HOUSE OF LORDS

Select Committee on Science and Technology

Corrected oral evidence: Life Sciences and the Industrial Strategy

Tuesday 17 October 2017

11.50 am

Watch the meeting

Members present: Lord Patel (The Chairman); Lord Borwick; Lord Colwyn; Lord Hunt of Chesterton; Lord Maxton; Baroness Morgan of Huyton; Baroness Neville-Jones; Lord Oxburgh; Lord Renfrew of Kaimsthorn; Baroness Young of Old Scone.

Evidence Session No. 6 Heard in Public Questions 32 - 38

Witnesses

Dr Ian Hudson, Chief Executive, Medicines and Healthcare Regulatory Agency (MHRA); Sir Andrew Dillon, Chief Executive, National Institute for Health and Care Excellence (NICE).

USE OF THE TRANSCRIPT

This is a corrected transcript of evidence taken in public and webcast on www.parliamentlive.tv.

Examination of Witnesses

Dr Ian Hudson, Sir Andrew Dillon.

Q32 **The Chairman:** Good morning, and thank you for coming today to help us, Dr Hudson and Sir Andrew. We have a lot of questions for you to help us with. Some comments we have heard about you are complimentary but others not so complimentary—whether you are a block or going to be a help in driving the strategy forward. Of course, both of you are mentioned in the strategy. For the record, from my left, Ian first, would you introduce yourself and who you represent? If you have an opening statement to make, please do so and then we will get on to questions.

Dr Ian Hudson: My name is Ian Hudson. I am chief executive of the MHRA. I welcome the opportunity to discuss the life science strategy. We see the life science strategy as very important to ensuring a healthy industry that enables new products to come through for the benefit of public health.

Sir Andrew Dillon: I am Andrew Dillon. I am chief executive of NICE. NICE supports the health and care system by taking an evidence-based approach to producing guidance on the use of interventions and other forms of practice to get the best outcomes for patients and service users.

The Chairman: Do either of you want to make any comments before we start? No. Let me start first. The whole life sciences strategy is about getting the UK at the forefront, globally, in an economy that is life science-driven. In that respect, as regulators, what part can you play in developing that business side of the economy? Are your processes appropriate or do you think you need refinement in your processes or more latitude for that to happen?

Dr Ian Hudson: Perhaps I could start. First, I very much welcome the life science strategy, and, while the MHRA's focus is very much on promoting and protecting public health, we are very keen to support innovation to see new products being developed that will make an impact on public health, particularly in areas where there is a need. That is part of our remit. To me, supporting innovation goes hand in hand with supporting the life science industry, in that you need a vibrant life science industry and mechanisms in place to ensure that innovation is supported and all the steps to enable new products to come through for the benefit of public health. We put a lot of weight and effort behind our support for innovation to do our utmost to ensure that those developing new products understand what is required. We try to put in place a flexible and adaptable regulatory system—I am talking about the quality, safety and efficacy part of regulation relating to that. We established an innovation office, which is open to all-comers, SMEs and big companies alike; we have a lot of regulatory information service, scientific advice—we have put in place all sorts of mechanisms—to do our utmost to provide a supportive environment for companies to develop their products to be able to progress them through and understand what they need.

Sir Andrew Dillon: The life sciences industry has made a huge contribution to public health over the last 75 years. The fact that we are all sitting here is, to some extent, a testament to the productivity and the success of the industry and the science that underpins what they do.

The Chairman: It's their genes, man.

Sir Andrew Dillon: For some of us, clearly, that is the case. Their contribution to the economy, similarly, continues to be significant. Making sure the UK has access to the industry's products and promoting a thriving industry in the UK is going to continue to be enormously important to public health and the health of the UK economy. The role NICE has is, in some respects, to act as a broker between the industry and the healthcare system. When Ian has finished with his evaluation of pharmaceuticals, diagnostics or medical devices, it is our job, not for all of those things but for the most significant of them, to test their value. Two of the critical, simple questions we ask are: first, what is the additional therapeutic benefit of this new thing compared to the current standard of practice—the thing we have already invested in, the cost of which is discounted across the system, and which is in broad use in the NHS or in the wider public health or care system? What is that incremental therapeutic benefit? The second question is: is what the company concerned is asking for by way of remuneration for that product worth or equivalent to that additional therapeutic benefit? Two simple questions but enormously complicated, in some respects, mainly because, in reality, we are dealing with uncertainty. We never have enough information to conclusively and completely answer either of those questions at the point at which we ask them the first time. There is always some paucity of information.

It is inevitable, and in some cases very complicated, to reach a conclusion on those questions. It is hugely important that we do so, mainly because when we make a recommendation we want to be sufficiently confident that the benefit we are expressing though a recommendation to use something new is not going to unreasonably raise expectations or hopes on the part of those who might benefit. Secondly, when we are making that recommendation we are saying to the NHS, "You should spend some money that you could otherwise spend on lots of other things which you already are entirely confident represent good value for money; you will have to take some of that away and use it on this new thing". We need to be confident that that recommendation makes sense and is appropriate, particularly in circumstances where the NHS is facing its toughest period of financial constraint.

The Chairman: When companies have a product, whether drugs, diagnostics or devices, that is found to be effective, they want to get it to market as quickly as possible. Do your regulatory mechanisms in any way hinder the process to do that quickly, particularly in comparison with competitive markets in other countries?

Sir Andrew Dillon: The short answer is yes, if you have convinced yourself, as a developer, that your product is both effective and cost-effective, any lapsed time between the point at which you have convinced

yourself that that is the case and the point at which you start to make a return is an unnecessary delay, both in terms of you making a return and your product starting to benefit patients. It cannot simply be the case that an individual entrepreneur or a company decides this is both clinically and cost effective in the case of a life sciences product; they have to convince people who have stewardship responsibility for the system, both in making sure that the investments made are the right ones, given the current circumstances, and making sure that patients are being offered things that will improve outcomes. You have to have an evaluative process between the point at which a producer considers that he or she has a great product and the point at which that product is released into the system.

The Chairman: The question related to the comment we had that, for instance, a drug takes longer even after the approval process has been through to get to patients in the UK than in other health services overseas or globally. Is that true or not?

Sir Andrew Dillon: In some cases, yes, it is true. We know from comparative data that the diffusion time for life sciences products is more rapid in continental European systems than in the UK. There are a number of reasons for that, some of which you heard from your previous panel. They are not related to the regulatory process, so we can let Ian off the hook here, because we are fully integrated with the European system.

The Chairman: Hitherto.

Sir Andrew Dillon: The timelines for regulation are common. It is what happens next that is critical. If there is going to be some national decision-making, whether it is NICE or NHS England or somebody else, that decision-making needs to be as rapid as possible to minimise the elapsed time from the point at which something gets regulatory approval to the point a clinician can start using it. Through the years that NICE has been going we have been gradually reducing that elapsed time. The case now is that for a new cancer drug, for example, NICE guarantees that unless there is some external factor beyond our control, such as a licensing issue or a supply issue, we will issue final guidance to the NHS within 90 days of that product being licensed. Furthermore, NHS England has committed itself to saying, "We will fund that product from day one, after it receives its marketing authorisation", providing NICE's draft guidance, which we issue before the marketing authorisation, is positive. We are currently proposing that we should apply that approach to non-cancer drugs as well".

That process does not apply to everything; there are diagnostics and medical devices which NICE never looks at and which go through more diffuse and complicated processes, and you might want to return to that. Once you have gone through that evaluative stage you are into the NHS, and the dynamics that enable and frustrate the diffusion of products in the NHS are complex and varied.

The Chairman: You would not expect me to say anything negative about NICE as an idea because I wrote the paper that established it. The

processes that you are now accelerating is good news.

Baroness Morgan of Huyton: Could I push you on that last bit a little? It would be useful for you to spell it out a bit more. When you have done your approval, and you are saying that is becoming quicker for a lot of significant drugs, you then tantalisingly said what happens in the NHS is paramount but very diffuse and complicated. Spell that out a bit for us. Clearly, in our earlier evidence sessions some people were concerned about that part of the story.

Sir Andrew Dillon: Yes, of course. It is important to remember through this conversation that when we talk about life sciences products we have three broad categories. There are digital products as well, which are becoming more common, and completely new therapies which will complicate the picture further. At the moment, any answer to that question splits between pharmaceuticals and medical devices and diagnostics—so-called med-tech products. With pharmaceuticals, about 60% of new licensed products go through NICE. The other 40% do not. They traditionally go into local decision-making, so would be subject to individual clinical commissioning group policies. Though NHS England has recently introduced four regional committees, those committees are not analogues of NICE but they have some evaluative capacity. Where NICE has not made a national recommendation on a new drug, it is likely that the other 40% or so of new drugs will go through these regional committees. Where a drug goes through NICE and NICE makes a positive recommendation, NHS organisations have a statutory duty to make funding available to allow those drugs to be used. That is a statutory duty to fund; it is not a duty laid on a clinician to prescribe or indeed for a patient to ask for that treatment, necessarily, but it is a very powerful signal to the system that there is an expectation that money will be made available.

That does not apply to the recommendations we make about diagnostics and medical devices. They run through a separate programme and the Department of Health's funding direction does not apply to the outputs of those programmes. For those med-tech products there is a question, I think, as a consequence of both the life sciences strategy and the Accelerated Access Review about whether we collectively, as a system, should do more to evaluate more of them and consider what status we want to apply to the recommendations that come out of NICE, NHS England or whoever is undertaking that national evaluation. Beyond that, whatever the product is, you have to rely on sometimes tens of thousands of clinical decision-makers to be aware of the recommendation and make the same or a consistent decision about the use of those products. That is an enormously complicated process. Anybody who has worked in the NHS and with clinical teams will know that you have to persuade them to change practice or to adapt. Sometimes they want to do it off their own bat, but if they do not it is sometimes a complex process to get them to do so.

Lord Oxburgh: Who makes the decision about which drugs go through you and which bypass NICE completely?

Sir Andrew Dillon: There are published selection criteria which NICE applies to the pipeline of products as they come through that separates out those two groups.

Lord Oxburgh: You make the decision?

Sir Andrew Dillon: Yes, we start the process. We say to the Department of Health, "We have applied these criteria, this is what the criteria have come up with. Are you content to refer those products through to us?"

Lord Maxton: What is the difference between a preventive medicine and a curative medicine—if you see a difference? One is designed to cure an existing illness, the other is to prevent an illness happening in the first place. Is there a difference between them, in the way you look at them?

Sir Andrew Dillon: No.

Lord Maxton: You would look at them in exactly the same way?

Sir Andrew Dillon: Yes.

The Chairman: Baroness Young has a quick question and then I will move on.

Q33 **Baroness Young of Old Scone:** For both of you, but particularly Andrew, as a top-down, centralist control freak, I would go for national mandating of approved medicines, but that is not totally popular. If there was one change you could make to get better, faster and more comprehensive uptake, what would it be?

Dr Ian Hudson: For me, some of the areas have been picked up in the Accelerated Access Review and, as Andrew has already described, the closer alignment between the different players, such that when things go through quality, safety, efficacy—the regulatory piece through MHRA or indeed the European Union—there is a rapid review and decision from NICE and the NHS update follows. It is bringing them all together. Indeed, the Accelerated Access Review highlighted this. There will be the transformative pathway there, and some particularly high unmet medical-need products being pulled through a bit more, if you like, and the different organisations working more closely together. For me, that is the direction of travel we are already on that will make the greatest difference with us all working closely together.

Baroness Young of Old Scone: Does that overcome the problem of the clinicians not doing it?

Dr Ian Hudson: There is that element, but I think it addresses one part of the challenge where the regulatory piece has taken a decision, the HTA piece has reviewed it and there are the discussions on uptake. There is still the inherent conservatism, if you like, in the decision to use the product, but bringing the parties together to have a smoother pathway will address that part of it.

Baroness Neville-Jones: When is the AAR going to be implemented?

Dr Ian Hudson: There are discussions ongoing in government at the moment on the timings of that, and I do not think that has quite been sorted. Early next year is the likely timescale.

Baroness Neville-Jones: It is definitely going to happen in the form recommended?

Dr Ian Hudson: I think the Government are in the process of looking at a response to the AAR. The Government will need to respond to that.

Lord Maxton: Not much acceleration.

Baroness Neville-Jones: It may not be implemented?

Dr Ian Hudson: Many of the aspects of the AAR—certainly I was talking about the regulatory piece—we are already working on. For example, part of that was in relation to the early access to medicines scheme. We are already working on some of the recommendations in relation to that. We are already doing the horizon-scanning elements, et cetera. Many of the elements are already happening.

Baroness Neville-Jones: So if it is implemented it is not going to make much difference?

Dr Ian Hudson: Many of these issues are work in progress that we are already addressing and taking forward.

Baroness Neville-Jones: I see. Thank you.

The Chairman: It is one of the areas mentioned in the life sciences strategy as being important to do.

Dr Ian Hudson: Indeed.

The Chairman: Yet we are not so sure.

Dr Ian Hudson: My understanding is it will definitely be happening. The first meeting of the group that co-ordinates everything will be later this year. The Government are still formally working on the response to that.

The Chairman: We will stop at that answer. Lord Oxburgh, your question may have been covered, but do you have any additions?

Q34 **Lord Oxburgh:** Yes. I judge from your answers that you like the Life Sciences Industrial Strategy, the Bell report. It states that there was input from the Life Sciences Industrial Strategy Board. Are you familiar with that?

Sir Andrew Dillon: I think that was a group brought together to support John Bell's work.

Lord Oxburgh: You were not involved?

Sir Andrew Dillon: There were various structures in place which evolved during the course of the strategy. If this is a helpful answer to your question, we certainly had all the opportunity we needed to contribute to the life sciences strategy. I do not think we were formally a member of the life sciences board.

Dr Ian Hudson: Perhaps I can also address that. My chair, Sir Michael Rawlins, was part of the steering group. Indeed, our experts have been involved in discussing some of the recommendations coming out, so the agency, MHRA, has been involved in this.

Lord Oxburgh: It is simply the question of the scope of that strategy, because one of the comments about the Bell report is that it focuses on biomedicine, whereas the life sciences, from a national point of view, are very much broader than that. For example, veterinary science and plant science have significant economic impact but are not covered. I just wondered whether the so-called Life Sciences Industrial Strategy Board incorporated people with those backgrounds.

Dr Ian Hudson: I cannot answer that question.

The Chairman: The focus is on the strategy, so our focus is on an inquiry that is based on the strategy as published. There are other issues around whether they should have gone wider or not, but to me that is a secondary issue. It is an important issue.

Q35 **Baroness Morgan of Huyton:** I would like to go to a different issue, which is Brexit, which I am sure you will both have views on. What do you think is the likely impact? Are there any particular issues that you want to raise with us today? Are there any particular implications for future investments that companies are likely to make? Describe the picture and the priorities that you think the Government should be addressing as we move forward on Brexit.

Dr Ian Hudson: For the MHRA, Brexit is very significant in the sense that our legislation is European in nature and quite a number of our procedures are European in nature. We established a task force. We have been working with the Department of Health and other parts of government—DExEU, BEIS, the Office of Life Sciences—in relation to the Government's preferred outcome from the negotiation and what the alternative might be in the event that it does not happen. The Government have outlined their preferred position in the letter in the *Financial Times* that the two Secretaries of State signed, offering ongoing collaboration with the European system. The UK has led 25% to 30% of the whole work of the European network over the years. From a public health point of view, there is scope for continued collaboration for the benefit of everyone.

Clearly, it is a matter for negotiation whether that ongoing collaboration is achieved or not, and it is right that the Agency working with other parts of government, is thinking of alternatives if that is not achieved. Yes, there may be some opportunities there. The principles here must be that patients are not disadvantaged; there remains a robust system to ensure that patients are protected but not disadvantaged, and that there are no delays for patients. Indeed, we must be careful of burdens on industry and ensure that industry is supported to be able to bring forward new, safe products. It is right that those priorities are set and, in that context, we think of alternatives. There may be alternatives in terms of accelerating the review process, closer links between our organisations,

building on the early access to medicines scheme—that sort of thing—but these are things we are currently working on. On top of that we are thinking of specifically day one issues, if you like, and working through those to make sure that we can address specifically day one issues to ensure continuity of supply.

Baroness Morgan of Huyton: In terms of your European colleagues working here and people with whom you currently collaborate with in the rest of the EU, what are their expectations and hopes going forward?

Dr Ian Hudson: If you are referring to the EMA and the Commission, it is probably a question that they would have to answer. The UK Government have put an offer on the table of ongoing collaboration, but that will be subject to negotiation, and negotiations at the moment have started on areas such as goods on the market. They need to get, in due course, into the wider areas.

The Chairman: If regulation is different in the UK from the EU, what impact might that have on companies not doing business here?

Dr Ian Hudson: First, as of day one we will be harmonised. Of course, it depends where we get to in the negotiations as to whether there is an ongoing relationship with the EMA and us operating in the system or not. In the event of the preferred position of that ongoing relationship not being achieved, there may be opportunities in an alternative scenario. We are very conscious that we do not want to increase burdens on industry, but there are perhaps things we could do. I have outlined some of them in terms of speeding up the assessment process, based on the same requirement. We do not want to instigate different sets of requirements for the UK versus Europe versus the rest of the world. Many of these requirements are more harmonised internationally. There may still be, within that, without increasing burdens, some opportunities for us there.

The Chairman: You are saying we will be totally harmonised with EU regulations so that companies based here are not disadvantaged in any way, but at the same time there will be opportunities where we might have a different regulation that will help companies develop here. Are the two things contradictory?

Dr Ian Hudson: The first point is that as of day one we will be harmonised, we have the common regime, and it is only a question of subsequent evolution if the Government decide to change something. Many of the requirements for data to be submitted in a dossier are international sets of standards, if you like, and much the same sort of data requirements would be used for both a European and a North American filing. I do not see us deviating from the sorts of data, by and large, that would be required for international filing. We do not want to say that the UK has to do completely separate studies, or anything like that. Clearly, that would be hugely burdensome.

The Chairman: The data protection legislation we will have in the UK does not match up to GDPR regulations in the EU. Would that hinder any transfer of data in relation to what we are talking about?

Dr Ian Hudson: Companies will run development programmes to international standards. We are very conscious of not asking for any additional burdens for the UK. We would want to make sure that we still are compliant with international standards to enable that.

The Chairman: Does the proposed data protection legislation going through Parliament give that protection?

Dr Ian Hudson: The data generated as part of the clinical trial programme is done with consent, et cetera. It is a little different, for example, from the healthcare records-type situation. We need to ensure that it does not in any way inhibit the movement of data. My understanding is that there would not be any inhibition of movement of the clinical trial-type data that is used to support applications.

Baroness Neville-Jones: The draft Bill does align.

Lord Hunt of Chesterton: Is there something equivalent to NICE in other European countries?

Sir Andrew Dillon: There is no precise analogue of NICE elsewhere in Europe, but there are organisations variably integrated with healthcare systems that undertake evaluations of new pharmaceuticals.

Lord Hunt of Chesterton: Do you share it out amongst the others? When a new drug appears, do you say, "Germany can look at this bit and we'll look at that bit"? Is there pure duplication?

Sir Andrew Dillon: Not with the evaluative process. The regulatory process that Ian is responsible for, which assesses the safety, efficacy and quality of the product, is done on an integrated basis, so there is a sharing of capacity. The MHRA is part of that European capacity. When it comes to a healthcare system deciding whether or not and how it wants to use something that has been through the regulatory process, it is a country-specific decision and there are variable mechanisms in place across European countries to help their healthcare systems make that decision.

There is a lot of collaboration across agencies. NICE is part of the European network that shares information and advice on methods and processes to help make the whole business more consistent for life sciences companies, for example, who are engaging with 28 countries currently, and we can learn a lot from each other. In the end, the decision is always a country-specific decision, and so we are different in that respect from the regulatory process that Ian has described.

Q36 **Lord Renfrew of Kaimsthorn:** For the record, I have no commercial or financial interests in this area. I would like to go back to aspects of regulation. What aspects of regulation are currently a block to making progress in the field of innovation and commercialisation? Perhaps you could summarise these for us.

Dr Ian Hudson: I am not aware of any that are a block. Clearly, there are areas where we need to ensure we are prepared for the future. The agency does horizon scanning to try to identify potential areas coming

along that we will need to regulate. We are very keen to engage with developers of products at a very early stage, either through the innovation office or through some of our other mechanisms, to have a dialogue with them to make sure that we do identify a path forward for the product or service. Clearly, there are some areas in the future where we recognise we will need to work out how they are best regulated. The artificial intelligence, machine learning-type environment may fall within the definition of a medical device regime, and we are working within the agency and others on how we might regulate that in the future. We are very keen to establish a flexible and enabling regulatory regime that is predictable and enables innovation, but recognise that in some areas we will have to work with partners nationally and internationally to make sure that is addressed ahead of products coming through.

Lord Renfrew of Kaimsthorn: What can be done to make the system appear more open? You say there really are no substantial barriers, but for SMEs there clearly is a feeling of inhibition sometimes. What can be done to overcome that impression?

Dr Ian Hudson: We try to be as open as we possibly can for people to come and talk to us about products they are developing so that we can give them the best advice we can. We have established an innovation office particularly for people working in innovative areas, whether it be in products or, indeed, innovative manufacturing techniques, et cetera. Probably about a third of all the people who come to talk to us through our innovation office—and we have had 500 queries—are SMEs. Similarly, we offer scientific advice services. We have close to 400 scientific advice meetings every year for all-comers; it may be academics, it may be SMEs or it may be big pharma. We have information lines and all sorts of ways that people can contact us. I would urge people, SMEs and companies working in difficult areas to come and talk to us about it. Sometimes people are reticent in doing that, but I would very much urge companies, SMEs, to come and talk to us about their products so that we can advise them on what is necessary and understand the issues.

Sir Andrew Dillon: I do not think there are any blocks deliberately built into the system for the sake of frustrating innovation, but there is a whole series of capacity issues which can have that effect. The system has a limited ability to absorb the new things that are made available to it, partly because the decision-making processes have limitations on the amount of new product they can consider. The system, as a whole, has resource capacity limitations that prevent it from simply saying yes to everything that has some potential for improving outcomes for patients or service users. That has ever been the case in the NHS and it ever will be. In a sense, that is the problem we all deal with, whether we are producing stuff or responsible for pulling new things into the system. The question is how we maximise the ability of the NHS—talking about life sciences products primarily—to be aware of what is available and to make a good enough evaluation to enable it to make a decision about whether it represents a good opportunity for improving outcomes and a good use of resources, and how we can drive the uptake of that product into the system.

I was listening earlier to your previous panel members talk about a new development piloted in a hospital in, I think, Northern Ireland. It seemed to work really well there, but for the developer, the question then, arises: "How do I get this scaled up so it is adopted across the entire healthcare system in Northern Ireland and then in the UK?" That is a critical question for a small organisation with a great idea. In England the solution, in part, has been the creation of the Academic Health Science Networks, whose role in part is to be a place for innovators of the kind we were listening to earlier on to go and say, "I have got something. I have already got some data" or "I haven't got data but I would love to get it. Can you put me in touch with one or more institutions that would be interested in working with me on it?" "When I have that data, help me to take it where it needs to go, whether that is NICE or NHS England or somewhere else, to get into the decision-making process that will allow me to scale this up nationally, provided that the evidence base I have is compelling." The elements of a more agile decision-making process are being put in place and, of course, were referred to and indeed promoted in John Bell's report. In the end, there will always be limitations. Not everybody's great idea will be pulled into the system and evaluated. The important thing is to make sure that the best of them are.

Q37 **Baroness Neville-Jones:** Could I perhaps pursue what you have said and add something else, if you would not mind? You described an ecology which ought to work and ought to create a situation in which the delays are not excessive and unreasonable. Yet, we have a lot of evidence that it is slow in this country; it is slower than elsewhere. There are two things. One is: you give advice on the processes, but can they be simplified, truncated, and made more efficient? Secondly, if you can do that, do you take the view, as we have heard earlier on, that some local activity might be a good idea or do you take the view that it has to be done nationally? There is another question I would like to ask you, if you would not mind. I do not know if you were in the room when, I think it was in the first set of evidence, we had some testimony to the effect that NICE evaluation systems are better adapted to general population chronic illness, and evaluating drugs and applications in that context, than in relation to minority conditions, some of them often very difficult, where modern medical techniques are now being made available in a way that previously was not the case. The assertion was that the evaluation criteria applied, in a sense, were disadvantaged and not adapted to the kind of evaluation you should put on conditions of that kind. You may want to take that first, but I would like you to take both.

Sir Andrew Dillon: I can remember the first and third of your questions. I apologise, I have slightly lost the middle one, but I am sure you will remind me. On the first one, the answer to your question is that yes, it is always possible to make our current arrangements more efficient. From that point at which Ian's organisation has decided that something is safe and effective. There are improvements we can make in the efficiency of the processes that NICE applies and in the interface between NICE and the NHS, particularly the interface between NICE and NHS England. NICE is certainly not a counsel of perfection, but we have always tried to

evolve over the, almost, two decades now that we have been going to refine the processes we have on advice from the people who use them, including the life sciences industry, and to make sure that we strike the right balance between the time we need to look at the science and to allow advisory committees to consider it, and to consult on their conclusions. It would, of course be a lot easier and quicker if we simply all went into a little room somewhere and looked at the data.

Baroness Neville-Jones: I do not think anyone is suggesting that.

Sir Andrew Dillon: We cannot do that. What is the right balance? We are always looking for improvements. Earlier this year we made some improvements, introducing a faster appraisal process. We are now out to consultation on further changes which will enable us to do what I mentioned earlier on, which is to produce draft guidance on new pharmaceuticals before the marketing authorisation is granted and to produce all our recommendations on new drugs, subject to external constraints, within 90 days. We are hopeful we can start to put those arrangements in place from 1 April next year. The other change we are putting in place is to bring the appetite for commercial discussions—an appetite that exists on the part of companies and on the part of NHS England—and integrate it into the assessment of effectiveness and cost-effectiveness which NICE undertakes.

Baroness Neville-Jones: Is this a parallel assessment?

Sir Andrew Dillon: Yes—parallel but integrated. It does not go on separately. Any commercial negotiation on the introduction of a new life sciences product has to be informed by the judgment that NICE makes about its effectiveness and cost-effectiveness. That is where you start. If you want to have a commercial negotiation, you use that information. We want to try and avoid these things being sequential, potentially leaving a gap between the point at which NICE finishes and when a negotiation begins that would frustrate companies. The proposals we are consulting on would have the effect of bringing those two things together. As Ian was saying earlier on, that was very much one of the ambitions of the Accelerated Access Review and, as a result of the natural evolution of NICE and NHS England's processes, one that we want to be able to put in place very quickly. We can do all those things, but we still need to work with the 10,000 clinical decision-makers—to encourage them to put in place the recommendations we have made.

We need the right set of incentives and encouragement from NHS England and the Department of Health to local commissioners, to individual clinical teams and those who lead them, making clear that this system has an ambition to have these good-value products that have been through a rigorous, forensic process—probably the most challenging anywhere in the world. These are things we have decided we want to use and it is now our job, collectively, to make sure that patients can have access to them where it is the right choice for them to make. There is no doubt that the system is committed to that, but we all come up against the reality of the resource constraints that we are operating under. We have to accept that, for all that we have an ambition to get all these

things into the system quickly, we will not be able to avoid recognising the inevitable constraints that the tight fiscal regime is currently applying.

Baroness Neville-Jones: If I might say so, I think you said earlier on that a NICE decision does imply an obligation to fund, and that sends a powerful signal. We also hear that in the day-to-day decisions, particularly if they have a contract for a different way of doing something, it does not happen. What can we do about that? That is not the clinician; it is the trust and the management of the NHS.

Sir Andrew Dillon: I do not think anybody is in a position to confidently argue the extent to which parts of the NHS, if they do, try to avoid or delay activating that commitment in the NHS constitution, whatever you might hear from individual companies or other sources. I do not think you will find a manager or clinician in the NHS who will say that they are not committed to the provisions of the NHS constitution. I do not know of examples where there have been deliberate rejections of a clear recommendation from NICE by a local part of the NHS to fund something which is the subject of that funding direction. Clearly, at particular points in the year and for particular parts of the system, a recommendation from NICE for a new drug that carries that funding direction can add considerable stress. We have to recognise that that is the reality of it. The fact that stress exists is not, in any way, representative of the views held locally about the importance of putting the guidance into practice.

Baroness Neville-Jones: Could you respond to the point about evaluation? I do not know if you were in the room during our first session. The distinction was drawn between the effect of your evaluation systems, which were geared, it was asserted, towards chronic illness—

Sir Andrew Dillon: I do not accept that. If you look back through the years we have been making recommendations about new treatments we have covered pretty much the full range of innovation as it has evolved over the last two decades. We have been able to adapt our evaluative framework to take into account the different modes of action, the different evidence base and different populations in order to reach a reasoned conclusion on the effectiveness and cost-effectiveness of new products. We look at treatments designed for tens of thousands of patients and we look at treatments designed for tens of patients. We recognise the different circumstances but, ultimately, it is still the same judgment. What do we do at the moment? What does this new thing do? What is the difference? Is the company producing that product asking a fair return for that quantum of additional therapeutic benefit?

Baroness Neville-Jones: You do not think there is a different evaluation system that ought to be applied to a "minority condition" which can be materially improved or helped by a drug that is only going to be applied to a relatively small number of people and, therefore, per unit, is going to be expensive?

Sir Andrew Dillon: We do have processes which recognise the difference in the evidence base for treatments for very rare conditions, in the nature of the way in which the intervention interacts and in the relative value for money, as it is expressed through a standard

cost/utility approach. We know, for example, that something new for controlling blood pressure, if it is really effective, is going to be in the tens of thousands of pounds per quality-adjusted life year. That is the ratio NICE uses in order to underpin its recommendation on cost-effectiveness. A new treatment for one of the enzyme deficiencies, for which there might be just a few families in the United Kingdom, could be hundreds of thousands of pounds per QALY. We already recognise that. We do not say, "Because you are above our standard £20,000 to £30,000 threshold range for very rare conditions, we are never going to say yes". We have a different approach that still starts with the science and the understanding of that quantum of additional therapeutic benefit but recognises that the country as a whole, ever since the NHS started, has accepted that for treatments designed for very small populations it will be prepared to pay a sometimes very significant premium. Our methods for evaluation incorporate that societal judgment—the policy decision made by those who have stewardship responsibility for the system.

Baroness Neville-Jones: You think the accusation is misguided?

Sir Andrew Dillon: As a general accusation, yes. Clearly, in individual cases, if patient groups or professional groups or manufacturers have been disappointed in the outcome of a NICE appraisal, I would hope we could explain that that is a result of uncertainty or absence of evidence as opposed to some kind of inherent bias against that kind of product.

The Chairman: We had some comments earlier about the access review process. Lord Hunt.

Q38 **Lord Hunt of Chesterton:** We heard a comment this morning about how, in the United States, there can be approval of a drug and the next day doctors can use it. I presume that remark, made by industry, was because a lot of the treatment will be done by private medicine in the United States and there will be lots of people who, of course, will not benefit from that. My question is: the life sciences strategy says that, in line with Accelerated Access Review, industry wants parallel processing of MHRA and NICE assessments. What is your response to that suggestion? Are there risks or disadvantages? I guess there is an international comparison as well to be mentioned.

Sir Andrew Dillon: It cannot be simultaneous; there has to be some sequential element to the process. We need to know that something is safe or efficacious. The question is: how do we minimise the elapsed time between a conclusion coming from the MHRA and a decision from NICE? The processes I was describing earlier on, the changes we have introduced earlier this year and the ones we intend to introduce from April next year, I think achieve the absolute minimum elapsed time. To all intents and purposes, we are already at or very close to what anybody might regard as a parallel set of regulatory and evaluative processes.

Lord Hunt of Chesterton: You have said, "We're doing this"; industry is obviously implying it is not being done sufficiently, or fast enough.

Sir Andrew Dillon: The people you speak to are those who have been through an evaluative process in years gone by, so may be talking about

their experience then. I am talking about changes and improvements which are being put in place currently, partly in response to the perfectly reasonable suggestions that companies have made. Yes, it is understandable if they are talking about it from a historical perspective; I am talking about it from a current and near-future perspective.

Dr Ian Hudson: I very much support Andrew's comments. To streamline the process as much as possible is in everyone's best interests. NICE will, of course, have to take a view when it wants to start. Clearly, during the licensing process things will change in terms of the potential indication that will be granted at the end—which population is appropriate for a drug to be used for—and some of that will not happen until quite late in the day of the review process, depending on the responses from the company. The principle of greater collaboration between the quality, safety and efficacy regulator and NICE, such that the process is streamlined, is absolutely right. In fact, a number of years ago we introduced joint scientific advice between NICE and MHRA to enable applicants to come and talk to us both at the same time, such that we can take account of each other's needs in the advice we give them. It has not been hugely popular in take-up, but it is a service we offer.

Lord Hunt of Chesterton: One of the very large expenditures of the NHS is the building of hospitals. Does that come under MHRA?

Sir Andrew Dillon: No.

Dr Ian Hudson: No, not at all. We are simply medicines, devices, blood, et cetera.

Lord Hunt of Chesterton: The infrastructure of the NHS has quite a big impact.

Dr Ian Hudson: Yes, but it is outside the remit of the MHRA.

The Chairman: The NHS not being good at adopting innovation comes up in the strategy document, too. I take the point, Andrew, that when NICE recommends something there is a statutory requirement to fund that drug, or whatever. In other areas, where drugs may not be evaluated by you, or devices or diagnostics have been evaluated but there is no statutory requirement to fund, what can be done to get more of those innovations adopted quickly in the NHS?

Sir Andrew Dillon: It is a fair criticism. The NHS is cautious in its approach to adopting new approaches to delivering care, not just in relation to the use of new pharmaceuticals or other life sciences products. We should remember that there are circumstances where that is not a bad thing. We know there are examples, certainly in relation to new life sciences products, where a rapid uptake of a new product has been followed by an equally rapid de-escalation of its use when evidence relating to its safety, efficacy and effectiveness, which has accumulated since the product was licensed, suggests that the original decision to move rapidly to uptake was not the right one. Nevertheless, on balance, I think it is a fair criticism. What can we do about it? We certainly need to make sure that those products that have real potential to improve outcomes or system efficiency—or, ideally, both—are identified as early

as possible in their development, and certainly before they become widely available to the healthcare system, so that we can do the regulatory and evaluative stuff, we can make a decision about whether we want to use it and we can work out how to adopt this at scale in the system as quickly as possible. It is certainly an ambition of the Accelerated Access Review and the life sciences strategy to do that. Quite a lot of what we have been talking about today will have the effect of enabling that to happen.

We need to think about the barriers for adoption in the NHS on a day-to-day basis and how we can overcome those barriers. Some of the elements of how we might do that are in place. For example, the Academic Health Science Networks are not just about spotting local talent, as we were discussing earlier, and pulling that through into a national system; they are also about diffusing good practice that might have been identified at a national level through NICE or some other process, so we can use the reinvigorated Academic Health Science Network for that purpose. NHS England has put in place a special tariff variant. This is a fiscal incentive to hospitals and other providers to pick up innovative, new products into the system. To the extent that, locally, there is concern about whether the money is in place to enable something new to be used, through this tariff the signal can be sent clearly that you can be compensated through the—you will get the money back—for making this intervention available.

There are things we can do in conjunction with individual companies. Companies are very keen, obviously, to make sure their products are used in the system. They often have resources and ideas about how to engage with local clinical teams, with local commissioning groups, if it is a product that needs a commissioning group signal to support its use. We need to harness that capacity in a very deliberate way and take advantage of it, and jointly put our shoulder to the wheel with companies where the healthcare system has decided we want something to go into the system.

In the longer term a cultural change needs to take place as well as new health professionals trained. Those health professionals trained in that rather cautious environment in the past I was describing will have inevitably inherited that view and will apply that consciously and unconsciously. Perhaps with a newer generation of health professionals we can inspire them to take a different, considered approach to new things coming through—perhaps in some circumstances to be more alert to, and more adventurous in their application of, those new products. That is, obviously, a longer-term fix.

The Chairman: Ian, do you have a short comment?

Dr Ian Hudson: I do not think there is anything I can add. We are very much at the heart of the process. One thing we can do is be as transparent as possible in relation to the basis for the approval that we have given—for example, such that that information is available to others through the system.

The Chairman: The comment was made to us by a chief executive of

Cancer Research UK that diagnostics, for instance, will become the key part of healthcare delivery and usage, particularly in the area of cancer. We heard in the earlier session about companies that develop diagnostics and how that innovation can be embedded, particularly when it is possible to do multiple analyses to pick up different diseases.

Baroness Neville-Jones: They do it earlier than it is done now.

Lord Hunt of Chesterton: Ninety-five per cent of the product of this diagnostic company went abroad; only 5% was used in the UK.

Sir Andrew Dillon: That is an indication that there are aspects of the outputs of the life sciences industries that the NHS, at the moment, does not have the evaluative capacity to spot, to evaluate and then do all the things we have been talking about to signal to the system that they need to be picked up. I hope that, as part of the Government's response to the Accelerated Access Review and whatever follows on from the life sciences strategy, one of the things that occurs is that we increase the capacity and the ability to pull those really good, new things through.

The Chairman: Thank you both very much indeed. It has been very useful and it is very good to hear from you.