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Finding Growth In A Tough Environment

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Within the global pharmaceutical industry, generics are far from flavor of the month. Around the world, large-scale pharma companies are reducing their interests in the off-patent sector, be it through Pfizer merging its Upjohn mature brands unit with Mylan, Novartis selling off Sandoz's oral-dose and dermatology interests in the US or Sanofi divesting its Zentiva European generics business to private-equity investor Advent.

And amid a tough operating environment for generics, especially in the US, many other players are reconsidering whether they want to compete at often minimal profit margins. Mallinckrodt, for example, is spinning off its generics division in a bid to double down on its patented prescription brands business, while Perrigo is pursuing a similar strategy as it seeks to focus on its core consumer health care operations.

Against this industry background, senior pharma industry executives gathered at the UK's House of Lords in late November to discuss the future of the pharma sector at a roundtable hosted by Accord Healthcare, *Scrip* and *Generics Bulletin*.

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PANELISTS

Lord Jitesh Gadhia, *Non-Executive board member,* Accord Healthcare

James Burt, *Executive Vice-President EMENA,* Accord Healthcare

Shaun Chilton, *CEO,* Clinigen

Mark Hersee, *Partner,* BC Partners

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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Reflecting on recent moves to separate branded and generics elements, Accord's executive vice-president for Europe, the Middle East and Africa, James Burt, questioned whether suggestions of a lack of synergies between such elements were well supported. Quite apart from the potential to share back-office and supply-chain functions, he argued that there were more commonalities than differences.

"At Accord, we are very committed to having a generics and brands interplay through what we term holistic selling," Burt stated. "At the end of the day, the patient does not care if it is a generic or branded medicine they are taking. They just want us to do our job, which is to make it better."

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Elisabeth Stampa, CEO of Spanish generics developer and raw materials supplier Medichem, observed that the pharma industry was currently in a cycle of shifting away from diversification, citing the example of how many traditional Indian generics players such as Glenmark were carving out their drug-discovery arms from their core off-patent business. "I think everyone is refocusing on their core business, no matter whether they are in generics or original drugs," she remarked.

Placing recent pharma industry trends in a broader context, Mark Hersee – a partner at the BC Partners private-equity fund that currently invests in complex generics developers Pharmathen and Synthon, as well as in contract manufacturer Aenova – pointed out that diversification was out of fashion. "The power of compounding means that when you get very large, you cannot grow anymore," he noted. "Where are you going to find billions of growth every year?"

Acknowledging how originators were shifting away from using a presence in generics to hedge against the effects of patent expiries, Hersee observed that "now, as a chief executive, you get rewarded for focus and for people understanding the story of what your company stands for." Investors, he said, built up their own broad portfolios and did not need CEOs to do their risk diversification for them.

"You focus on the real highest-quality part of your business and you grow from that point," Hersee summarized. Given the current low interest rates, he said investors were keen on health care businesses that generated steady cash flows. "There are pockets of bubble behavior, and there are pockets that we think are quite reasonably valued," he commented.

Responding to Hersee's comments around the difficulty of finding sufficient growth engines in large companies, Burt argued that the rationale of realizing economies of scale and squeezing out smaller players was flawed. "In reality, as you get to very large scale you are a bit slower and a little less focused on what you are good at," he asserted.

Reflecting on the position of his own company as it prepared to merge with Pfizer's Upjohn, Mylan's commercial

head of global biologics and insulins, Chrys Kokino, said the company had made a concerted effort to diversify away from being a pure-play generics supplier to build differentiated franchises in areas such as biosimilars, respiratory, women's health care, antiretrovirals and OTC. Focusing on the biosimilars business for which he is responsible, he pointed out that Mylan had used partnerships to build a world-leading portfolio and pipeline, but stressed that the rapidly changing nature of the biologics market meant investments should constantly be reviewed.

Accord's vice-president of specialty brands, Paul Tredwell, agreed that having a clear strategic focus on core franchises or therapy areas was important. And while scale could be an advantage, allowing commercial strategy to be dictated by the regulatory status of products made less sense. "Getting the right product to the patient and making it better for both the patient and the physician is what is important."

"There was a saying that branded companies always wanted a generics company, and generics companies always wanted a branded company – and once you have got both, you go into OTC," Tredwell remarked. "For me, it comes down to focus and skill sets," he said, pointing out how possessing scale in retail pharmacy or hospital settings brought credibility and relevance with customers and clinicians.

Picking up on the discussion around strategic portfolio selection, Markus Sieger, CEO of Polish branded generics player and biosimilars developer Polpharma, said his company offered a broad range of company-labeled generics, branded generics, OTC medicines and food supplements. "We believe the key is not the legal category, but rather building up therapeutic franchises," he explained. As an example, he cited how Polpharma had been able to capitalize on its prescription heritage with the Maxigra sildenafil branded generic to develop an OTC switch version, advertised on television as Maxigra Go.

"We are building our business in our four core countries, where we are really focusing on being in the top 10 by building our presence and creating growth through this franchise concept," Sieger outlined. "I truly believe a regional or local market approach will be successful in the long term. The closer we are to stakeholders in the markets, the better we can perform."

"The question of size is an interesting one – we constantly ask ourselves whether or not we would be better off as part of a bigger structure," he continued. Highlighting the Polpharma Group's five manufacturing facilities in Poland, as well as one plant each in Kazakhstan and Russia, that gave the firm flexibility around issues such as batch sizes, Sieger insisted: "There is a sweet spot in being local and using the strength of our regional brand, along with from an industrial and research and development perspective in creating centers of competence that focus on particular therapeutic areas or delivery forms."

Within their roles on the executive board of industry association Medicines for Europe, both Sieger and Burt said they had been wrestling with concerns about how consolidation on the customer side was leading to fragility in terms of security of supply.

Burt argued that the sartan recall issue had been exacerbated by supply-chain consolidation, whereby manufacturers had been forced by customer consolidation to rely to a large degree on a single raw-materials supplier.

In Europe, Sieger highlighted, hundreds of molecules were no longer available because it was simply not economically viable to make and market them. Regulatory barriers and quality requirements often put additional strains on supply chains, he added.

Cautioning against a "race to the bottom," Burt appealed for a "middle ground where value is recognized" and customers, including monopsonies such as national health systems, understood the commercial imperatives on

suppliers. "Payers often feel they can run a command economy and trample over free-market economics with no consequences," he argued.

While Accord's average ex-factory selling price in the UK was around one euro per pack, Burt complained that media reports sometimes focused on isolated cases of percentage-based price increases that were often only a rise from an unsustainable price of a few cents per pack and never recognized the discounting that lowered the price of many more items. He referenced the recent Oxera report which demonstrated in a comparison with five European countries that UK prices are generally lower (up to 3 to 4.5 times lower) and freedom of pricing and low regulatory barriers in the UK are likely to be critical factors in driving this outcome.

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Pointing out how the global supply chain had been shaken up by new environmental regulations in China closing down at least 2,000 intermediates and active pharmaceutical ingredient suppliers almost overnight, Stampa questioned whether relocating intermediates production to Europe was viable from an economic or environmental perspective. But Sieger believed that vertical integration, supported by European health care policy, was the only way for local industry to truly control its supply standards.

"I do not think security of supply is about controlling the manufacturing," countered Shaun Chilton, CEO of clinical trials and unlicensed medicines specialist Clinigen. "Security of supply is understanding the imbalance between demand and supply, which comes back to the choice about regional or global." Controlling the channel was key, he believed, adding that this was also a way to combat counterfeit drugs.

Noting that his company had been referred to as "the Amazon of unlicensed medicine," Chilton argued that Internet access had revolutionized how patients thought about procuring medicines.

Hersee believed pharmaceuticals fitted perfectly with Amazon's business model of "looking for a product that has brand, where there is loyalty, that is small but high value, and you can put it through a letter box." But Chilton was skeptical that Amazon would be willing to engage in such a highly regulated sector.

Sieger saw in the progress of online pharmacies and pharmacy chains, especially in the OTC sector, opportunities for manufacturers to cooperate within their core therapeutic franchises.

"I am less worried by Amazon," Sieger asserted. He posited a future business model whereby pharma companies would focus on offering tailored, holistic health care services, including preventive medicine, directly to consumers through a Netflix-style subscription model. "Compliance is a huge issue for our industry, as more than 30% of drugs are not taken at the right time, or at all," he stressed, adding that modern technologies such as apps could encourage patients to engage and add value to treatment outcomes.

Burt agreed that companies providing medicines needed to go "beyond just the tablet" to add value and potentially secure intellectual-property protection for innovating around known molecules. His Accord colleague Tredwell insisted that improvements such as taking hospital drugs into homecare settings, backed by digital services, was a key means to differentiate and compete beyond lowest-price

tenders. For such strategies to succeed, he said industry must lobby for authorities to adopt a most economically advantageous, or MEAT, approach to procurement that attributed additional value to improved product features.

Sieger maintained that technology could improve compliance without imposing cost burdens on payers, with countries such as Belgium starting to adapt their procurement practices to reflect improved treatment outcomes. But given political election cycles, getting politicians to engage long-term could be difficult.

Mylan's Kokino outlined how short-term thinking was also blunting the savings potential from biosimilars in the US. He appealed for all stakeholders to compromise on sharing the economic benefits of biologics competition in the interests of patient access. Otherwise, he feared for the long-term sustainability of the biosimilars sector. Payers obsessed with making immediate savings needed to understand the biosimilars investment timelines to ensure that competition continued.

Burt voiced concerns over how price reductions due to biosimilars competition were not always translating into greater usage in countries such as in Eastern Europe. "Lower prices are not going to facilitate better outcomes if prescribers do not shift their treatment paradigms," he argued.

Tredwell warned against legislative moves in Europe toward large-scale pharmacy substitution of biologics and other complex medicines, insisting that this could lead to both shortages due to lack of supply-chain flexibility and to poor patient outcomes. "I do not believe patients taking chronic medicines that have good adherence to a given device are well served by changing the device the following week," he stated.

Burt cited the greater propensity for variability with large biologic molecules, even seen with reference biologics, as a further argument against automatic substitution. "Aside from this, substitution creates a race to the bottom, forcing supply chains to consolidate, which then brings fragility as we have seen with small-molecule generics," he warned.

In the biosimilars sector, Kokino believed global scale was essential to diversify commercial risks and maximize returns on development costs. "Our interactions with customers in the US show that the portfolio does make a difference," he asserted, pointing out how managed-care organizations would see value in a company offering diabetes solutions that included small molecules such as metformin as well as large-molecule insulin pens.

Tredwell agreed that having a broad biologics portfolio in certain therapeutic areas was important. Observing that both he and Kokino had worked for both biologics originators and biosimilars suppliers, he argued that for biosimilars "you need a commercial acumen that only the generics companies can offer. But an appreciation of the branded approach to marketing and product differentiation was also important."

"In five years' time, I think the biosimilars market will look very different," Tredwell predicted, stressing the importance of an efficient cost base. Sieger concurred, outlining how Polpharma Biologics' control from the cell line upward enabled it to maximize margins.

Tredwell's Accord colleague Burt highlighted how biosimilars developers were able to capitalize on the latest technical advances in biologics production and questioned whether originator companies would be satisfied with the profit margins generated by biosimilars in the medium term.

"I think there is more likelihood of success for people from the generic world going up the value chain than the people at the top of the value chain going down," Burt asserted.

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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