



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA reorganisation: changes to handling of certain evaluation procedures for human medicines to be introduced from 1 April 2014

Handling of all other evaluation procedures to remain unchanged until further announcement later this year
March 26, 2014 – The reorganisation of the European Medicines Agency (EMA) is now entering its next chapter. Starting from 1 April 2014, the Agency will begin revised operations for the following evaluation procedures for human medicines:

- Type IA and IB variations;
- Type II variations;
- Periodic Safety Update Reports (PSURs);
- Administrative procedures such as transfers, 61(3) notifications, and corrigenda.

The main change for applicants to these procedures will be a change in their EMA contact persons. Applicants will be informed directly by product and procedure if and when their contact person will change. Nothing will change before the applicant has been notified.

The changes will be implemented for new applications for the above-mentioned evaluation procedures submitted as of 1 April 2014. For ongoing applications, the Agency has put in place a controlled transition plan, which foresees proactive and direct communication with applicants if and when changes occur.

The handling of all other evaluation procedures, including initial evaluation applications, will

remain unchanged for the time being. Their roll-out is planned for later in the year.

The upcoming changes to the handling of evaluation procedures follow the structural reorganisation of the Agency from September 2013. They are the results of an intense period of analysis and consequent redesign of operating processes, introducing a new operating model for how medicines are managed through their entire lifecycle at the Agency, focusing on scientific and procedure management.

The new operating model is designed to strengthen the support provided by EMA staff in terms of regulatory science and overall procedural management to its scientific committees throughout the lifecycle of a medicine. This will support the committees in focusing on their core expertise, the scientific assessment of medicines and delivery of high-quality opinions, while it also ensures consistency and streamlining of handling of applications, leading ultimately to more efficient and consistent scientific assessment procedures. This is also part of the EMA's effort to streamline internal processes for increased efficiency so that increases in workload can be absorbed by the existing resources.

As part of this new operating model, the Agency is revising the existing product team lead concept and replacing it with two new roles:

- A Procedure Manager to oversee all aspects of the management of specific procedures. Procedure Managers ensure regulatory consistency at the EMA and are responsible for managing the regulatory process surrounding each application. Procedure Managers provide guidance on regulatory procedural matters and serve as the primary contact point for applicants and experts from the national competent authorities in respect to their specific procedure.
- An EMA Product Lead or EPL to maintain oversight of a medicine as it moves through the different stages of its lifecycle. EPLs are responsible for the overall knowledge about a medicine and the wider context of a therapeutic area. They provide regulatory science input and facilitate discussions within and between the EMA's scientific committees when needed.

A Procedure Manager will be appointed at the start of a new application procedure and will be the primary contact for applicants during the course of the evaluation. For queries that may come up before submission of an application, the EMA is establishing a dedicated service, which applicants can contact by email. This service will become operational from 1 April 2014 for all pre-submission queries related to the post-authorisation procedures mentioned above, and will be expanded in scope over time.

All procedural changes will be incorporated in the EMA post-authorisation procedural advice for users of the centralised procedure. Following the update, which will be made shortly, the post-authorisation procedural advice will provide more detailed information for applicants, including on how to use the pre-submission queries service for each of the evaluation procedures.

The new processes will be rolled out gradually and the Agency will continue to provide updates.

European Medicines Agency releases best practice guidance on parallel scientific advice with health-technology-assessment bodies

Guidance to facilitate early dialogue between regulators, health-technology-assessment bodies, and medicines developers

May 8, 2014 – The European Medicines Agency (EMA) has published today for public consultation best practice guidance for pilot parallel scientific advice procedures involving the EMA and health-technology-assessment (HTA) bodies.

The document is a key outcome of the EMA-HTA workshop on parallel scientific advice, which took place in November 2013 and brought together over 280 representatives from, among others, the European Commission, European regulators, HTA bodies, the European Network for Health Technology Assessment (EUnetHTA), the pharmaceutical industry, payers, patients, and healthcare professionals. The report of the workshop is also published today.

“I believe that this guidance can be a major tool for medicines development, which will help new medicines with a positive benefit-risk balance and expected added value to reach patients in a faster and more transparent way,” said Tomas Salmonson, Chair of the Agency’s Committee for Medicinal Products for Human Use (CHMP), at the November workshop.

The draft guidance sets out the different phases of the process for EMA-HTA parallel scientific advice

and highlights ideal timelines and actions for all parties, including HTA bodies, the EMA and applicants undertaking a parallel advice procedure.

The document has been drafted in collaboration with HTA bodies based on the experience gained so far with the EMA-HTA parallel scientific advice pilot project and on the input provided by stakeholders during the November workshop.

Stakeholders are invited to provide comments on the proposed process by 14 July 2014, using the online form accessible via the draft guidance document.

The EMA established a pilot project for parallel scientific advice with HTA bodies in 2010, to allow medicines developers to receive simultaneous feedback at an early stage from both regulators and HTA bodies on their development plans for new medicines. The aim of this early dialogue is to facilitate agreement upon a development plan that generates data that both the EMA and HTA bodies can use to determine a medicine’s benefit-risk balance and value, respectively. This strong interaction is critical to enable innovation to reach patients, and ultimately for the benefit of public health.

The EMA is also associated with the Shaping European Early Dialogues for health technologies (SEED) consortium, which is financed by the European Commission to explore a number of scenarios for conducting early dialogues.

The outcome of the EMA-HTA parallel scientific advice pilot, which is still running, the public consultation on the draft process, as well as the results from the SEED project, will be taken into consideration to best meet the objective of the early dialogue for health-technologies exercise at the EU level.

European Medicines Agency welcomes publication of the Clinical Trials Regulation

May 27, 2014 – The European Medicines Agency (EMA) welcomes the publication of the Clinical Trials Regulation in the Official Journal of the European Union (EU). This legislation will open up a new era for the conduct of clinical trials in the EU, ensuring that Europe remains an attractive centre for clinical research. This will foster European competitiveness and innovative capacity, and facilitate swifter development of new medicines for patients. In addition to simplifying clinical trial approvals, the Regulation foresees transparency on the conduct of trials in the European Economic Area, from the point of their authorisation to the publication of the results of those clinical trials.

While authorisation and oversight of clinical trials remains the competence of Member States, the new

legislation mandates the Agency to prepare the IT platforms to support sponsors and experts in the Member States in carrying out their roles in relation to the authorisation of trials, their supervision, safety reporting, and compliance activities, as well as to enable public access to information on clinical trials.

EMA policy on publication and access to clinical trial data

The new Regulation provides for the first time a direct legal basis for the release of clinical trial results. This is directly in line with the Agency's commitment to increased transparency of these data, through its draft policy on proactive publication and access to clinical trial data. This policy, currently in the process of being finalised, will provide a bridge until the new legislation comes into force, which can be no earlier than mid-2016.

In drafting its policy, the Agency has carried out a broad public consultation, taking stock of the diverse views that were expressed. In the current absence of a specific legal framework for the proactive release of clinical trial data as soon as the authorisation procedure on a new medicine has been finalised, the challenge in this exercise was to find a balance between the often competing views that would allow the Agency to move forward with its policy.

The Agency recently completed a last round of targeted stakeholder consultations and the final policy is to be presented to the EMA's Management Board in June 2014. The Agency believes its policy finds an acceptable balance between all those competing interests. Once implemented, this policy will give all stakeholders the opportunity to learn from this first step while preparing for the Regulation to come into force.