COVINGTON

COVINGTON & BURLING LLP

E-ALERT | Life Sciences

October 6, 2014

EMA MANAGEMENT BOARD APPROVES NEW POLICY ON PUBLICATION OF CLINICAL TRIAL DATA

On October 2, 2014, the Management Board of the European Medicines Agency (EMA) unanimously approved a new policy *on publication of clinical data for medicinal products for human use*. The policy will come into effect on January 1, 2015. Data will start to become accessible once the European Commission reaches a final decision, which is expected to take 18 months.

The policy governs publication of clinical trial data for medicines that have received a marketing authorization. Applicants for a marketing authorization routinely submit such data to the EMA. The new policy clarifies the extent to which the EMA will publish this data and under what conditions. The new policy will only affect publication of new marketing authorisation applications and article 58 applications (medicines that are intended exclusively for markets outside the European Union) submitted to the EMA after January 1, 2015. The policy does not apply to clinical data that the EMA holds for applications received under the centralised procedure before January 1, 2015. For post-authorisation procedures for existing centrally authorised medicinal products, the effective date will be July 1, 2015 for extension of indication and line extension applications that have been submitted as of that date.

As the EMA described in its press release, in the absence of any specific legal provision mandating the EMA to publish data, the EMA has developed the policy taking into account the views and concerns of a broad range of stakeholders and European bodies. Patient and consumer organisations, healthcare professionals, pharmaceutical industry associations, transparency campaigners, and representatives from academia, research bodies and medical journals all have contributed actively to the development of the policy. Since 2012, stakeholders have attended workshops, responded to public consultations, and participated in advisory groups to discuss protecting patient confidentiality, clinical trial data formats, rules of engagement, good analysis practice, and related legal issues.

The policy seeks to address several concerns that stakeholders have raised in relation to these topics:

- To protect against unfair commercial misuse of published data, the EMA has established Terms of Use, which govern the access to and use of clinical data, and a user-friendly technical tool allowing such access. The policy also establishes principles regarding the redaction of commercially confidential information (CCI).
- In relation to patient confidentiality, the EMA is aware of the need to balance protecting patient privacy and ensuring published data retains its scientific value. To achieve this objective, the EMA considers further consultation with stakeholders is necessary to establish a methodology.
- The policy will be brought into effect in phases. In a first phase, to address the concept of "raw data" -- now referred to as "individual patient data" (IPD) -- clinical trial reports will be published *excluding* IPD. The EMA will initiate further discussions about providing some access to IPD in a later phase.

- To resolve concerns that were raised during consultations in 2014, the EMA also has eased restrictions over access to data. Subject to the applicable Terms of Use, clinical reports will be available on-screen for any user following a simple registration process, and downloadable reports will be available to identified users.

The adoption of the policy is an important milestone in the on-going debate over access to clinical research, data sharing, and transparency. The EMA's Q&A document provides more details of the newly developed Terms of Use and access rules, the different phases of implementing the policy, and how the policy relates to the new Clinical Trials Regulation (Regulation (EU) No. 536/2004). Copies of the Terms of Use, details of information contained in clinical reports that may be considered CCI, and the process for publishing clinical reports are set out in the annexes of the policy.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

Brian Kelly	+44.(0)20.7067.2392	bkelly@cov.com
Mark Young	+44.(0)20.7067.2101	myoung@cov.com