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The UK's Future As Innovator In A Post-Brexit, Post-Coronavirus World

Top Industry Exec Sees Chance To Map Out Key Roles For MHRA

by Ian Schofield

Regulatory flexibilities combined with experience in cell and gene therapy and the wider use of technologies such as AI could help to keep the post-Brexit UK at the forefront of innovation in the life sciences. A UK regulatory conference will be discussing these and other key issues next week.

There are lessons to be learned from the response to the COVID-19 pandemic, particularly in terms of regulatory flexibilities, faster clinical trial approvals, and greater use of virtual meetings, telehealth and artificial intelligence. The question is how to make sure those lessons are incorporated into overall regulatory practice for new medicines and vaccines in future, says Steve Bates, CEO of the UK BioIndustry Association.

"We have seen close engagement from the regulators on flexibility on regulatory pathways," Bates said, noting in particular the UK government's proposal to allow the use of COVID-19 vaccines once the clinical data are in but before they have been licensed. (Also see "*BIA Applauds UK Plan For Pre-Approval Use Of Coronavirus Vaccine*" - Pink Sheet, 1 Sep, 2020.)

This was the "clearest example of agility we have seen from regulators and government to make sure they are ready and that they have novel approaches, that have been publicly consulted on, to deal with what may be very innovative products arriving very quickly in a pandemic period," he told the *Pink Sheet* in an interview.

Bates was speaking ahead of the Regulatory Innovation Conference 2020 that the BIA is hosting virtually on 17 September, together with the UK's Medicines and Healthcare products Regulatory Agency. The organizers say it will cover a wide range of crucial topics as the UK comes to terms with the "new normal" wrought by the coronavirus and prepares to leave the EU regulatory

system at the beginning of 2021.

The *conference* will cover topics such as "interactive and responsive" regulation, stimulating and fostering access to innovation through the MHRA's new partnership with the health technology assessment body NICE, new approaches to clinical trials, and the use of real world data. Bates said the conference "should allow regulatory affairs professionals to have as clear a sense as possible of what will be a few tumultuous months ahead."

> *"The question is, how do we capture what is best, what has worked, and embed it into regulatory practice?" – BIA CEO Steve Bates*

One question thrown up by the coronavirus crisis is what permanent regulatory changes the UK could make to ensure it is better prepared for future emerging health threats, for example in new drug and vaccine development. The lessons learned from COVID-19, and how to ensure the UK remains competitive in newly emerging technologies, will be addressed by Lord Bethell, the innovation minister, in his keynote address.

"I would be interested to see how the minister sets this out because practitioners in clinical trials and the clinical development pathway have seen many changes in the COVID-19 era," Bates observed. "People have found things that work and there is a strong desire to build those efficiencies in." Examples he gave included faster ethics committee approvals for trials, and the widespread use of Zoom or other virtual meetings.

There had been some other "fundamental changes" too. Telehealth "is here to stay – there has been a decade's worth of e-health developments in a few weeks, forced on us by lockdown." The question now is "how do we capture what is best, what has worked, and embed it into regulatory practice?" he said.

One example of how things had worked out well during the crisis was the clinical trial authorization process for COVID-19, where the MHRA, National Health Service hospitals, companies, the Health Research Agency and the National Institute for Health Research worked together quickly and efficiently to get clinical trials for vaccines up and running. "Is this something we could see more of in the future, for other medicines and treatments?" Bates asked.

The MHRA's New Look

From next year the MHRA will become a fully freestanding regulator, with responsibility for

evaluating all the novel, innovative medicines that are coming through company pipelines. Its new chief executive, June Raine, will be speaking at the conference on the agency's "transformed regulatory role" in the UK innovation ecosystem.

Bates sees opportunities to make the most of the MHRA's experience in the EU context, particularly as a regulator of innovative cell and gene therapy. The UK remains "a global center for much of this development, so it is a natural step to think about the MHRA continuing to do this work in a global context," he said.

"Increasingly we are seeing... the desire for standardization and industrialization of some of these things as they move from being practices in academia to fully industrialized processes. I think there is an opportunity there and we will have the right people together" to talk about these issues at the conference, he added.

"One challenge we face is that few regulators are expert in everything and there may be a need to build expertise in certain subsets or to take a global lead in certain areas," Bates noted. He said it would be "interesting to see where the MHRA is in that discussion, and to bring a global regulatory flavor from companies" to the event.

The UK's Role In R&D

As for new ways of conducting R&D in future, Bates said the UK had "a strong genomics heritage with significant data sets," and a single health care system with patient identifiers, and it would be useful to leverage some of those capabilities. For example, something that had emerged from company thinking in the COVID-19 era was the use of AI, for example in improving target selection and "being able to give closer predictions" at an early stage of drug discovery.

"The question is, as AI or machine learning algorithms come into use, and we have some larger datasets that are novel and could be of use, how do you adapt the capacity that you have?" he asked. For example, there is "real time data now coming in from people saying whether they have been for a COVID-19 test, and you have a whole host of other types of data available."

This is not "gold quality randomized clinical trial data" but it is "not unhelpful," he said. Sir Michael Rawlins, former chair of the MHRA board who has been succeeded by Stephen Lightfoot, was "very keen on this and I'll be interested to see if the new chair and leadership is too."

Asked what the MHRA should offer the UK biotech industry that it currently gets from the European Medicines Agency, Bates said that "innovation advice to SMEs for free is something that would be great and would enable the UK SME base to engage easily with the MHRA. This is not in [the MHRA's] current thinking, so it would be interesting to talk to them about that."

Clinical Trials

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Much has been said about the potential role of the UK in looking at new ways of designing clinical trials, and Bates feels it has a head start, not least given the streamlined patient data flows offered by the NHS.

As a concrete example of what could be done, he cited Novartis's deal with NHS England in January this year to give speedy access to the gene silencing cholesterol lowerer, inclisiran, which the Swiss firm acquired through its purchase of The Medicines Company. The deal includes the provision of the drug through a "population-level" agreement for high-risk patients, a large-scale clinical trial in primary prevention, and an industry-academia collaboration on manufacturing synergies.

"This is a good example of novel design that the MHRA was happy to work with, but it is also the type of thing that only a health care system with the data flow of the UK could easily construct," Bates declared.

He said it was important to "make sure the MHRA has the innovative capacity to do this, because I am conscious that they are going through a big change in the nature of the agency's remit. From an industry perspective we need to understand how big a change the transition from being within a European system to a standalone agency is, not only for the individuals involved but also for the business model of the MHRA, which is changing significantly."

He noted though that the UK Recovery trial platform and other studies had "given global players increased confidence in the UK's ability to deliver good results for patients and statistically valid clinical development." The Recovery trial showed, among other things, the potential of dexamethasone as a treatment for COVID-19 patients. (Also see "*Coronavirus Notebook: EU In More Vaccine Talks, HTA Rolling Reviews, and RECOVERY's UK Expansion*" - Pink Sheet, 25 Aug, 2020.)

Regulation And HTA

Another development to be discussed at the conference is the partnership between the MHRA and NICE on the data needed on new therapies for both regulatory and cost-effectiveness purposes.

"There is a clear synergy between work of several of agencies that look at both safety and efficacy and cost effectiveness of novel therapeutics, and we can see the desire to work together," Bates said.

Noting the change of leadership at NICE – Gillian Leng was appointed chief executive in March this year and Sharmila Nebhrajani took up the post of chair in May – Bates said there was the "chance for modernization and harmonization and some new players who may bring fresh approaches, and this is one reason why this is a really interesting time."

As for efforts to harmonize HTA evaluations across Europe, he said he was “keen to hear more from the new NICE leadership on how they see the opportunities here.”

Finally, Bates cited the advantages of the virtual format of the forthcoming BIA-MHRA conference in terms of reaching a wider regulatory audience. “We are looking to see stronger global participation that may link to some of the ideas that might feed into future engagement with players around the world,” he declared.