Interview: Warwick Smith – Director General, British Generic Manufacturers Association (BGMA)

"It's important to recognize that generic competition does not only reduce cost and increase patient access to medicines, it spurs innovation."

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Warwick Smith, director general of the British Generic Manufacturers Association (BGMA), discusses the potential impact of Brexit and recent policy changes on the British generics industry and extols the benefits of inter-stakeholder collaboration.

Entering 2018, three key themes affecting the British generics industry are Brexit, a new life science industry policy, and the medicines value program. Is this a very particular moment or is it just business as usual?

I think that you've put your finger on three important points. But, with all these initiatives, business as usual never stops. These three are more about shaping the environment in the medium-term rather than having a direct impact today or tomorrow. I think there are a number of issues underlying those. As you know, the NHS is always a big political issue in the UK; British voters and taxpayers always think that it is awful, but when compared internationally, the NHS always comes out extremely well. I think there is a natural in-built political tension here. Generations up to now have taken the view that "I pay my taxes, I pay my national insurance, therefore the NHS should do everything for me from cradle to grave," whether it's warranted or not. When NICE was formed, people wondered how healthcare can possibly be rationed.

As an aside, when Barack Obama was introducing reforms in the US, I chaired a conference on healthcare in the US. The Republicans on that panel described NICE as a death panel. So I asked

whether private insurance entitles you to everything forever? They said, no that's insurance. Well what do you think the NHS is? It's just insurance paid for through taxation.

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I think there is a big political tension here that will never go away. NICE is the basis of assessing the value of medicines. The medicines value program is all about judgments. I think a challenge for the industry and for patients is whether the government really means value or whether they mean price. The two are different. This is something that healthcare administrations across Europe are wrestling with. If you take recent hepatitis C products, they are very expensive; but rather than keeping a patient on medication for 30 years, you have them on meds for six months. How do you judge the value of that significant expenditure? You can't really say what the value is based on an annual spend. You actually have to say what the value of this product over a 30-year patient life. It can then receives NICE approval. But when you then go the payer and say you have to pay this over a six-month period, it's less welcomed.

The big challenge for the industry, for patients and payers is how we collectively get our heads around funding breakthrough treatments that take people out of healthcare and are curative rather than stabilizing patients forever. I don't think anybody has really got the answer to that.

Now how do I see generics and biosimilars fitting into to all this? We can cater for identified patients with identified existing effective treatments at a comparatively low cost, and we can therefore provide more access to innovative medicines for patients.

We need innovators to focus on breakthroughs to deal with currently unmet patient need: people who at the moment don't have effective treatments and need the breakthrough research to help them. There can then be a virtuous circle with the generic and biosimilar industry producing known treatments, which might be old but still very effective, to serve the majority of patients at modest cost while investment goes into finding cures or treatments for patients that cannot be treated at the moment. People will sign up to this, but it is difficult to put into practice. These new treatments can be very expensive albeit potentially with good value. In the UK we have some of the lowest generic prices in Europe. So there is no give there. That's a good thing because there is already very significant value released into the NHS by generic and biosimilar manufacturers.

Do you believe this division between innovators and generics is a true division?

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I think we're seeing less differentiation. There are fewer companies that are purely innovative or purely generic. In my experience, there has been a cycle over the years. When I was first involved with the generic industry it was mainly subsidiaries of global research-based business. They then decided they couldn't get enough margin out of generics and sold them all off. Then they started launching their generic subsidiaries. Some of the generic companies have gone more into R&D. I don't think it's a simple answer, I think it's a cycle.

How are your relations today with the Association of the British Pharmaceutical Industry (ABPI)?

Pretty good. Mike Thompson and I speak regularly, and we agree on 80 percent of issues. It is a very civilized relationship, and I think this is very important if we are to serve patients. There is a certain degree of trust between the two associations. We know that when we argue we argue as strongly as possible, but we also realize that at the end of the day, we are each trying to create an environment where more patients get treated. We might argue about the how, but we don't argue about the what.

The British government released a few months ago the 'Life Sciences Industrial Strategy' report. What are your thoughts on this paper?

The industrial policy is interesting. Whether we would have a pharmaceutical industrial policy that is quite as well developed if we didn't have Brexit is perhaps another discussion. There is a recognition that if you are potentially leaving a significant regional market you need to make the country as attractive as possible.

It does of course focus on innovation, and that's where the big money goes, and the higher levels of employment. We welcome that industrial strategy. It could be a little bit more overt in recognizing that it is the cost savings due to generic competition that actually allow that expenditure on research and innovation to take place. We know the government does recognize that and maybe it doesn't make for a good headline to say so. But it would be nice if they said it a little more clearly.

This is actually one industry with different parts and different players. It survives through innovation to create new treatments. Generic competition comes in, reduces the price, and maintains more patients for less money on those treatments, therefore releasing budget to pay for new innovation. If the patent went on forever, an originator could just keep making money off its first product. The expiry of the patent is the driver of innovation.

It’s important to recognize that generic competition does not only reduce cost and increase patient access to medicines, it spurs innovation. If you compare the UK with other European countries or the US, we pretty much come out second in terms of innovation, behind the US. It is interesting that the US has lower intellectual property rights than the UK or the rest of Europe. When people say we need to drive innovation by having more intellectual property rights, it is not true, there needs to be a balance.

When we talk about whether the UK remains the base for the life sciences industry post-Brexit, there are a variety of reasons it will: access to capital, the science base, language and Heathrow Airport (there are few better connected places in the western world). The size of the market is another. There are a whole variety of reasons on why you’d expect the UK to remain a strong base for life sciences going forward. That said, the industry’s view is that we would be better off in the EU. Also, it will be important to remain part of European regulation; it does not make sense to have a medicine licensed for 30 countries and then have the same licensing procedure effectively repeated for one.

Would you say that the ‘Life Sciences Industrial Strategy’ is a top-down approach or more of something consensual?

The industry is generally being consulted. We’ve all been able to make out our input. It obviously focused more on innovation and research, but I think there are elements of that strategy that will benefit generic and biosimilar manufactures. It is indicative of the UK government’s focus on this industry. It may have been one of the first sector-industrial strategies that has been brought forward. It’s a good thing for the government to do given some of the challenges that will come out of Brexit.

The UK economy is heavily service-based without a real industrial backbone. Do you think that a real industrial policy in terms of growing manufacturing here is needed?

I don’t think there is a straight yes or no to that question. If you look historically, it was the lack of the so-called ‘Bolar provision’ – the ability to develop the product during the patent term – which really led to the comparative lack of generic manufacturing in the UK. This was simply because you were not allowed to develop the product in the UK. British manufacturers had to develop elsewhere. Where you develop, you tend to manufacture; and you could look at particular concentrations of generic manufacturing and export to the UK. There are quite a few central and eastern European countries such as Czech Republic, Hungary and Poland – which had fewer barriers to manufacturing around their patent law. Those countries also have a good science base

and lower costs. Once you move your production there because of regulation that wasn't generic friendly in the UK, you stay there. A lot of the investment in those countries was in the lead-up to the UK's accession to the then European Community. Why would you come back and increase your cost base?

There are some companies that have kept manufacturing in the UK and they need to demonstrate their productivity and efficiency to remain active, which they do. Under different legislative requirements around patent law in the past, could manufacturing in the UK have been more sustainable? Yes, it could and we have some examples where it still thrives. However, if the pressures change, maybe it could come back. The biosimilar market is perhaps more attractive where the manufacturing processes are more complex and play more to the traditional UK market skills.

I think there is a fascinating paradox here. If you accept that the British people voted for Brexit to take back control, in terms of supply of goods like medicines, this is something that has not been a big issue in the UK for a long time. It's a very strong Anglo-Saxon approach to these things. Until the fears about the flu pandemic were around a few years ago and people were asking where they could get emergency supplies from, I don't think anyone was worried about where medicines were made. That concern led to emergency stocks being put in place by the government. They don't own that medicine; they pay manufacturers to hold it for them.

Tell us more about the British Biosimilars Association (BBA) that you also head and the potential of the UK to play a leading role in the biosimilars field?

One of the things that we have worked on very closely with the government has been the uptake of biosimilars. I think the UK's approach has been unique in this field. NHS England set up the National Biosimilars Medicines Program Board (NBMPB), which brings together everyone involved: the BBA of course but also the ABPI, NICE, MHRA, NHS procurement pharmacists, clinicians, patient groups, etc. to the Board gives advice to the government on how to best deal with the introduction of biosimilars. The first thing that came out of that was a booklet called "What is a Biosimilar". It lifted the veil of concern.

Moreover, over the three years' work of the Program Board, levels of take-up have gone from the lowest in Europe to the highest. Today, we have eight biosimilars approved in the UK. NHS England is also increasing its commercial capability. It's open to deals particularly with innovators for monopoly products though for biosimilars, where there is more than one manufacturer, there is a tender process.

What would be a decent outcome or success for you, in the coming two to three years?

A clear understanding amongst payers and policy makers that the UK market is very efficient and what makes it efficient, and industry driving the virtuous circle I mentioned with originators focused on meeting unmet clinical needs by developing new products that society lacks and while generic and biosimilar manufacturers focus on more cost-effective production of medicines to increase patient access to all medicines. We basically need to segment the market. We've each got a responsibility that is combined and joined to meet the needs of society. What I think shouldn't happen, which we've seen happen in other countries in Europe, is to have greater government intervention in supply and pricing because it doesn't work. If you look at countries where governments intervene more, you normally have less resilient supply chains and higher prices. The efficient UK market works well for all.

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