GENERICS BULLETIN
CITELINE COMMERCIAL

07 Oct 2021 | **Interviews**

Teva's Baeder: We Need To 'Crack The Nut' Of Complex Generics

US Generics Division COO Says Optimum Environment Needs To Be Created

by David Wallace

Industry and regulators need to collaborate to provide complex generics with the opportunity to build even further on the significant contributions already made by off-patent medicines to savings and access, Christine Baeder, senior vice president and chief operating officer of Teva's US generics division, tells *Generics Bulletin* in the first part of an exclusive interview.

When *Teva* published its *economic impact report for 2020* earlier this year, the numbers were a reminder of the significant impact that generic medicines have on healthcare systems worldwide.

Across 14 countries, the company said it had contributed savings to healthcare systems of $43.1bn in 2020. Of this total, $28.8bn came in the US alone, where the firm said its savings contribution came to $374.6bn over the past decade.

And speaking with *Generics Bulletin*, Christine Baeder – senior vice president and chief operating officer of Teva's US generics division – said that in order to continue building on this progress, it was key for both industry and regulators to come together and make the most of advances in complex generics and biosimilars.

Referring to the economic impact report, Baeder said Teva "really couldn't be prouder of the impact that we have for local communities, for local communities, and the actual dollars saved in healthcare systems and in patients' pockets."

"Not only do we save $28bn for the US government, we save $4bn for patients," she highlighted. "That's not insignificant, that's very important."

And "I guess my view on the most important piece of that is that we continue to provide those savings," she said, "which requires us to crack the nut of complex generics and bringing those products to market. And then obviously the natural progression into biosimilars" which although it revolves around "different and different issues, is closely linked. And to do that I think requires a few very specific things."

One of these was greater certainty in terms of product review cycles and the predictability of timeframes for getting products to market, she indicated. "Investment in generic products requires business cases that often have very thin margins," she pointed out. "And one piece that is controllable in that puzzle is a little more certainty on the review cycle, and therefore getting products to market in a more predictable timeframe leads to increased investment. So that would be one of the things that I would certainly call out as an important piece of things."

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"Then in addition, as the whole globe struggles with the economic impact of the pandemic as well as the pre-existing pressure in healthcare costs globally, you get to this place where we really do need to have the co-operation and support of the policymakers, obviously in the US but also globally, to continue to encourage and support the generics industry."

However, Baeder was upbeat on this prospect, "because the generics industry is actually a success story, and one of the places where policymakers, regulators and manufacturers all have the exact same goal, which is affordable medicines that can be available more broadly."

Nevertheless, she said, "we need to ensure that as policies change, some in response specifically to the economic crises, that we don't make mistakes that injure the generics industry and therefore don't allow us to continue to bring this amount of savings, which is extremely impressive and important, globally as well as in the US." Ultimately, she highlighted, "$28bn is not a small investment, and that's before we even get to the number of jobs that we create and the economic impact around those jobs. So it's important that we have support to keep the generics industry healthy."

Asked whether the solutions and pathways forward in this area were more in the regulatory or legislative arena, she said "I think it's both. Certainly we've made some steps, and there's been a

lot of negotiation on GDUFA III, that are important, and we are hopefully moving in the right direction there."

The US Food and Drug Administration's complex generics program will see changes under GDUFA III as sponsors look for more ways to speed the process of bringing products to market. Specifically, the GDUFA III agreement includes updates to the mid-assessment cycle meeting and post-complete response meeting processes. (Also see "*GDUFA III Talks Completed*" - Generics Bulletin, 3 Sep, 2021.)

But Baeder said that "I also think that as we go into this budgetary cycle – and there may be changes, it's been all over the press but I think you'd need a crystal ball to know what those changes might be – we need to ensure that we don't do things that injure the overall sustainability of the generics industry, because I do believe that it plays such a key role in the overall affordability and access to healthcare."

US Price Erosion 'In Line With Historic Norms'

Asked about whether there were lessons that could be learned from experiences with small-molecule generics as the industry increasingly shifts its focus towards complex generics and biosimilars, Baeder said "I think there are some lessons, but look, if you go back 10 or 20 years in generics, there were things that we didn't know how to do well then. And as an entire market, manufacturing, R&D, regulatory… as the science progresses and becomes more complex, the benefit to patients is that opens up innovative care that wasn't available before, and that's fantastic."

"We then need to have a generic ecosystem that helps us bring those innovations to the patients as a more affordable play. So everything evolves over time, and as the science is complicated, the way that we respond to it needs to continue to progress as well."

Touching on price erosion in the US – especially given the context of Teva's recent portfolio rationalization activities that have seen the company prune unprofitable products – Baeder suggested that the breadth of Teva's product offering gave the firm a unique perspective.

"Overall, sustaining a generics business requires discipline in where you spend your capital and what you prioritize," she summarized. "So it will be always an ongoing process, and it probably is in all businesses, that you look at where you want to invest and where you feel like you can compete and add value."

"There are of course molecules in any generic manufacturing portfolio that maybe on their own don't make financial sense but [where] you do have an obligation to patient care that we also take very seriously. So it's not always just a financial decision."

"That said, as far as price erosion, Teva has a very broad portfolio so our view on this may be different to some of our competitors, but I tend to see erosion on a molecule-by-molecule basis."

"Do I see certain molecules that are undergoing a very aggressive erosion cycle? Sure I do. Do I see other molecules that are quite stable? Yes I do."

"So I think it's a bit of a blend, I would say it's probably in line with historic norms, but I do think it really does depend on your portfolio mix."

Teva Remains Neutral On Erosion Worries After Sandoz Remarks

By Dean Rudge

30 Apr 2021

Teva was drawn into the conversation around generic price erosion, especially in the US and Europe, after Sandoz singled out the unfavorable effect during a lackluster Q1.

Read the full article here

Oncology And Diabetes Are Key Areas For Complex Generics

Asked about specific opportunities for Teva in complex generics, Baeder said that "complex generics, in our portfolio and in the broader market, they treat everything from cancer to psoriasis to diabetes," and areas like this were where Teva saw "the drugs that are actually bringing a lot of these advancements in healthcare."

"So it's across a broad spectrum of usage. And I would say that Teva is going to be in many of those disease states."

"One of the things that I think is one of the most concentrated benefits," she suggested, "is that there will be a lot of drugs brought to market by Teva and others specific to cancer, different cancer treatments." These currently "have very high prices and are a very big cost area."

"The other disease state where I think you'll see a real shift in the next five to ten years will be diabetes, when we can get to generic GLP-1s and GLP-2s and all of those types of exciting treatments that are coming."

> ***"I don't know that I would say that progress is too slow, but what I would say is that there is the opportunity to do better, in co-ordination with manufacturing and the FDA."***

Asked whether regulators were keeping step with developments in complex generics or whether a lack of progress on the regulatory side was acting as a brake on the industry, Baeder said "I don't know that I would say that progress is too slow, but what I would say is that there is the opportunity to do better, in co-ordination with manufacturing and the FDA."

"Objectively, if you look globally, the US tends to be behind the number of biosimilars that are on the market versus Europe and Canada," she acknowledged as an example, "but we are quickly catching up. And I find that extremely encouraging, because what I see there is that we are, as manufacturers and regulators and legislators, working together towards the same goal of bringing the affordable medications to the market."

That meant that "sometimes we have to reset on how we communicate, how do we do things, how do we work together quicker, more collaboratively in order to get across that finish line," she observed. "And that's happening, and that's a lot of what was discussed in GDUFA III. And I think that we're moving in the right direction."

So overall, Baeder summarized, "I'm strongly encouraged. One of the things that I often say – and you really can't say it much about politics – is that this is one place where every stakeholder's goal is aligned. Everyone wants to bring affordable medication to populations, that's probably true globally. So that's one of the few places where there's true alignment. Which should make figuring out how to do it much easier."

'Nuanced Conversation' On Need To Win Prescriber Confidence

On the question of whether prescribers' confidence in complex generics was a barrier for the off-patent industry that needed to be overcome, Baeder suggested that "I think that that's going to be a little bit more of a nuanced conversation."

"I think there's a very different comfort level for some disease states for others, and quite frankly, if you go back to traditional generics, that's true too – there are narrow therapeutic index drugs where doctors have very strong opinions about generic fluctuations versus brand products."

"So I think we're going to have the same amount of work to do, and I think it will be more dependent not so much on the class of complex generics or biosimilars, but the specific disease and the specific treatment."

Asked whether that would require firms to unlock the market by individual disease areas – and have similar conversations with prescribers and physicians each time new therapeutic areas were opened up to competition – she acknowledged that "I think there's an education process, [and] that is fair."

“If you’re taking care of someone’s life and someone’s health, the fact that you want to have more information before you make a change or ask a patient to be comfortable with something that’s new or different, that’s fair and that’s responsible,” she commented.

“And I applaud the physicians who ask those questions, and it’s beholden on the industry to be able to answer them. And I think we all need to be open to what makes sense in a more macro sense.”

In the concluding part of this interview, Baeder discusses Teva’s experiences with biosimilars and interest in value-added medicines. (Also see "Teva Blends Branded And Generic Mindsets To Boost Biosimilars" - Generics Bulletin, 7 Oct, 2021.)