OVERCOMING 3 PATIENT SAFETY PLANNING PITFALLS IN BIOSIMILARS

With the promise of biosimilars inspiring countless initiatives across the biopharmaceutical landscape, competition is fierce. Regardless of your organization's experience in clinical trials and commercialization of original products, biosimilars represent a very different challenge with very different rules. Potential for a swift shutdown of your initiative in the event of a regulatory error or omission is greater than ever. Unexpected delays impede time to market and the ultimate goal: product profitability. Here are three misconceptions that often lead to inadequate planning.

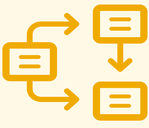
1 PRODUCING IDENTICAL LABEL INFORMATION

While the FDA and other agencies require label information for the biosimilar and the licensed reference product be identical, this is not a simple cut-and-paste exercise. For a biosimilar, you need to demonstrate the physiochemical and functional similarity between the proposed biosimilar and the reference product.

ADVICE: If structural and functional data demonstrate similarity with a high degree of certainty, biosimilars would need only to be tested in a limited clinical program involving relevant endpoints in healthy volunteers. In reality, most biosimilar products developed today are required to undergo therapeutic equivalent trials in patient populations.

2 AN INCOMPLETE RISK MANAGEMENT PLAN

As a prerequisite for approval, the risk management plan is a critical component to support regulatory submissions. A common error we see is the underestimation of what is involved in developing the plan, which typically is an arduous effort that requires many months and detailed thought.



THINGS TO CONSIDER:

- To what extent is a pharmacovigilance (PV) system required with a full safety database?
- Have you implemented a quality management system
- How will call centers be established, and personnel trained to answer questions from healthcare professionals and pharmacists?
- What risks are associated with the product relative to the indications it is intended to treat?
- What are the side effects?
- What contingencies must be considered in the patient's condition while being treated
- What monitoring might be required?
- Have you considered the PV measures, the immunogenicity risk and whether the implementation of special post marketing surveillance is required?

3 UNDERESTIMATING PHYSICIAN AND PATIENT EDUCATION

It may sound simple but one of the most common challenges is that physicians and patients still struggle with the differences between biosimilars and generics. For example, some expect the regulatory pathway to be much the same, however, due to the complexity of a biosimilar molecule, they are required to go through a much more stringent approval process. In many cases, implementing a robust medical information call center, with industry experts that can help guide and educate physicians on biosimilars, equipping them with the appropriate documentation and navigating the next steps, is critical to success.

CHOOSING THE RIGHT PARTNER

Despite the significant challenges with biosimilars, working with an experienced partner can help guide meaningful discussions with regulators and cost-conscious healthcare payers. They should be able to champion biosimilar products that have a sound basis for safety and efficacy, with careful and comprehensive planning, which can help be the key to success.

For more information: Access@PAREXEL.com

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