



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Updates to product information templates for all medicines for human use

10 June 2015 — Changes will enhance presentation of information for patients and healthcare professionals

The European Medicines Agency (EMA) has introduced a number of changes to the templates of the product information that accompany all medicines authorised for use in the European Union (EU). These changes are expected to improve the way information is presented on medicines.

The product information is part of the marketing authorisation of all medicines. It provides objective and up-to-date information about the quality, safety and efficacy of the medicine. The product information consists of the package leaflet with information for patients and the summary of product characteristics (SmPC) that is intended to guide doctors, pharmacists and other healthcare professionals in prescribing, dispensing and administering medicines. It also includes the labelling, information to be included on the outer packaging of medicines or on the immediate packaging.

The changes to product information templates are detailed in the updated guidance for the pharmaceutical industry published on June 10: http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500004368

The main modifications are:

- the printed package leaflet for patients may only contain the address of the local representative of the marketing-authorisation holder in the Member State where this particular medicine is sold, instead of the contact details of all local representatives in all EU Member States;

- all strengths of the same pharmaceutical form of a medicine can now be combined in one SmPC, whereas until now a separate SmPC was required for each strength of the same pharmaceutical form.

EMA publishes video and presentations from the 24 June webinar on the implementation of its transparency policy

29 June 2015 — The European Medicines Agency (EMA) has published today the video recording of its webinar held on 24 June to provide an update on the implementation of its policy on the publication of clinical data, as well as the slides of all the presentations given.

The video and presentations are available on the EMA website at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/06/event_detail_001163.jsp&mid=WC0b01ac058004d5c3.

EMA's policy on publication of clinical data entered into force on 1 January 2015 and applies to clinical reports contained in all marketing-authorisation applications submitted on or after this date. The first reports will be published as soon as a decision on the application has been taken, currently foreseen for mid-2016.

To help stakeholders anticipate the requirements and prepare for the publication of clinical reports, the Agency explained the work processes which are foreseen. The topics covered by the webinar included an explanation of the principles for the submission of redacted clinical reports, the redaction consultation process, as well as guidance on redacting commercially confidential information in clinical reports and on the anonymisation of clinical reports for the purpose of publication.

During the webinar, participants had the opportunity to comment interactively on these topics and share their views.

A face-to-face meeting will be organised on 6 July 2015 at the EMA to allow more detailed discussions on the draft guidance on anonymisation of clinical reports for publication and on redacting commercially confidential information in clinical reports. Stakeholder organisations have been contacted to nominate experts as participants in this meeting. The guidance is expected to be finalised and published after the summer.

Regulatory information – Electronic application becomes mandatory today

EMA application forms should be used for all human and veterinary centralised procedure applications as of 1 July 2015

1 July 2015 – Companies are obliged to use electronic application forms provided by the European Medicines Agency (EMA) for all centralised marketing authorisation applications for human and veterinary medicines. Forms are available for initial marketing authorisations, variations and renewals and can be downloaded from the electronic Application Forms (eAF) at <http://esubmission.ema.europa.eu/eaf/index.html>.

The electronic application forms reflect and capture the same content as the previous paper-based versions, but offer a more structured application process for users. Their use is expected to reduce the administrative burden for both the regulatory authorities and pharmaceutical companies.

Since their initial release in 2012, the forms have been significantly improved following feedback received. Further testing exercises will be conducted prior to new releases of the next versions in the coming months to collect user comments and further improve user experience.

From January 2016, the use of electronic application forms will also be mandatory for all other EU marketing authorisation procedures for human and veterinary medicines, i.e. the decentralised (DCP), mutual recognition (MRP) procedures and for national submissions.

Further information on the new requirements can be found on the eSubmission website (<http://esubmission.ema.europa.eu/eaf/index.html>) and in a new information leaflet (<http://esubmission.ema.europa.eu/eaf/docs/eAF%20communication%20-%201%20pager%20-%2017.02.15.pdf>).

FDA, European Commission and EMA reinforce collaboration to advance medicine development and evaluation

US and EU regulators aim to enhance trust in quality, safety and efficacy of medicines

14 July 2015 – Senior leaders from the United States Food and Drug Administration (FDA), the European Commission and the European Medicines Agency (EMA) reviewed their ongoing cooperative activities and discussed strategic priorities for the next two years at their regular bilateral meeting held on 19 June 2015, at FDA Headquarters in Silver Spring, Maryland, USA.

Over the past years, EMA and FDA have significantly increased their level of collaboration and

sharing of information to advance regulatory excellence worldwide. There are now daily interactions, most of them structured around scientific and regulatory working groups or “clusters”. The focus of the cluster reviews during this bilateral was pharmacovigilance, biosimilars, paediatrics and veterinary medicines.

Strategic priorities

Looking ahead, EMA, European Commission and FDA decided to establish a new cluster on patient engagement to share experience and best practices regarding the involvement of patients in the development, evaluation and post-authorisation activities related to medicines.

Participants also agreed that communication on the ongoing successful cooperation should be enhanced and that efforts to support communication activities and align core messages should be strengthened.

They also agreed to further strengthen their collaboration in inspections and data integrity, safety monitoring of medicines, biosimilars, paediatric medicines, rare diseases, timely access to new medicines and veterinary medicines. This will help EU regulators and FDA increase efficiency on a global level and avoid duplication.

Planned focus for each area includes:

Patient engagement: In the US and in the EU, patients are well informed and expect that their voice is heard by regulators when it comes to the way studies are designed and the assessment of the benefits and risks of specific medicines. Involving patients in the evaluation discussions adds meaningful perspectives to the process. EMA and FDA aim to expand patient input during the regulatory process, for example to better understand how medicines and the availability of treatments affect patients and how patients approach quality, safety and efficacy of medicines.

Safety of medicines: The long-term collaboration between EMA and FDA in pharmacovigilance has facilitated the exchange of critical information and the coordination of communication to patients and healthcare professionals in the EU and the US. The participants agreed to further strengthen collaboration in the International Pharmacovigilance cluster with a more strategic focus on, among others, the assessment of everyday use of medicines.

Biosimilars: Activities in this cluster will continue to support the global development of biosimilars. The agencies are interested in aligning their scientific approaches to biosimilars to avoid regulatory divergence that may delay patients’ access to medicines.

Paediatric medicines: Regulatory collaboration is of vital importance for the development of paediatric medicines. Because the development of paediatric medicines is largely driven by legislation in the EU

and the US, EMA and FDA will continue to align their scientific approaches including through “common commentaries” and development plans which help to achieve a rational approach to the conduct of the necessary clinical trials. A workshop to share EU and US experience under their respective regulatory frameworks may be organised in 2016 to further support these efforts, resources permitting.

Rare diseases: Collaboration in the area of rare diseases is of growing importance. Medicines developers can already use a common template to request orphan designation of their medicine in the EU and the US. Building on this success, and the Paediatric Cluster’s work on rare diseases, EMA and FDA will establish a joint working group, the Team of International Global Rare Disease Experts (TIGRE), to better support the development of safe and effective medicines for children who suffer from rare diseases.

Timely access to new medicines: Improving timely access to new medicines to treat serious diseases has been at the core of the collaborative endeavours of EMA and FDA. By sharing information to facilitate joint approaches, e.g., in scientific advice or the evaluation of medicines, and by building on the best available regulatory practices the two regulators aim to minimise divergence and support patients’ early access to new treatments.

Veterinary topics: Recognizing that the One Health concept is a worldwide strategy for expanding interdisciplinary collaboration in all aspects of healthcare for humans, animals and the environment, FDA and EMA continue pathways for effective communication and information sharing activities. Cooperation is particularly strong in the area of novel veterinary therapies such as stem cells, oncology products and cytokines. EMA and FDA are focusing their efforts to further encourage the development of novel veterinary medicines and to further reduce antibiotic resistance.

Inspections: Progress was also made for the mutual reliance on inspections of drug manufacturing sites. EU regulators and FDA are evaluating how their respective inspectorates, in addition to their regulatory and procedural frameworks to inspect manufacturers of human medicines compare. This is an essential prerequisite to relying on each other’s inspection findings, avoiding duplication of efforts, and enabling wider inspection coverage. Both agencies are working expeditiously towards a plan for a final framework for an agreement and an implementation plan.

Data integrity: Both agencies stressed the importance of data integrity as a cornerstone to establishing and maintaining confidence in test results and agreed to work on communication and training to help increase the awareness of manufacturers.

The European Commission, EMA and FDA organise in-person bilateral meetings routinely to monitor progress and ensure that their collaboration delivers on agreed strategic priorities that promote the safety, efficacy and quality of medicines to the benefit of global public and animal health.

Fast track routes for medicines that address unmet medical needs

Launch of two-month public consultations on revised guidelines on accelerated assessment and conditional marketing authorisation

27 July 2015 – The European Medicines Agency (EMA) has revised its guidelines on the implementation of accelerated assessment and conditional marketing authorisation, two key tools in the European legislation to accelerate patients’ access to medicines that address unmet medical needs.

The public consultations on the revised guidelines are open until 30 September 2015. Comments should be sent using the forms provided.

Accelerated assessment and conditional marketing authorisation are intended for innovative medicines that target a disease for which no treatment is available, or that provide patients with a major therapeutic advantage over existing treatments.

Based on the experience gained in implementing accelerated assessment and conditional marketing authorisation in recent years and taking into account discussions on the optimisation of the use of these tools at the European Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP), EMA has revised its guidelines to improve these existing frameworks. The updated guidelines are expected to optimise the use of these tools by medicine developers and consequently allow more medicines that address unmet medical needs to reach patients earlier.

Accelerated assessment

EMA’s accelerated assessment procedure allows for a faster assessment of eligible medicines by EMA’s scientific committees.

The main changes included in the proposed revision of the guideline are detailed at:

http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500190554

They include:

- more detailed guidance on how to justify fulfilment of major public health interest, which is the basis for a request for an accelerated assessment;

- optimisation of the assessment timetable by better balancing evaluation phases to reach a CHMP opinion within the 150 days after the start of a marketing authorisation application procedure (compared to 210 days in non-accelerated procedures);
- emphasis on the importance of early dialogue with EMA so that accelerated assessment can be planned well ahead of the submission.

EMA highlights that the eligibility criteria laid down in the accelerated assessment guideline are also being considered for a new scheme, currently under development, that is designed to facilitate the development and accelerated assessment of innovative medicines of major public health interest, in particular from the viewpoint of therapeutic innovation.

Conditional marketing authorisation

Conditional marketing authorisation allows for the early approval of a medicine on the basis of less complete clinical data than normally required, if the medicine addresses an unmet medical need and targets a seriously debilitating or life-threatening disease, a rare disease or is intended for use in emergency situations in response to a public health threat.

While less complete, the available data must still demonstrate that the medicine's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data after authorisation within a timeframe agreed with the CHMP. In addition, the benefit to public health must outweigh the risk due to the limited availability of clinical data at the time of marketing authorisation.

The revised guideline emphasises on the importance for medicine developers of planning a conditional marketing authorisation prospectively and engaging in early dialogue with EMA and other stakeholders, for example through parallel scientific advice with health technology assessment bodies. This is expected to help translate conditional marketing authorisations into early access to medicines for patients.

In addition, the revisions include:

- clarification on fulfilment of unmet medical needs, i.e. medicines providing major improvements in patient care over existing therapies can be eligible in certain cases;
- clarification of how a positive benefit-risk balance is to be substantiated where there are less complete data, with further guidance on the level of evidence that must be provided at the time of authorisation and the data that can be provided after authorisation;

- updated guidance on the extent and type of data required to be included in annual renewal submissions.

An overview of the proposed changes to the two guidelines is available on the EMA website (http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500190556).

Updated guidance on good clinical practice released for consultation

Comments on the ICH E6 addendum are invited until 3 February 2016

21 August 2015 – The European Medicines Agency (EMA) has released an addendum to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E6 (R2) guideline on good clinical practice (GCP) for a six-month public consultation.

Stakeholders are invited to send their comments using the template provided by 3 February 2016. The completed template should be sent to ich@ema.europa.eu.

GCP is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical-trial data are credible.

The current ICH E6 guideline provides a unified standard on GCP. It describes responsibilities and activities of sponsors, monitors, investigators and ethics committees.

Since the finalisation of this guideline in 1996, the scale, complexity and costs of clinical trials have increased. Developments in technology and risk management processes offer new opportunities to increase their efficiency by allowing sponsors to focus on relevant activities. With this in mind, the guideline has been amended to:

- encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while continuing to ensure the protection of clinical trial participants, and data integrity;
- update standards regarding electronic records and essential documents intended to increase the quality and efficacy of clinical trials.

Updates have been made to several sections of the guideline and are highlighted in the document.