HOUSE OF LORDS

Select Committee on Science and Technology

Corrected oral evidence: Life Sciences and the Industrial Strategy

Tuesday 16 October 2017

10.05 am

Watch the meeting

Members present: Lord Patel (The Chairman); Lord Borwick; Lord Colwyn; Lord Fox; 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. 4 Heard in Public Questions 22 - 26

Witnesses

Dave Allen, Senior Vice President, Respiratory Disease R&D, GSK; Menelas Pangalos, Executive Vice President of Innovative Medicines and Early Development (IMED) Biotech Unit, AstraZeneca.

USE OF THE TRANSCRIPT

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

Examination of Witnesses

Dave Allen and Menelas Pangalos.

Q22 **The Chairman:** Thank you for coming today to help us with our inquiry. First, I would say to Members and you and the visitors at the back that we are on broadcast and if you have a private conversation it will be picked up, so the best thing is not to have any private conversations. Mene, this is your second appearance. Thank you for making time to come. Last time you were between two international flights; I hope this time it is a bit more relaxed.

Menelas Pangalos: I am straight off to Boston after this.

The Chairman: Why did I ask?

Lord Maxton: In Lincolnshire, I assume.

The Chairman: Thank you for coming. The evidence of the two of you, from two of the biggest pharma in the UK, is crucial in trying to understand how you, as big pharma, contributed to the life sciences industrial strategy. I have no doubt you were involved in producing the document that we all now have. It would be interesting to hear from you as to why Britain needs a life sciences strategy. Normally if there is a need, the industry will go there and develop, so why is it necessary that we have it? Is this going to put the UK at the forefront of developing a life sciences economy? Do you think the document covers all aspects of life sciences in its broadest sense?

Before you answer those questions, if you would like to introduce yourselves and make any opening statement, please do so.

Dave Allen: Good morning. I am Dave Allen. I work for GSK and have done for many years. I am a scientist. I work in the respiratory R&D area. In fact, I head the respiratory R&D area, which is a really important one for GSK. I am also GSK's chief chemist. I am really pleased and thank you for the opportunity to come here today.

Menelas Pangalos: I am Mene Pangalos. I run research and development at AstraZeneca as well as worldwide global business development, which is all of our asset acquisitions and licensing deals we do across the whole of the business across the world. For those of you who do not know or were not at the meeting a few weeks ago, AstraZeneca employs around 7,000 people in the UK. We are the largest private investor in R&D in the UK at £2 billion and the life sciences industrial strategy is obviously critically important to us in maintaining, hopefully, our position in the UK and maintaining the UK in a leadership position scientifically.

The Chairman: Shall I repeat my question or did you get it the first time?

Menelas Pangalos: Do we need a life sciences strategy? Absolutely, and it is critically important from our position that we have a vibrant life sciences community that makes the UK one of the best places in the

world to do life sciences and applied life sciences research. To put this into context for you, UK life sciences employ around 200,000-plus people, export about £30 billion-worth of goods and have a net trade surplus of £3 billion. Obviously, this is a very important industry for the United Kingdom and because of the ever-increasing age of our population and the advances that we are seeing in science, life sciences has the potential to continue to grow and be a very successful industry for our country and the future prosperity of our country. We believe that Sir John's report is very comprehensive. It leaves no stone unturned. We are very supportive of the document. It is incredibly ambitious and is aimed at positioning the UK as a leader, putting us in a globally competitive position relative to countries such as the United States.

There are various very important themes, but one of the things that differentiates the UK, and is very prominent in the document itself, is the role that the NHS has to play in being a very important contributor to the overall health of life sciences in the UK and our ability to translate science and ultimately turn that science into medicine.

Obviously, there is a very large ask in the level of investment that is needed. One of the topics we will be talking about is how we go about generating that level of investment and where that level of investment should come from. I have no doubt that we need an increase in overall funding in R&D across the sector. We need to see reforms for access to medicines because right now the UK, while okay in some areas, is poor in others. We need improved capital allowances for industrial plants, manufacturing and building and we need to improve our overall infrastructure across the UK to enable collaboration and cross-fertilisation for various sectors of the country.

One final point is that working with John Bell and the steering group on the life sciences strategy itself has bought together many parties from somewhat disparate sectors to think about how to create the best environment for life sciences in the UK, and we should capitalise and build on that because we now have that sort of forum where we can all speak together and hopefully make a difference.

Lord Oxburgh: When you say life sciences, do you mean life sciences or do you mean biomedical science, because there is a difference?

Menelas Pangalos: I consider those the same. Our world is evolving such that life sciences now includes chemistry, physics and mathematics. I think it includes more than just the biological sciences.

Lord Oxburgh: Yes, that is not quite the point. There are life sciences which are not included in that group which could be regarded as important.

Menelas Pangalos: Which ones do you mean?

Lord Oxburgh: Plant sciences, for example.

Lord Fox: Animal health.

Lord Oxburgh: And veterinary science.

Menelas Pangalos: Veterinary science, yes; plant sciences, probably not so much for us in what we are talking about—but, obviously, agrichemicals and the agricultural industry are also important.

The Chairman: Mr Allen.

Dave Allen: I will not repeat Mene's comments, although I agree with all of them. The real question is around opportunity. If we look at the UK, we have all the individual components to make an incredible infrastructure to meet a huge opportunity. We have really good basic research in our universities. We have fantastic basic scientific talent. We have good pharmaceutical companies that are embedded in the UK in a way that we are not embedded in any other country. Our interactions in the UK are unique. Certainly from a GSK perspective they are unique to the UK. We have the NHS—and we may be able to talk about it—and if we can get to that idea of an innovation hub from the NHS, it brings together so much information which, if you tie that into the progress in genetics/genomics and into real-world evidence, gives us every single component that other countries, frankly, would dream of. The question is whether we can tie all the different parties together. Everybody seems willing. You clearly need a strategy—but, above anything else, you need a way of executing that strategy.

The Chairman: Both of you mentioned the NHS and we have a question coming up later which discusses that at greater length. Neither of you mentioned whether the regulatory aspects in the United Kingdom are a block or a benefit.

Dave Allen: From a regulatory perspective, we run a lot of clinical trials here and it is a business that is looking increasingly competitive, so the speed to enact clinical trials becomes critical. We need to think about that. The regulatory environment in the UK is constructive. As we look to the future, there will be challenges around things such as cell and gene therapies as they evolve, and we need to be very clear that we have clear pathways through for those. My final point about the strategy is that there is a timeliness to it. We are looking at phenomenal advances in basic science and basic medicine and there is a moment-in-time opportunity to start to tie this together and capitalise on it before everybody else does, from a UK plc point of view.

Menelas Pangalos: Can I add a couple of comments to the question around the regulatory environment? The meeting I am going to after this is the UK life sciences strategy group, where I am representing our CEO, Pascal Soriot, and we are talking about the impact of Brexit. The UK regulatory environment is quite innovative and has been very important in determining regulatory strategy across Europe. One of the big threats and questions that we currently face is what will happen as the EMA moves somewhere else, which it is going to do over the coming years. We are not exactly sure where, but we know there are two or three countries right now which are at the top of the pecking order for that move, and we are not sure what disruption that will cause. It is estimated that around 20% of current EMA employees will not make that move from the UK, and there are questions about how that will impact overall

regulatory strategy, not just in the UK but across Europe as a whole. Importantly, how will the UK regulatory authorities tie up with the European regulatory authorities, because we need a seamless regulatory approval process?

Moving on from that, historically while we have an innovative medical agency and also have a relatively innovative pricing agency—NICE—we need to work out how to get access to medicines so we are in the top tier of adopting innovation. That is important for the future of the NHS and for life sciences as a whole because you need your healthcare system to be cutting edge. You do not want it to be using old generic drugs that are not as good as the most recent innovations. It is very important that we work out a process for enabling our NHS to use the most cutting-edge therapies, whether they be in cancer, diabetes or cardiovascular health to, first and foremost, improve the outcomes for our population in terms of health. Secondly, if the NHS is not cutting edge, it means it will eventually become obsolete and we will not be doing our clinical trials in the UK and will not be able to apply our basic research in our hospitals and in our translational work and as a consequence, over time, things will start to move outside the UK.

Lord Fox: In your comments just now you talked about unique interactions that make the United Kingdom special. Can you give us some examples of what these unique interactions are?

Dave Allen: Both ourselves and AZ have it at all sorts of levels. GSK worked with Open Targets. The European Bioinformatics Institute and the Sanger Institute form Open Targets, which is publicly available information to validate basic targets for biomedical research. It is public/private partnerships of that sort.

Lord Fox: Is that unique to the United Kingdom?

Dave Allen: It is not unique because you get them elsewhere, but the way and the extent that we do them in the UK is an order of magnitude difference. The fact that you can get genuine public/private partnerships where both parties are excited to collaborate, and it is not just a flow of money one way or the other, is quite special, and we should preserve that. There are things such as the UK Biobank where Regeneron and GSK were sequencing genes in the first 50,000 of the 500,000 genes of the individuals who contributed to the UK Biobank. It is really basic research that is moving science on and attracts people to the UK. A critical thing of which we have to be very careful is to make sure this information goes into the public domain to grow the infrastructure of the UK and pull in more people and more science. We have to be careful that we do not, for the sake of trying to monetise a small bit of information, keep everybody else out. There is something very welcoming about the UK science base that lets people get at information. We could do loads more, but there is something quite special that attracts people.

Like AZ, we spend £1 billion a year doing R&D in the UK, and for good reason. There are hard-nosed commercial people who make a lot of these investments and they are doing it because the infrastructure is right and

the science base is right. There is something very special to protect there.

Baroness Morgan of Huyton: I want to come back to something Mene said. You said the NHS—in relationship to NICE, I presume—had to be cutting edge, so in a sense NICE has to allow the NHS to be cutting edge. What I was not clear about is what you were saying is the position now.

Menelas Pangalos: What I would say is that it is mixed across the board. If you look at patient outcomes in the cardiovascular and diabetes space, they are not the best, but they are relatively good in the UK in terms of how patients with those diseases do. Perhaps it is easier to give you some examples. A drug such as Brilinta, which is a drug that people use when they have a heart attack to prevent them having another heart attack and subsequently dying, was approved by NICE as being a cost-effective medicine, but adoption across the NHS was patchy to say the least. It took about four years for it to be uniformly adopted, after a lot of pressure and work from us, across all the NHS trusts and across the UK population—the reason being that, even though it was viewed as being good value for money and clinically effective, some trusts felt that they could not afford the new medicine and, as a consequence, were worrying more about their budgets than the outcome for their particular patient population, because the outcome of the clinical studies we did was a reduction in deaths, and that is why it has been adopted uniformly now.

In areas such as cancer—and this is not just true in cancer; it is true of the way our area and the life sciences are moving—medicines are becoming much more targeted. They are what we call precision medicines. For example, a drug we have recently launched is called Tagrisso and it is for a very specific type of lung cancer; a single mutation in a gene which causes the cells in your lung to proliferate and causes cancer. It affects a few hundred people in the UK. It is an expensive drug. The reason it is an expensive drug is because it is only going to be used by a few hundred people in the UK. Because it is an expensive drug, it does not pass through the thresholds that NICE sets, which have been set to be more relevant to diseases such as diabetes and heart attacks and more common primary care diseases versus secondary and tertiary care diseases such as cancer. One of the things we need to work out how to change a little is how we value medicines in cancer versus medicines in diabetes versus medicines in depression because they are different and the economics are different as well.

Baroness Neville-Jones: It sounds like it is a bad idea to have a rare condition.

Menelas Pangalos: That is right.

Q23 **Baroness Neville-Jones:** Could I explore with you a little further what contribution the big pharma companies can make to this country or to the implementation of the strategy? In particular, given the fairly positive picture that you have painted of the situation here, can I note and ask you why therefore—and this includes AstraZeneca—some pharma companies have moved their R&D out of the UK in recent years? It would

be interesting to know, against the background that you have painted, why that was and whether the implementation of the strategy would reverse that kind of move. In relation to the problems that you have painted with the NHS, do you believe that the Accelerated Access Review and the recommendations that it made would help and make a difference to what you have been saying about the delays and difficulties about take-up?

Menelas Pangalos: When I started my career doing my PhD, sponsored by Merck just down the road from where GSK are now, there were 10 or 11 major pharmaceutical companies in the UK conducting research and development. It was a wonderful time, I have to say. Today there has never been a better time to be life scientist in our industry anywhere in the world with the breakthroughs that we are seeing in science around the world. Why are there fewer companies than they were? There has obviously been a consolidation in our industry where the number of companies has decreased. As a consequence, sites have been closed. One has to look at the environment and productivity of those sites in each individual company and, as a consequence of that, certain sites have closed, including ones in the UK. For us, while we have closed sites in the UK, we have maintained being an Anglo/British company with a significant presence in the UK. This holistic environment over decades—because it has happened since the early 1990s—is incredibly important. When you have an environment with a good science base, which the UK has and hopefully will continue to have, but that is also an adopter of innovation, has a modern, forward-thinking health service, is able to integrate healthcare and value properly, that encourages companies to place their research and development in the United Kingdom.

You also asked about accelerated access. It is important and accelerated access will help, but I do not think it is the panacea that it is made out to be, for the simple reason articulated earlier about NICE and how we value medicines. This is where it gets a little challenging and where we have to think about the level of evidence needed by disease area. You have accelerated access to an oncology drug, which is cutting edge and clinically meaningful, but the data that is generated will be using something called progression-free survival. That means the cancer patient goes on the medicine and we slow the progression of the disease down by three months, six months, 12 months, whatever the period is, and that is generally the data that you would have to gain accelerated access. NICE asks to see the overall survival data, which takes years to get. Accelerated access and NICE do not go hand in hand. There is a fundamental misalignment there in accelerating the approval of a medicine versus not reimbursing it. Again, we have to round off the square peg to be able to fit the hole.

Dave Allen: I will pick up on accelerated access because there is a model anticipated in the report which talks about a relatively early provisional type of approval for new medicines while we go on to generate the sort of data that will ultimately support the value of the medicine, so you get things such as conditional approval ideas. To do that, one of the things that we have to move to is an infrastructure within the UK to generate

the information that both UK payers and global payers will want to see. There are ideas such as regional data hubs where we collect what is called real-world evidence, which is the value of the medicine in a real-world setting; in other words, not in the very, very controlled setting of a clinical trial but in day-to-day usage in patients going about their normal lives, taking their normal other medicines and everything else. As GSK, we ran one of these studies in Salford, called the Salford Lung Study, which was hailed as the way that this needs to be done. It could be a model for some of these regional data hubs. We are keen to share that learning because we learned a huge amount in it, but it is worth reflecting on the level of difficulty of this ambition. Salford took us five years and cost us an absolute fortune to run.

Menelas Pangalos: £200 million.

Dave Allen: So it is sometimes quoted. It cost a lot of money. I tend to round down slightly from that.

Menelas Pangalos: It was a good study.

Dave Allen: Interestingly, the treatment pathway that was shown by the clinical study with statistical significance has not been adopted by Salford after the study. In fact, it has not been adopted anywhere in the UK. I get very difficult questions around, "Would you do that again—with your study delivering with a statistical significance and then not being adopted?" The other thing to think about is the cost base for things such as these regional data hubs. It is sobering that the Salford infrastructure having been built has not been used since. Frankly, one of the reasons is that the price has gone up tremendously such that it is not cost effective to use that infrastructure. The ambition is right but there are a lot of very difficult questions to overcome. Part of it is about the immediacy versus the long-term benefit. Having this infrastructure in the long term is absolutely critical. I recognise the short-term difficulty of doing that.

Lord Fox: Is it your impression that NICE is resisting your no doubt very well-reasoned attempts to get them to change this practice because of a philosophical reason or because they need to hit a budget?

Menelas Pangalos: It is a combination of both those things.

Lord Fox: So what is the philosophy?

Menelas Pangalos: NICE has great value and adds great value and is a very important body for us, but it was set up a long time ago and I do not think it has evolved in some of the areas in the way that it needed to in order to be able to value certain types of drugs appropriately. I think we absolutely need to keep it. As an industry we have to demonstrate good value for money. Once NICE has approved something as being good value for money, it needs to be adopted uniformly across the health service.

Lord Fox: Are you saying that it does not understand your point of view or it has a different point of view to you?

Menelas Pangalos: I think it understands our point of view. The challenge is that it is a zero-sum game and we are run by budgets, and

they have a certain budget. One of the reasons why the life sciences industrial strategy is important is because it asks for a 1% increase as a percentage of GDP, which is a huge investment in healthcare. That is what you need to be able to afford the medicines as well as be able to change the NHS. You are asking what is unique about the UK. When you look at the quality of the universities that we have relative to the amount that we spend, we are unique. We have two of the top 10 universities and six of the top 20. When you look at it pound per high-impact publication or patent, we are the most productive country scientifically. That is not being translated into commercial return in the same way that it is translated in the US.

One of the other differentiators for the NHS—and we talked to John Bell yesterday about this—is this idea of how you use the advantage the NHS has. The NHS is starting to integrate electronic health records across the whole of the UK where primary, secondary and tertiary care records are all related and you can do these real-world evidence studies—this is a differentiator. No other country has the size of population and the NHS to enable you to do these types of real-world-evidence studies that will enable you to demonstrate value, help with accelerated approvals and, ultimately, make the UK a very attractive place to do research and development.

The Chairman: What is your level of R&D spending in the UK and in other countries?

Menelas Pangalos: We spend close to $6 billion a year on R&D and we spend about £2 billion of that in the UK.

Dave Allen: We spend about £1 billion a year in the UK out of a budget of about $3 billion globally. It is very disproportionate. Could I add something on NICE? If we are not careful, we end up saying, "Kick NICE if there's a problem". I agree with Mene; it is enacting its remit as best it can. There is something about the way it is structured which suits chronic diseases rather than acute interventions and, increasingly, oncology is looking like an acute intervention; you need to get in and hit it hard. Even with NICE-approved medicines, there is good data to show that their uptake is very, very low post approval. When you look at competitive indexes, the UK comes well down compared to similar countries. I think there is something after NICE as well that is stopping the uptake. Of course, that makes it really hard as we cannot do clinical trials if we do not have standards of care in our centres because they would not be used in the rest of the world.

The Chairman: We have the point. Baroness Young.

Q24 **Baroness Young of Old Scone:** I was going to ask what makes the UK attractive to investment, but you have pretty well answered that, so perhaps we could focus on an international setting and ask whether there is somewhere else that is better than us and what they have that we do not have. Perhaps we could also look at the Brexit issue. You have talked about the risks of the move of the EMA, but are there other things that Brexit could put at risk in our attractiveness as a place for investment?

Dave Allen: One thing we have not talked about is the UK talent base. You asked about other countries and everything else. We need to recognise that the US brings a phenomenal amount of money and talent to the table when its wants to do so something, but you are seeing emerging economies privatising, and biomedical sciences is one of the areas they want to be globally competitive in. We need to think hard about the UK talent base, which is ably supported by our universities and everything else. Of course, it talks very much to Brexit because, with a population of 65 million, we cannot expect to have all of the talent we need all of the time. The collaborations that we do with Europe, the exchange of scientists as well as science, and the fact that those scientists come with families—we are asking people to come to the UK and become part of that infrastructure and we need to make it simple for them to do that. The skills that they bring are absolutely critical or we are not going to compete with countries that are prepared to make it much easier for people to move and thrive in those countries. I do not know if you want to talk a bit about Brexit.

Menelas Pangalos: I will talk about both, if I may. We are starting to see it now for the first time and I have had my first conversations where I have started to become worried about the impact of Brexit on our employees, both UK employees in Sweden and mainland Europe as well as European employees in the UK, which is about 10% of our workforce either way. They are worrying about the uncertainty. We are being as positive as we can and saying, "We are going to look after you", but the fact that we have no idea what is going to happen is a real problem. We are starting to see people turn us down now in the UK because they do not know what the outcome will be for future employment, even though we tell them we have no doubt that great talent is going to be accepted down the road. They do not have that certainty, so they are saying, "Until we have it, we would rather go and work somewhere else".

I will give you some numbers on EU funding because it is a significant concern for the private sector but even more of a concern for the public sector, for the universities. The UK gets more than our fair share of European Union funding through IMI (Innovative Medicines Initiative) and Horizon 2020. Close to 30% of all that European funding from IMI comes to laboratories and research centres in the United Kingdom. Approximately €300 million has come to the UK from the IMI that is at risk of no longer being available for funding.

You asked what other countries do with the commercialisation piece or which ones have a vibrant life sciences sector. In Europe, we are not bad, based on the fact that we have really good grass-roots basic science that starts up the small companies. They get that series A funding and can survive and thrive as small companies. In 2016, the level of venture capital investment we had was around £680 million. I would contrast that with Boston and San Francisco, which were each £1.5 billion. It puts it into context for you. China is trying to move in Shanghai and Beijing to the Boston/San Francisco model level of funding. Even in Russia, I was in Moscow a few weeks ago and I saw a city that was being built just for biotechnology, with 30,000 people focusing on biotech and new

technology. While we have the really good science here and we are able to start fledgling companies, what we have not been good at—it gets back to the conversation about how many R&D companies and how many pharma companies there are—is keeping those companies in the UK and growing them in the UK. Inevitably, they have all migrated to the US, either east coast or west coast. We do not have a Celgene or a Gilead Sciences. These are all $50/$60 billion companies now. They started as $20 million companies not so long ago. That is what we need to have here in the UK because the science base and the starting point is here but it is not staying here.

Baroness Young of Old Scone: That is not just a factor of scale that we are never going to be big enough to pull it off?

Menelas Pangalos: No. Money is one of the reasons, but our financial capital markets are pretty robust and strong. One of the things that we do not have is the talent that understands both finance and science; business and science. When I go to the US and speak to sell-side analysts or venture capitalists, they have as much insight into the science and our pipeline as they do into our EPS in our balance sheet. In the UK you tend to find people who are more focused on the finances and the balance sheets and not on the science. You have good scientists but you do not have the combination of both. We need a stronger cadre of businessmen who are also scientist physicians.

The Chairman: If that is a crucial issue—and we all take your point very well that we have good science but we do not translate that into innovation, and, of course, if you look at the rankings of universities, one does extremely well but the other side does not—and if small companies do not grow here but move out, and business is important to the understanding of life sciences, the strategy does not say anything about it.

Menelas Pangalos: Within the life sciences strategy document there are sections around how we create patient capital and an environment which attracts investment and, as a consequence, starts to generate a cadre of CEOs and CSOs that can start to cycle through companies and grow the business here versus growing it somewhere else. I think it is covered. One thing we talk about—and I am sure GSK talk about as well—is how we engage with our scientists and create courses at universities and opportunities through secondments where we can teach and grow that population of scientists who can also get a business background.

Lord Oxburgh: Can I take advantage of my position to pursue that slightly? I take your point completely about the difference in scientific qualifications of our venture capitalists; it is a very marked contrast. I am really speaking from knowledge of the electronics area but it is different from what one finds in the US. Fundamentally, it is a question of what sort of people the venture capital companies recruit. At Imperial College, before I left, we had introduced a combined MBA with the MD. I do not know if that still functions and whether any of these people come to you, but it was certainly a need that we recognised.

Menelas Pangalos: I met with the president of Imperial College just a few weeks ago. We are doing the same at Cambridge University. These are exactly the type of people and courses we need to have. The challenge is they need to have the businesses to get the experience. We need to have those start-up companies; the GSKs, the AstraZenecas and the other pharma companies. They can do this experience anywhere in the world as long as they come back to the UK. That is absolutely right.

Dave Allen: Going back to the strategy, if we can tie together the different stakeholders and redevelop this life sciences strategy, that should nurture smaller companies because, in a way, the big pharma can deal with complex regulations and take a bit of a hit on the timelines. If you do not have VC funding, you are bankrupt while somebody is still thinking about whether an ethics committee is going to approve your study. There is a swing out of the big pharmas into the small and medium-sized companies and into the contract research organisations. A huge number of former big pharma people are now COOs in the UK and they are quite silent and relatively invisible, but have the most to gain. One of the things that keeps us really engaged in the UK is being part of a sort of scientific ecosystem with small companies emerging and with talent coming through. It is in everybody's interests. One of the things that the strategy perhaps could focus more on is how we can nurture these medium-sized companies. The talent is critical but so is the environment.

Q25 **Lord Oxburgh:** I was supposed to pursue a topic that we have already explored to some extent, which is the question of innovation and the NHS and so on. If you have a new device or pharmaceutical product that has been approved by NICE, could each of you say where you go from there? How do you promulgate this fact? Is it just left to people to make a list of things that NICE has said are okay? How does this work? I do not have a very clear picture of what happens next.

Menelas Pangalos: Fortunately—or unfortunately—I spent a few days with our marketing company in the UK. I am a scientist, so this is not my area of expertise. I went to them and said, "I don't understand. This has been approved by NICE as a medicine; why isn't it getting used everywhere?" Every single interaction with an NHS trust was an individual interaction to get it onto the formulary of that particular trust. Every trust had a different position depending on its budget and its population. It was not like having one engagement with the NHS; it was like having 20 or 30 engagements. That is why the uptake was so patchy. I would say the conversations were predominantly driven by the budget: "Can I afford to take a new medicine, even if it is better in the long term financially for my trust, if I can't make my quarterly budget this quarter?"

Dave Allen: I am in much the same position. From an R&D perspective, once the medicine is approved, we hand over to our commercial colleagues in each country. Dealing with each individual trust in the UK is very time consuming. The only other thing to think about is as you divide groups smaller and smaller into individual trusts, as you do, you become very susceptible to the key interests of the members who are making

those decisions. If you get somebody who is very influential in a particular trust who is very taken by cardiovascular medicine and they are reviewing a new oncology drug, it is very hard. It is not that we do not have the right talent but that, as you subdivide into smaller and smaller areas, by necessity you are driven by fewer and fewer people, and having the breadth to understand the increasing diversity of medicines becomes a real challenge, so you tend to get quite different speeds of movement in different areas and different regions. The newspapers do that postcode thing, and it starts to feel a little postcode-ish.

Lord Oxburgh: Would there be any role within the NHS for some kind of central body which assessed what had come through from NICE and was able to provide informed guidance to local trusts on what was really going to work for them? Or would it simply duplicate what is there already?

Menelas Pangalos: That is almost happening with one of the recommendations. We are introducing more bureaucracy into a system that is already incredibly bureaucratic. The whole premise of NICE is that it is meant to determine the value of cost-effective drugs that are good for our patient population to be taking. My personal view is that once a drug has been deemed to be cost effective, we need to work out how it gets adopted in the UK tomorrow or the day after. I will give you an example in the US. When a drug is approved by the FDA, it is used the next day. Here it can be 12 months. Brilinta took four years. I know you mentioned this, Dave, but I want to quantitate it for you. In high-income countries we are one of the poorest at adopting what are deemed to be cost-effective drugs by NICE: 18% of the international average. It is terrible.

The Chairman: A quick question from Baroness Young and a quick answer.

Baroness Young of Old Scone: Can I have a two-second rant first? When I ran Diabetes UK we had the ability to identify a model of care that would save a billion quid from the NHS budget. Could we get health economies across the country to adopt it? No, we could not. Have we reached a point now where we need a bit more direction rather than local determination? Particularly, will things such as an outcomes focus and standards of care be helped by just saying, "This is what the NHS is going to do in this particular care area"?

Menelas Pangalos: That would be quick, which again gets to your question around having a central policy, "We are using this drug broadly across the NHS now". It is not just medicines; it is devices, physiotherapy and all sorts of things. We need standards and we need them to be adopted quickly in order to improve outcome consistently across the UK. I completely agree with you. There is an inherent pressure on trusts and budgets because of the squeeze—everyone is working to not having enough money—and when there is not enough money to fund the things we need to fund that have a better outcome on patients, you have to make choices. These are all bad choices. It is not like we are making a choice of a good drug versus a bad drug. These are good drugs and good

drugs and, "I can only afford to pay for one them". Fundamentally, we need to spend more, but we also need to think about how we create the room to save money over three years versus saving money over a quarter because, ultimately, if you applied what you are talking about in diabetes, the healthcare costs would come down; they just do not come down in the next quarter.

Lord Fox: Just as an observation, one of the easiest ways of spending money is to do the same thing 25 different ways. Looking back and avoiding my remit slightly, because we have answered some of those questions, the holy grail of access to the NHS's wonderful data is stated by lots of people, and I wanted to interrogate that slightly. My anecdotal interaction with the data of the NHS, whether it is through my GP or through a hospital, does not convince me that it is a data-driven enterprise. While I can see why we would want to access it, in practical terms I wonder if we ever will.

Dave Allen: There are a couple of things. Data is always hard. We know that inside our companies and we have complete control of it there. It is always much harder to do than it sounds. I am always a little more sympathetic to the problems, having tried to live with this. The major point is: let us not be put off by the fact that it is hard. The real benefit, and the real goal here, is that when you look at areas that have huge potential, things such as genomics, the genomic data in itself is important, but if we can tie that to clinical feed times—

Lord Fox: I get the benefits in spades; what I do not get is the practical route to unlocking them.

Dave Allen: It is doable. We may have to do it regionally first and join up the regions because, obviously, you have integrated data systems. One of the reasons we went to Salford for our study was because it has a good integrated data system. Regions can do it but we are into the same problem of different priorities in different regions against everything else. It is a huge goal, but it is doable and I genuinely think we should not be put off because it is hard. It is a massive benefit if we can get it, but it will be hard.

Menelas Pangalos: There are pockets of it and that approach is exactly right: you find the regions that are ready to do it and you start with those as examples of good. You show the power of doing it in terms of the positive impact it has on the welfare and outcome and cost for that particular region, and slowly you start to join them together. It requires, again, investment but it is absolutely doable. I have no doubt it would be a differentiator for the UK, which is the very first question that you asked. There is not another country of the UK's size that has this integrated healthcare system from cradle to grave, with the quality of science and genomics application. It would make us unique, I think.

The Chairman: Your comment there is correct but what Lord Fox was getting at is that we do not have the system yet to collect that data that goes from cradle to grave. We talk a lot about how good our system is and how good our data collection is, but when you look at it, it is not there.

Menelas Pangalos: I agree with you that it is not there uniformly across the country, but we have made a lot of progress. The GSK case study in Salford was exceptional. We have just done one in diabetes with our SGLT2 inhibitors where we had a very large proportion of patients coming from UK databases, where, in effect, we ran a phase 3 clinical trial using real-world data from GP records. We were able to demonstrate that we could improve mortality benefit to patients with diabetes. If you can do that consistently in the UK—and it is very challenging and I have no illusions about how difficult it would be to set up—it would be one of the things that differentiates the UK from other countries.

Lord Hunt of Chesterton: One international comparison concerns the question of regulation. I was on the Committee 10 years ago on animals and scientific procedures and, as I understand it, there is still a considerable difference and things are allowed to happen in the US that are not able to happen here, and there may be other regulatory constraints. In general, where does the UK sit in the listing of regulatory constraints?

Dave Allen: From a basic research point of view we have a very rigorous but very sensible framework of regulations. It is consistent with the expectations of the UK population. We have to be respectful of the fact that to conduct research in the UK we need people on board with it.

Lord Hunt of Chesterton: Which is different from some other countries.

Dave Allen: It is very different, but it is consistent with the expectations of the UK population

Lord Hunt of Chesterton: That is very diplomatically put.

Dave Allen: We need permission to do research. Society needs to give us permission to do research, including animal research, and society as a whole needs to be comfortable with those guidelines, the regulations and everything else. Having a very rigorous framework is right because that is what is expected.

Menelas Pangalos: I have run laboratories in the US, in Europe and in the UK and there is no difference in terms of impediment; in other words, there is no additional impediment in the UK to being able to conduct animal research. I think the standards we have are the right ones in terms of quality of housing, size of cages relative to the US. It is not impeding our work in the UK in any way, shape or form.

The Chairman: Lord Maxton, would you like to declare your interests?

Lord Maxton: I have no interests whatsoever in this. You keep talking about the UK, but of course there are four NHSs in the UK. I would just make that point.

Menelas Pangalos: Yes, in addition to all the trusts within the NHSs. Again, I will make a comment on that, if I may. NHS Scotland, for example, where we have a big genomics collaboration, has been at the forefront of creating single systems with electronic health records and making the adoption of genomic data much more accessible and routine than it is in other parts of the UK.

The Chairman: That is because there has been one health record in Scotland for a while.

Menelas Pangalos: Yes.

The Chairman: Lady Young, do you want to declare your interests?

Baroness Young of Old Scone: I ought to declare my interests. I am a chancellor of Cranfield University and former chief executive of Diabetes UK and was the chairman of the Care Quality Commission in a very unhappy period of my life.

The Chairman: I am stuck for words. Did you have a question to ask?

Baroness Young of Old Scone: You asked me to declare my interests.

Q26 **The Chairman:** I have a question. We have covered a lot about how we make the environment more amenable to developing companies, how we make the environment more amenable to big guys such as you doing further R&D in this country and how we might use the NHS, and what are the blocks there and the regulatory framework, which I gather from you could be improved upon. What is one recommendation you would like us to make in our report that will help progress this further? You do not have to have the same recommendation, by the way. Mr Allen, I will start with you.

Dave Allen: The report is excellent and the ambition is right; this is all about implementation. It is phenomenally hard to get anything like this sort of ambition implemented. We have had evidence in the past where ambition itself is not sufficient. You guys are much better able to work out the governance process and everything else. Sir John has done a great job in getting everybody together to get the recommendations; it is about how we implement these and whether we are going to do it and whether we are going to do it in a sensible timeframe. If I worry about anything, it is how we are going to implement and how we are going to keep the momentum that the vision creates to execute and get something done.

Menelas Pangalos: My recommendation is the most difficult one; we are saying that we spend on R&D in the UK 1.63% of GDP right now. That has been projected (by Government) to be increased to 2.6% over 10 years. I would say we need it to be done over a five-year period, not a 10-year period. We need to do this fast. It is that level of investment. If we tinker around the edges with £1 billion here and £1 billion there, it is not going to have the impact that we want that will create a world-class life sciences industrial sector in the UK.

The Chairman: What would be your comment about the Industrial Challenge Fund?

Menelas Pangalos: The Industrial Challenge Fund is a very good idea. It builds on things that are being done in the US, but the investment holistically across the UK needs to be such that it enables all the things we have talked about across both the private and public sector and the NHS to take place. Unfortunately, these things cost money.

Baroness Neville-Jones: In relation to these answers, it seems you are saying that we ought to inject more money sooner. In relation to implementation, would you see it as worth while to ask people to work out an implementation plan?

Dave Allen: Yes.

Menelas Pangalos: Yes, absolutely. You need to have accountable people for this as well who are on the hook for delivering this plan, if you believe it is a plan that is worth delivering.

Lord Fox: Who do you think should be the accountable people? Where does the accountability lie? You do not have to name a name.

Menelas Pangalos: We talked about this last time and this is a really tricky question which you are probably in a better position to answer than I am. It needs to be a combination of leaders from the private and public sectors.

The Chairman: You commented on the Industrial Challenge Fund. Would you have comments about the money that is spent on doing this third phase of industrial audits? The Government have just announced money for three further audits of different areas of the industrial strategy.

Dave Allen: All these things are great, but they are not sufficient. We have talked about data, implementation and everything else, but substantially more money is needed to make this happen, with a promise of some good returns in the longer term. All the current things are great; they are just not sufficient and they are piecemeal. We need the strategy to tie it all together.

The Chairman: Thank you both for coming. It has been most interesting. We appreciate the time you have taken. Thank you very much indeed.