Marketing Authorisation Holder can track the PSUR-procedure status after the procedure has been started.
To use the eService a singular registration under the following link is necessary: https://kundenregistrierung.basg.gv.at/kundenregistrierung/faces/main

How does a consultant get the authorization to track the PSUR-procedure status on the eService platform "Marketing Authorisation & Lifecycle Management of Medicines"?

Please take into consideration that the consultant also needs to be registered on the eService platform:
https://kundenregistrierung.basg.gv.at/kundenregistrierung/faces/main

Can the MAH of a generic product, for which no PSUR is requested, receive the assessment report of a PSUSA procedure?

No, but the outcome of the PSUSA will be published on the EMA homepage or on the BASG homepage:
https://www.basg.gv.at/en/companies/pharmacovigilance/pv-wordings

Risk Management Plans (RMP) NEW

Which medicinal products require RMPs?

At the time of application for a marketing authorisation, companies must submit an RMP as part of the dossier to the Agency. This also applies to medicinal products applying for marketing authorisation using referencing pathways (§10 of the Austrian Medicinal Products Act).

Traditional herbal medicinal products and homeopathic medicinal products authorised under Austrian Medicines Act §11 are exempt from submitting an RMP.

Furthermore, existing authorisations are required to submit RMPs and are obliged to continually modify and update their RMPs:
when significant changes to the marketing authorisation are applied for, such as:

- new dosage,
- new type of application or pharmaceutical form,
- new manufacturing processes (for biotechnologically produced substances),
- paediatric indication, or
- other significant changes to the indications.
- at the request of the Austrian Federal Office for Safety in Health Care (BASG) or the Austrian Agency for Health Care and Food Safety (AGES), as the result of new information being received that may lead to a significant change to the benefit-risk profile
- resulting from application for renewal

When should RMP be updated?

RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. Companies need to submit an updated RMP whenever a significant change in the benefit-risk balance is detected or new information is being received that lead to changes in the pharmacovigilance plan or risk minimisation measures.

Attention should bei paid, that alterations to the RMP should be submitted in the clean finalized version, as well as the tracking mode, which highlights all changes to the original document.

What format should the RMPs have?

The risk management system should present the identified and potential risks of the medicinal product and relate it to the need for post-authorisation safety data.

For guidance on the format for RMPs please consult Guideline on good pharmacovigilance practices: Module V – Risk-management systems. The templates for the RMPs can be taken from the respective:

- Guidance documents
- https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-format-risk-management-plan-rmp-eu-integrated-format-rev-201_en.pdf

What information in connection with RMPs will be made public?

- A public summary (Part VI: Summary of the Risk Management Plan), issued by the MAH in accordance with the guideline of good pharmacovigilance practice, will be made public.

The above documents for publication need to be submitted as Word-documents.

Summaries of RMPs of centrally authorised medicines will be publicly accessible on the EMA webpage. Summaries of RMPs of nationally authorised medicines will be publicly accessible on the webpage of the Austrian Federal Office for Safety in Health Care (BASG).

How are RMPs of existing medicinal products or RMP updates submitted?

RMPs of existing medicinal products, which had no RMP previously, and RMP updates are equivalent to variations of the marketing authorisation (section 1.8.2.).

All submissions will therefore be considered to be formal requests for variation. Details see:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh_257_2012_Rev23_2020_12_clean_QA_on_PhV.pdf

Pharmacovigilance System NEW

When should a summary of the pharmacovigilance system be submitted?

Applicants for a marketing authorisation (or registration) have to submit a summary of the Pharmacovigilance-System (PSMF summary).
Applicants have to maintain a pharmacovigilance system, which is described in the pharmacovigilance system master file, of which the PSMF-summary is a short description.

- In general for all new applications for a marketing authorisation
- When submitting an application for the approval for sales as “parallel import” (AMG §10c Abs.3 Z 13 i.d.g.F.) a description of the pharmacovigilance and, if necessary, the risk management system, that the applicant will introduce, are required.
- When submitting an application for a herbal traditional use product, the submission of a PSMF-summary for national application is required.
- Pharmacy-registrations (“apothekeneigene Registrierungen”)

Exemption:
Registered Homoeopathics

PSMF= Pharmacovigilance system master file
PHV=Pharmacovigilance

Implementation of PHV issues / DHPC and Educational Material

We have received a request to implement a safety-relevant word in the productinformation, which is already contained in our texts. How should we proceed?

In this case, please send us an e-mail.

Are the MAHs always informed by the BASG when a safety-relevant wording has to be included in the productinformation?

If it has been decided during the PRAC referral, a PRAC signal recommendation or a PSUSA e.g. to include new safety-relevant information in the productinformation, marketing authorisation holders of nationally (and MRP/DCP, if AT=RMS) approved medicinal products usually receive a request to adapt the texts. However, this does not release marketing authorisation holders from their obligation to screen the relevant sources regularly.

We have received a request to implement PRAC signal recommendations into the productinformation. The specified deadline for submission cannot be met. How should we proceed?

In this case, please request a deadline extension in a timely manner by e-mail. The request has to be made in time so that in case of rejection a timely submission by the MAH is possible.

We have received a request to implement PRAC signal recommendations into the productinformation. However, the texts of the concerned products are currently under medical review due to another change. How should we proceed?

In this case, please state in the coverletter and in the application form that another textrelevant variation is ongoing.

How should DHPC Letter and Educational Materials be submitted?

The submission should be done by e-mail to the following addresses: dhpc-em@basg.gv.at.

Necessary documents are: German translation and English original version, communication plan

Would it be possible, to make educational material of the individual MAHs available on the homepage of the AGES (possibly with access only for experts)?

It is currently not planned to publish the Educational Material on the BASG website.

Is a joint design or sending of DHPC or Educational Material, which refers to an active substance (cross-company) or to a Class Labelling, controlled and coordinated by the BASG?

The cooperation of the companies concerned is supported by the BASG. A coordination by the BASG is not possible.

What are the requirements with regard to the distribution list? The companies will certainly define different distribution groups / address lists for the same active substance. How can it be ensured that all affected physicians are reached?

The distribution list must only be proposed to the BASG in form of groups (as also indicated at the EMA communication plan). E.g. general practitioners, internists ...
The responsible MAH must ensure that a current address list is used.

The "Blaue Hand" symbol has already been implemented in Germany. Can we expect the same for Austria?

In Austria, the "Blaue Hand" symbol is currently not implemented and in use.

What would be acceptable distribution methods for training materials for the AGES? Only by mail, or also via emails, homepages?

In principle, distribution is possible via all these channels. Which way the distribution of DHPC / Educational Materials can take place is a case-by-case decision. Therefore, the desired distribution method should already be specified at the time of submission.

Adverse reactions

Reporting of suspected adverse reactions

In the interests of effective pharmacovigilance, it is essential that reports of suspected adverse reactions are received by the competent authority.

Accordingly, § 75g Austrian Medicines Act stipulates that **healthcare professionals** must report suspected adverse reactions to the Federal Office for Safety in Health Care without delay.

According to § 75h Austrian Medicines Act, **patients** can and should also report suspected adverse reactions to the Federal Office for Safety in Health Care.

Another way of reporting suspected adverse reactions is to report them to the **marketing authorisation holder**. According to § 75j Austrian Medicines Act, a marketing authorisation holder may not refuse the acceptance and examination of reports from healthcare professionals and patients. Marketing authorisation holders are obliged to submit information on all suspected adverse reactions electronically to the Eudravigilance database. This ensures that the competent authorities also become aware of reports of suspected adverse reactions received by the marketing authorisation holder. Furthermore, the marketing authorisation holder is obliged to inform himself regularly about the reports in accordance with §§ 75g and 75h Austrian Medicines Act by means of the Eudravigilance database.

The Austrian Medicines Act does not provide for other types of reporting of a suspected adverse reaction.

The reporting channels for suspected adverse reactions described above ensure that these reports of suspected adverse reactions are assessed for causality, that the benefit-risk ratio of all approved drugs is continuously monitored in close cooperation with the European network of authorities, and that a continuous evaluation takes place, which is reflected in the current version of the technical information.

Can also patient/ relatives report adverse reactions to the Federal Office for Safety in Health Care?
Yes, the following possibilties are available:

- Via electronic form
- Via paper form

Medication errors

Medication errors are unintentional errors in the prescribing, dispensing, administration or monitoring of a medicine while under the control of a healthcare professional, patient or consumer. They are the most common single preventable cause of adverse events in medication practice: An estimated 19 - 56% of all adverse drug events among hospital patients result from medication errors that would be preventable1.

According to a WHO statistics, 18% of all European citizens claim to have experienced a serious medical error in a hospital and 11% to have been prescribed wrong medication.

Since July 2012, the new European pharmacovigilance legislation has required all adverse drug reactions resulting from medication errors at the European level to be reported to EudraVigilance, the European database of adverse drug reactions.

The legal requirements detailed in Title IX of Directive 2001/83/EC and chapter 3 of Regulation (EC) No 726/2004, which are applicable to competent authorities in Member States, marketing authorisation holders and the European Medicines Agency as regards the collection, data management and reporting of suspected adverse reactions (serious and non-serious) associated with medicinal products for human use authorised in the European Union are addressed in Module VI of the "Guideline on Good Pharmacovigilance Practices" (GVP): Module VI – Collection,management and submission of reports of suspected adverse reactions to medicinal products(Rev 2) ".

Medication errors are an important topic on the agenda of the European Medicines Agency. In February 2013 the European Medicines Agency organised a regulatory workshop on medication errors.

The Committee for Medicinal Products for Human Use published a position paper on potential medication errors in the context of risk-benefit balance and risk minimisation measures (EMA/274183/2012).

1 'Creation of a better medication safety culture in Europe: Building up safe medication practices', Council of Europe Expert Group on Safe Medication Practices (2006).

Is any testing for marketing authorisation holders with Federal Office for Safety in Health Care required?

No. Testing should be performed only with the European Medicines Agency. For further information see http://www.ema.europa.eu.

How do MAHs transmit literature cases?

Literature cases have to be sent as attachment of ISCRs in the mandatory E2B(R3) format to the Eurdravigilance database.

How to report "Emerging Safety Issues“?

Events or observations that do not fall within the scope of spontaneous reporting or do not fulfill the reporting obligation, which may have major impacts on the risk-benefit balance of the product and/or on patients or public health, must be reported as soon as possible, at least within 3 working days according to GVP Module IX rev. 1 and AMG §75m upon becoming known as "Emerging safety issues" to the EMA by e-mail or also by e-mail to the national authority where a marketing authorization exists.

When reporting an "Emerging safety issue", the marketing authorization holder should describe the issue, the source(s) of information, any actions planned or taken with timelines, and provide any relevant documentation available at the time of the initial report. Any other information relevant to the issue should be provided to the Agency and the relevant national competent authorities as soon as it becomes available.

Examples of such events are:

- significant safety issues identified in ongoing or newly completed studies, such as an unexpectedly increased rate of fatal or life-threatening adverse reactions
- significant safety issues identified through spontaneous reports or publications in the scientific literature that may lead to consideration of a contraindication, restriction of use of the drug, or its withdrawal from the market
- important safety-related regulatory measures outside the EU, e.g. a restriction of the use of the medicinal product or its suspension

What pharmacovigilance obligations does the holder of a parallel import marketing authorisation have?

Pursuant to Section 10c para. 3 no. 13 AMG, the holder of a parallel import license must also have a pharmacovigilance system and, if necessary, a risk management system.

Although the holder of a parallel import license is not obliged to submit a periodic assessment report (PSUR), pursuant to Section 94h (9) of the Medicines Act (AMG), he must record and report to the Federal Office for Safety in Health and the Agency on

- suspected side effects, or
- suspected side effects in humans, or
- the improper use, or
- the absence of expected efficacy, or
- insufficient waiting time, or
- frequently observed improper use and serious misuse, or
- quality defects, or
- any suspected transmission of pathogens by the medicinal product that has occurred in a third country.

In addition, he has to inform the Federal Office for Safety in Health Care of all observations and data that may be of significance for drug safety.

Pursuant to Section 75q (6) of the Medicines Act (AMG), the holder of a licence for parallel import marketing must also record quality defects that have occurred in Austria and that have been brought to his attention in accordance with (2) or otherwise come to his attention and report them to the Federal Office for Safety in Health Care without delay, but no later than 15 days after they become known.

The holder of a licence for parallel import distribution shall document the original wording of the relevant notification made to him and keep it for five years and, upon request, forward it without delay to the Federal Office for Safety in Health Care. Furthermore, the holder of a marketing authorisation for parallel imports must inform the marketing authorisation holder or the holder of a registration of this notification within the specified period.

If a notification pursuant to § 75g (notification by health professionals) concerns a medicinal speciality which has been brought to Austria on the basis of a licence for parallel import marketing, the Federal Office for Safety in Health must inform the holder of the licence for parallel import marketing immediately, but no later than 15 days after it becomes known. The information must be provided in anonymous form.

Further inquiry note

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