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Chief Policy Adviser

Finalisation of the EMA policy on publication of and access to clinical trial data – Targeted consultation with key stakeholders in May 2014

Summary report

Introduction

The EMA from its creation has pursued the strategy of increased transparency of information on medicinal products starting with the European Public Assessment Reports (EPARs). The EMA is committed to extending its approach on transparency. Its current initiative, under Article 80 of Regulation (EC) No. 726/2004 and with the agreement of the European Commission, is the development of a policy on publication of and access to clinical trial data.

Following a public workshop in November 2012 and a three months public consultation on a draft policy in June 2013, comments received have been reviewed by the EMA. The Management Board (MB) at its December 2013 meeting endorsed the principles proposed by the EMA to revise the draft policy, in terms of the scope of the policy and a stepwise approach for its implementation. The policy was discussed at the March 2014 MB meeting, and the MB agreed that the EMA should continue to work with key stakeholders through targeted consultations in order to achieve the broadest possible consensus.

Outline of the stakeholder consultation

Three meetings/teleconferences were held in May 2014 with (1) patients/consumers organisations and healthcare professionals (HCPs) organisations, (2) pharmaceutical industry associations, including small and medium sized enterprises (SMEs), and (3) representatives from academia, research bodies, and medical journals.

The aim of the meetings was to

- update these stakeholders on progress since the end of the public consultation on the draft policy,
- clarify and fine-tune specific aspects of the policy prior to its expected finalisation in June 2014,

- in particular, consult on the principles set for possible redaction of the clinical study reports (CSRs) to be published, and the technical measures to make the data available under the policy, including the terms of use (ToU).

The following documents were provided prior to the meeting:

- Slide deck, providing an outcome of the public consultation, the follow-up undertaken to the public consultation, and the main characteristics of the revised draft policy.
- Draft ToU.
- Draft redaction principles.

As regards the main characteristics of the revised draft policy the following was elaborated on:

- Clarification on the scope of the EMA policy.
- Clarification on the stepwise implementation of the policy.
- As regards the first phase, the introduction of a publication process for CSRs and clarification on the application of commercial confidential information (CCI) in CSRs.
- With respect to the publication process, the introduction of ToU which govern the access to and use of clinical trial data, accompanied by a technical tool allowing access to clinical trial data.
- In relation to the clarification on the application of CCI in CSRs, a description of the redaction principles as well as the procedural mechanism for redaction.

Outcome of the targeted stakeholders meetings

The outcome of the discussions at the three meetings/teleconferences is provided below, classified according to the main themes for discussion, i.e.

- Revised principles of the EMA policy.
- Draft ToU.
- Draft redaction principles.

The comments and viewpoints expressed by the various stakeholder groups have been summarised and, where relevant, the EMA reply has been provided.

Revised principles of the EMA policy

Scope of the policy

All stakeholders supported the principle of transparency set out in this policy. Patients/consumers organisations and HCPs organisations acknowledged that the public will have more information available for patients.

Pharmaceutical industry said that it accepted the need for these data to be published. Pharmaceutical industry including SMEs expressed its understanding of the journey to transparency. It acknowledged that the data will allow all pharmaceutical industry to learn from each other in terms of regulatory approach in a way that has not been possible up to now.

Timing of publication of clinical data

Pharmaceutical industry including SMEs sought clarification on the exact timing of publication of the clinical data as it is important for pharmaceutical industry that the decision making phase should be fully completed.

The EMA in its reply confirmed that the clinical data will be published after the decision on the marketing authorisation has been made, i.e. after the European Commission's decision to grant or refuse the marketing authorisation.

The EMA in its reply to SMEs on the question if the EMA could assist them with the implementation of the policy, asked to be provided with possible examples of practical support.

The importance of the protection of personal data

Patients/consumers organisations and HCPs organisations emphasised this aspect especially in the case of rare diseases. Pharmaceutical industry too was concerned about protection of personal data of patients. Academia and research bodies highlighted the value of patient line listing information for research purposes.

The EMA will not publish individual patient data (IPD) – contained in the appendices to the CSRs – in the first implementation phase of the policy since there are important issues of protection of personal data that must be addressed to a high standard before these data can be published. In addition the EMA will clarify during the second phase (1) when to submit IPD for subsequent scientific review by the EMA, and (2) in terms of publication how to best provide access, including the conditions to be fulfilled. The EMA explained that it would not seek to obtain IPD solely for the purpose of publication.

The EMA stated that it will undertake a consultation with stakeholders on the aforementioned aspects of IPD. First, however, a task force will be set up with all concerned stakeholders to discuss specific concerns as regards (re)-identification of patients, with a first focus on patient data included in the CSRs (not the appendices).

Academia, research bodies and medical journals highlighted the value of individual patient data line listing information for research purposes. An understanding of the need to assure the confidentiality of patients was expressed. The possibility was raised if confidentiality or data sharing agreements as an option by which this guarantee could be provided. Many participants considered that such a guarantee should allow access to additional information that would enable research.

The EMA agreed to further examine this proposal in the context of the second phase of the stepwise implementation of the policy.

Other personal data

The clarification that names of principal investigators and investigators will be published was welcomed by patients/consumers organisations and HCPs organisations. The personal data of other study personnel will be protected. Pharmaceutical industry found that this approach to other personal data was reasonable.

Other regulatory authorities

Pharmaceutical industry associations, academia, research bodies and medical journals asked whether the EMA will take the policy forward with other regulatory authorities. The EMA indicated that it would

welcome if other regulatory authorities across the world would follow a similar approach. It was confirmed that the FDA was kept updated on progress made.

Access to unpublished data

The EMA confirmed to all stakeholder groups that access to documents continues to apply to any clinical data that is not published.

Implementation of the policy

Once the policy has been endorsed, the EMA will aim to involve stakeholders in testing the publication tool in advance of its live release. The dates for implementation of the policy will have to be further determined, depending on progress with the practical arrangements to be put in place.

Draft ToU

Use of the CSRs

Patients/consumers organisations and HCPs organisations, academia, research bodies and medical journals were concerned if abstraction of the data with source acknowledgement was possible, which the EMA confirmed. A user that has accessed the clinical data published on the EMA website may quote from or re-use these data. The source of these data must be acknowledged. Academia, research bodies and medical journals were concerned that attributions would be reasonable which EMA assured them would be ensured.

Pharmaceutical industry considered that watermarking the data as proprietary information to be essential. It understood that many interested parties act in good faith. Yet, it pointed out that a risk does exist of regulatory misuse of the published clinical data in other regulatory regimes. It sought assurances that misuse would be deterred.

Patients/consumers organisations and HCPs organisations, and pharmaceutical industry asked how cases of misuse would be followed up. Pharmaceutical industry sought information about its rights in the event of misuse of the data. It pointed out the important impact of such a problem for a SME and the cost of the resources to address it. The EMA replied that should there be misuse for regulatory purposes it is for the marketing authorisation holder to act. Its rights for this purpose are contained in the ToU.

Publication tool

Academia, research bodies and medical journals, as well as consumers organisations and HCPs organisations criticised the view on screen only concept. They considered that it was too limited as only view on screen. Academia and research bodies questioned the usefulness of view of screen and disagreed with this type of access envisaged making it unworkable. View on screen was seen as an impediment to serious researchers rather than a way to prevent unfair commercial use. They sought assurance that at least the data would be searchable. Academia, research bodies and medical journals were also concerned about users accessing the data being tracked.

The EMA confirmed that the clinical data will be accessible on the EMA website in a searchable, view on screen format. The data will be permanently available and can be referenced in publications or communications with colleagues, who can in turn easily obtain their own user id and password, log on

and review the study reports, in a similar way that many other on-line information resources are accessed. There is no screening or tracking in any way of any person accessing these data. The short terms of use explain the proprietary nature of the data and that it should not be misused for regulatory submissions.

Pharmaceutical industry said it was interested if legacy data could also be published in the frame of this policy. The EMA replied that it would further explore this possibility.

User-friendly access system

Patients/consumers organisations and HCPs organisations emphasised the need for a user-friendly access system. The EMA confirmed that the log on and overall access process will be easy. The EMA will involve stakeholders in testing the tool in advance of its live release.

Draft redaction principles

Pharmaceutical industry explained that protection of CCI is very important for its interests. It pointed out that a balance has to be struck between the value represented by transparency and the protection of legitimate commercial rights. Pharmaceutical industry understood that it will have to justify and explain the basis for any elements it seeks to redact. It accepted that most of the clinical data that will be published by the EMA is not CCI. The EMA will publish the principles set for possible redaction of the clinical data (redaction principles) as an annex to the policy.

Patients/consumers organisations and HCPs organisations, academia, research bodies and medical journals expressed major concern about the extent of redaction of CCI. Patients/consumers organisations and HCPs organisations pointed out that it represents a loss of public information. Academia, research bodies and medical journals stressed the impact of the absence of this part of the information for research purposes, e.g. information on statistical methods is fundamental to come to a judgement about the validity of an analysis and questioned how disclosure of such information could impair commercial advantage.

The EMA explained that only in limited circumstances the CSRs could contain CCI and, therefore, be subject to redaction prior to publication. The large majority of the content of CSRs will be fully accessible.

Patients/consumers organisations and HCPs organisations were concerned that pharmaceutical industry would take the opportunity to add to redaction. Under the policy the pharmaceutical company will have to identify, to justify and explain to the EMA any elements that it considers CCI and which should be redacted. The burden of proof lies with the company. The EMA has developed redaction principles to define the parameters of CCI. These redaction principles, with a list of exceptions that may be considered CCI, are derived from past experience with the handling of requests for access to documents.

Academia, research bodies and medical journals sought more detail about the redaction decision maker. The EMA will consider the requests using its redaction principles and it will take the decision following consultation with the company. The EMA will take this decision in the full spirit of transparency while acknowledging the balance of competing interests and the economic and commercial interests that must be respected. Only information that the EMA decides is CCI following review of the company's justification will be redacted.

Patients/consumers organisations and HCPs organisations, academia, research bodies and medical journals considered that the EMA should give the details of specific cases of its redaction decisions. The EMA replied that the basis for redaction is contained in the redaction principles that will be revised and

updated as experience evolves. Case by case details will not be published. Rather than only the receiving party knowing what has been redacted as is the case now with access to document requests, the redacted areas will be visible. All persons will be able to see the limited redacted areas within the great majority of information that is published.

EMA confirmed to all stakeholders that it will apply the same principles in relation to CCI and redaction for requests under access to documents, and to publication of clinical data under this policy. The redaction should, however, evolve over time. Fewer elements are accepted now as CCI compared to the past. This transparency trend is expected to continue.