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Transparency Matters: New EMA Agreement

The European Medicines Agency (EMA) has come to an agreement about its policy pertaining to the publication of clinical trial data, which will allow the agency to proactively share study results that are submitted with applications for marketing authorisation. The policy will enable academic and non-commercial researchers to download, save and print such data with a view toward greater transparency of clinical trial results. The reworded policy will be submitted for adoption by the Board in mid-July, with an effective date of 1 October 2014.

Since June 2013, the EMA has worked to achieve consensus among its stakeholders, who often hold competing interests and opinions, regarding the regulation of medicines across Europe. A targeted consultation conducted in May 2014 indicated widespread support for the policy on clinical trial data publication, but concerns were raised about the limited method of data access. The so-called “view on screen only” access would have restricted the viewing of clinical trail findings, prohibiting the possibility of printing, transferring or distributing clinical study data for scientific analysis and scrutiny.

Transparency Matters to Patients, Physicians and the Pharmaceutical Industry

Clinical trial data transparency affects patients, healthcare professionals and the pharmaceutical industry. The EMA’s policy is a critical step in its campaign to ensure that the latest scientific findings are made visible and are available to decision makers who determine if, when and how new medicines reach the marketplace. The agency has pledged to protect citizens’ rights under all existing legislation related to document access and the new regulation about clinical trials.

In a statement released by the European Association of Hospital Pharmacists (EAHP) ahead of the EMA’s Management Board meeting on 12 June, EAHP President Dr. Roberto Frontini explained why transparency is so important in the reporting of clinical trial results: “It matters because it is important in avoiding duplicated efforts. It matters because patients participating do so on the basis that they are assisting wider scientific understanding of medical issues. It matters because independent secondary scrutiny of clinical trial results frequently yields new insights.”

New Policy A Result of Ongoing Advocacy Efforts

The Board’s decision comes in response to intensive efforts by transparency advocates and more than a year’s worth of consulting by the EMA with patient organisations, the pharmaceutical industry and healthcare professionals. Written concerns about the proposed view-only access to clinical trial results were formally expressed to the EMA ahead of the 12 June meeting by several health organisations including the AllTrials campaign, the British Medical Journal, the EAHP, the European Consumer Organisation, the European Ombudsman and Health Action International.

Reference: European Medicines Agency
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