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ALERT

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Relaunch of the EMA's policy on the proactive publication of clinical data

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In September 2023, the European Medicines Agency (**"EMA"**) will reinstate Policy 0070 (the **"Policy"**), pursuant to which clinical data submitted to the EMA for the purpose of regulatory approval will be proactively published.

Background

The Policy, which first came into effect on 1 January 2015, aimed to make clinical data upon which regulatory decisions are based available proactively for public scrutiny and the application of new knowledge in future research in the interest of public health. This was achieved by the EMA's proactive publication of clinical reports, submitted to the EMA for the purpose of regulatory approval, on its Clinical Data portal which registered users were free to view.

In December 2018, the Policy was temporarily suspended to ease pressure on the EMA whilst it relocated from London to Amsterdam as a result of the United Kingdom's vote to leave the European Union. When the pandemic struck, the Policy was reinstated on an exceptional basis for COVID-19 treatments and vaccines only. Most recently, in December 2022, the EMA Management Board agreed to gradually reinstate the Policy, and on 16 May 2023, the EMA hosted a webinar in which it shared its reinstatement plans. The EMA is yet to publish the latest iteration of the Policy.

What's new?

- During the webinar, the EMA explained that the reinstatement of the Policy will take a phased approach. In particular:
    - The first phase of the Policy's reinstatement will concern only clinical reports which were submitted alongside initial marketing authorisation (**"MA"**) applications for medicinal products which contain a new active substance and for which the Committee of Human Medicinal Products (**"CHMP"**) issues an opinion beginning in September 2023 and onwards.
    - At some point in 2024, the Policy will be fully reinstated for all types of applications, including those seeking approval of new indications and line extensions.
    - During the first phase of the Policy's reinstatement, the EMA's publication of clinical data related to COVID-19 and other public health emergencies will continue as usual, (i.e. it will concern initial MA applications as well as new indications and line extensions).
    - The EMA will strive to formulate a reasonable approach to the publication of clinical data that were evaluated whilst the Policy was suspended.
- Whilst the substance of the Policy has not changed, certain procedural aspects have been amended. In the previous iteration of the Policy, the EMA was obliged to publish redacted/anonymised clinical reports within 60 days of the issuance of a Commission Decision. Under the reinstated Policy, the EMA will be required to publish redacted/anonymised clinical reports within 120 days of the adoption of a CHMP opinion.
- In relation to the redaction of commercially confidential information (**"CCI"**), during the webinar, the EMA explained that:

- Consistent with the current policy, any data which are already in the public domain (e.g. data which have already been included in the Summary of Product Characteristics) cannot be considered CCI.

- The redaction of entire paragraphs or pages will not be accepted. Examples of what the EMA had previously considered CCI includes detailed manufacturing information, assay information, and data related to candidate products which were not developed further.

- When the previous iteration of the Policy was in effect, Regulation (EU) No 536/2014 (the Clinical Trials Regulation or the **"CTR"**) had not yet entered into application, meaning that the Clinical Trials Information System (**"CTIS"**) was not in operation. By way of reminder, pursuant to the CTR, clinical trial results must be recorded in the CTIS, and all information stored in the CTIS should be publicly available unless exempted. The EMA explained that the teams responsible for each platform are working closely to ensure consistency in the approach to redactions. In practice, this may prove administratively burdensome given that under the CTIS, redactions will be coordinated by the relevant National Competent Authorities and not the EMA.

Practical implications and next steps

The EMA has explained that it will be sending detailed invitation letters at the end of May 2023 to applicants who will be directly impacted by the Policy (i.e. in-scope applications for which a CHMP opinion is expected beginning in September 2023 and onwards).

On a practical level, the EMA has advised applicants to prepare their Redaction Proposal Document Packages early, to make use of the pre-submission meetings offered by the EMA and to contact the EMA proactively for any specific product issues. When redacting CCI, applicants should cite detailed and precise justification explaining exactly how its publication would undermine the applicant's economic interests. Applicants should also ensure consistency of redactions of CCI across clinical data that are both submitted to the CTIS and which are subject to publication under the Policy.

During the webinar, the EMA explained that it is currently in the process working out certain details and finalising the various guidance documents. Whilst not yet available, the EMA explained that these documents would be made available in advance of the September 2023 restart date.

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