In Landmark Vote, EU Passes New Clinical Trial Regulation, Including Data Transparency Measures

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By Alexander Gaffney, RAC (/SearchRegFocus.aspx?name=Alexander Gaffney)

The European Parliament (EP) today overwhelmingly passed new rules requiring pharmaceutical companies to make public the results of clinical trials, clearing the way for adoption of the rules in the EU later this year.

The 2 April 2014 vote saw approval of the new rules by a margin of 594 in favor to 17 against, with 13 members of parliament abstaining.

Background

The vote comes after months of extensive debate and numerous delays, reflecting the broad scope of the passed legislation. In addition to making clinical data publicly available, it also repeals Directive 2001/20/EC-the clinical trials directive (CTD)-and replaces it with an amended rule.

The overhaul of the CTD was first called for in July 2012 by then-Health Commissioner John Dalli, who pointed to the 25% decline in EU clinical trials. The reason, he said, was mostly attributable to the difficulties associated with conducting trials in the EU under the CTD, which Dalli said was "arguably the most heavily criticized piece of EU legislation in the area of pharmaceuticals."

Dalli said an ideal proposal would include faster assessment procedures, reporting mechanisms, timelines for approval and trial extensions, mechanisms for all of which were included in a framework proposal he put forth in July 2012.

[For more, please read our 18 July 2012 story, "New EU Clinical Trials Proposal to Ease Pharmaceutical Industry's Concerns (http://www.raps.org/focus-online/news/news-article-view/article/1938)*."]*

Then, in February 2013, the European Parliament's (EP) Committee on the Environment, Public Health and Food Safety (ENVI) announced the release of an amended version of Dalli's original proposal, which called for full publication of all clinical trial data.

"Clinical trial data should not be considered commercially confidential once a marketing authorization has been obtained," legislators wrote. "For the sake of transparency, once a clinical trial has led to marketing authorization, data generated during the clinical trial should be fully accessible."

Legislators also proposed requiring companies to generate standardized clinical study reports (CSRs) using International Conference on Harmonisation (ICH) guidelines (ICH E3). "The introduction of the clinical study report is in the interest of increased transparency," legislators explained. "These are internationally accepted guidelines on preparing a full description of a clinical trial and its results. This will help sponsors provide

harmonized information, and increase transparency by greatly increasing the amount of data available to the public and independent researchers."

[For more, please read our 5 February 2013 story, "Amended EU Clinical Trials Proposal Calls for Full Publication of Clinical Trials Data. (http://www.raps.org/focus-online/news/news-article-view/article/2820)*"]*

The legislation continued to move forward throughout 2013, but despite efforts to vote on it prior to the end of the parliamentary session during an October 2013 Plenary Session of the EP, a final vote was postponed until 2014.

New Changes

The final changes to the CTD are extensive (http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2013-0208&language=EN), and reflect literally hundreds of changes.

Among the law's important changes is a harmonization of requirements among EU states, allowing for simpler reporting procedures and centralized-rather than country-by-country-requirements. The law will make cross-border trials "much easier to conduct," especially for rare disease products, Glenic Willmott, a sponsor of the legislation, said in a statement (http://www.europarl.europa.eu/news/en/news-room/content/20140331IPR41186/html/Clinical-trials-clearer-rules-better-protection-for-patients).

The most significant change, however, is likely to be the clinical trial data transparency measures. While public advocates have been clamoring for additional transparency in the wake of a string of drug scandals involving covered-up drug risks and questionable efficacy, drug firms have countered with proposals (https://www.raps.org/focus-online/news/news-article-view/article/4814) that allow select researchers to access that data.

The fear, companies say, is that data will be misinterpreted by non-experts, casting unnecessary doubt on the safety or efficacy of their products. Also at issue is the use of data by competitors. Companies have expressed fears that their data could be used to find and patent new uses for drugs before the originating company is able to study the data, or that companies in other (i.e. developing world) markets may use the data to obtain their own approvals from local regulators.

Parliamentary officials said (http://www.europarl.europa.eu/news/en/news-room/content/20140331IPR41186/html/Clinical-trials-clearer-rules-better-protection-for-patients) they had negotiated a compromise with companies in which "detailed summaries" would need to be published in a publicly available database, with full study data to be reported at the time of a drug's approval, or once a drug's application had been withdrawn.

To be seen: Will pharmaceutical companies delay marketing their drugs in EU markets in order to preserve or protect their drug data? Or will this force the hands of drugmakers and provide a long-sought-after glimpse into the clinical data supporting many drugs?