

Biosimilar Developers Prepare For Applications In 2014, Approvals Mid Decade

Author: Alaina Busch

Publication: FDA Week

Date: Jan 9, 2014

Biosimilar industry stakeholders will be spending 2014 educating consumers and healthcare providers, and pressing for state pharmacy law updates in preparation for product submissions possibly this year, with the first approvals expected to start in the middle part of this decade. Companies developing these products say it will be critical to prepare the market for emergence of this new class of biologics and 2014 will be key to that effort.

Companies have been laying the groundwork at the state level, where physician notification and other substitution requirements were fiercely debated throughout 2013. The myriad stakeholders are continuing efforts to find consensus on this issue and many say they are hopeful.

Policy decisions made this year are going to influence how biosimilars are viewed once they hit the market, an industry source said. Naming, labeling and state-level record keeping requirements will be key policies debated in 2014, he said.

"From a policy perspective, the formative year is (2014) hands down," said Geoff Eich, executive director for regulatory affairs at Amgen, an innovator company also developing biosimilars that has been pushing for distinguishable names and after-the-fact physician notification requirements on the state level.

Naming -- whether the biosimilars and their reference products are distinguishable or have shared names -- will be a continued point of contention, and it is unclear what form FDA's decision will take -- be it a product approval or guidance. FDA is not expected to give details about interchangeability in the near term, industry sources said.

Last year set the stage in terms of getting ready for critical conversations in 2014, said Sumant Ramachandra, senior vice president and chief scientific officer at Hospira.

"I think 2014 is about putting it into action and 2015 is when the rubber starts hitting the road when biosimilars start getting approved in the U.S.," he said. Hospira is developing a biosimilar of Epogen and hopes to submit a dossier to the agency in late 2014, early 2015 at the latest, he said.

FDA's first biosimilar approval will occur at least 10 months after the initial product submission since the agency has 10 months to act under the negotiated biosimilar user fee program goals. Indications from industry late last year were that an application had not been filed, but it could happen sometime in 2014.

Industry sources also said they soon expect input from FDA about labeling. Agency input could address when a biosimilar pursues some of the reference product's several labeled indications. It is unclear whether the biosimilar would include all of the originator's indications or carve out the selected indications, said David Gaugh, senior vice president of science and regulatory affairs at the Generic Pharmaceutical Association. He said he expects this input to come in the form of a guidance document that could also address biosimilar naming.

The debate over biosimilar naming is playing out through a series of citizen petitions, agency submissions and lawmaker letters. Novartis and GPhA submitted petitions in 2013 advocating for shared names, while Amgen and Johnson & Johnson countered with requests for a distinguishable naming scheme. Some lawmakers say unique names would undermine congressional intent, while others believe the decision is up to FDA.

The naming debate heightened with a World Health Organization meeting in October and the international organization is set to have another international nonproprietary naming meeting in April. The competitive effects of biosimilar naming is also on the agenda for a Federal Trade Commission biosimilar meeting in February.

As companies engage in conversations with payers, consumers and healthcare providers, there are other outstanding policy questions, including substitution standards at the state level. Several companies developing biosimilars said they agree with some type of after-the-fact prescriber notification, but GPhA opposes notification requirements.

"I think what we want to espouse is that it's very important to ensure there's a transparent system that engenders communication, that communication occurs within a reasonable time period and it's really only applicable when there's an interchangeable biosimilar," said Ramachandra. He said Hospira is among many other industry stakeholders discussing the issue.

In 2013, more than a dozen states considered biosimilar substitution legislation. Laws were enacted in Oregon, Utah, and Virginia which include a sunset clause for physician notification requirements. A North

Dakota law includes physician notification but does not sunset, and a Florida biosimilar substitution law does not include a physician notification requirement. Legislation stalled in 11 other states, including a high-profile veto in California, according to GPhA statistics.

Ralph Neas, president and CEO of the GPhA, credits the industry group with blocking the stalled bills, forcing all stakeholders to have a dialogue about how to update state pharmacy laws. GPhA believes notification requirements could undermine substitution.

"The board made it quite clear in terms of its opposition to notification," said Neas, although noting that there could be other ways to address the issue that have not been discussed.

Charlie Mayr, chief communications officer at Actavis, which is teaming up with Amgen in some of its biosimilar development programs, said the state-level fight over biosimilars is different than the debates that followed the passage of Hatch-Waxman and the establishment of small-molecule generic drugs. He said notifying the physician of the substitution following dispensing is not about creating a barrier, and more about making sure patient information is up-to-date. The challenge moving forward is overcoming prejudices from those older battles.

"We were all small molecule guys," he said. "We were all fighting the brand guys not to erect barriers -- 30 years of not trusting the other guy. I think that perception is a challenge for us to overcome because I think in some cases people looking at this legislation are fighting a 20th century fight in the 21st century."