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Physician Views: New FDA biosimilar guidance – an initial reaction from oncologists and rheumatologists

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Abstracts

Last week, the FDA published new guidance on the requirements for developing biosimilars for the US market – specifically focused on clinical pharmacology requirements. The guidance covers issues relating to bioanlytical methodology, safety, immunogenicity and the types of study design that can be used to support a biosimilar application. However, the guidance stops well short of providing any solid direction in specific clinical trial design.

This is unsurprising in many ways, given that the FDA (like its European counterpart) has always maintained that biosimilar development programmes will be assessed on a case-by-case basis, whereby seeking scientific advice from the agency is highly recommended.

On one hand, therefore, the new guidance is broadly as anticipated – although notably the FDA has also introduced a ranking system for similarity between a biosimilar and originator brand ('fingerprint-like similarity,' 'highly similar,' 'similar' and 'not similar') that will be determined by comparative analytical characterisation (i.e. data that is collected in a non-clinical setting, and could include molecular weight of the protein, its higher order structure and post-translational modifications, heterogeneity, functional properties, impurity profiles and degradation profiles denoting stability).

This assessment will also determine the type, scope and rigour of clinical testing for a proposed biosimilar, and is a key feature of the latest guidance given that the FDA is the regulator that has openly acknowledged the potential approval of interchangeable biosimilars; a subject on which further guidance is expected sometime later in 2014.

Comparative analytical characterisation data for a proposed biosimilar product therefore

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looks poised to not only play a key role in how products are approved, but potentially how they are used by physicians.

In light of the FDA's new guidance, FirstWord is polling US-based oncologists and rheumatologists to ascertain how the administration's proposed assessment and approval process could influence their prescribing habits. Specifically we are asking them...

Whether their prescribing decision for a biosimilar will be influenced by comparative analytical characterisation data?

In addition to comparative analytical characterisation data, what other key attributes of a biosimilar product will influence their prescribing decision?

To what proportion of patients they would prescribe a biosimilar product approved primarily on the basis of comparative analytical characterisation data, (i.e. approval not based on safety, efficacy or immunogenicity data collected for the product during clinical studies)?

Their level of concern for patient safety if a biosimilar product was approved by the FDA based primarily on comparative analytical characterisation data, and awarded interchangeability status (i.e. substituted for the reference product without the intervention of the prescribing healthcare provider)?

To what extent they agree with extensive labelling requirements, that for products initially not deemed similar enough, but which are subsequently upgraded on the basis of manufacturing changes?

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