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‘Putting Electric Motors Into Classic Cars’ – Burt Sets Out European Potential Of Value Added Medicines

Medicines For Europe’s New Sector Chief Highlights Opportunities For Innovation

by David Wallace

Pharmanovia CEO James Burt recently took over as chair of Medicines for Europe’s value added medicines sector group. In an exclusive interview with *Generics Bulletin*, he looks to the future for innovation around known medicines in Europe, including landmark EU legislation on the horizon and the importance of stakeholder dialogue throughout the supply chain.

Medicines for Europe’s fifth annual value added medicines conference, held in Brussels in November, not only marked a milestone for the sector in Europe – in the form of EU legislative efforts to recognise the value of repurposed medicines with a proposed four-year period of data exclusivity protection for new indications (Also see "*European Opportunities Loom For Value Added Medicines*" - Generics Bulletin, 15 Nov, 2023.) – but also marked the transition from one Medicines for Europe value added medicines sector chair to the next.

At the conference, James Burt – formerly head of the EMENA region at Accord Healthcare, now CEO of value added medicines specialist Pharmanovia – took over the role from Viatris’s Arun Narayan (*see sidebar*). Burt spoke with *Generics Bulletin* on the sidelines of the conference to set out his view of the sector as he took the reins.

“I think Arun has done a fantastic job,” Burt said as he marked the transition. Noting that he had already served as vice-chair of the sector group for the last couple of years, he suggested that “what’s really important is that continuity.”

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As such, "Arun is going to maintain, as part of his portfolio, direct involvement in the project around closing out the legislation" while it was still at the amendment phase, Burt indicated.

Then "as of April next year, it then moves into pretty much the final phase. And in parallel with the European heads of government, amendment and dialogue. And then there's [European Parliament] elections next year."

"So we're getting close maybe to being at the beginning of the end, or maybe the end of the beginning. But it's not done yet."

However, once this legislation was in place, Burt said, the conversation around value added medicines in Europe would once again evolve. "It really then moves into: great, you've got the regulatory pathway for a value added medicine, that's been shored up." And "hopefully, there's a reference to a period of exclusivity," he added, all of which was "aping the [US] 505(b)(2) type approach."

But Burt cautioned that these efforts were "all well and good, if you can get HTA [health technology assessment] buy-in." Therefore, moves towards a more informal interaction between the European Medicines Agency and national HTAs were "vital," he suggested.

"So one of the other key objectives over the next two years, definitely what I will be focusing on, is that engagement with HTAs," Burt outlined. "I think we all want the same thing: it's going to be a cost-effective way of improving health outcomes. But it's not necessarily going to be a slam dunk, even if we've got the legislation."

Going Beyond Repurposing

Asked whether repurposing was at the forefront of the value added medicines sector in Europe, especially in light of the proposed data exclusivity protection for new indications, Burt said "I'll be honest, for me, value added medicines is much bigger than that repositioning."

"I think that's a vital part of it," he acknowledged. "There's plenty of unmet need out there." But he also pointed to recent technological advances that held a huge amount of potential for known

'Parts Of The Dream Are Coming True' – Narayan Marks Progress On Value Added Medicines In Europe

By David Wallace

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Clear progress is being made in the European value added medicines sector, Medicines for Europe's outgoing sector chair Arun Narayan has highlighted in an interview with *Generics Bulletin*. However, there is still more work to be done to ensure that the market is supported by imminent legislative and regulatory initiatives, to ensure patients' access to continuous innovation for existing medicines.

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medicines.

“You have this explosion of pharmaceutical technology over the last 20-30 years,” he described. “A lot of old medicines have utility today – they’re perfectly efficacious, they’ve got decades of pharmacovigilance information around the place.” And by applying new technologies to existing medicines, he said, “the whole use, reduce, re-use, recycle mentality swings into gear.”

“You’ve got ways to modify kinetics now that didn’t exist before, we’ve got new routes of administration – it doesn’t just have to be an immediate-release, fixed-dose combination, we can actually have different pharmacokinetics of different components. All of this is in the mix. And I don’t think we want to miss the opportunity to incentivize bringing that tech to bear on well-known medicines.”

Moreover, this idea went beyond small-molecule drugs, he suggested – “it also applies to the first-generation biologics. It’s the same concept, I don’t think we need to differentiate between small molecule and big molecule, value added medicines encapsulates both.” The question was, “how do you make a better version?”

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“My short form of how to explain value added medicines is like a classic car,” Burt set out. “We’ve got the ability in this room to put electric motors into these classic cars – to make them fit for the future, make them fit for the emissions standards of tomorrow. And it’s the same with medicines. The sort of central philosophical need is to create incentives to do it.”

It was therefore important, he insisted, when looking at the market to “get away from this idea that there’s the generic off-patent end [and] there’s the branded new blockbuster end. There’s plenty of space in middle.”

“Countries like the US have capitalized on that,” he said, “because they’ve had a pathway and incentive system that allows you to get some reward. No-one is expecting to get the same pitch points that you would for a first-in-class medicines; but at the same time, if you don’t create a stepping stone on incentives, where’s the incentive?”

Asked whether there was now a more tangible sense of a growing momentum for value added

medicines in Europe – especially given the traction seen for projects such as the European Commission's expert group on safe and timely access to medicines for patients (STAMP) or REMEDi4ALL – Burt replied "100%."

"Look, we're at the amendment phase on the pharmaceutical strategy," he recalled. "We've still got some tweaks we want to make today. But it's being listened to. And you're getting stakeholders like EMA, like others, the consortium groups starting to recognize we'd get a much better outcome if we work together."

"My view with the NGO inclusion is that I think they're brilliant for sourcing ideas," Burt said. "And they've got lots of understanding, along with the patient advocacy groups, of the real world problems that are out there. Sometimes with the academic groups, you've got fantastic formulations scientists and people who can get to a point."

"I'm lucky in that I've got a very end-to-end job. And in my role, I have to deal with [a product] from the ideation, through the clinical development, through the manufacturing, through the supply chain, through the quality affairs, into regulatory, into price, into sales and marketing. That's what we've got as industry. And that's what NGOs and some of these other stakeholders don't have."

And even when a product was successfully brought to the registration stage, he said, "I think there's a lot more to it than just getting your registration. It's what happens after that registration. And you want to do things before the registration, to make sure it carries on after."

"So my strong view [for the sector] is that there is traction, it's good that we've got stakeholders coming together, and more of that would be appreciated."

No Room For Complacency On EU Legislation

Finally, asked about major milestones coming up for value added medicines, Burt touched on the passage of the proposed EU legislation and whether there were any counter pressures that could threaten to derail it.

"Different parts have different beneficiaries and detractors, you know – it's not done until it's done," he acknowledged. Having said that, "I do genuinely think there's a general groundswell of positivity from policymakers and regulators to get recognition of a fair reward for genuine innovation."

And "the next trick is then, as I say, making sure that cascades down to the HTAs. That's a national competence."

In general though, he concluded, "it feels like we're on a good trajectory. I'm just not prepared to

get complacent about the legislation."