News from the EMA

The articles included in this section are a selection from the European Medicines Agency’s news and press release archive for April 2016 to July 2016.

Listening to the public’s views on the safety of medicines
PRAC adopts rules of procedure on public hearings on selected safety reviews

April 15, 2016 – The European Medicines Agency’s Pharmacovigilance Risk Assessment Committee (PRAC) has adopted the final rules of procedure for public hearings to be held by the Committee. The rules of procedure describe the process and practical arrangements for the preparation, conduct, and follow-up of public hearings.

As part of the implementation of these rules, the European Medicines Agency (EMA) will now organise an internal dry run exercise in order to test the process and procedures of public hearings. The dry run is scheduled to take place at the PRAC meeting in July 2016. Public hearings could take place as early as the fourth quarter of 2016, as soon as a relevant topic is identified.

Public hearings are a new tool for EMA to engage European Union (EU) citizens in the supervision of medicines and to listen to their views and experiences. The pharmacovigilance legislation has given the PRAC the possibility to hold public hearings as part of certain safety reviews of medicines, particularly in relation to their therapeutic effects and available therapeutic alternatives, as well as the feasibility and acceptance of proposed risk management and minimisation activities.

Contributions made by the public during a public hearing will be considered by the PRAC and inform the Committee’s decision-making. Public hearings will be held on a case-by-case basis, where the Committee determines that collecting the views of the public would bring added value to its review. More details are outlined in the rules of procedure document.

Draft rules of procedure were published by the Agency for comments in July 2014 and drew 200 comments from 22 stakeholder contributions representing 25 organisations. The rules were updated and revised in light of the comments received.

Improving safety of first-in-human clinical trials
EMA starts EU-wide reflection on necessary changes to best practices

May 27, 2016 – The EMA has started a review of the guidelines that describe first-in-human clinical trials and the data needed to enable their appropriate design and allow initiation. This is being done in cooperation with the European Commission and the Member States of the EU.

The review will identify which areas may need to be revised in the light of the tragic incident which took place during a Phase I first-in-human clinical trial in Rennes, France, in January 2016. The trial led to the death of one participant and hospitalisation of five others.

EMA’s review will take into account the findings from two in-depth investigations into what went wrong during this trial, one carried out by the Temporary Specialist Scientific Committee (TSSC) set up by the French medicines agency ANSM, and the other by the Inspection Générale Des Affaires Sociales (IGAS), the inspectorate for social affairs in France.

Both reports include a series of recommendations regarding the requirements for authorisation and conduct of first-in-human clinical trials for further examination by the international regulatory and public health community.

EMA’s work will focus on best practices and guidance. The aim is to agree a concept paper by July identifying areas for change and proposals to further minimise the risk of similar accidents. The concept paper will form the basis for an EU-wide review of the guidelines. This process will include targeted discussions with stakeholders and a public consultation on proposed changes later in 2016.

The EMA review has started with two groups of experts who are carrying out preparatory work. One group is looking at pre-clinical aspects and the data needed from laboratory tests or animal studies to safely initiate first tests in humans. The other group is looking at clinical aspects of the design of first-in-human trials and how these could be improved to better ensure the safety of human volunteers taking part in these trials. This will lead into one EU-wide expert group discussion.

More information can be found on the Agency’s website: www.ema.europa.eu.

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Volume 25 Number 3 | Medical Writing September 2016 | 55
Clinical trials are essential for the development of medicines and without them patients cannot gain access to new potentially life-saving medicines. In the EU, the approval and conduct of clinical trials is within the remit of the relevant authorities of the European Member States.

EU guidelines are in place to ensure that these clinical trials are conducted as safely as possible. These guidelines include the requirement for extensive studies, including in animals, to gather information about a medicine before it is given to humans.

Severe adverse reactions in healthy volunteers such as those observed in the trial in Rennes are extremely rare during clinical trials. Since 2005, approximately 14,700 phase I clinical trials (with participation of 305,000 subjects) have been conducted in the EU, including 3,100 first-in-human studies. Only one other severe incident has been previously reported in that time in the EU.

Single, central platform now mandatory for all periodic safety update reports

PSUR repository facilitates information exchange on the safety of human medicines authorised in the EU

June 10, 2016 – As of June 13, 2016, all periodic safety update reports (PSURs) for human medicines authorised in the EU must be submitted to the PSUR repository, which has been developed by the EMA in close collaboration with EU Member States and the industry.

The PSUR repository is a single, central platform for PSURs and related documents to be used by all regulatory authorities and pharmaceutical companies in the EU. It was introduced by the EU pharmacovigilance legislation to facilitate the exchange of information on the safety of authorised medicines between regulators and pharmaceutical companies.

Marketing authorisation holders must now use the repository as a single point for all submissions and should no longer submit their PSURs to national competent authorities. The eSubmission Gateway is available on the eSubmission website.

The PSUR repository provides an important simplification for marketing authorisation holders allowing them to send all PSURs to a single recipient. It also facilitates the assessment of the reports by ensuring that national competent authorities, EMA and its scientific committees have timely and secure access to all relevant documents.

In June 2015, EMA’s Management Board gave the green light for the use of the repository following an independent audit that confirmed that the tool meets the agreed functional specifications. Since the initial release of the PSUR repository in January 2015, EMA has been supporting companies and national competent authorities to ensure they are ready to use this new tool. The system has been implemented...
using a phased approach and feedback from users has been taken into account to improve the system. Guidance, interactive training sessions and links to all relevant documents have been made available on EMA’s eSubmission website.

PSURs are reports providing an evaluation of the benefit-risk balance of a medicine. Marketing authorisation holders must submit PSURs at defined time points following a medicine’s authorisation. PSURs include the results of all studies carried out with this medicine, both in its authorised and unauthorised uses.

EMA uses the information in PSURs to determine if there are new risks identified for a medicine or whether the balance of benefits and risks of a medicine has changed. It can then decide if further investigations need to be carried out or can take action to protect the public from the risks identified, for example by updating the information provided for healthcare professionals and patients.

**EMA goes electronic for PDCO opinions and subsequent EMA decisions**

PDCO opinions and subsequent EMA decisions will be transmitted to applicants electronically only

July 6, 2016 – From August 1, 2016 the EMA will transmit the opinions of the Paediatric Committee (PDCO) and subsequent EMA decisions to applicants as a PDF via EudraLink – the European medicines regulatory network’s secure file-transfer system. EMA decisions, as well as PDCO opinions, will no longer contain a signature.

The move from printouts to electronic documents responds to stakeholders’ feedback collected over the years. Among the benefits of this change are: accelerated delivery of documents, more convenient receipt of documents as well as a shift towards greener solutions in line with EMA’s environmental policy.