European Federation of Pharmaceutical Industries and Associations

Executive Summary*:* EFPIA submission of comments on 'Policy 0070 on publication and access to clinical trial data'

This June, the European Medicines Agency released its draft Policy on the publication and access to clinical-trial data, for a three-month public consultation closing on 30 September. In response to the EMA's call for comments, EFPIA's Clinical Trials Data Sharing Working Group (CT Data Sharing WG) has prepared the attached submission. Feeling the need to share its concerns regarding the EMA draft policy more widely, EFPIA's response to the EMA draft policy is being made publicly available. These comments reflect the concern that the EMA's proposal may result in greater transparency, but compromise some critical public health interests.

As it stands, the EMA draft Policy would weaken three essential elements for promoting public health both within Europe as well as at the global level: patient privacy; the integrity of scientific research and the regulatory systems; and incentives for investment in biomedical research. There is concern that the draft EMA Policy will:

1. Weaken safeguards intended to ensure the privacy of patients and other individuals identified in marketing authorization application (MA) dossiers;

2. Undermine the trust in the regulatory approval system governing biopharmaceutical products and introduce risks of misinterpretation and misuse of clinical data into the process;

3. Weaken incentives for companies to invest in biomedical research by disclosing companies' commercially confidential information (CCI), without due consideration of the competing interests that may or may not justify disclosure.

The comments prepared by the EFPIA CT Data Sharing WG address these points. In addition to the public health risks and uncertainties inherent in the draft Policy, such broad transparency is furthermore unwarranted.

EFPIA believes that implementation of the joint EFPIA-PhRMA Commitments to Data Sharing is the best means of advancing responsible transparency –that will promote public health interests by safeguarding patient privacy; preserving the integrity of regulatory systems; and maintaining incentives for investment in biomedical research. EFPIA and PHRMA companies have committed to:

1. Share upon request from qualified scientific and medical researchers patient-level clinical trial data, study-level clinical trial data, and protocols from clinical trials in patients for medicines.
2. Enhance public access to clinical study information, by making publicly available, at a minimum, the synopses of clinical study reports (CSRs) for clinical trials submitted to the FDA and EMA.
3. Share results with patients who participate in clinical trials.
4. Certify on a publicly available web site that they have established policies and procedures to implement these data sharing commitments.
5. Consider all company-sponsored clinical trials for publication in the scientific literature irrespective of whether the results are positive or negative.

1. **Fundamental Comment: How the EMA draft Policy threatens those safeguards intended to ensure the privacy of patients and other individuals identified in MA dossiers (*Protection of Patient Privacy and Personal Protected Data (PPD), Fundamental Comment p.3)***

EFPIA agrees with the EMA draft policy that "protection of patient privacy is a paramount concern when sharing raw CT data". However, EFPIA is concerned that the draft policy does not do enough to protect against re-identification of patients based on this data.

- As written in the EMA draft Policy, it appears that the Agency plans to widely release de-identified patient data. Recent studies have shown that there is particular risk of re-identification when such data are made widely available. Additionally, we must consider that re-identification technology is advancing rapidly.
- The EMA draft policy also neglects to address the protection of personal data of investigators and study personnel in MA submissions; the privacy of a*ll* individuals involved in clinical studies needs to be protected.
- In addition to considerations of personal data privacy, there remains the imperative of respect for the terms of the informed consent given by the patients participating in clinical trials, both in the EU and 3rd countries, with regard to the subsequent or secondary use of their data (whether "anonymised" or not), as a matter of ethics and a central tenet of good clinical practice. In the draft Policy, the EMA appears to infer a broader scope to individual patient informed consent than is usually the case, especially historically in past clinical trials, when the current issues now being debated were not envisaged. The draft Policy ambiguously refers to the "spirit of informed consent", whereas in reality trial sponsors (and by definition, any other party handling the data, including the EMA) must respect the informed consent in its particular terms and according to the laws of the country where it was given. The release of clinical trial data – whether by the sponsor or EMA - can only ethically and lawfully take place within the scope of the specific informed consent given by the patient to the trial sponsor and is not distorted so as to deprive the concept of 'informed' of its meaning, and the party releasing the data must bear this responsibility.

2. **Fundamental Comment: How the EMA draft Policy could undermine the trust in the regulatory approval system governing biopharmaceutical products and introduce risks of misinterpretation and misuse of clinical data into the process (*Providing Access to Data for Legitimate Research, Fundamental Comment p.5)***

Secondary analysis and research of clinical trials data must be robust and for good scientific purposes. Data can be misunderstood, misrepresented and misused through inappropriate secondary analysis. The misuse of data can lead to public health scares and undermine confidence in regulatory systems. The EMA draft policy fails to secure the legitimacy and scientific rigour of the use of the data:

- It does not require the requester to provide or publish statistical analysis plans
- It does not allow for a prior review of the requestor's statistical analysis plan or qualifications

EFPIA believes these missing elements are essential to avoiding poor secondary analyses which may threaten public health as well as trust in regulatory systems.

3. **Fundamental Comment: How the EMA draft Policy weakens incentives for companies to invest in biomedical research by disclosing companies' CCI (*Maintaining incentives for investments in biomedical research – protection of CCI – open access to clinical trials, Fundamental Comment p.6)***

The CT data in a MA dossier may contain commercially sensitive information. The protection of this information helps to maintain the incentive for companies to continue innovating and making the enormous investments needed in medical and scientific research. The EMA's plans to release this data are therefore a threat to research and innovative medicine development. Problems with the EMA's proposal include:

- According to the EMA draft Policy, CCI will not be divulged; "in general, however, CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI". This is inconsistent with the definition of CCI stated in the EMA draft policy, as "any information that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the owner of the information".
- The EMA draft Policy's claim that "CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI" is inconsistent with EU law, which requires that analysis weighing the relative CCI and public health interests be made *on a case-by-case basis*.
- The EMA draft Policy fails to give CCI and public health interests the equitable due consideration required. The draft Policy's assertion that MA data can be disclosed because it cannot be

considered CCI has already been challenged in the recent interim decision on EMA data release as determined by the General Court of the EU in the AbbVie and Intermune cases. The Court ordered the EMA not to release certain clinical trial information from the MA dossiers– considered to contain CCI by the applicants in these cases - pending the final outcome of this litigation. The Court determined that it is not "entirely unfounded" to conclude that a clinical study report – hundreds of pages long – could contain CCI. These cases are ongoing.

By employing terminology and conditions which are too broad, the EMA draft Policy suggests a lack of protection of CCI that not only threatens incentives to innovate, but also comes into conflict with EU law.

EFPIA believes that publicly sharing its concerns regarding the EMA draft policy is an important element – and integral to the spirit of the public consultation process - in advancing the debate on data transparency, and continues to encourage open dialogue on the topic. EFPIA will continue to engage with all relevant stakeholders on the topic of clinical trial data sharing, in pursuit of a responsible data sharing solution that will serve innovative research and the patients who benefit from its output.