Interview with Warwick Smith, Director, British Generic Manufacturers Association (BGMA)

03.11.2010

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Together with Germany, the UK the highest generic penetration rate in Europe. Since you have been with the association since 1995 and obviously saw the great emergence of the generic medicines, can you please explain the success of generic medicines in the UK?

The important aspect about the UK, which is not unique but quite unusual in Europe, is that it is an International Nonproprietary Name (INN) market where medical students are trained to prescribe by INN. The system that we have for reimbursement to pharmacists requires that if they receive a prescription for a generic and the generic is available, they are reimbursed at the generic rate. Thus, once branded medicines go off-patent, the market already exists. INN prescribing happens during the patent term because doctors are trained to write by INN. When they are in General Practice (GP), there are pharmaceutical advisers in the Primary Care Trust (PCT) who keep an eye on what they are doing and again encourage this INN prescribing. That is why we have almost 83% of prescriptions that are being written by INN irrespective of the patent status of the product. That is the largest single element that has lead to the growth of the generic market.

You mention the pharmaceutical advisers that are part of the PCTs, but now that this layer in the system will disappear, what will happen?

We have to wait and see. The pace of change within the NHS at the moment is tremendously fast. The proposal seems to be that a central National Commissioning Board will be responsible for

advice on procurement and prescribing of medicines, so we expect to see something very similar to now that will be focusing on encouraging cost-effective use of medicines. Most of the time, this means prescribing generically.

In general, how do you expect the NHS reforms to impact your members?

At the moment I do not see any significant impact on the medicines market. I think the general system as it affects purchasing, prescribing and dispensing of medicines, will remain largely the same.

You mention the pace of change is tremendously fast, while some have argued that the reforms are even going too fast. Would you agree?

Frankly, I look at the part that affects the pharmaceutical industry, which will undergo very little change. I do not have a view on the speed of the other changes. One of the differences between the Department of Health (DH) and other departments under the relatively new Coalition Government is the fact that Secretary of State for Health Andrew Lansley had that role in opposition for six years. Therefore, I think that everyone already knew what his policy was when he took office, which may be one of the reasons why the pace has been so fast.

In view of the high penetration rate we spoke of before, some might say there are limited opportunities for growth. What do you still see possible in this respect? Where will growth come from?

First, the share of Britain’s NHS market is still less than, for example, the USA, implying that there is still room for some growth within the market as it exists today. The DH thinks there is another five percent to go. I think that rather more of the market is still available. Secondly, there is a “patent cliff” coming up, where a number of large products lose their patent protection. This will obviously be quite a boost for the generics industry, both in terms of the quantities of medicines and of course the initial market price. This will be a very positive period for the generic industry.

Thirdly, we must pay tribute to the European Commission for bringing forward the biosimilar regulatory pathway before elsewhere in the world. In the next five to ten years, we will have a tremendous growth in biosimilar medicines which will largely come forward from the generic industry.

There are thus three pathways for growth which will undoubtedly require some adaptation. However, if there is anything the generic industry has shown in the last couple of decades, it is that it is very good at adopting new methods and strategies very quickly.

Lastly, if you look at the average cost of brands and generics in the UK, if there was no generic competition and the average cost of all medicines was the average cost of brands, the NHS bill would increase by GBP 8.6bn. This is an enormous cost that would double the drugs bill. This fact alone already makes the generic industry absolutely invaluable to Government. Additionally, the many other benefits of generics are evidence of the fact that it is clearly in the interest of Government and patients for the generic contribution to continue. Thus, apart from the adaptation that will be needed from the industry over the next decade, we will also see provision made by Government to ensure that this can happen.

Now that we see the budget cuts as announced by Chancellor Osborne, do you see more opportunities for generics?

I think the need for generics is enhanced by the budget cuts but there is also a crucial role for generics in reducing the cost of the drugs bill to enable the NHS to afford giving patients access to newer medicines that we wish to see developed, particularly to meet currently unmet needs, and also to allow the NHS to bring forward other treatments to patients. I believe this role of promoting patient access to medicines and other medical treatments is one that we will need to continue to play.

When we met with Dr. Richard Barker of ABPI last week, he mentioned that the PPRS2009 is a rock of stability for the pharmaceutical industry in the UK. At the same time, we are obviously also talking about going to a value-based pricing system from 2014. What factors do you believe have lead to this change and how do you see this affecting your members?

Ministers have made it clear that their proposals for a successor to PPRS are focused on those products where there is no competition as there is in the generic market. The high level of competition in the generic market controls the price very effectively, which is why these proposals are aimed not at generics but at branded products where you do not see the sort of multi-source competition from the generic market. I therefore think there will be no direct impact on generic manufacturers.

A number of factors lead to this policy being brought forward. First, there was an Office of Fair Trading (OFT) report on the PPRS which recommended the introduction of value-based pricing. This proposal consisted of a fairly blunt form of value-based pricing. Interestingly, both ABPI and BGMA jointly opposed this proposal which would have significantly reduced the incentive for innovation. It needs to be said that BGMA is as pro-innovation as ABPI in the interest of patients. Indeed, generic competition is a very strong incentive for originator companies to bring forward new treatments

once their existing patents expire. Our members also need new medicines coming forward to have a generic pipeline fifteen to seventeen years down the track.

We therefore felt that the proposals of the OFT did not take into account the need to continue to incentivize innovation. Without looking at the broader picture, there was too much focus on reducing cost alone. Clearly, you also have to look at cost-benefit in this sector. If you keep forcing down price, even in generics, you risk people going out of business and you lose the very competition that brings down the price. In this way, you end up killing off the goose that lays the golden egg. There needs to be sufficient money for generic companies to afford to invest and bring out new products.

I think the government is now looking at a developed version of the National Institute of Clinical Excellence (NICE) to put a societal value on innovative products coming forward. This system has the promising potential of becoming far more sophisticated than anywhere else in the world. It will be an amalgam of the work that NICE already does, the Swedish model and part of the French system. This will be an interesting mixture and an innovative way to ensure that society receives value for money.

It has been quite questionable whether the information NICE gathers is substantial enough to prove this value for money while it was also confirmed that its responsibility would be shifting to raising quality standards. What do you think the role of NICE will be in proving the value for money?

I think NICE will play a crucial role in this. Just like all organizations that are cutting edge when they are launched, NICE was criticized heavily at first. The reason was that it was the first time that value for money was questioned rather than just the cost. We were supportive of the concept of judging value for money and I think the issue is that NICE was being put in a position to take decisions that were essentially political rather than technical or economic. It could do assessments of the value of a product, look at its effectiveness as well as its cost-effectiveness to some extent. But by setting a threshold of the Quality-Adjusted Life Year (QALY) benefit of a product, NICE was not only doing the assessment but also taking the decision on whether it should be paid for by the NHS. Health Secretary Lansley’s argument is that such decisions should be for Ministers rather than a body that is applying an arbitrary cut-off point.

In terms of the criticism of NICE’s operating methods and the ability to get the right data, this is largely unfounded. I believe that of all the government agencies that I know, NICE goes out of its way to give all parties a phenomenal ability to challenge, question and put more data and to have that data peer-reviewed. NICE is clearly in the lead of this sort of approach. I am therefore very

supportive of NICE in terms of “does it reach the right decisions”, “does it get to the right data”, “does it take account of the right factors” and “does it interact with the right people”. I think the answer to all of those questions is yes. I do also have sympathy with the Health Minister’s point that deciding whether a patient should have a medicine paid for by the NHS or not is actually a political decision. Shifting these decisions from NICE to Ministers is absolutely the right way to go.

On another note, when we spoke to Sheila Kelly from the Proprietary Association of Great Britain (PAGB), she argued that most of her members would like to enter European markets with their OTC products. Nevertheless, they were restricted in doing so, because of the regulatory burden. What opportunities do you see for the British generic manufacturers to move onto the international scene and do you see some restrictions or challenges there?

If we look at the UK generic market some fifteen years ago, it was largely a national market that consisted of national manufacturers, many of whom were owned by originator companies who then divested themselves of these small local national businesses. This divestment created an independent national market in the UK until these companies were bought up by growing multinational generic companies.

This created today’s structure where the greatest proportion of generic medicines is made by global businesses such as TEVA, Sandoz, Actavis, Mylan, etc …. These companies meet by far the largest proportion of the need for generics in the UK.

At the other end of the UK market, we do have some specialty niche players with for example one company that specializes in liquid versions of solid dose products typically for pediatric use. Another company that focuses on antibiotics is locally owned and manufactures more antibiotics in the UK than GSK. We have thus seen an evolution of the market where the focus is on either a small local niche player or a global multinational, a balance that is unlikely to change in the near term.

If you look at the larger end of the market, these companies operate at least at a European level and will use European regulatory procedures. I believe the generic industry is now by far the greatest user of the decentralized registration procedure in Europe, seeking to get European rather than national approvals. Very few of those companies are still seeking UK national approvals. The smaller niche players may do so because it is their sole market. For the traditional generic company, however, this is a European business already.

The issue of PAGB is slightly different. We have seen, partly as a cost containment measure, government policies that promote switching prescription medicines to OTC products. The

regulatory approval for safety, quality and efficacy of a product is European, but the rules for marketing are national. This is a problem BGMA does not really face. We do not yet have a single 27 member state market and there are things that BGMA would like to change, but overall, we operate as a European industry.

If we look at where manufacturing takes place and consider the emerging Eastern European and Asian markets, we have seen a shift in manufacturing processes towards these markets. What can be done to keep manufacturing in the UK and how attractive is Britain to keep manufacturing here?

I believe around one sixth of all generics in the UK is manufactured by one single factory owned by one of my members. It is simplistic to say that everyone is moving out. Looking at the history, there was indeed an exodus from the UK, largely related to Britain's patent law that did not have the so-called Bolar exemption in place, meaning that it was a breach of the patent to develop a generic product during the patent term. This meant that developing a product in the UK could only get your product on the market approximately two years after the patent expired. By that time, the prices would have dropped so much that it would not be commercially viable anymore. In other words, generic companies simply need to be there at patent-off, which in the past meant that in order to compete, generic manufacturers had to move their R&D out of the UK. Clearly, generic companies do not undertake the same extent of R&D as research-based pharmaceutical companies do, but it must not be forgotten that there is a significant period of R&D to bring a generic to the market. Researching and developing an equivalent product can take up to two years.

As the EU increased its number of member states, some of these countries had the Bolar exemption that allowed for drug development during the patent term. Naturally, it also became cheaper to keep manufacturing in the same place. The main reason that manufacturing left the UK was this patent law. The manufacturing exodus simply followed the export of R&D.

This has now changed, so there is less pressure to move out. However, those companies that moved to a lower cost economy will not easily be tempted to move back to the UK. When people talk about lower costs of labor and so on, this is of course a factor but only secondary to the old patent law. Going forward, I am not sure what will happen. There are some benefits in having shorter transport distances. Some companies go for vertical integration while others prefer to do separate deals along the production and supply chain. I think one of the changes we have seen with the economic volatility over the past years is a greater focus by governments on manufacturing in Europe and the UK in particular.

We also now see a greater focus on keeping control of your own destiny. The issues around pandemic flu planning taught people a few lessons. I think most governments did not realize how long some of the supply chains really were. It was a shock to some governments that many suppliers of API were located in China.

One of the things that is always clear in these debates is the fact that the shape and structure of the generic industry is in part a response to government policy and legislation. The shape and structure of the industry is therefore as much a function of government decisions as it is of commercial ones. Moreover, the commercial decisions are significantly influenced by the government ones.

In this context, governments do not only need to worry about cost reduction, but rather also about the sustainability of the industry. Increasingly, governments are starting to realize this but this thinking still remains to be developed. I think the British government is a step ahead in realizing the broad points of this argument. Governments need to be very careful that there is not too much focus simply on reduced costs, which will lead to an insufficient focus on the other benefits that generic medicines bring and eventually drive generic manufacturers out of the country. If you make a product commercially unattractive and people pull out of the market, you only leave the originator and thus remove the very same competition that brought down the price in the first place. For a number of countries, the cost-cutting has been an emergency and arbitrary reaction to the need to save money in the short term without care for the long term sustainability of the industry. The decision on generic substitution does not have a very significant impact and only relates to approximately five percent of the market, according to government figures. Moreover, Government made it very clear in its announcement that it would find other ways of increasing the use of generics. BGMA is looking forward to the outcome of these discussions. In short, this decision does not represent a shift in government policy to be less pro-generic. Government made it very clear that it continues to be very pro-generic. Of course, this government is very different from the previous one that agreed on the PPRS. Today, it has been made very clear that Government does not want to impose central systems, but that is a basis on which to discuss other changes that will further help the industry.

Indeed, Government and BGMA share the frustration over prescriptions that are written by brand where there is absolutely no clinical justification for spending ten or fifteen times more than the generic. This is a waste of taxpayers' money, a waste of NHS resources that denies patients access to medicines and other treatments, and only results in a transfer of NHS funds into shareholders' pockets from patient care. Part of the generic industry's role is to promote the greater use of

generics to provide NHS the money to give those patients access to new treatments for unmet need.

We look forward to seeing how the generic market will further develop in the coming years. On a more more personal note, what has been the rewarding and motivating elements of your 15 year long career at BGMA?

Over these years, there have been some very significant changes. The negotiation of the original “Scheme M” for the reimbursement of generics, and its renegotiation and extension earlier this year, set the basis for a significant period of cooperation between the generic industry and the Government. We introduced much greater transparency, put in an agreement on freedom of pricing of generics so long as competition was working; and more recently, we established mechanisms for us to debate with the Government anything that is not working properly. At a European level, I think the introduction of the new decentralized procedure and the regulatory pathway for biosimilars are very important steps. The outcome of the European Commission sector inquiry by DG Competition and the keenness and willingness of them and the UK competition authorities to bring enforcement action when there might be anti-competitive behavior by originators to delay generic competition are very positive signs. The willingness of the MHRA to find how it can work more efficiently and cost-effectively is of considerable support to the future of the industry.

One of the things that is fascinating about this industry and this market is the fact that there is always something new every day. In the fifteen years I have been with BGMA, there has not been a single day where I have not come across a novel problem or challenge to deal with.

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