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24 Aug 2022 | **Interviews**

US FDA Plans Education Efforts As Humira Biosimilars Launch

by Derrick Gingery

Just-in-time education may be preferred, so patients and providers see it as they are making decisions, OTBB Director Sarah Yim says in an interview.

The US Food and Drug Administration is expecting to play more than a regulatory role in the upcoming launches of the Humira biosimilars.

Sarah Yim, director of the FDA's Office of Therapeutic Biologics and Biosimilars, said during a 22 August interview with the *Pink Sheet* that agency staff will be educating stakeholders and patients about the regulatory classifications of the competitors for *AbbVie Inc.*'s Humira (adalimumab), including the difference between biosimilar and interchangeable.

"I think there is a lot of potential for confusion and misinformation," she said. "One thing is the interchangeable versus biosimilar confusion. That's going to be triggered by Humira because there is an interchangeable among the Humira biosimilars."

"I think that's going to be a piece that we're really going to have to work on," Yim added.

The FDA has conducted educational campaigns about biosimilarity and interchangeability already, but Yim said the concept still is difficult to grasp.

US FDA's Biosimilars Group Will Conduct Some Supplement Reviews, Become 'Like Another Discipline'

By Derrick Gingery

23 Aug 2022
Office of Therapeutic Biologics and Biosimilars Director Sarah Yim says in an interview with the *Pink Sheet* that more staff are being added to deal with labeling supplements.

Read the full article here

“We’re going to have to be creative in terms of breaking through people’s sort of already pre-existing assumptions and biases about differences between biosimilars and interchangeables,” she said. “We are trying to partner with folks to get our education sort of more widespread.”

Those organizations include the US Centers for Medicare and Medicaid Services, Yim said. The agency also signed a contract with Medscape to develop and disseminate biosimilar education materials for practitioners.

Medscape’s continuing education courses for physicians, pharmacists and nurses are expected to improve health care professionals’ general understanding of biosimilars and help integrate the products into practice. (Also see "*Medscape To Develop FDA Biosimilars Educational Program*" - Generics Bulletin, 21 Feb, 2022.)

Multiple Humira biosimilars, including an interchangeable product, are expected to reach the market in 2023. (Also see "*Samsung Bioepis And Organon Get First High-Concentration Adalimumab Nod In US*" - Generics Bulletin, 17 Aug, 2022.)

The launch is considered a bellwether for the biosimilar sector because the treatment for rheumatoid arthritis, psoriatic arthritis, Crohn’s Disease and other conditions, remains a top selling drug, generating $17.33bn in net revenue in 2021, according to AbbVie.

Yim said the Humira biosimilars will help patients become more familiar with the products overall.

“Once everyone is sort of starting to use them, I think people will see that there’s really not a difference no matter what FDA says,” she said. “They’ll start to believe that there really isn’t a difference and they’ll be more receptive to future biosimilars that are coming out.”

Direct patient education about biosimilars also is in development. Yim said the timing of educational efforts also will be important to ensure its impact.

“I think a lot of times what you need is just-in-time kind of education,” she said. “People will be looking it up as they’re trying to make a decision. So timing is going to be a lot of it and accessibility, ease of access to this education. Those are the kinds of things we’re thinking about and working toward.”

(*See the sidebar above for more from the Pink Sheet interview with OTBB Director Sarah Yim.*)

Some Sectors More Difficult To Crack Than Others

Yim also said that educational efforts may be difficult for insulin and TNF inhibitor biosimilars, in part because they are patient-administered and used chronically.

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“There’s a lot more loyalty built up to a specific product,” she said. “It’s going to be both a challenge and a really pivotal moment for the biosimilar market.”

Viatris Inc. and *Biocon, Ltd.*’s Semglee (insulin glargine-yfgn) was approved and deemed interchangeable to *Sanofi*’s Lantus in 2021. (Also see "*With Interchangeability Nod, Viatris' Semglee Loses Its Identity*" - Pink Sheet, 29 Jul, 2021.)

Several problems have hurt the product, as well as Viatris’ unbranded insulin glargine biosimilar, in the market (Also see "*Labels The Issue For Viatris Again As It Recalls Insulin Glargine Biosimilar*" - Generics Bulletin, 20 Apr, 2022.), although Semglee’s placement on *Express Scripts Holding Company*’s largest national formulary for 2022 could help increase its market share. (Also see "*Semglee's Boost On Express Scripts Formulary Reflects Interchangeability – And Rebates*" - Scrip, 20 Oct, 2021.)

FDA Still Must Be Careful With Biosimilar Education, Yim Says

Yim also said the FDA must be careful not to be viewed as favoring certain products in its education efforts. She said agency education materials will not be product-specific.

“We don’t want to necessarily be leading the charge against any particular product, against or for,” Yim said. “Our education has been more science-based, like it’s been more general topic kind of education.”

But Yim acknowledged that education about individual biosimilar products could be helpful.

“I do think that people probably need to bring it down to the product level,” she said. “That might be something that we have to partner with other folks and help them as they create their product-specific education. I think there’s just some inherent problems with FDA selecting specific products to produce educational materials for.”

Indeed, individual product marketing will be left to the sponsors with competition expected to increase. The FDA is moving past a COVID-19-related slowdown and allowing more sponsors to enter the market. (Also see "*Competition Intensifies As Access Increases For US Biosimilars*" - Generics Bulletin, 20 Jun, 2022.)