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US FDA's draft biosimilar labeling guidance falls short on patient safety measures, says AfPA

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A critical response has been given to draft new guidance issued by the US Food and Drug Administration on the labeling of biosimilars by the Alliance for Patient Access (AfPA).

This group is a network of physicians who work to ensure patient access to approved therapies, and it has been quick to comment after the FDA last week invited feedback on its recommendations for the new labeling of biosimilar products.

Labeling is important in communicating a product's safety and effectiveness to the practitioners who decide whether to prescribe it to patients.

Amanda Conschafter, the communications director at AfPA, has written a blog post arguing that the proposed guidance could put patient safety at risk as it does not require details from clinical trials on the biosimilars to be included on labels.

The FDA recommends that practitioners use data from the reference product's label when prescribing biosimilars.

But Ms Conschafter writes: "The decision clashes with requests from health care providers and patient advocates. They have urged the FDA to require clinical trials data from the biosimilar itself, as well as a statement on whether the data's source was trials on the biologic or the biosimilar. This information could aid health care providers in determining which biosimilars might be appropriate for which patients."

Ms Conschafter also argues that the FDA has overlooked physicians and advocates' requests on indication extrapolation, the estimating of a biosimilar's impact for certain diseases based only on their similarity to the reference product.

"Given the wide range of conditions some biologic medicines treat, extrapolation may carry varying degrees of risk for patients," she writes.

Her blog echoes calls made by AfPA member Joshua Stolow for physicians to be given "transparent and clear

information about what disease states have been tested and what the clinical outcomes and potential side effects of the approved product are for that indication."

She adds: "By directing biosimilar drugs to use indication information consistent with the reference product's, however, the draft guidance undercuts physicians' ability to know which approved uses reflect rigorous testing and which result from extrapolation."

The FDA, which is accepting comments on its recommendations over the next two months, promises to review and consider all feedback received as it finalizes its guidance.