Interview with Stephen Whitehead, Chief Executive Officer, Association of the British Pharmaceutical Industry (ABPI)

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What are the priorities on your agenda as the new head of ABPI considering the successes and difficulties the association has experienced in the past?

If you look at the recent history of the pharmaceutical industry in the UK, perhaps one of the areas that we have been most successful in has been life science policy. This is reflected by government initiatives, such as the Patent Box and tax credits on R&D, which aim to foster a healthy and sympathetic environment for R&D. These have been definite achievements for ABPI and our members recognize this

Perhaps where we could have been doing more is in building a credible and trustworthy reputation for our industry. Given what we do as an industry in terms of treating and curing people, it seems anomalous that we do not have the reputation we deserve and are still not trusted fully in healthcare delivery. This is the fundamental battle that I feel I have to fight. Ultimately there is a need to correct the perception of this industry to make people understand the true value of pharmaceuticals and how they change people's lives. If you consider that only 10% of NHS health expenditure goes to pharmaceuticals, this alone illustrates the incredible value for money that these products bring. If you take away that 10%, the system would not be able to function. Looking forward strategically, I would like the industry to be seen as a genuine partner in healthcare.

Recent studies have shown that our reputation is good amongst patients and government, but within the clinician population there is still some skepticism that is linked to the old blockbuster model of sales. The reality is that the industry has changed, particularly in that we are no longer a blockbuster driven business with huge sales forces, into something much more complex with many tailor-made solutions coming out of the pipeline to reach specific patient populations. You can no longer get to those patient populations through general sales mechanisms, but rather pharmaceutical companies have to establish genuine partnerships with the patients and healthcare providers. Many people today talk about access, but I hate that word, because it sounds like we are trying to gain access to patients. Instead it is best to talk about partnerships because only then can we properly serve the patient. This means that we have to change the relationship with the NHS—the ultimate purchaser of medicines in the UK.

At the moment that relationship is not completely based on trust, although we are making progress. There is an historical perception of what this industry used to be. . We need to move away from a simple transactional relationship with the NHS to one of genuine joint-working and collaboration. For example, when it comes to pricing and how the NHS tracks data on the use of a pharmaceutical once it is on the market, there is a need for real world data that can only be obtained by establishing a partnership with the industry. The critical element is that the relationship does not end at the sale of a product, but is carried onwards in the long term. It is this kind of collaboration that needs to improve so that we can find better ways of working together. I believe part of my job is to be a passionate advocate on behalf of the industry in order to establish that sort of relationship.

This transformation of the relationship between the industry and the NHS that you speak of would ultimately require a full cultural shift within pharmaceutical companies. Has this already happened in the UK?

Yes, I think it has definitely happened within the industry in the UK. I also see other markets in Europe where this is occurring, but I feel that the UK is a leader in this mentality shift. The UK is unique in that it has a healthcare system that is entirely free at the point of delivery and requires no economic participation from the patient. There is also no private system that works around the NHS even though there are alternative private options. This has made the NHS one of the UK’s most dear institutions; I like to say that the UK has no national religion, instead it has the NHS. This has meant in the past that unsustainable levels of healthcare expenditure were not always questioned.

Changes are being made though, and luckily the current government is open enough to express that they see the pharmaceutical industry as part of the solution rather than the problem. That doesn't mean that we might not fully agree at times on issues such as pricing and costs, but it also doesn't prevent us from building a better and closer relationship. One example that comes to mind relates to a recent conversation that I had with a senior government minister during which we discussed a King's Fund report on Alzheimer's and I expressed that if the pharmaceutical industry does not find a treatment for the disease within the next 15 years, then the national healthcare system will collapse. It will be absolutely unaffordable to manage this disease without a pharmaceutical treatment, and this is why we need to collaborate further with national authorities so that we can find a solution together.

I would like to see an NHS that is quick to uptake innovation and that is devoid of regional variations. As it stands today, there are new medicines that you may find in one place, for example, but you would not be able to find in another. This is an issue of major concern to the industry because it is not fair to the patient. The UK has a great pharmaceutical industry and a strong R&D base. Unfortunately, we have a weak commercial environment because this is considered to be a low-priced and slow uptake market. The next step is to ensure that the government understands that this does make a difference and that change is required.

How exactly do you expect to achieve that? What measures will you be implementing?

We have already started working on some collaborative efforts. To begin with, the ABPI is working closely with the government to determine how we can dramatically accelerate the uptake of innovation within the healthcare system. The government recognizes that innovation is a key part of the solution to cutting costs. They have also recognized that perhaps in an annual cycle you might see an increase in expenditure when investing in new technologies, but in the long term some of that investment will be recovered in savings from secondary costs.

Another issue is to stop thinking about the product lifecycle as the patent lifecycle, because the real lifecycle of a product extends beyond that, closer to 40 years. The value of a medicine, starting from discovery to the point where it is replaced by something else, is much greater than what is currently taken into account because medicines are typically used for about 40 years before a replacement treatment is available. As an industry, we tend to think that once the patent is gone then the medicine has no more value, when in reality that product remains in use for decades after patent expiry at an incredibly cheap price. This is how we need to think about our products, because this also means that we can think about the role of generics in generating savings that can be reinvested in further innovation. The UK, in particular, has an extremely

efficient generics market so we must take them into account when thinking about the true value of a product.

This holistic approach to assessing the value of medicine is what the new value-based pricing (VBP) scheme aims to achieve. Do you believe it will be effective or is it just another way for the NHS to cut costs?

We support the Government's goal for a system that prices medicines according to their value and which takes into account all the benefits they deliver. But I am not sure how VBP will fit with the current pricing scheme that already includes a health economic assessment by NICE. The truth is that we are broadly happy with the way the current system works, because it underpins the industry by encouraging R&D. It also allows a certain amount of commercial freedom by letting companies decide how to price their products within a given profit cap. One of my main concerns with VBP is how a molecule will be priced at launch when you do not know ahead of time what other indications that molecule will be used for. Will we have to reassess the price of a molecule after every indication? What is needed is a pricing system that accepts that the innovation process is highly complex. The reality is that drugs tend to build on each other, so what needs to be priced is the innovative process rather than individual molecules. What I would like to see is a value based approach incorporated in to a new PPRS-type scheme. That way we get the best of both worlds and we don't have two separate systems awkwardly running side-by-side.

Parallel to the slow uptake of new medicines and a preference for generics, we are also witnessing a trend in the UK of decreasing investment in R&D. How is the ABPI addressing this issue to attract inward investment back to the country?

Firstly, I disagree with the premise that R&D investment is decreasing in the UK. Yes, it is true that we have recently seen the closure of R&D sites by global pharmaceutical companies, but this represents the sort of "bricks and mortar" old model of research in which massive facilities were needed for in-house research. The trend that we are seeing worldwide is that companies are retreating from that model of research anyway, so it is not directly linked to the attractiveness of the UK per se. What might be perceived as a decline in the country's R&D is actually a change in the nature of the research that the industry is now conducting and moving towards in order to become more productive. This is in line with my previous comments on the need for further collaboration with the NHS and the wider healthcare system, because the move now is to establish partnerships at every stage of the value chain. In R&D this trend has taken on the shape of tapping into the science of small start-ups, biotech and academia to take on a more collaborative-based approach.

One area that has been in decline is in late-stage clinical research in collaboration with NHS. This is a key area that we need to work on and needs to be boosted, because without it you cannot increase the uptake of new medicines. Without this late-stage research within the healthcare system, there will be a shortage of experienced clinicians. Another related concern is the duplication of ethical committees at the local level, rather than having a single national approach.

How can the UK position itself as a competitive clinical research hub once again?

Firstly, it is important to put things into perspective and understand why there is a perception of declining R&D in the UK. The healthcare sector represents about 35% of all the UK's R&D expenditures then followed by the aerospace industry with 7%. Due to this heavy reliance on our sector for R&D investment, the UK is very significantly exposed to global trends of the industry. As pharmaceutical companies decide where to invest in research, any decision to invest in high-growth countries will immediately have a noticeable impact on the UK. This unusually high exposure to R&D expenditure needs to be taken into account when evaluating the UK's research environment.

This being said, the main thing that needs to change in order to make clinical research a lot more appealing in the UK is to devise a single national research center that grants a country-wide approval for a trial. Essentially we need to remove all the barriers that exist at the regional level. The government is currently working on this and we look forward to seeing this expedite approval times in the UK.

As it stands, there is no doubt that we are a part of the government's growth strategy and that they are putting in place as many initiatives as it can to support and retain the research that already exists here. They are also trying to attract more, and we have yet to see whether the steps they are taking will be enough to do this. There are still things that we can do better to become more competitive, such as better exploiting the NHS's data to assist the industry in their research efforts.

What then is your long-term vision for the UK pharmaceutical industry?

The UK will always be a world leader in science and R&D policy because we have some of the best universities, some of the best pharmaceutical companies and we have strong R&D bases here for these global companies. This country is chosen for such operations because of its geographic and language advantages that other countries in Europe do not have. Furthermore, the UK has a highly-skilled workforce with well-trained professionals. For all these reasons I am sure the UK will always remain a core market for the pharmaceutical industry. My concern at the moment is not with the

industry itself but rather in making sure that patients have access to innovation. This is where I see the most room for improvement and this has to be addressed system-wide.

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