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UK Industry Hit By Brexit Uncertainty, Spies Opportunity

by David Ridley

While post-Brexit regulatory alignment remains a priority for the British self-care industry, the increased flexibility afforded by the MHRA becoming a sovereign regulator could allow the UK to become a beacon of innovation on the edge of a re-aligned Europe, says PAGB CEO John Smith.

Britain's consumer healthcare industry is feeling the effects of months and months of uncertainty with regards to the UK's exit from the European Union, according to the country's self-care industry association, PAGB.

A series of delays and rejected Brexit deals have made firms operating in the UK market think twice about investing in new OTC products or innovative switches, PAGB's chief executive officer John Smith told *HBW Insight*.



JOHN SMITH

Part of a trilogy of exclusive interviews, this piece explores the challenges of Brexit, but also the opportunities presented by the possibility of the UK's Medicines and Healthcare products Regulatory Agency becoming a sovereign regulator in the future.

John Smith has always been a forward-thinking leader. According to Smith, and the increased flexibility afforded by Brexit could allow the UK to become a beacon of innovation on the edge of a re-aligned Europe.

Q A lot of the guidance issued with regards to Brexit by the UK medicines agency, the MHRA, focuses on the importance of maintaining the supply of prescription medicines. Can you comment on why OTCs must also be an important part of the conversation?

A Just think if parents can't buy medicine to treat their sick child. They are going to end up going to their general practitioner (GP) or will turn to other primary care providers like a hospital's Accident and Emergency (A&E) service. This will cause havoc, particularly in winter when those services are already under pressure. The point is that if there is a shortage of OTC medicines, or if it becomes more difficult for whatever reason for people go out and get OTC medicines, then this is going to place additional pressure on the UK's National Health Service. But I do think that the MHRA understands that OTCs are important and that they have to make sure that they are thinking about what the future of the UK consumer healthcare market looks like going forward. It is also important to say that the UK's Department of Health and Social Care has included OTC medicines in its no deal contingency planning and we have worked very closely with them on that.

Q What would you say are the most pressing concerns for the UK OTC industry?

A I think staying aligned with EU regulations for medicines and medical devices is very important for us. We don't want two regulatory systems in the UK and EU respectively, which is what might happen if we crash out without a deal. What we've tried to do is understand the key concerns of our members with regards to Brexit and communicate those to the UK government and the MHRA. We need to make sure that batch testing of medicines in the EU is fully recognized in the UK and vice versa, for example. Otherwise, firms are going to have to do this twice, which would be an absolute disaster. That's probably top of our list of things that we want to make sure continue after Brexit.

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Other questions we want to address include: How do we stay aligned with the EU on safety issues? How do we make sure that safety reporting is the same? Because what you don't want to do is create a two-tier system. We're also trying to work well with all the other trade associations. We're very much aligned with what the ABPI (Association of the British Pharmaceutical Industry) is saying on Brexit, for example. Clearly for us it's, how do we stay aligned with the EU so that we don't have any problems? And if there is going to be any change, how do we have a decent transition period to ensure companies have enough time to move to the new arrangements?

Q Are there any opportunities for UK industry with Brexit?

A I think the MHRA is also thinking about what it means to be a sovereign regulator. I think if the MHRA does end up with more flexibility to do things that it couldn't do in the EU, with their pragmatic and sensible approach to medicines regulation, it could be quite an exciting time for the UK consumer healthcare industry. We could be a shining light through Europe. I think we're a bit like that anyway to be honest, but it's about trying to find the best of both worlds. You've got to be careful.

Q That is the problem with the Brexit negotiations generally though isn't it? The UK wants to have its cake and eat it, so to speak.

A To extend the metaphor, we want the cake but then we also want to pick the cherries we want from the cake as well. I think we've got to be really careful because the downside of divergence from the EU could outweigh any possible upside. At the moment, our key position is that we want to stay aligned with the EU regulations and any changes have got to go through a proper transition period so that industry can

make sure there is a constant supply of OTC medicines to citizens on both sides of the English Channel.

Q How is all this uncertainty affecting your members?

A I think it is making them think twice before making investment decisions. I think things are being put on hold a little bit because you never know what is going to happen next. There's been so much time and effort spent on just discussing and being prepared for all the different scenarios of an EU exit. When you think about it, firms should be thinking about other things.

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How can we make sure we are maximizing production? How can we make sure we providing access to products? How can we look at a reclassification? According to a recent PAGB survey, there are several of our member companies spending millions of pounds just on Brexit.

Q What is PAGB doing to get its members ready for Brexit?

A We've been supporting our members with regular updates on the negotiations and no deal planning for the last couple of years. Most recently we ran some webinars on Brexit preparedness. These were mainly concerned with bringing all the parts of the UK government's Brexit guidance that are relevant to the UK consumer healthcare market – OTCs, self-care medical devices and food supplements – together into one place.

Q What's your personal feeling about Brexit?

A I think we've got a lot to lose. I'm also quite sad that we've lost the European Medicines Agency, which used to have its headquarters in London. The EU also is set to lose a pragmatic and sensible competent authority in the MHRA. A lot of the work on the Medical Devices Regulation and its implementation has been done in the UK, for example. Who's going to be the leading light for the OTC industry in Europe after Brexit? But if we do have a deal and we end up leaving, we've got to find some positives. If we've got a sovereign regulator, how can we work with them to support the UK consumer healthcare industry?

Part 1 of this exclusive trilogy of interviews with the PAGB's chief executive officer John Smith will be followed in the next few days by Part 2, in which Smith discusses the challenges of digitization for UK industry.