Interview: Sir Andrew Dillon â?? CEO, UK National Institute for Health and Care Excellence (NICE)

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In an exclusive interview at the BioPharma Ambition Conference 2016 in Dublin, Sir Andrew Dillon, founding CEO of the UK National Institute for Health and Care Excellence (NICE), shares his thoughts on the establishment of NICE in 1999, transparency and the evaluation of cost-effectiveness as the organizationâ??s hallmarks, the dialogue it is establishing between all healthcare stakeholders within the UK, and the need for healthcare systems to be clear on their priorities and constraints.

Sir Dillon, you set up NICE in 1999 as the National Institute for Clinical Excellence and have seen its evolution since. What have been some key milestones?

NICE was initially established with the idea of having a national point of reference for healthcare professionals, patients and the general public in order to resolve the inevitable uncertainties surrounding disease and drugs. This saw strong support from all stakeholders: the NHS, the principal national professional bodies and politicians across the spectrum.

Politicians within a publicly funded healthcare system should distance themselves from the interpretation of science, particularly in something as sensitive as healthcare, and we were a very sensible response to the need for an independent and objective assessment of the science in uncertain circumstances where you need to gain and retain public confidence.

Our expectations of the relevance and importance of NICEâ??s position were fortunately quickly validated by the degree of cooperation we saw from the life sciences industry. They saw the challenge and the opportunity that NICE represented almost immediately: the challenge, inevitably, because NICE became yet another organization scrutinizing and questioning pharmaceutical products, creating, as it was initially and still sometimes perceived, another hurdle to surmount before the products could reach the market. But also an opportunity, because if their value proposition was deemed to meet the evaluation criteria imposed by NICE, that meant a significant reputational advantage for both their products and the overall company within the UK.

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Establishing relevance and significance â?? and demonstrating, not only to health professionals and the private sector, but also to ourselves, that we could perform the job well â?? was a critical early milestone.

How have you seen support for NICE change in the years since its establishment?

We have dealt with a variety of reactions for nearly 18 years now. I do not believe we can do the work we do without attracting challenging criticism. NICE approves most products, but inevitably, on the minority of occasions when we have to say no or significantly restrict recommendations in some way, people will be disappointed and upset, even angry. That is inevitable.

What we have to do is make sure that the evaluation has been performed to the best of our abilities, and just as crucially, to explain clearly how the conclusion was reached.

One of NICEâ??s hallmarks is that that we have always been prepared to explain our reasoning and evaluation process to patients, companies and the public, usually through relevant media channels. Transparency and taking responsibility for our decisions have been key tenets of NICE for the past 18 years.

As a watchdog organization that evaluates pharmaceutical products, how would you characterize NICEâ??s relationship with the private sector?

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For a life sciences company wanting to present the value proposition of their product within a particular jurisdiction, an organization like NICE is a real challenge. It is almost inevitable that they begin in an adversarial relationship with us.

Alignment is therefore critical. We have tried really hard over the years to shift from that default position to a much more collaborative approach. We wanted to make sure that the industry were absolutely clear on what we were looking for, what our evaluative processes and methods were, and when they would have the opportunity to speak to us to clarify and if necessary, contest the emerging conclusions.

In recent years, for instance, we have moved the dialogue even further upstream by offering companies opportunities to speak to us through our Scientific Advice Programmes. We are also holding â??safe harborâ?? meetings between the NHS, companies and ourselves, where companies can provide feedback without fear of reprisals.

We want to de-risk the evaluative process for companies as much as possible. Ultimately, it is for the companies to craft the own value propositions for their products but we are doing our best to equip them with as much knowledge as we possibly can, not just about the evaluative challenge that NICE

represents but also the adoptive challenge that the NHS represents.

What has been enormously important to us is having this dialogue with companies about their products â?? going beyond openness to engagement.

The English healthcare system, like many others in Europe, is under significant stress at the moment with the Brexit issue and unsustainably increasing expenditures. How do you see it evolving to meet these challenges?

It is of course far too early to comment on what Brexit would mean for the UK as a whole. There will clearly be questions about the future of the regulatory processes because the UK is currently part of the European Medicines Agency (EMA) regulatory system. However, we can be confident that there will still be an NHS after it leaves the EU â?? the UK will still want to buy pharmaceutical products.

For NICE, similarly, our rationale for existing will not change as a result of leaving the EU. The NHS will still need this national point of reference to help it make coordinated and consistent responses to new products being introduced by the life sciences industry.

That said, the NHS, like all health systems regardless of their funding structure, is under significant pressure to restructure and reevaluate its way of functioning. If you compare the projections of the costs of running the healthcare system in England up to 2020 based on current expenditure plans with the amount of money currently budgeted for the NHS, there is a multi-billion gap. This has to be bridged, not just by buying different and cheaper products, but by adopting a completely different system that better meets patient needs.

I think the onus is also on the health system to be absolutely clear about its priorities, ambitions and limitations, and how these necessarily impact the nature of products the life sciences industry wants to introduce to the NHS. Health systems need to clearly communicate its constraints, financial and otherwise, to companies so that the latter can craft their product value propositions to meet these requirements as closely as possible.

One of the key initiatives undertaken by the NHS, and supported by the principal national commission body (NHS England), is the shift in balance from more expensive hospital-based care to less expensive out-of-hospital care, whether that means individual patients being provided with home health support or using less expensive community-based facilities. There are a series of models being pursued at the moment around England, almost as experiments, and they are undergoing a process of evaluation to determine which promotes the best balance. There are still no conclusive results as it is early days yet, and it is entirely possible that different parts of the country will choose different models. This is just one example of how the NHS will need to reorganize itself to meet the challenges it is currently facing.

What lessons do you think similar entities in other countries can learn from NICE, which is often seen as a model of best practices internationally?

First of all, I caution against seeing NICE as a model for evaluative health authorities in other countries. It has been exquisitely designed to plug into the UK and to connect the life sciences industry with the UK healthcare system, and therefore only works in the UK in its totality.

That said, we are clearly of interest internationally. A positive assessment by NICE became significant outside the UK as a result of the UK becoming a reference market for a number of countries. Going through the NICE process successfully thus became important to companies not only within the UK but also in some international markets.

There are ways in which we have gone about doing things that can inform the work of our counterparts in other countries. Some of these would be the robustness of the methods and the processes that we employ; the point about transparency and communication; and the openness to a full engagement with the life sciences industry as a partner in the process of evaluating their products.

I think the fact that we have always looked at both effectiveness and cost-effectiveness has marked NICE out as being different from other agencies. We make a very clear call on â??value for moneyâ?? on the products we assess, which is fundamentally different from a discussion about the relative merits of the products.

Looking forward, what I would hope for other countries to see in NICE is the flexibility and the creativity with which we adapt our current arrangements to the future needs of the health system, in order to make it as easy as possible for all stakeholders within the UK to engage with each other.

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