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Chief Policy Adviser

Outcome of public consultation on "Policy 0070 on publication and access to clinical-trial data"

Summary of comments received during the public consultation and next steps

1. Background and consultation

The European Medicines Agency is developing a policy on the proactive publication of clinical trial data. From the beginning of this process, the Agency has taken a considered approach to developing a policy based on respecting the views and concerns brought forward by a broad range of stakeholders and European bodies.

The process started off with a workshop on clinical trial data and transparency on 22 November 2012 to discuss the practical and policy issues that needed to be addressed before the Agency can begin to release these complex data sets. The workshop gathered the views, interests and concerns of a range of institutions, groups and individuals with an interest in the issue.

Following the event, the Agency set up advisory groups to inform it on five specific topics: Protecting patient confidentiality, clinical trial data formats, rules of engagement, good analysis practise and legal aspects.

More than 200 people from all stakeholder groups applied to participate in one or more of the five advisory groups. The groups met between January and April 2013, with meetings taking place via teleconference.

In June 2013, the Agency released the draft policy on publication and access to clinical-trial data for a three-month public consultation, providing a further opportunity for stakeholders to send their comments.

2. Contributors

More than 150 individuals and organisations submitted over 1,000 comments. Healthcare professionals, academics and the pharmaceutical industry responded in broadly similar numbers and together represented almost half of all contributors. There was also significant input from patient organisations, regulatory authorities and health-technology assessment bodies and payers.

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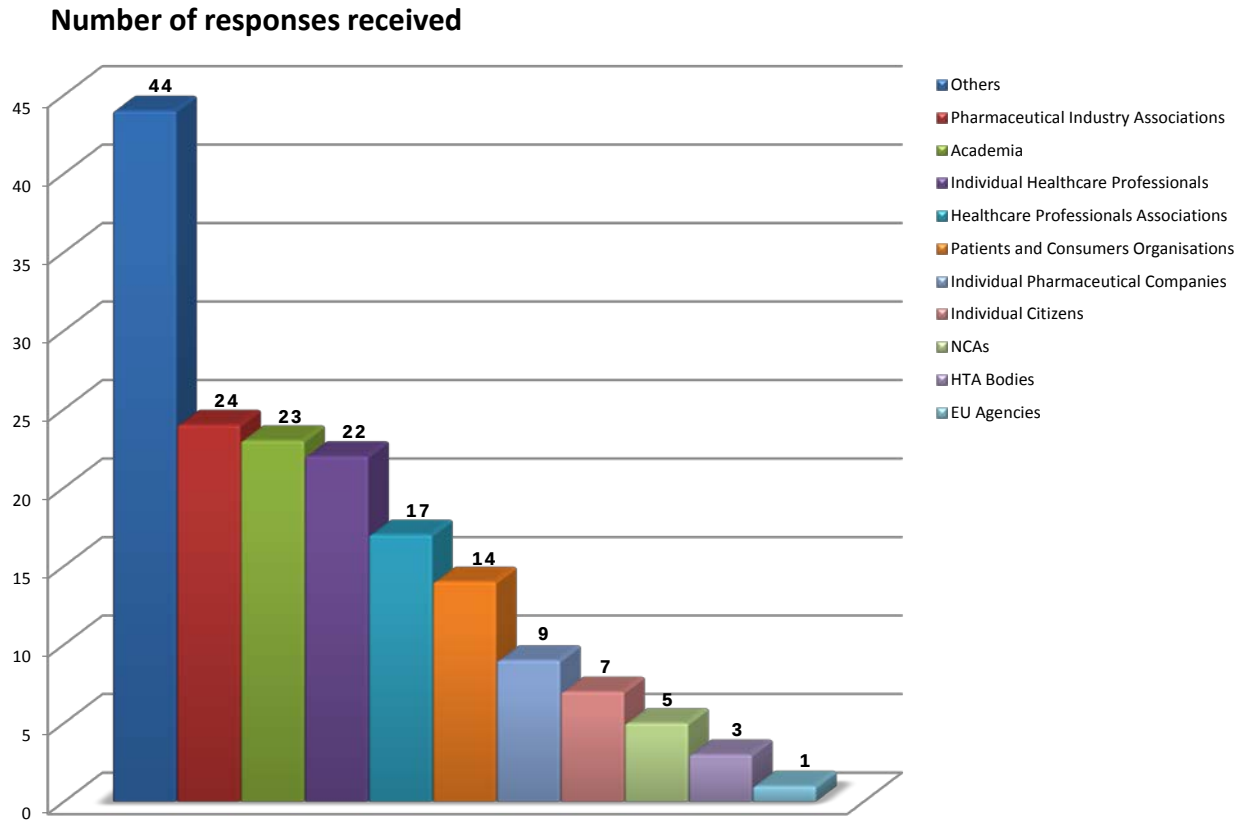
A large proportion of respondents were individual citizens expressing their support for the Agency's initiative to increase clinical-trial-data transparency.

The distribution of respondents is given below.



3. Summary of main points raised during the consultation

The Agency has reviewed and analysed all the comments received during the consultation. In general the majority of the comments expressed support for the Agency's initiative to increase transparency in relation to clinical trials.

A large number of general and specific comments were received on various parts of the policy. Due to the amount and diversity of the comments received, this summary will focus on the main points expressed by the respondents.

The main comments made relate to the following areas:

- Protecting confidentiality
- Rules of engagement
- Legal aspects.

3.1. Protecting confidentiality

The question of the informed consent was raised. The draft policy stated that the patient's initial informed consent is given in the context of a particular medicine and their particular disease and that

the boundaries for the informed consent should be respected. Comments were received in support of this statement querying the correctness from an ethical point of view of allowing use of data which the patients included in clinical trials have not consented to. This issue is also linked to the controlled access requirement which included ethic committee approval as appropriate. This was seen by some respondents as putting an additional obstacle in the way of secondary analyses of the data.

The draft policy stated that “protection of patient privacy is a paramount concern when sharing raw CT data”. Whilst agreeing that it is a paramount concern, the respondents raised the issue of de-identification. Especially the risk of re-identification is greater where the patient group is small e.g. in the case of orphan diseases. Although the draft policy foresaw two measures to protect against retroactive patient identification (de-identification and controlled access), the respondents commented that an accepted, suitable, common standard for de-identification was needed. It was also highlighted that re-identification techniques are increasingly available and it is therefore important to ensure that the proposed de-identification measures are adequate to protect patient privacy. Other respondents considered that there are methods to uphold the patients’ privacy and that this argument should not be used to block publication of data.

According to the draft policy the personal data of clinical trial personnel would not be considered as confidential as public health reasons would override the considerations of protection of personal data. Respondents were highlighting that clinical trial personnel mentioned in the clinical trial reports have different levels of responsibilities and therefore the overriding public health reasons would not be applicable to all.

3.2. Rules of engagement

A number of comments received related to the concept of commercially confidential information (CCI). On one hand comments were made that commercially confidential information should be protected and measures should be taken to guard against inappropriate use of the published data. On the other hand comments were made that the definition of CCI is too broad and detailed information should be required to justify why data could be considered to be confidential.

The draft policy stated that the publication of the clinical trial data would take place at the time of the publication of the European Public Assessment report (EPAR) or 30 days after withdrawal in case no withdrawal EPAR was published. This was seen by some respondents to be an issue in relation to other regulatory procedures outside Europe and in particular in relation to negative or withdrawn applications where the publication could affect re-submission or further development. Other respondents argued that the proactive publication was not sufficient and that the policy should also include publication of data for products that had already been authorised.

3.3. Legal aspects

Some comments questioned the legal basis for the Agency to request an additional set of de-identified data and highlighted the additional burden on industry of producing the data.

The legality and enforceability of the data-sharing agreement between the EMA and the requestor needed in case of access to confidential data were questioned. For the pharmaceutical industry the issue was protection of data against unfair commercial use. For others the issue raised was that the requestor might not be in a position to objectively asses the criteria for entering in a data sharing agreement.

The question was also raised that by introducing the policy for the centrally authorised products but not for non-centrally authorised products, the Agency was introducing different standards of transparency depending on the route of administration.

4. Next steps

The comments received and the consequent impact on the draft policy was discussed at the December 2013 Management Board meeting. The Management Board agreed a set of key principles to guide the further development of the policy.

The key principles include:

- a stepwise approach for implementation with, as a first step, preparation for the publication of clinical study reports redacted as appropriate;
- development of a methodology for de-identification of patients;
- definition of a standard format for the submission of data.

The principles also foresaw the introduction of preliminary steps prior to data access designed to address the risk of possible unfair commercial use of data, while ensuring proactive and non-selective access ('use control' not 'access control').

In March 2014 it was agreed by the Management Board that the Agency should continue to work with stakeholders including industry, academia and civil society organisations, to further clarify and fine-tune the proposed rules to achieve the broadest possible consensus through targeted stakeholder consultations.

The stakeholder consultations, which took place in May 2014, aimed at providing an update on progress made since the end of the public consultation on the draft policy and clarifying specific aspects of the policy prior to finalisation of the policy in June 2014. In particular, stakeholders were consulted 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. The summary of the meetings is published on the Agency's website.

5. Annexes

The list of contributors and the individual comments are published in separate documents. Both are available on the Agency's website.