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Rx-To-OTC Switch, Digitalization And CBD High On The Agenda For UK Industry In 2021

by [David Ridley](#)

The PAGB's Michelle Riddalls tells HBW Insight about the association's hopes for post-Brexit Rx-to-OTC switch, its exciting research into the impact of digitalization on the UK consumer health industry, as well as its intention to look at whether to welcome the country's fast-growing CBD food supplements manufacturers into the fold.

One of the potential silver linings of the UK's exit from the European Union at the beginning of this year is greater flexibility for the country's Medicines and Healthcare products Regulatory Agency.

Outside the regulatory systems of the EU, the MHRA will have the opportunity to explore different pathways to Rx-to-OTC switch, for example, and break new ground in considering real-world evidence generated from digital tools to expedite reclassifications.

That's the hope shared by PAGB CEO Michelle Riddalls in an exclusive interview with HBW Insight, in which the UK industry association head also expresses optimism about the possibilities for post-COVID Britain.

PAGB CEO MICHELLE RIDDALLS

Riddalls gives an update on the work already done by the association on digitalization, and promises an event this summer showcasing the findings of the PAGB working group investigating the impacts on the UK consumer health industry of e-commerce, social media marketing and mobile health apps, among other things.

Cannabidiol (CBD) is also on the agenda for the association, Riddalls reveals, as the increasingly



popular food supplement ingredient approaches a more regulated future this April.

Last time we spoke, you suggested that Brexit may bring some increased regulatory independence and flexibility for the MHRA, especially with regards to Rx-to-OTC switch. Do you think that's still the case?

I certainly think that Brexit opens up the opportunity for us to look at more innovative pathways for Rx-to-OTC switching in the UK. We were talking to the MHRA about this last year but it went on hold because of COVID. So, we've already started those conversations and we hope they'll continue this year to help things move forward. It's an exciting proposition. Digital technology may be able to help, especially given the huge shifts in this direction during the pandemic. We can also think about the progression of a medicine to general sales list status as soon as it becomes pharmacy-only. We know what needs to happen for a medicine to become GSL, so we can start thinking about this early on and help companies gather the evidence needed as soon as a product becomes a P medicine. The MHRA have talked a lot about rolling reviews in other areas. Perhaps that's something that we can look at further.

Q You mentioned the impact of digital technology. Before the pandemic, PAGB created a working group looking into how e-commerce, advertising and social media, digital self-care, patient information, and mobile apps were shaping the UK consumer health industry. How has this work progressed since then?

A We did an awful lot last year to move the agenda forward in all of these areas. We're now getting to the end of this project and we've generated a lot of data. We're looking to plan a digital week in early July to present some of our findings and recommendations. Topics will range from how to leverage real-world evidence to creating social media guidelines, which companies have been crying out for and are

needed now more than ever. All of this is even more timely given what's going on, and we're excited to present the work we have done. We've already published our Digital Self Care Audit, which you've written about previously and which looked at the quality and accessibility of online platforms and apps commonly used by UK consumers during the pandemic. (Also see "[UK Industry Urges Policy Makers To Help People Towards Digital Self-Care Services](#)" - HBW Insight, 17 Nov, 2020.)

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One of the things we found was that there isn't a real hub for people to go online and find good sources of self-care information. We are now having conversations with the NHS about how to provide this in a way that helps our members add value to their consumer health products via digital technology. Some of our members already doing interesting things with apps, for example Johnson & Johnson's Nicorette QuickMist SmartTrack product and Alliance Pharma's Living with Eczema app (Also see "[I&I Leverages Power Of Digital Personalization With Nicorette UK Extension](#)" - HBW Insight, 26 Nov, 2020.). These can help educate consumers and allow them to take more control of their treatment, which ultimately relieves the burden on the National Health Service. The pandemic and associated lockdown forced many health services to go digital very suddenly. That had some downsides – it put NHS 111 under significant pressure, for example – but overall, it helped speed up a transition with positive benefits that otherwise would have taken years to happen. It's great that there are some silver linings in terms of enabling things to move forward more quickly.

Q What about e-commerce? Has the shift online been beneficial to industry? And how has bricks-and-mortar pharmacy come out of this?

A The shift has been a natural fallout from the pandemic. E-commerce does widen access for consumers, particularly people who can't easily shop in person – and there have been many more of those than usual because of COVID-19. The shift to online shopping also enables companies to target and personalize their products and empowers consumers to self-care, with a wealth of information about products available at a click of a button. For me, when I'm shopping online, clicking between screens sometimes makes it easier to understand and compare and contrast than if I'm looking at products on a shelf in a supermarket. But there's still a really important role for bricks-and-mortar pharmacy, which has been at the forefront of the response to COVID-19 in so many ways.

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Pharmacies have kept their doors open, quite literally, when that wasn't the case for some other healthcare providers. They've been under huge pressure. I don't think that e-commerce will necessarily detract from community pharmacy because if people want to have a conversation with a healthcare professional about an OTC medicine, the best way to do that is still face to face in a pharmacy. So as I see it at the moment, they're complementary. And of course, many of the first COVID-19 vaccines have been administered in pharmacies and drugstores. That's a really positive illustration of the kind of service they provide.

Q Will 2021 be the year that PAGB takes a position on cannabidiol – a food supplement ingredient that has taken the consumer health market by storm over the last couple of years, and has proven to be a headache for regulators

like the MHRA?

A We are already starting to look at it for sure. There's been a lot going on with CBD as you know, and for a number of years it's been an unregulated environment with people not knowing what is and isn't legal. It really helped last year when the Food Standards Agency announced that by 31 March 2021 all products on the market would need to be backed up by a Novel Food dossier. That's helped clarify requirements for CBD food supplements in the UK. The on-going debates about CBD in Europe have also been interesting. We were waiting in anticipation for the ruling by the European Court of Justice following the case brought against CBD vape marketer Kanavape in France. Now that the ECJ has concluded that CBD extracted from the Cannabis sativa plant in its entirety is not a narcotic drug, we can deal with CBD as a novel food going forward.

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At the moment we're evaluating how CBD can fit with existing legislation and how to ensure the safety and quality of CBD supplements on the market. We're trying to ascertain whether we then want to move forward and say that CBD companies can apply for PAGB membership. For us, we've got to make sure that we feel that it's safe and compliant. We do have member companies that are interested in CBD, but there's been a general reticence because of the uncertainty in the market up to this point.

