New Route for Cooperation Between the E.U. and the U.S. on Biosimilars

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The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) have set up a new "cluster" on biosimilar medicines. Clusters are specific topical areas of mutual interest where the agencies have agreed to periodically share information.

As we have discussed previously, there are numerous differences between U.S. and European biosimilar regulation and litigation. BioCentury reports that Rachel Behrman, associate director for medical policy in FDA's Center for Drug Evaluation and Research stated in an interview that "fundamental differences in the laws they administer make harmonization difficult." It will be interesting to see whether the agencies will be able to substantively harmonize their approval processes or whether there will be biosimilar products eligible for approval in one jurisdiction but not in the other