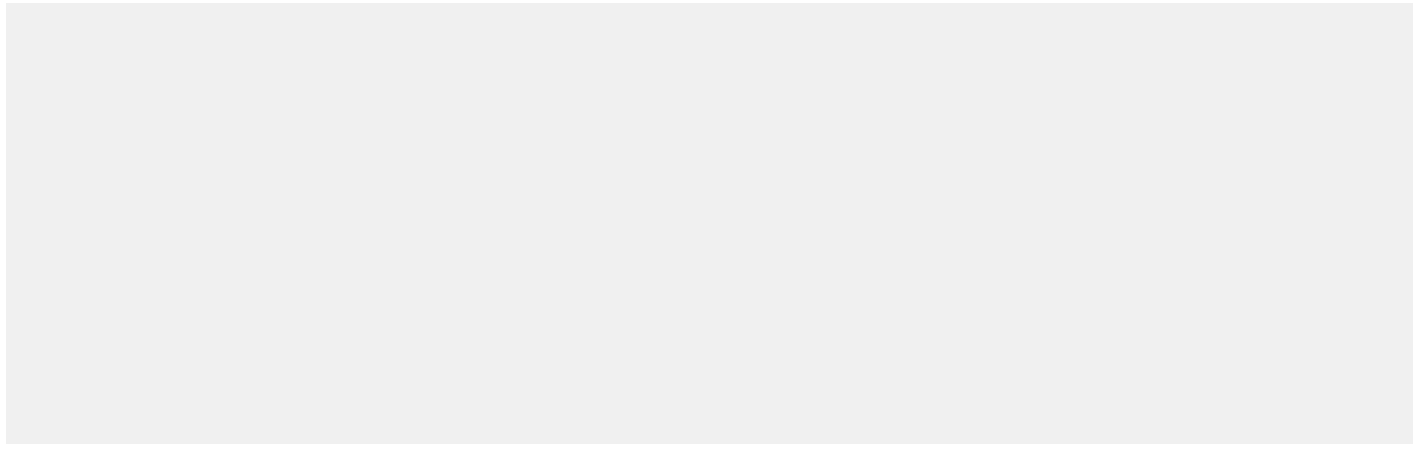


Interview with Dr Richard W Barker, Director General, Association of the British Pharmaceutical Industry (ABPI)



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Taking a look at a key achievement of the ABPI in recent years, we recognize the role you played in negotiating the revised PPRS that was put in place last year. How did the latest revision contribute to taking the research-based industry forward and what has been the impact of the new PPRS agreement on your members?

The PPRS is a rock of stability for the pharmaceutical industry in the UK and has many beneficial features. Firstly, it represents a voluntary agreement between the UK government and the industry, underlining a strong relationship between the two which is widely envied internationally. Although this does not of course mean we necessarily agree about everything. The PPRS was renegotiated earlier than expected, at the request of the British government. The ABPI achieved a much better outcome than might have been the case. The more important point is that a so-called Innovation Package was integrated into the PPRS. This included, for example, a benchmark for the uptake of new medicines in different parts of the country as well as between the UK and its international comparators. This is important because in the past the UK has had a slower uptake of modern medicines than countries like France for example.

The PPRS negotiation is a lengthy and quite tough process. The ABPI leads this process on behalf of the British pharmaceutical industry, with teams of negotiators and analysts from various

companies..

The timing of the negotiation was fortunate as it turns out, since it preceded the major financial problems that hit the world economy. ABPI negotiated the PPRS in the middle of 2008 and it was eventually implemented in January 2009. The coalition Conservative-Liberal government that came in earlier this year has agreed to honor the 2009 PPRS agreement to the end of 2013. This allows for time to negotiate a new type of agreement; the Coalition calls this value-based pricing, but we refer to it as value-based reimbursement. The industry is now constructively engaged with this.

We all know the devil is in the detail of this system, but if we could design a system that firstly, recognizes all of the types of value the medicine delivers, which is broader than the type of value that NICE currently evaluates and secondly, contains elements of the usage of medicines, then it could be a very important step forward.

The broader changes in the National Health Service (NHS) are also very significant because if the architecture of the NHS changes, then so will the way in which the NHS selects medicines, the place of medicines as part of patient care and so on. Therefore, we have to design a pricing and reimbursement system alongside a redesign of the NHS. We are already starting conversations with the government about how a value-based reimbursement system can be linked together with how the NHS takes up new medicines. It is not sufficient simply to have a value-based reimbursement price; you also have to work on the mechanisms by which patients get access. I am very pleased that we are moving away from “the medicines’ bill” to thinking about the “burden of disease” instead. We do not say how much we pay for bandages, operations, etc. so instead of talking about how much we are paying for medicines as a line item of the budget, we have to look at the problem vertically, focusing on the big burdens of disease, such as Alzheimer’s, diabetes, heart disease, cancer, etc. The health and economic burden of these diseases needs to be defined in order to find out where pharmaceutical intervention makes most sense. In most cases, pharmaceutical intervention is during early stages of disease and it can be relatively inexpensive to prevent the really expensive things such as hospital admissions and operations. We thus have to shift the mindset of the NHS from thinking about medicines as an individual line item to considering it as part of the armory to deal with the burden of disease.

You mentioned that changes within the NHS will reflect on the industry in general. Particularly now in the UK, I believe everyone was following the news of the announcements of Mr Osborne with a lot of anxiety. While the NHS received the government’s support, we have to recognize the many challenges that lie ahead, such as an ageing population. In your view, how do you see the Spending Review affecting your member companies?

The gap between the healthcare we would like to deliver and the healthcare we can afford to deliver is not a temporary phenomenon, but a long-term structural problem. I have just finished a book on the future of healthcare and how we can close this gap, which is being published in November entitled “2030: The Future of Medicine” and can already be found on <http://www.2030healthfutures.com>. This gap threatens to widen year on year as a result of increasingly expensive technologies, an ageing population as well as the major tsunamis of disease that we inflict upon ourselves such as obesity, diabetes, alcoholism and so on. In addition, there is unpredictability in the world’s pandemics. These are not included in anyone’s budget, but nonetheless happen on a periodic basis. We have seen two or three in the last decade alone. The NHS sees its ‘gap’ problem amounting to GBP 15 to 20 billion in the planning period of the next three years. This has to have an impact on us, but the point is that we need to have the NHS thinking about these problems the way I just described: by identifying the big burdens of disease and finding the most cost-effective way of dealing with those problems, rather than relying on short-term budget cuts.

Unfortunately we already see arbitrary targets laid out to reduce medicines expenditure. This is the wrong way to think about healthcare and the Secretary of State is aware of that: publicly stating that he prefers a “health bill” over a “medicines bill” to manage the totality of health. This of course does not stop the NHS at the local level trying to save money as best they can. The outlook for the industry is highly volatile. If we were to sit still and simply produce new medicines whilst leaving the rest to the health systems of the world, we would have a very difficult time. If we do what we have done in the UK, working with the NHS on major problems of disease, the so-called joint working programmes, we can work together on the early stages of chronic disease and on how cancer therapy can be more cost-effectively delivered. This programme is called the Pharmaceutical Oncology Initiative and further programmes exist to assist the NHS in different disease areas.

The announcement of the Comprehensive Spending Review (CSR) on October 20th 2010 was a pretty positive day for the pharmaceutical industry, with the healthcare budget being held constant in real terms. While the growing gap is a global problem, we will have to be part of the solution and cannot afford to be part of the problem. We have to prove the value of our medicines, which has now become central, in the context of best practice healthcare and pathways of disease management. Only companies that manage to do so will be successful. It will not simply be a matter of getting through bodies such as the National Institute for Health and Clinical Excellence (NICE), but a matter of how medicines are positioned everywhere in the world.

The other positives from the CSR are that, firstly, the whole science budget was frozen in cash terms while the budget for the Medical Research Council (MRC), which is the most important piece of the science budget for us, was kept constant in real terms. This is a tribute to the fact that the UK knows that life sciences is a key element of future economic growth. Of course the banking sector will remain an important contributor to the British economy, but we all now know how vulnerable banking can be. We also have a strong aerospace industry, good media companies, etc. But the only big science-based industry we are strong in is life sciences, of which pharmaceuticals makes up the largest part. We have to invest in this for the future, so congratulations to the Coalition government for recognizing this and going ahead with it.

One of the things the ABPI has been doing is to bunch the so-called Life Sciences Supercluster, which brings together centres of excellence and creates a world-class capability that combines them, in specific therapeutic areas. The first are in joint inflammatory disease and lung inflammatory disease, (including all the problems related to COPD, asthma and so on). We realised that we should not think about Britain competing against the USA or against China; the real competition is with the big centres like Boston, San Francisco, Singapore and Shanghai. If we can have the “best of British” working together in a network, this can be much more powerful than Boston or San Francisco. We have had nine universities in each of those two areas coming together to say how they would do translational medicine as a group. This enables companies to have one conversation about an area of exploratory medicine they want to get into or an early stage compound they want to examine. I believe this has not been done anywhere else in the world. All universities were invited to submit proposals and had to go through a rigorous process of examination involving research funders from the industry and public sector.

Before, you mentioned the importance of the uptake of innovative medicines to enhance cost-effective care. How do you assess current patient access? Is it going the right way?

It is going the right way, but much too slowly. The big challenge ahead of us over the next few years is to have the NHS join the life sciences team. We have now pulled together the life sciences sector with the four leading trade associations (ABPI, BIA, ABHI, BIVDA) working together. The Supercluster chaired by me and Sir John Bell, (chairman of the Office for Strategic Coordination of Health Research), contains industry representatives, charity representatives (such as the Wellcome Trust) as well as the public funders. This is just one example of close collaboration at the R&D end of the value chain.

So, the ABPI is very proud of its achievement to pull together the whole life sciences sector, which has been achieved by the joint efforts of all its members. However, we still do not have the NHS

fully on the team. Conducting clinical trials, using new medicines and tracking outcomes is part of the UK PLC life sciences enterprise, not just a part of treating patients.

Is this industry-government collaboration the new model to go forward?

I think so. I do not see why we should step back, especially considering the fact that we have already seen interest from the USA and other countries in the model we have developed. However, as long as we do not have the customer in the loop, the NHS, a clear challenge persists. It is difficult for example to imagine a powerful aerospace industry without lead customers who trial your aircraft. We need to have the same mentality across the NHS.

What will it take for the NHS to think this way and to collaborate more fully?

I do not have a clear answer for this yet, but what I usually say to our members is that this is a “body contact” sport. In other words, the senior people of the major companies in the industry, not just the trade associations, need to be out there meeting their counterparts in the NHS to talk about common problems and address disease burdens. If we do that, the NHS would realize that the industry fundamentally has the same mission, namely to transform the healthcare of people. People join the pharmaceutical industry to make a difference rather than to make money. Yet, the people in some of the health services in the world simply look at the pharmaceutical industry as a money machine, thus questioning their need for cooperation. Of course it is a private sector that needs to make returns on the investments it makes over twenty year periods and maintains very complementary perspectives and skills.

When I refer to the term body contact sport, it is important to note that it does not only require the actions of the leaders of the companies, but in fact every contact between the industry, prescribing physicians, nurses and pharmacists should be reinforcing the industry mission to transform the lives of patients. We will have more tools to target medicines to particular patient populations and be able to demonstrate economic in addition to clinical value. We are coming to these conversations a lot better equipped than we were ten, or twenty years ago. It is not about writing policy papers, but about forming personal relationships. This is what is happening with the government, where we have formed relationships with senior officials and ministers in successive governments. What we have not yet really achieved is that level of trust-based relationship with the NHS, which remains the big challenge.

You mentioned an important aspect within the renegotiation of the PPRS was to include the Innovation Package. We also see that you were actively involved in the creation of the Office for Life Sciences to promote innovation. Can you illustrate how this can play a role in driving industry

innovation forward?

The Office for Life Sciences (OLS) was created under the last government to join not only the trade associations from the industry side, but also the government itself, largely the Department of Health (DH), the Department for Business, Innovation and Skills (BIS) and the Treasury, to have a common government perspective on the needs of the industry. In almost all European countries you see an industry ministry which supports the pharmaceutical industry and a health ministry that largely sees itself as a purchaser for medicines. Their perspectives never get connected properly as both ministries do not work closely together. The OLS has created the platform for this vital cross-collaboration in the UK.

The OLS has made some significant differences, changing some of the processes of NICE allowing companies to participate in the discussion of their medicines. Furthermore, it created an Innovation Fund to invest in early stage companies and regenerative medicine. It also created the Innovation Pass, which has been superseded by the Cancer Drug Fund under the Coalition, but already established the principle that something different needed to be done for highly specialised and expensive new medicines, which are clinically but not always economically justified. This has been the driving force for the Cancer Drug Fund. Furthermore, OLS launched the idea of a Patent Box, similar to what has been done in Belgium. Instead of taking intellectual property offshore and building manufacturing plants in places like Singapore, Ireland and Puerto Rico, the idea is to keep intellectual property and plants within the UK. Historically, the UK has been a major manufacturing hub, a status that has been declining over time. Without an incentive to invest here, companies simply go to where there are more tax benefits and lower costs. What we are seeking to do is to create a mechanism where the company is rewarded rather than penalised for investing here.

Do you see any other strategic initiatives necessary to keep the UK attractive for such investments?

All of the aspects mentioned earlier, such as extra investment in the creation of the Supercluster, the work of the National Institute for Health Research to build a clinical research network across the UK, etc. have all been very important. The next innovation will be the creation of a single research regulator. The problem in the UK is that clinical research has become very bureaucratic. There are several agencies that are involved nationally, but even when you gain approval from them, you have to negotiate with every health trust and every major hospital individually. This process takes a very long time causing people to look for places where the process is simpler. We are hoping for the publication of a report by the Academy of Medical Sciences (AMS) before the end of the year, on how this whole process can be simplified. Instead of losing clinical trials, I believe

we can regain our position. I firmly believe that companies want to do clinical research in the UK. They know that it is a respected system, that there are key clinical authorities in many of the major diseases and people can be trusted for the high quality work they deliver. However, due to the bureaucracy and the lengthy processes, many trials have moved away to Eastern Europe and Asia. Therefore, I am quite hopeful for the establishment of a single research regulator to reverse this trend.

And the role of the ABPI within this, what can you do to help?

If you look back at the advances I've described, most were either ABPI initiatives or involved the ABPI at a very early stage. But of course, the major companies are important too; particularly the major UK companies GSK and AstraZeneca, but also overseas based companies like Pfizer, Eli Lilly, Novartis, Eisai and Merck, in support of the industry position. It is sometimes difficult to distinguish between what the ABPI does and what the industry does as a whole, as we should be the single voice of the industry. Of course, the ABPI needs to work with and through its members as it does not have the resources to tackle all of the industry's issues.

Simon Jose of GSK pointed out the importance of the pharmaceutical industry in the UK, but apart from that he also praised your role as a driving force behind the ABPI over the past six years. Now that you will hand over the torch in May 2011, I would like to ask you on a more personal note how satisfied you are with what you have achieved so far and whether there are still certain goals you aim to achieve?

Most of the time, this job is very fascinating and enjoyable. Internally what I am most pleased about is that we are a focused organisation around the Value, Innovation, Trust and Access (VITA) imperatives. Instead of a very wide range of things, the ABPI now has a small number of things which I believe it does a superb job on.

We have a very high quality team with a lot of new faces around the table. Furthermore, the ABPI's way of working with its members has improved. The question "what has the ABPI done on this?" has changed into "what can we do together through the ABPI?" Most of our major initiatives are led by board members which signify the increased commitment and engagement of the Association's members.

Externally, the ABPI has built a much better and broader relationship with the government.. The life sciences sector is now more integrated. Instead of thinking of other trade associations as competitors for attention or membership, we now see ourselves much more as a team. We will soon create "Life Sciences UK" as a formal entity. I have also formed the Atheneum Group, which

consists of many of the senior regulators, industry figures and patient groups – working very hard on what is probably the industry’s biggest problem, the “unaffordability” of new drugs because of the lengthy and costly process of clinical development. A new and flexible blueprint for clinical development was laid out. This could not be done without bringing together the heads of the MHRA, the EMA, NICE, the Commission for Human Medicines, the patient groups and leading companies. The theme at the end of my career at the ABPI is to create teamwork across the boundaries between companies, trade associations, R&D partners and the major agencies who control their lives.

Before I leave this job we will move the London office to the new premises. This will provide an all-in-one-space platform, with the purpose of making our team at least as dynamic and progressive as the best of ABPI’s members.

What is next for you when you hand over the reins?

I’m planning to remain for a year as a senior advisor, continuing things that the new CEO may not immediately want to pick up. We have for example done quite a bit of work already on the international scene and contributed to the developing world.

What I would really like to do next is explore in business terms some of my ideas about changes that are needed within the NHS and in the world of global health. You get a wonderful perspective and range of contacts in a job like this. One example is the Commissioner of the FDA: perhaps we should be creating something together across the Atlantic to tackle the key challenges in regulatory science?

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