



BLURRED LINES: Is The Generics Industry Moving Into Big Pharma's Space?





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Once upon a time the divisions, differences and unique capabilities of the innovative biopharmaceutical and generics industries were clear-cut and easy for all to see. The generics industry was an opponent for innovator pharma to keep a close eye on and underestimate at its peril. However, it may be argued that the battle lines have started to blur, and a competitor industry is now a potential partner for licensing and co-promotion. Could there come a time when these two once distinct industries merge into one?

A group of industry experts from the pharmaceutical industry gathered at the House of Lords in London, UK on November 20, 2019 to discuss these themes when considering the pharma model of the future's shape and breadth. Up for discussion were topics such as how originator and generics industries are diverging, and to what extent do innovators want to play in the hybrid value-added/specialty space? Are originators still interested in life cycle management to sustain brands? Who will win the biosimilars race?



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Chrys Kokino, *Head Global Biologics & Insulins Commercial, Mylan*

Markus Sieger, *CEO, Polpharma Group*

Elisabeth Stampa, *CEO, Medichem*

Paul Tredwell, *Vice President Specialty Brands, Accord Healthcare*

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When considering the impact of the generics and biosimilars industry on the innovator industry, and the way in which it operates in the competitive environment, it is difficult to look past the most recent move from one of the biggest beasts in the pharmaceutical world. Pfizer's move to merge its off-patent branded and generics medicines business Upjohn with Mylan will establish the top generics drug company in the world based on consolidated revenues. The combined company has been given a new moniker – Viatris – and will be led by Upjohn CEO Michael Goettler.

While this deal accelerates Mylan's plans to globalize its footprint, leveraging Upjohn's commercial infrastructure for its portfolio and the pipeline, Pfizer may have also made a shrewd move by uncoupling itself from a maturing business in decline, leaving it able to sharpen its focus on innovative technologies such as cell and gene therapies and charter its future past biosimilars and generics.

Swiss major Novartis has also been repositioning its relationship with its generics business Sandoz. It has been given more autonomy to operate by its parent company and a new CEO in Richard Saynor. A spin-out has been widely speculated about in the media. Other examples, such as Mallinckrodt spinning off its generics business in 2018, and the announcement from Perrigo in August 2019 that selling its prescription pharmaceuticals will allow the generics business to better capitalize on its unique portfolio, have signalled that innovator pharma is realigning its strategy.

RETRACTING AND REFOCUSING

Originator pharma seeking to unbuckle itself from generics pharma and double down on core capabilities is a trend, said the panel, and a cyclical one. "I think everyone is refocusing in their core business," said Elisabeth Stampa, CEO

of the Spanish API manufacturer Medichem. "Maybe five to eight years ago big pharma had to have its big core business and some other businesses around that, having a foot here and a foot there, and now all of a sudden everyone is trying to get rid of those businesses and focusing." This is a global trend, she continued, seen in India with Glenmark and in Europe with Spanish companies Ferrer and Esteve.

This strategic wave, of refocusing on core capabilities, follows off-patent peaks, said Accord Healthcare's non-executive director Lord Gadhia. Mark Hersee, of the private equity house BC Partners, agreed that the trend was cyclical and pointed out that this was not peculiar to health care. Diversification gets rid of the risk and creates scale, increasing company value, but the power of compounding means it is difficult to grow exponentially. "Originators became massive and you had to own a generics business," he recalled. "It was a protection against when the patents fell away. Now everyone is running to the other side of the ship and there are all these carve-outs. It is not just a health care thing. Now, as a chief executive of a company, you get rewarded for focus and for people understanding the story of what your company stands for. Investors build their own portfolios. They do not need CEOs to do the diversification."

James Burt, EMENA head for Accord Healthcare, said that it seemed that generics companies had historically struggled to grow to much more than \$10–12bn in yearly revenues. "The argument was always about economies of scale," he said. "If you could get to that massive size you could really squeeze out smaller players. In reality you cannot because you are a bit slower and a little less focused on what you are good at."

GIANT GENERICS

Mylan is a very recent example of a generics company di-

versifying into multiple therapy areas and increasing in size. Chrys Kokino, Mylan's global head of biosimilars and insulins, told the gathered panelists that the company had "changed rather dramatically" since he joined five years ago. Moving from being a pure-play generics firm, it now has diverse capabilities including respiratory products, sterile injectables, topicals and transdermals, biologics and insulins, OTC products and oral solid-dose formulations. "If you now look at Mylan we have one of the broadest portfolios of any manufacturer and are on our way to become one of the global leaders in this space. With additional competitors, there will always be pricing pressure. From a pure business perspective, we must always reevaluate the business opportunity with all products," Kokino said.

"The market changes in a week let alone in three or four years," he said. "All the money you have invested you have to re-think to yourself, 'What is the real strategy here?' With a company like Mylan we are constantly changing direction, although there is a global vision for sure to become diversified. Having said that, there is a lot of commitment to those four or five different businesses as well as the core therapeutic areas - oncology, immunology, dermatology, endocrinology and others. That helps the organization."

Although the generics industry is seemingly broadening the spectrum of therapeutic areas it serves, the trend to de-diversify may be counterintuitive to the business model the originator industry has built up, said James Burt. Commenting on a recent example of a firm's plans to separate its generics and brand companies, claiming the activities had no synergies, he said he felt a dissonance when it was set out that the two models were so different there seemed



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little point in keeping them together. "Apart from the regulatory functions, the back-office functions, apart from your relationship with key Integrated Healthcare Professionals, apart from your supply chain, your warehousing, manufacturing, regulatory," he argued.

"If you look at the core business, there is a huge amount of synergy between generics and brand. Sure, at the engagement level with the health care professional it might differ in terms of the audience you are trying to influence, but on the whole the vast majority of it, nine-tenths of the iceberg, is pretty common. I think there is synergy." Accord is committed to having a generics and brand interplay, he explained, calling it holistic selling. "At the end of the day the patient does not care if it is a generic medicine or a branded medicine they are taking, they just want to be made better. Our job is to make it better."

Accord Healthcare's head of specialty brands Paul Tredwell highlighted the fact that generic scale opens the doors to branded product revenue streams. "One of the benefits we have is that there are no added-value products without the generics side and there are no added-value products without the retail arm in certain countries. If you provide one in five medicines to the UK as generic medicines you have a scale where you can interact with retail pharmacy, and if you are strong in hospital pharmacy in Europe you bring meaning to that hospital giving you a platform to launch branded products."

"When it comes down to size and scale that sort of holistic approach buys you a lot of credibility, whether it be health care professionals or clinicians," he continued. "Scale will buy credibility."

Tredwell also concurred with Kokino's sentiments, that scale is good but focus is vital. "From my perspective, scale is good to a point but potentially can get too big if there is not focus. If you have a strategic focus, whether you call it franchises or therapy areas, Accord is focused on five core franchises, we are very set up to develop, market and sell products, with a clear specialist focus into those franchises. We do not mind if it is a biosimilar or a branded product as a novel chemical entity."

BIOSIMILARS WINNERS

The panelists were asked to consider who is the likely winner in the biosimilars arena. Big players such as Biogen, Amgen and Merck & Co. are operating in this area, but is it likely to be those using the generics model who are used to playing in tender community markets? Or originators who claim to have the manufacturing expertise, reputation and relationships? There are of course pure-play developers such as Coherus Biosciences that must not be discounted.

Mylan's Kokino believes that the portfolio approach his company is rolling out makes a huge difference to customers. The company operates in 165 countries, he explained, to capture volume in multiple markets versus relying solely on price in larger markets. As prices decline in some markets, Mylan may offset these potential revenue losses due to price erosion by having the ability to sell more volume in many more countries.

"I think [for] those organizations that do not have that [portfolio], we cannot predict whether they will succeed or fail but, clearly, it is an advantage to have that portfolio to be able to participate," Kokino said.

Tredwell concurred with Kokino's sentiments and explained that this is also an approach Accord is taking, sticking to the core key therapy areas of oncology, autoimmune, CNS, critical care and fertility. "If you look at mine and Chrys' background, we are both from a branded company origin but we have worked in a generics business, and I firmly believe that is what is required for success," he said.

"You need a commercial acumen that only the generics companies can offer, to drive the immediacy of results, but a branded side to ensure that differentiation exists, whether through the drug, its delivery or the wrap-around care. That acumen has to flow through your bloodstream as you develop these complex products. You do also however want the lowest cost base, so need the generics mentality on vertical integration, development and ensuring clever cost minimization. That will be a clear marketing leading attribute to cover yourself for any future eventuality."

Markus Sieger, CEO of Polpharma, added that the cell lines at its Dutch cell line production company Bioceros were "as effective as the innovator cell line. You have to control the whole production setup from API to the finished products to stay competitive, especially for tendered products."

James Burt concurred, adding that it was "amazing how the state of the art progresses," pointing out that a cost base is going to be much better if you are making a biologic drug seven years or 10 years after the original, both in terms of yields and ancillary factors, such as the plug-and-play nature of disposable bioreactors now (compared with stainless steel), which did not exist 10 years ago.

In five year's time the biosimilars market "will look very different" said Tredwell. "We started this biosimilars journey around 20 years ago so I have seen it evolve through many phases. The manufacturing capability and yields are important as the cost base is crucial."

Panel moderator Aidan Fry ended the discussion by asking, at what point do biosimilars become so diluting to originator companies' operating margins that they do not want to be playing in this field? Accord's Burt succinctly summed up the general panelist view that there is more likelihood of success of companies in the generics world going up the value chain than the people at the top of the value chain going down.



ABOUT ACCORD HEALTHCARE

Headquartered in the United Kingdom (UK), Accord Healthcare Europe is one of the fastest growing pharmaceutical companies in Europe. Accord has one of the largest market footprints of any European generic and biosimilars companies selling generic medicines in over 80 countries around the world.

This global footprint enables us to deliver vital, affordable medicines to national health systems supporting healthcare professionals to transform patient lives worldwide.

Our approach is agile and inventive, always seeking to improve our products and patients' access to them. We're driven to think differently and deliver more for the benefit of patients worldwide

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