BIOSIMILAR DEVELOPMENT

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2018 Outlook: Biosimilar Trends To Watch

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*Last week, I published the first installment of a three-part roundtable discussion highlighting which 2017 trends/occurrences were most notable to the members of Biosimilar Development's editorial advisory board. Given the differences in companies, career focuses, and geography, their answers varied greatly. Topics of discussion included the role of Phase 3 clinical trials, market barriers, regulatory development, stakeholder education, public perception, and reimbursement frameworks. In addition to discussing 2017's impact on the future of the industry, these experts also shared their thoughts on what to expect in 2018.**

What new biosimilar trend(s) should companies pay attention to in 2018? What impact will these have on the industry moving forward?

In 2018, CMS will implement the new coding and reimbursement policy for biosimilars under Medicare Part B, which could further incentivize manufacturers to develop more competing biosimilar products in the future. Next year, CMS will work on finalizing a proposed rule that that will lower biosimilar cost share for low income subsidy enrollees in Medicare Part D. Additionally, Congress may help level the playing field in Part D through legislation that would require biosimilars to provide the same 50 percent discount as brand biologics in the coverage gap, which would lower cost sharing and improve access for enrollees, as well as provide an estimated $1 billion in savings to the federal government over 10 years. It will also be worth watching the level of success and potential barriers faced by the first biosimilar (not follow-on biologic) to be covered under Medicare Part D, which is expected to be an epoetin alfa biosimilar.

— Brian Lehman, strategic consultant, Humana Pharmacy Professional Affairs

Companies will need to address the uncertainties and fears that still remain about biosimilar use. Biosimilars are unknown to most people in the U.S., and the public is rightfully skeptical of the unknown — especially when it relates to healthcare. One way companies can do this is by laying the groundwork for introduction of their biosimilar medicines. It will not be enough to simply announce the product is now available and then expect physicians to prescribe it.

—Hillel Cohen, executive director, scientific affairs, Sandoz

There is developing interest in secondary markets and the approval of biosimilar drugs in those markets, including Latin America, Asia, and the Middle East and North Africa (MENA) region. This is creating new markets which, to date, haven't been explored to a great extent by multinational companies. The companies manufacturing in these regions are producing drugs which are beginning to be approved in Europe and North America, in turn advancing price-competitive biosimilar drugs into the first-world markets. Moving forward, this trend will encourage companies to focus on low-cost, high quality manufacturing to meet market demand and the demand of regulatory agencies in those markets.

— Don Stewart, CEO, PlantForm

Internally, some companies may question their place in the biosimilar market and their level of investment given the uncertainties constantly evolving and developing. Others may question the comprehensiveness of their strategy and chosen tactics to see if they are sufficient to manage risk and optimize the likelihood of expected returns. And, finally, others may need to seek commercialization partners to not only get to market more quickly but also to fund upcoming investments while managing risk. However, given the challenges in the generics industry, many will come back to a question they have perhaps deferred in recent years — should they begin to focus on complex injectables, 505(b)(2)s, and/or biosimilars going forward to fuel their growth and allow them to build a truly sustainable business?

—Edric Engert, managing director, Abraxeolus Consulting

New biosimilar trends to watch include the new CMS Hospital Outpatient Prospective Payment System rule and how biosimilars in Part B will be reimbursed under the 340B program. Overall, I expect to keep watching market uptake in the U.S., which has been rather slow. The IP landscape remains a challenge in the U.S., and ongoing litigation between various companies remains a key topic as it will set precedents for future decisions and may impact market access strategies.

—Sue Naeyaert, global head of pricing, market access, government affairs and policy, biosimilars, Fresenius Kabi SwissBioSim

Ensuring the sustainability of the biosimilar medicines sector will remain an essential and multi-fold process. In the pre-marketing phase, companies will continue to seek more efficient biosimilar development and regulatory processes. Considering the 35-plus years of biologic medicines, which include the 40-plus approved biosimilar medicines, Europe has a wealth of scientific data that can inform and encourage further advances of the regulatory science (e.g., reduction of confirmatory trial sizes). In addition, global regulatory convergence can be further enhanced, starting with consistent implementation of existing international guidelines. In the post-marketing phase, the stakes are high: governments fully comprehend the cost of inaction. Procurement models, pricing, and reimbursement procedures need to evolve in order to provide broader and faster access to biologic therapies as well as and resilient supply chains.

—Julie Maréchal-Jamil, director, biosimilar policy & science, Medicines for Europe

Biosimilars are expected to play a major role, not only in the field of rheumatology, but also in the field of oncology. They can be used in combination with expensive new drugs, which will lead to an overall decrease in treatment costs. The industry should plan to not only make biosimilars, but also add value to medicines by developing biobetters and new medicines that offer enhanced convenience — essentially moving toward more personalized medicines. The introduction of anti-drug antibody and pharmacokinetics monitoring kits and sub-cutaneous formulations, all of which were added, for instance, to Celltrion's infliximab biosimilar, are prime examples of how a company can differentiate its biosimilar from other biosimilar products.

— HoUng Kim, head of strategy and operations, Celltrion

There will continue to be emphasis on maintaining a high level of pharmacovigilance activities in order to adequately gather information on adverse events. The other trend I'm watching has to do with "Big Data" generation, which payers are more regularly requesting. This is a request that cannot and should not be ignored.

—Francois-Xavier Frapaise, M.D., ClinExcel

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