



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

The articles included in this section are a selection from the EMA's news and press release archive for August–November 2014.

More information on the work of the EMA can be found on its website: <http://www.ema.europa.eu>

## European Medicines Agency publishes booklet on European regulatory system for medicines

26 August 2014 – The European regulatory system for medicines and the European Medicines Agency (EMA) – A consistent approach to medicines regulation across the European Union (EU).

The EMA today published an illustrated leaflet explaining how the European regulatory system for medicines operates. It describes how medicines are authorised and monitored in the EU and how the European medicines regulatory network – a partnership between the European Commission, the 50 medicines regulatory authorities in the EU and the European Economic Area (EEA), and the EMA – works to ensure that patients in the EU have access to safe and effective medicines.

The booklet is available at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Brochure/2014/08/WC500171674.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Brochure/2014/08/WC500171674.pdf).

## Regulatory information - European Medicines Agency updates guidance on European Union periodic-safety-update-report single assessment for nationally authorised medicines

1 September 2014 – The EMA has updated its procedural guidance to ensure that marketing-authorisation holders are prepared for the submission of periodic safety update reports (PSURs) for nationally authorised medicines subject to EU single assessment.

The single assessment of nationally authorised medicines is a deliverable of the 2010 pharmacovigilance legislation. It aims to harmonise and strengthen the

review of the benefits and risks of all medicines across the EU. PSUR single-assessment procedures involving a combination of centrally authorised medicines and nationally authorised medicines have been in place since April 2013.

All EU PSUR single assessments result in a recommendation from the Agency's Pharmacovigilance Risk Assessment Committee (PRAC).

Marketing-authorisation holders with medicines subject to a PSUR single assessment involving nationally authorised medicines only, for which the frequency and dates of submission of the PSUR have been established in the list of EU reference dates (EURDs), have to submit their PSURs to all Member States where their medicine is authorised, and to the EMA. This applies to medicines with data lock points falling on or after 1 September 2014.

These PSURs will be assessed by either a PRAC member for single-assessment procedures involving a combination of centrally authorised medicines and medicines authorised through mutual-recognition, decentralised or purely national procedures, or a Member State appointed by the Coordination Group for Mutual Recognition and Decentralised Procedures – Human, for PSUR single-assessment procedures involving nationally authorised medicines only. This will result in one single-assessment report which will be shared among the marketing-authorisation holders whose medicinal products are part of the PSUR single-assessment procedure. Marketing-authorisation holders have the possibility to comment on the assessment report, following which the PRAC will adopt its recommendation.

For all EU PSUR single-assessment procedures starting from October 2014, the procedure number will be published in advance in the EURD list. Marketing-authorisation holders should therefore include their procedure number when preparing their submission. Marketing-authorisation holders of nationally authorised products should also complete Annex I of the formatted table template of the cover letter.

The PSUR timetable has also been adapted to integrate the PSUR single-assessment procedures containing nationally authorised medicinal products. This timetable was published in July 2014.

As of 26 August 2014, marketing-authorisation holders have to pay a fee for assessment of PSURs.

The updated procedural guidance further clarifies how and to whom PSURs should be submitted. For

nationally authorised medicines containing substances or a combination of active substances for which no single-assessment procedure has been established in the EURD list, the assessment of the PSUR will remain at national level.

PSURs are reports providing an evaluation of the benefit–risk balance of a medicine. They are submitted by marketing-authorisation holders at defined time points following a medicine’s authorisation. The Agency uses the information in PSURs to determine whether there are new risks identified for a medicine or whether the balance of benefits and risks of a medicine has changed, to decide whether further investigations need to be carried out or to take action to protect the public from the risks identified such as updating the information provided for healthcare professionals and patients.

## **New legislation for veterinary medicines**

10 September 2014 – New rules have been proposed by the European Commission to improve the health and wellbeing of animals by stimulating the development and availability of veterinary medicines.

The legislative proposal also tackles the growing concerns over antimicrobial resistance by proposing a series of tools to minimise the risks that may arise from the use of antibiotics in veterinary medicine.

The proposal represents a major evolution of the legal framework for the authorisation of veterinary medicines in the EU.

The document has been published on the Commission’s website together with questions and answers under Revision of the legal framework for veterinary medicinal products [External link icon](#).

The revision aims to:

- simplify the regulatory environment and reduce administrative burden for companies developing veterinary medicines through streamlined marketing-authorisation procedures and simplified pharmacovigilance rules;
- stimulate the development of new veterinary medicines, including products for small markets (minor use and minor species), with the introduction of special rules in certain areas such as apiculture and aquaculture and better mechanisms to reward companies’ investments in the development of innovative medicines;
- facilitate the circulation of veterinary medicines across the EU, through streamlined procedures and clear rules for internet retailing of veterinary medicines within the EU;
- fight the development of antimicrobial resistance through specific measures such as a

restriction of the use in animals of certain antimicrobials that are reserved for the treatment of infections in people.

The EMA welcomes the publication of this proposal as the availability of veterinary medicines and the fight against antimicrobial resistance are two major priorities for the Agency, as reflected in its work programme.

Today, the Commission has also adopted a proposal for a revision of the EU legislation on food for animals containing medication. The aim is to ensure that medicated feed is only produced by approved manufacturers using authorised veterinary medicines.

Other EU institutions, including the European Parliament and the Council, will now consider the Commission’s proposals and will adopt their positions in due course, in accordance with the co-decision procedure.

## **Regulatory update - Changes to scientific advice procedures as of 17 November 2014**

24 October 2014 – As of 17 November 2014, the EMA is introducing changes to the procedures for scientific advice, parallel advice with health technology assessment bodies, protocol assistance, and qualification of novel methodologies. These changes are expected to further streamline the timetables and will apply to applications starting in January 2015 onwards.

These changes are as follows:

- the time between submission of the letter of intent and the start of procedure has been reduced to approximately three weeks for applications that do not require a presubmission meeting;
- the time between submission of the letter of intent and the start of procedure has been reduced to approximately seven weeks for applications that require a presubmission meeting;
- a draft briefing package should be submitted together with the letter of intent to allow quicker start of procedure. The final briefing package is expected in the week prior to the start as per current procedure.

For any enquiries please contact [scientificadvice@ema.europa.eu](mailto:scientificadvice@ema.europa.eu).

## **Regulatory update - EMA encourages companies to submit quality type I variations for 2014 by end of November**

24 October 2014 – The EMA is advising marketing authorisation holders to submit any type IAIN and type IA variations for 2014 by Friday 28 November

wherever possible. This will enable the Agency to acknowledge the validity of the submissions before the Agency's closure between 24 December 2014 and 2 January 2015 within the 30-day timeframe set out in Article 14 of Commission Regulation (EC) No. 1234/2008 [External link icon](#).

Marketing authorisation holders intending to submit type IB variations or groupings of type IBs and type IAs in December 2014 should liaise with the EMA prior to submission. An email should be sent to: [IBquery@ema.europa.eu](mailto:IBquery@ema.europa.eu) indicating in the subject line: 'Type IB December Submission' and mentioning in the body of the email the name of the product, the intended submission date and the scope(s) to be applied according to the Classification guideline [External link icon](#).

Type I variations are minor changes to the marketing authorisation of a Type IAIN and IA variations have no impact on the quality, safety or efficacy of the medicine. Type IAIN variations must be notified to the national competent authority or the EMA immediately following implementation, in order to ensure the continuous supervision of the medicine. Type IA variations do not require immediate notification and should be notified to the national competent authority or the EMA within 12 months of implementation, or earlier in certain cases.

Type IB variations must be notified to the national competent authority or the EMA before implementation, but do not require a formal approval. Upon acknowledgement of receipt of a valid notification, the marketing authorisation holder must wait for a period of 30 days to ensure that the notification is deemed acceptable by the national competent authority or the EMA before implementing the change.

## **Regulatory update – All referral procedures to be sent via eSubmission Gateway / Web Client from 1 November 2014**

24 October 2014 – Companies subject to a referral procedure for human medicines should send all their submissions via the eSubmission Gateway or the Web Client [External link icon](#) from 1 November 2014. After that date, the EMA is no longer accepting electronic submissions for referrals on CD or DVD.

The use of the eSubmission Gateway or the Web Client allows companies to submit their documentation to the EMA securely over the internet, thereby improving efficiency and reducing costs.

The use of the electronic Common Technical Document (eCTD) and electronic submission channels, i.e. the eSubmission Gateway or Web Client, has been mandatory since 1 April 2014 for submissions related to referral procedures for centrally authorised medicines.

For submissions related to referral procedures for nationally authorised medicines, the EMA is now strongly encouraging companies to make their submissions using the eSubmission Gateway or Web Client in either the eCTD or Non-eCTD electronic submission format. Submissions on CD or DVDs will no longer be accepted.

The use of electronic submission channels offer companies the following benefits:

- easier and quicker way to send eCTD submissions securely over the internet with possibility for companies to send updates within very short deadlines;
- feedback to the sender on the receipt of the submission, the outcome of the eCTD technical validation and the upload to the EMA's eCTD review system;
- no need to submit a physical copy of a dossier to the EMA.

All marketing authorisation holders are invited to register to use the eSubmission Gateway or the free web-based Web Client solution as soon as possible.

For more information on the eSubmission Gateway/Web Client go to the eSubmission website.

## **European Medicines Agency publishes first summary of a risk-management plan for a medicine**

3 November 2014 – The European Medicines Agency has published the first summary for the public of the risk-management plan (RMP) of a newly authorised medicine. This RMP summary, which concerns the medicine Neuraceq, describes what is known and not known about the medicine's safety and states what measures will be taken to prevent or minimise its risks.

The Agency will pilot the publishing of RMP summaries for all newly centrally authorised medicines during 2014 and at a later stage will start producing RMP summaries for previously authorised medicines.

This new type of publication is a further step towards increased transparency and public access to relevant information on medicines and is one of the requirements of the new European pharmacovigilance legislation. The RMP summaries complement the public-friendly information already available in the Agency's summaries of the European public assessment report (also known as EPAR summaries).

The RMP summaries are expected to be consulted by stakeholders with a professional interest in medicines, but will also be a useful resource for any member of the public who would like to have more information about their medicines.

This initiative is part of the Agency's continuous drive to improve information about medicines for the general public. The Agency recently revised its EPAR summaries based on feedback received from various stakeholders, particularly patients and healthcare professionals.

The format and content of EPAR summaries have been updated in order to make them more user-friendly and to better explain the reasons that led to the approval of the medicine. In particular, changes have been made to the way a medicine's benefit and safety profile are described and more information is provided on the benefit-risk balance. The Agency has been using this new format since 2013 for all new summaries and is also gradually updating previously published EPAR summaries.

### **Regulatory information – New tool for companies to facilitate maintenance of information on authorised medicines**

10 November 2014 – The EMA has made available a new tool to facilitate editing of key data fields by marketing-authorisation holders as part of the maintenance of information on authorised medicines that they have submitted to EMA.

This tool is available to users of the eXtended EudraVigilance Medicinal Product Dictionary Data-Entry Tool (EVWEBExternal link icon). A user manual explaining how to use this tool has been published.

As announced in January and June 2014, marketing-authorisation holders are required to complete previously submitted information on medicines with additional data elements that are included in the new data-submission format by the end of 2014. Companies are also required to bring medicine information up-to-date and to check that the quality of the information is in line with the updated reporting requirements.

Companies are reminded that they need to complete this process by 31 December 2014.

For user convenience, a direct link to full details on the data-submission requirements is now available on the homepage of this website (see 'Data submission for medicines').

In line with Article 57(2) of the 2010 pharmacovigilance legislation, holders of marketing authorisations must submit information to EMA on all medicines authorised for use in the EEA and keep this information up-to-date.

This database reinforces the supervision of medicines in the EU, as it supports pharmacovigilance data analysis, facilitates follow-up of regulatory actions and monitoring of legal obligations, and strengthens communication with EMA's stakeholders and partners. By streamlining the identification of products relevant to pharmacovigilance procedures, this database is expected to simplify adverse reaction reporting for marketing-authorisation holders and ensure that fees are calculated accurately.