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Fixing The UK Market: Government Must Move From 'Transactional' To 'Strategic' Approach

BGMA Chair Diane DiGangi Trench Explains Why A Fresh Relationship With Industry Is Needed

by David Wallace

With the UK market experiencing approval delays, shortages, and regulatory complexity, the government's "policy vacuum" and complacent approach to off-patent medicines risk undermining the sector, says BGMA chair Diane DiGangi Trench. In an exclusive interview with *Generics Bulletin*, she urges a shift from a "transactional" to a "strategic" relationship with industry to fully unlock the benefits of generics and biosimilars.

"The last few years have been challenging, and I think we still see a multitude of issues potentially undermining the commercial attractiveness and resilience of the UK market." That is the blunt assessment provided by Diane DiGangi Trench, chair of the British Generics Manufacturers Association – and country head and general manager for Sandoz UK and Ireland – when asked to summarize the current state of the UK operating environment for generics and biosimilars.

Citing aspects such as the sluggish performance of the UK's Medicines and Healthcare products Regulatory Agency; product shortages; complexity of post-Brexit regulations; pricing agreements like the recently renegotiated voluntary scheme on pricing, access and growth (VPAG); and preparations for upcoming regulatory changes in Northern Ireland, DiGangi Trench had no shortage of current hot-button issues to touch upon as she spoke with *Generics Bulletin* for an exclusive interview in which she passionately advocated for improvements necessary for the off-patent industry to thrive.

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"I think most of all, we feel like the biggest problem is that there's a policy vacuum overall for the off patent sector, which really needs to be addressed," she underlined. "That's really what we believe will help increase the attractiveness of the market and sustain it more for the long term."

A dedicated policy for the UK off-patent industry has long been urged by the BGMA, which has made clear its disappointment in being snubbed by government life sciences strategies in the past. (Also see "*BGMA 'Astonished' By UK Government Snub*" - Generics Bulletin, 7 Jul, 2021.)

More recently, the association has issued a manifesto urging specific action that the off-patent industry would like to see translated into government policy, against the backdrop of a looming UK general election within the next year (*see sidebar*).

BGMA Warns That Policy Vacuum Risks UK Becoming 'Supply Backwater'

By David Wallace

25 Mar 2024
With a UK general election looming, local generics and biosimilars industry association the BGMA has warned that the country will be "deprioritized as a supply market" without a more focused and supportive policy environment for the off-patent sector.

Read the full article here

Tangible impacts of this policy void are already apparent. In recent months, UK drug shortages have increasingly made headlines, with DiGangi Trench acknowledging that the "multi-faceted" problem involved both local and global factors. These included "challenges in the Red Sea, scarcity of active pharmaceutical ingredient for particular medicines" with these then "exacerbated by other global factors. Last year it was inflationary cost pressures with producing medicines. That's come a bit down."

"However, I think the common thread is that in the UK for too long there's really been this complacency around the benefits that the NHS [National Health Service] is receiving, and the government overall is receiving from the generics and biosimilars sector."

"I think it's really because the NHS has done a fantastic job," she suggested. "We have some of the lowest cost medicines across Europe. But I think in the long term, that downward price pressure has an impact on supply – and I think because the prices of certain molecules are pushed so low, it really isn't sustainable. And that's why some companies just stop producing certain medicines, and then that concentrates the industry obviously and puts pressure on supply."

"I think that will continue, unfortunately," she predicted, "unless there's greater incentivization for the off patent sector."

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Moving From A 'Transactional' To 'Strategic' Approach

In particular, DiGangi Trench highlighted the need for government policy to move from a "transactional" approach to the off-patent industry to a more "strategic" way of thinking.

On supply issues, she said, "I think it's a really fine balance. The NHS keeps asking to stockpile medicines, and to ensure that if you want to tender that you ring-fence an eight week supply for them." But this was "putting the costs and the risk all on the manufacturers and not sharing that."

"I know there is a risk for the NHS not to have medicine for patients that need it," she acknowledged, "but we need to really come together – and that's where the strategic relationship really needs to, I think, improve."

"Right now the transactional relationship works really well, and that's proven in the prices that are garnered in the UK." But where more action was needed was on the "bigger picture, whether it's a biosimilar strategy, whether it's a supply and shortage strategy. I think we really need to level up both with each other, the off-patent sector with the NHS and DHSC [Department of Health and Social Care]."

This thinking could extend outside the UK, she suggested. "I think things like becoming part of the Critical Medicines Alliance at the EU level, I think that could help the government have a more strategic relationship with suppliers, by taking a broader view of the situation and not having just a UK view; realizing that the issue is more global and it's not just UK-based, and so we need a more global solution." (Also see "*New Critical Medicines Alliance Says Join Us In Tackling Critical Medicines Shortages*" - Pink Sheet, 30 Jan, 2024.)

Dedicated Biosimilars Strategy Needed

Asked about biosimilars specifically – after the BGMA last year warned that the UK sector could become "economically unviable" for suppliers (*see sidebar*) – DiGangi Trench said that the industry was "at an exciting precipice, with 85 biosimilars coming out over the next five years."

"I think rough estimates would say that right now the off-patent sector overall saves the NHS about £15bn ($19bn) annually, and these new biosimilars over the next five years have the potential – again, rough estimates – of saving the NHS around £2.5bn annually. So it's a big opportunity for cost savings for the NHS."

But again referring to a "policy vacuum,"

UK Risks Becoming 'Economically Unviable' For Biosimilars

By David Wallace

21 Aug 2023

Amid increasing financial pressure from the

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she said "we definitely need a biosimilar strategy, and not just at the NHS."

"The NHS is quite open to this," she acknowledged. "I really feel like they've prioritized biosimilars. They're looking at this, they're aligned with the BGMA's goals around biosimilars. They know what's at stake."

VPAS rebate scheme and a lack of a national uptake strategy, the BGMA has warned that the UK risks losing its leading position in European biosimilars and could become altogether "economically unviable" for biosimilars suppliers.

Read the full article here

But "I think the broader government, from a life sciences vision or policy standpoint, that's really where they need to understand the value that biosimilars can bring over the next five years."

A new UK registration pathway for biosimilars introduced in the wake of Brexit – that would not typically require comparative efficacy data (Also see "*UK Could Become 'World Leader' On Biosimilar Regulation*" - Generics Bulletin, 29 Apr, 2021.) – was "a step in the right direction, especially globally to have the MHRA be a leading global regulator again, I think it's a sign that they can kind of return to previous leadership," DiGangi Trench suggested. But as far as the impact of this change was concerned, "I think it's too early to tell."

Another problem for biosimilars, she said was that "currently, there's no established way for NICE [the National Institute for Health and Care Excellence] to evaluate the value of biosimilars and potentially the wider use and expansion of biosimilars when prices drop considerably once the LOE [loss of exclusivity] happens."

Previous NICE decisions in this area – such as a 2021 move to expand access to adalimumab, etanercept and infliximab for rheumatoid arthritis patients, in the wake of biosimilar competition (Also see "*NICE Decision On Arthritis Opens Door For Biosimilars*" - Generics Bulletin, 15 Jun, 2021.) – had been made "on an ad hoc basis, unfortunately," she pointed out.

"There needs to be a process when a biosimilar comes out," she said, that would indicate "how NICE re-evaluates the value of the biosimilar and the expansion to other patient populations." This would "help the growth of biosimilars in the coming years."

"The MHRA is not in the place that we need it to be as a country."

Turning to discussion of the MHRA – which recently issued fresh guidelines outlining changes aimed at shortening assessments for established medicines (Also see "*UK Body Urges Action On Licensing Delays As MHRA Unveils Guidance For Established Products*" - Generics Bulletin, 6 Mar, 2024.) – DiGangi Trench said "obviously there's been a ton of challenges with the MHRA operationally. I think they've admitted things are not going well, but they're trying to get back on track."

"I think everyone's acknowledged the MHRA is not in the place that we need it to be as a country," she outlined. "I think we need to get back to having our medicines approved, new medicines within a year and changes to labels within three months."

"I do think they're putting the right steps in place to solve the backlog of issues," she volunteered. "I think what they're doing are the right things." But at this point it was early in the process, and "we need to wait and see how this pans out to make sure that the KPIs [key performance indicators] that they're outlining can be met."

'A Lot Of Work To Do' In Northern Ireland

Meanwhile, recent changes made to the regulatory status of Northern Ireland represented progress but also meant "a lot of work" for the off-patent industry in a short space of time, DiGangi Trench highlighted. (Also see "*Industry Welcomes UK-EU Northern Ireland Deal*" - Generics Bulletin, 28 Feb, 2023.)

"I think the implementation of the Windsor framework resolves the two main longstanding problems," she explained. "It enables the same pack of medicine to be made available to all patients across the UK regardless of where they live. And then it restores the UK-wide regulatory MA [marketing authorization], moving away from the fragmented market."

But "I think to achieve the goals that it sets out, the industry also has a lot of work to do," she underlined. "Most BGMA members have hundreds of labels, if not thousands, to revise with this UK-only pack label. So 10 months is a short time period to get this work done."

Nevertheless, she concluded "the Windsor framework I think is a welcome change to resolving the issues of the fragmentation of the past."

> ***"We didn't let the fact that we weren't at the [VPAG negotiation] table get in the way of really ensuring that the off-patent sector had a voice overall."***

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Another long-running cause for concern has been the negotiation of a voluntary scheme on pricing, access and growth, or VPAG, to replace the previous voluntary scheme for branded medicines pricing and access (VPAS) that featured an escalating rebate applied to branded generics and biosimilars as well as originator brands.

While the BGMA had been denied equal status to brand industry association the ABPI as part of the negotiations – despite the BGMA's protestation that its interests could not be properly represented by the ABPI (Also see "*BGMA Denied In Bid To Negotiate Over VPAS Rebate Scheme*" - Generics Bulletin, 11 Jul, 2023.) – the generics and biosimilars industry association continued to lobby for a differentiated approach to off-patent medicines. (Also see "*BGMA Sets Out Suggestions For VPAS Overhaul*" - Generics Bulletin, 16 Jun, 2023.)

It was ultimately rewarded with a scheme that "recognizes that a one-size-fits-all rebate doesn't work and a more nuanced approach is needed" (*see sidebar*).

The new VPAG scheme, said DiGangi Trench, "represents an improvement for the majority of companies, and we're really pleased for the first time that products that face more competition, like branded generics and biosimilars, that they're recognized and differentiated in the scheme."

BGMA Warms Up To UK's VPAG Scheme

By David Wallace

20 Dec 2023
Responding to the formal publication of the UK's new voluntary scheme on pricing, access and growth, off-patent industry association the BGMA has praised the scheme's new differentiated approach.

Read the full article here

"It's the first time ever the scheme has really recognized products differently, from a newer/older definition, and taken into account the value that's already being provided in terms of discount to the NHS. So we're really, really happy about that."

"Obviously, we were extremely disappointed that we didn't have a seat at the table for the actual negotiations," she conceded, "but I would say that it's because we really didn't give up – and we fully utilized and pushed for more frequent and more robust discussions with the Department of Health as well as the NHS – I think that's why you see a scheme that has this differentiation. Because we didn't let the fact that we weren't at the table get in the way of really ensuring that the off-patent sector had a voice overall and that the scheme would represent us."

"VPAG, as painful as it was at times and as disappointed as we were, I think it forced us to really amplify our discussions," DiGangi Trench suggested. "I think the industry came together like we never had before. I think with [BGMA chief executive] Mark Samuels' leadership, we were able to

have one voice across the government, across OLS [the Office for Life Sciences] and NHS – and the NHS especially really helped partner with us to help deliver our message and amplify it to the Department of Health, which I think resulted in some of the gains with the current scheme."

Not that VPAG was perfect, she recognized, acknowledging that "there's a lot more work to do." In particular, she suggested removing biosimilars from the scheme altogether.

"I think biosimilars as a whole, if you think about the value that they're going to provide over the next five years, I think that we really need to reconsider excluding biosimilars from a scheme like VPAG," she urged. "We've released white papers to show that there could be a lot more value if biosimilars were excluded from additional tax."

> ***"We're quite optimistic that a Labour government could represent our voice in a more prominent way."***

Returning to the BGMA's overall vision for the UK market, DiGangi Trench acknowledged that in an election year, there was a possibility of a change in government and perhaps a change in the strategic direction for the off-patent sector.

A life sciences plan recently unveiled by the Labour party – which current polling suggests is in line to form the next UK government, taking over from the Conservative incumbents – was recently welcomed by the BGMA, but was also seen as having room to go further in terms of being tailored to generics and biosimilars (*see sidebar*).

"I think it's quite an exciting time," DiGangi Trench said. "I think we believe whatever party forms the next government, it is critical that the life sciences strategy covers the off-patent segment of the market."

UK Industry Urges Labour To Go Further With Life Sciences Plan

By David Wallace

05 Feb 2024

A life sciences plan unveiled by the UK's Labour party – which polls indicate is likely to take power after the country's imminent general election – could "go further in considering the role of off-patent medicines," the BGMA believes.

Read the full article here

Indicating that the BGMA had already "met with numerous Labour politicians to brief them on the importance of the sector," she commented that "I think that whilst [Labour] released an early vision for life sciences, I would say there's still room for opportunity for them to form their full view. I think they're still learning, but the reception so far has been really positive. So I think we're quite optimistic that a Labour government could represent our voice in a more prominent way."

'Leveling Up' The Relationship Between Government And Industry

More generally, milestones on the horizon for the sector included "several high-value biologics going off patent," she observed, offering "huge savings, huge access opportunities for the entire sector."

"However, again, the operating environment needs to work, policies need to be in place," she said, reeling off a list of key areas where improvement was needed.

"We need a biosimilar strategy for England. We need regulatory reform and to fix the MHRA. We have to prioritize the 12 month application for new medicines, and it's currently taking about two years. I think we need economic and domestic growth to encourage inward investment. For example, the volume of medicine supplied by our industry should be afforded equal policy input representations, opportunities to bid on government funding, since both really are essential to driving innovation."

"I think we need access in terms of what to do about shortages. Again, there's a range of opportunities there. I think it's important that tenders are awarded in good time, so suppliers can make the product for the contract duration and the right quantity. I think if buffer stocks are required, as we've talked about before, then that buildup would need to take longer and should also be factored in."

And in terms of global partnerships involving intellectual property provisions, "the UK is looked at as a leader when it comes to decisions around IP in pharma, and I think we need to continue to be a leader and not take a step backwards there." (Also see "*BGMA Urges UK To Hold Firm On Trade Deals*" - Generics Bulletin, 10 Feb, 2020.)

> ***"I think we've made a ton of progress as an industry, the off-patent part of the industry, in really the last 12 to 18 months in having a stronger voice."***

In summary, she said, “I think it’s really just leveling up the strategic nature of the relationship between [government and] our industry.”

“I’m a natural optimist,” she reflected, “so I prefer to focus on progress – and I do believe, if you ask from a BGMA perspective, I think we’ve made a ton of progress as an industry, the off-patent part of the industry, in really the last 12 to 18 months in having a stronger voice. I think influencing VPAG I think was a really positive step in the right direction.”

“So there’s some things I feel quite bullish on and quite positive about the future. And then there’s other, I would say the bigger strategic issues, where we really still feel like it’s challenging and there’s a void and we need to start these discussions and having a more strategic relationship with the government.”

“I’m positive about it. I think we’ve made progress,” she said. “So I think we can do that. I think we can show our value, not just in the cost savings that we produce day in and day out, but I think we can show our more strategic value and work together with the government in the coming years.”

“I think it’s critical, especially in the state that the economy and the NHS is in, that we do that. And again, I’m a natural optimist, so I am positive that we can begin to do so.”