Should the European Union relax GMO clinical trial guidelines?

Four organisations representing pharmaceutical firms, biotech companies, universities, and research institutes are calling on the European commission to update, streamline and standardise regulations used to assess applications for clinical trials of new therapies using genetically modified organisms (GMOs), saying that the current process is outdated and cumbersome.

In a joint position paper, the organisations say sponsors applying to conduct GMO clinical trials now face complicated regulatory disparities at the national level that slow down the process. The position paper recommends 11 possible solutions for improving and harmonising the framework, adding that an update would boost Europe's biomedical sector and help 'avoid unnecessary delays in patient access' to innovative medicines consisting of or containing GMOs – for example gene or cell-based therapies.

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The position paper notes that while all clinical trials in the EU must be approved by medical agencies, applications for GMO-based clinical trials must also be reviewed at the national level by ethics panels and environmental and biosafety experts.

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An EU official tells Chemistry World that the commission is 'aware of the challenges faced by developers of gene therapy medicinal products.' The official adds that commission representatives met earlier this year with national authorities involved in GMO authorisations and in clinical trial authorisations and that dialogue has continued since the meeting.

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion, and analysis. Read full, original post: Call for overhaul of EU rules on GMO clinical trial