HOUSE OF LORDS

Science and Technology Committee

Corrected oral evidence: Innovation in the NHS: Personalised Medicine and AI

Tuesday 30 June 2026

11.15 am

Watch the meeting

Members present: Lord Mair (The Chair); Lord Booth; Lord Duncan of Springbank; Lord Ranger of Northwood; Lord Stern of Brentford; Baroness Willis of Summertown; Lord Willis of Knaresborough; Lord Winston.

Evidence Session No. 20 Heard in Public Questions 227 - 235

Witness

Lawrence Tallon, Chief Executive Officer, Medicines and Healthcare products Regulatory Agency (MHRA).

USE OF THE TRANSCRIPT

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

Examination of witness

Lawrence Tallon.

Q227 **The Chair:** Good morning. Welcome to the House of Lords Select Committee on Science and Technology. We are continuing our inquiry on innovation in the NHS, personalised medicines and AI. We are very pleased to have as our witness this morning Lawrence Tallon, the chief executive officer of the MHRA, the Medicines and Healthcare products Regulatory Agency. Mr Tallon, thank you very much for coming to speak to us this morning.

In recent years, the MHRA has increasingly positioned itself not just as a safety watchdog but as a body that aims to speed up access to innovative treatments for patients in the NHS, and indeed to support the UK's life sciences sector. By way of an opening statement, could you tell us what measures you are taking—particularly in the field of personalised medicines and AI—to accelerate the adoption of innovation in the NHS? Over to you.

Lawrence Tallon: Thank you to the committee for inviting me to speak today. I will try to describe the journey we have been on at the agency over the last few years. We describe the core philosophy of the agency as putting patients first. That is absolutely our guiding star and has not changed, but perhaps we have started to interpret differently what we mean by putting patients first. Of course, you have to have safety written through everything you do in the regulation of medicines and medical devices, but we believe that if we want to put patients first, as well as safety we also need to think about expedient access to the latest medicines and medical technologies, allowing patients to benefit from innovation—of which this country is one of the leading lights, but of course many other countries are too. So we think about safety, access and innovation as how we put patients first.

The agency has had quite a difficult time over the last few years—which is probably well known to the committee—but I am happy to say that we are in a much stronger position now. A few years ago, three key things came together around the same time. First, the departure from the European Union was particularly disruptive to the MHRA because we were collocated with the European Medicines Agency in London, so it was a very disruptive change to the organisation and our ability to workshare across Europe was removed.

Around a similar time we had the Covid pandemic, which in many ways was the agency's finest hour. I would like to pay particular tribute to my predecessor, Dame June Raine, who did phenomenal

work with the team at the MHRA in being the first regulator internationally to approve a vaccine for Covid-19. An authoritative report recently found that that was estimated to have saved 450,000 lives in England alone. That meant that, as for many other institutions, including the health service, all the non-Covid work was starting to build up in the background and our ability to share that work across Europe was diminished or removed. At the same time, the third shock was that there were quite significant budget cuts put through to the MHRA.

With those three things coming together, non-Covid workload went up, the ability to workshare with Europe was removed and our ability to service that demand in the agency was reduced. For a while, the MHRA got itself on the back foot with its approval times for clinical trials and new products, and that is well known as a matter of record.

However, we are in a much stronger position now. We have fully recovered all our performance targets. We will be sharing with the clerk of the committee our latest impact report, which shows that we hit all our statutory targets last year and are now in a more sustainable position. For example, our speed on clinical trials has moved from 91 days down to 41 days, so we are in a stronger position around our speed.

We also have great expertise within the agency, thanks to the core scientific strength of the country. We have set out to be particularly strong around AI as a medical device and around rare therapies, which I know are key interests for the committee. So we are faster, we retain our expertise and are growing our expertise, but we are also open to the health system, to academia and to working with industry, while retaining our objectivity and independence, to understand the pipeline of new therapies coming down the line so that we can approve them in an expedient form. That is my opening response to the committee.

The Chair: Thank you. That is very helpful. The first question is from Lord Booth, who is coming in online.

Q228 **Lord Booth:** Good morning, Mr Tallon, and thank you for coming along to speak to us this morning. It has often been raised throughout this inquiry that there is a long process for innovations or new medicines to get into routine care, and insufficient join-up between, first, the regulatory process of the MHRA, secondly, the appraisal and guidance process from NICE and, thirdly, the NHS commissioning of a medicine or technology. From the MHRA's perspective, what are you doing to align your approval processes

with NICE's appraisal and NHS commissioning to reduce duplication as far as possible and to accelerate these timelines?

Lawrence Tallon: Thank you for the question, Lord Booth. Medicines development, by necessity, is a long process, all the way from the pre-clinical work through clinical trials and into licensing. But we have seen—and we saw during Covid—that it is possible to do those processes more quickly than has traditionally been the case, and that will be true even more so with AI. I think we will come on to that later in the questions.

The key thing that we have been doing over the last year or so, between the MHRA and NICE, is to have what were sequential processes done in parallel. The MHRA's responsibility is to license new products, and we make that decision on the basis of safety and efficacy. NICE makes a decision on the cost effectiveness of those medicines for England. Of course, the devolved Administrations have their own arrangements, but they are generally quite closely aligned with NICE.

Previously the processes between the MHRA and NICE happened in sequence. We are now bringing them together so that they happen in parallel. That is somewhat complex because it means that NICE has to take provisional decisions on things before it knows whether the product has marketing authorisation. We are re-engineering that process, based on the model that already exists in Canada. We know that the authorisation and the reimbursement decision happen in parallel in other jurisdictions, and we have essentially been copying that approach for the UK.

From 1 April this year, we have offered product developers the ability to run those processes in parallel rather than in sequence. We estimate that that means medicines will get approved between three and six months earlier than would have been the case in the sequential process, which clearly is better for patients and earlier access. It is also better for product developers because it means that they get reimbursed earlier within their patent period, which is of significant value to them.

The other key thing that we have done with NICE is to align our scientific advice processes. This is when—I am sure you will know—a product developer wants to know what would be considered the appropriate evidence for success or the endpoint agreement. We are doing that in parallel with NICE and MHRA so that there are not two separate exams but one aligned examination.

The reimbursement and the marketing authorisation are coming much more closely together, and that has been welcomed by

industry. I think it is a reasonable challenge, though, that we have more to do in making sure that, subsequent to those decisions, the uptake within the NHS happens more rapidly than it does now.

The Chair: Just to clarify your point about doing things in parallel rather than in series with NICE, is that now standard for all new innovations and all new medicines?

Lawrence Tallon: That is the standard offer. It is possible for medicines developers to opt out of that, and sometimes they choose to because they prefer to build their evidence in real-world use before they go for the reimbursement decision. But our expectation is that more and more companies will want to avail themselves of the standard offer, and that is based on the industry feedback we have had so far. I think that will become the normal way of doing things.

The Chair: That sounds like a big improvement.

Lawrence Tallon: Yes.

Lord Stern of Brentford: As these go in parallel, if that is chosen to be the case by the applicant, how much interaction is there during that process?

Lawrence Tallon: Between the MHRA and NICE?

Lord Stern of Brentford: Yes.

Lawrence Tallon: Significant interaction. We are talking together much more regularly than previously. It is a fair and reasonable challenge to say, if we went back a couple of years, that people and companies found the process between the MHRA and NICE disjointed, and we have been making strenuous efforts—particularly over the last 18 months or so—to join those processes up. Of course, when you are doing this sort of thing, it is quite complex and takes time. It will take a little bit more time to embed fully, but we are absolutely committed to making those processes as easily navigable as we can.

Q229 **Lord Willis of Knaresborough:** Good morning. The MHRA must collect a huge amount of data on proposed innovations. As a committee, we recognise that that is a massive task, but do you see it as having any role in acting as the front door for innovations, making the priority to ensure that products fit within the clinical pathway of the NHS? Do you at any point advise training professionals on those innovations?

Lawrence Tallon: It is important to note that the MHRA is agnostic as to products. We are not a product sponsor and do not bring products forward to market. However, we have an important opportunity—and indeed a responsibility—to use the data that we hold to support innovation areas that are beneficial for the country. I will give you an example of how we do that in a moment.

We have a system called the clinical practice research datalink—CPRD—which holds anonymised primary care data from up and down the country. That is widely used by researchers to decide where to place their clinical trials and to find patients who would fit within their clinical trial protocol. That is already well used, but I think the opportunity ahead of us is much greater, not necessarily with the MHRA alone but working across the wider data system of the UK.

Of course, the really crucial new player on the scene here is the Health Data Research Service. I think you have had its leadership in front of the committee before. That organisation, which we are collaborating with incredibly closely, offers probably one of the most unique opportunities to leverage the data we have in this country for pharmaceutical and medical device development because we have whole-population, longitudinal and multimodal data, crucially including genomic data. This is a big advantage that other countries do not necessarily have. The other countries that do have that sort of data are often smaller and have a more homogenous ethnic characteristic than we have, so we really have a huge opportunity here.

To give you an example of how that might play out, 250,000 people are hospitalised in this country every year because of adverse drug reactions. The latest estimate is that that costs the NHS about £2.5 billion. We estimate that up to 40% of those adverse drug reactions have a drug-to-genome component. To understand that drug-to-genome interaction, you need the post-market surveillance data on the medicine itself and the genomic profile of the population to understand where those things are happening. No other country has the opportunity to do that at the scale we have and with the heterogeneous population that we have. I think there is an enormous opportunity for us to do that. That is not the MHRA alone; it is the MHRA working with NICE and with the Health Data Research Service.

Lord Willis of Knaresborough: How do you spread all that information to the other organisations?

Lawrence Tallon: The Health Data Research Service is the industry-facing platform that will do that. That has been recently incorporated as, I think, a company. I forget the exact organisational status, but it is a national body recently incorporated to provide anonymised data as a service to enable product development, including drugs.

The other example of where we can use our data within the MHRA is to point to research gaps where we know they exist. Specifically, one of the biggest research and product gaps we have is the gender gap, women's health. When we looked at the five-year clinical trial data that we hold within the MHRA, we found that fewer than 30% of clinical trial participants are women of childbearing potential. That means we are less confident of the applicability of the medicines and medical devices that are being developed in this country to women of childbearing potential than we ought to be, because the data is biased. Fewer than 1% of the trial participants—in all the clinical trials that took place in this country over the last five years—were women who were either pregnant or breastfeeding.

We have a major health gap here in that we are developing medicines and products, and we are less reliable on how they interact with women of childbearing potential and even less so with women who are pregnant or breastfeeding. This is data that we have published, put out into the public domain to help the people who are clinical trial sponsors understand where the need is for new interventions and new products to come forward. There are multiple examples of how we can use that data in that sort of way.

Lord Willis of Knaresborough: How do you deal with training professionals, or do you not deal with them directly?

Lawrence Tallon: Do you mean medical professionals? We do not do that directly, no.

Baroness Willis of Summertown: This is just for clarification. We have been hearing a lot about the funding of these different routes. If your data is showing this reaction to a medicine, how does that information flow through to someone like UKRI or somebody else then picking this up to do research into it? Where does that come through to?

Lawrence Tallon: At the moment it does not particularly. This is the early data that suggests that there is a huge opportunity to better understand adverse drug reactions when we understand the interaction between the drug and the genome. The point I am making is that, as a country, we do not fully leverage that

advantage yet. No country does, by the way. However, the incorporation of the Health Data Research Service is our opportunity. Now that we better understand those potential interactions, we have a big opportunity ahead of us. We do not currently do it, but I think the Health Data Research Service will be the way in which we do that.

Baroness Willis of Summertown: The flow of information will come from you to where?

Lawrence Tallon: To the Health Data Research Service.

Baroness Willis of Summertown: What is the next step after that?

Lawrence Tallon: There are lots of different datasets that will flow into the Health Data Research Service, including from the MHRA, NICE, NHS England and Genomics England. The Health Data Research Service—which is still in development, but has just been incorporated—will seek to curate that data in such a way that the pharmaceutical sector and the medical device sector can use it to develop their products in ways that start to address the gaps I have described.

Baroness Willis of Summertown: What about research? Where does that fit in?

Lawrence Tallon: Well, it is for research; the R in HDRS is for research. The whole point is to make it available for researchers, not just industry researchers but academic researchers.

Baroness Willis of Summertown: I understand. Thank you.

The Chair: Lord Ranger would like to come in online. Lord Ranger, can you hear us? We just need to unmute you.

Lord Ranger of Northwood: I think I am unmuted now.

The Chair: You are now. Good.

Q230 **Lord Ranger of Northwood:** Thank you, Mr Tallon, for your time today. One of the issues is assessing the huge volume of healthcare innovations now coming through in personalised medicines and driven by AI. We have heard that the MHRA is often considered lacking regulatory capacity to proactively engage with industry—this is heard across many industries with regulators, but in this case especially with SMEs—and to assess new technologies and medicines quickly. Do you think this is a fair criticism? If so, what is preventing the MHRA tackling these challenges more

rapidly? I am sure there are challenges that you might want to point out. Is it a question of budget, skilled personnel or something else? What do you think you require that can assist in dealing with the weight of organisations and expectations now on you?

Lawrence Tallon: Specifically, do I think it is a fair criticism? If we were to roll back a few years, it probably would be a fair criticism. I think it is much less so now, although we can of course go much further. I will share with the committee—which I think I mentioned in an earlier answer—our impact report. That shows how much we have speeded up our regulatory processes in the last year or two. Increasingly, you will hear from industry that we are much faster, and I will come on to the capacity point in a moment.

The mantra we talk about is being fast, expert and open, because we recognise that the cost of medicines development per week or per month is enormous. If you can shave a month or a couple of months off that timescale, that might well be the difference between whether a company chooses to bring its R&D to this country or not. It is a fiercely competitive landscape internationally. We are competing with many other countries that are seeking to bring the inward investment to their country, so we need a regulator—

Lord Ranger of Northwood: Sorry to interrupt you, but just on that particular point, that is very interesting. Have you done any modelling on how time can impact cost and value in doing that and on speeding up?

Lawrence Tallon: I have not done specific modelling within the agency, but there are various estimates out there from pharmaceutical companies about how much it costs them per month to develop a drug. It is millions and millions of pounds. If you can take a month out of someone's timescale, that is a really meaningful sum of money.

Where you are talking about SMEs—innovative biotech companies or medtech companies that have venture capital investors behind them, pushing them hard for results as quickly as possible—speed really matters, particularly as they often have less well-advanced regulatory affairs teams. We are absolutely cognisant, and I think this goes to the very opening question about our role not only safeguarding patient safety but making sure that we are responsible in expediently bringing medicines forward for patients so that developers want to bring their inward investment to this country.

One of the ways we can do that more effectively than we have in the past—and we are doing this increasingly—is the scientific advice process that happens early on in a regulatory affairs journey. Very often companies will seek what we call a scientific advice meeting, which is a quite structured and formal process where they explain to us which products they are bringing forward in their pipeline, so that we have sight of it and we can talk to them about the evidential or the endpoint standards we are looking for in that product. The earlier we can have that scientific engagement, the sooner we as the regulator can understand the products that are going to be brought forward and where we need expertise, and the sooner the developer can de-risk their regulatory journey by knowing what the regulatory evidential standards will be.

One of the things that is really clear to me in the year and a little bit since I have been in role is that we need not only to bring that service as early in the process as we can but to have a more flexible approach to scientific advice. At the moment we have a quite rigid, standardised meeting, very formal. We hear from developers that often they want a less formal, earlier meeting to essentially test ideas before the formal meeting. We will be bringing forward proposals this year for a more flexible, iterative approach to scientific advice. Again, this is often one of the key things that clinical trial sponsors use to decide where to place their trials.

If we come to the key point in your question about whether we have the capacity to meet the workload ahead, we have made big progress but we have a lot more to do because of the speed of product development ahead. To give you a sense of the progress that has been made in capacity terms, I described three shocks earlier: Brexit, Covid and budget cuts. At its lowest point in size, the agency had about 1,075 people. It now has about 1,600 people full-time equivalent. That is a very large part of how we have been able to hit all the performance targets in the way we have.

However, if we look at the number of products that are going to come forward to us, particularly driven by AI—whether that is AI as a medical device or AI speeding up drug development—the pipeline is growing. We want it to grow because that is more opportunities for patients and for inward investment in R&D in this country. We want to be able to absorb that pipeline.

I know that the committee knows this, but it is impossible to overstate how fierce the competition is for where that R&D investment goes. Many countries—allied countries and non-allied

countries of the UK—are competing fiercely to bring inward investment to their country, which is a crucial part of our life sciences strategy. We cannot have a situation where companies choose not to bring their R&D to this country because they say the regulatory process is too slow. That is very much on our minds.

To be able to meet that demand, we need to continue to grow in size and in depth of expertise in key product therapeutic areas and technological areas, and also to invest in technology. I know we will come on to this as we go through the meeting, but just like every other organisation and every other process, we are all thinking about how AI can speed up our regulatory processes while maintaining or improving rigour.

The Chair: I know that Lord Ranger probably has further questions, but can you give us a very broad breakdown of the expertise of the 1,600 or so people? Are they medics or pharmacists? What kind of expertise do they divide into broadly?

Lawrence Tallon: If it is okay with the committee, the analogy I use is from my former place of work—which I can see out of the window there, St Thomas' Hospital—where the core fee income earning part of the organisation would be the medical consultant body, but there is an enormous number of ancillary services such as IT, finance, HR, et cetera. The core of our assessment body are medics, scientists and pharmaceutical assessors. They are the people who assess products.

The Chair: How big is that core?

Lawrence Tallon: I would need to get the specific breakdown of the numbers for you. I can write to you. I do not want to give numbers and for them to be incorrect, but the largest part of the organisation is our assessment body. We also have another group of people, pharmacovigilance experts, who are doing the post-market safety and surveillance. They are looking for safety signals in medicines in use or medical devices. Then, of course, we have all the other ancillary services you need, such as finance and HR. IT is a big part of what we do as well, because there is so much technology involved in what we do.

The Chair: Thank you. Lord Ranger, do you want to continue?

Lord Ranger of Northwood: Yes, thank you. Mr Tallon, thank you for your very clear answer to my first question. Following on from that, you highlighted the point about the global marketplace that you are operating in. To what extent are you looking to align your regulatory approach and requirements with, say, the FDA in the US

or the European Medicines Agency, so that innovators could apply for approval with minimum friction between different jurisdictions?

Lawrence Tallon: To a great extent. We are really clear with regulation that we operate on the principle of convergence wherever possible, divergence only with a purpose. I will explain a bit more what I mean by that. If medicines developers or medical device developers have significant divergence in the regulatory regime of different countries, they will do the obvious thing—prioritise the larger markets and deprioritise the smaller markets. In our case that means we are behind the US by some considerable way, and also behind the EU in prioritisation for R&D but also for bringing new medicines through the authorisation process.

Those are the two main blocs where we are looking for alignment, and of course you sometimes have to choose between one and the other, the European Medicines Agency and the US FDA. We also have a third pillar that we call the Access countries, which are Australia, Canada, Singapore, Switzerland and the UK. This year the UK is chair of the Access Consortium. It is about 150 million people, not as large as either of the other two blocs but very high GDP-per-capita countries. We work very hard, wherever we possibly can, to align the regulatory requirements between those three blocs, and where they are divergent, of course, we have to choose.

It is convergence wherever possible but divergence where there is a purpose. There are certain areas—particularly those of interest to this committee around AI and personalised medicine—where innovation sometimes requires a different approach, a divergent approach, in the first instance to allow new products to come to market. If you are trying to harmonise the global regulatory environment, that has a lot of advantages, but of course you can see that it can potentially hold back innovation if you have to rely on everyone. So there are areas, such as AI and personalised medicine, where we will deliberately tolerate divergence to be a faster country to bring new products to market as quickly as possible. We will then seek, through the networks and relationships we have, to standardise post hoc on whatever is the new gold standard of care.

A particularly important relationship for us is the US FDA. The United States is so overwhelmingly the largest market for medicines and medtech that all product developers will almost always seek to design for the US market because of the size of that market. The more we can align with the FDA, where we think that is the right thing to do, the more we will have earlier access to

medicines and encourage product developers to bring their R&D to the UK, knowing that the UK system is closely aligned with the US.

The week before last, I announced with my counterpart, the deputy commissioner at the FDA, that we are going to have a unique new arrangement where the MHRA has a liaison office embedded in the FDA in Washington and the FDA will have a liaison office embedded in London with the MHRA. This is a really significant development in regulatory affairs land. It means that we will get earlier access to the products that go first to the US, and also that our product developers in this country can start, grow and scale their companies and their businesses in this country, knowing that they have a swifter route to the major market of the US.

Q231 **Lord Winston:** Thanks very much indeed for coming today. It is an important stage of our inquiry and I think we are finally getting to some interesting issues. One of the issues, of course, is the usage of software technology. We are increasingly concerned about how that might be regulated. Would you be kind enough to tell us how you do that? First, how many healthcare tools have you managed to license so far? Secondly, what are the processes if the tool needs to be modified in some way afterwards?

Lawrence Tallon: This is a really significant issue for us as an agency. When I came to the agency in April last year it was clear to me that the agency was very well set up around biopharmaceuticals, but it was much less mature around its devices regulation and, specifically, its AI regulation. So we have been growing the team very significantly there. In fact, we have brought over four senior people from the US who are now leading our AI regulation programme here, because that was the leading agency before.

The way that regulation has been set up historically in our agency, and I think in other agencies, has four underlying assumptions, all of which will be changed significantly by AI. The first is that there is a very long development time because, as we discussed earlier, bringing a medicine to market takes many years, but AI is a much faster development cycle. The second is that you have a very high barrier to entry because it costs many hundreds of millions or even billions to bring medicines to market. Again, that is not true for software as a medical device. The third is that the product of a small molecule medicine is essentially a static product that does the same thing before and after it is licensed. Again, AI does not do that. The final change is that most medicines are developed around fairly high-prevalence diseases, but increasingly we are targeting

medicines or software to smaller-population diseases. AI is changing all those assumptions.

About a year ago, we set up with the Government a thing we call the National Commission into the Regulation of AI in Healthcare. That could sound like an enormously long process that takes many years to develop, but it will conclude only one year later, this September. That has brought together clinicians, academics, big tech, small tech, patients and patient advocates, ethicists and regulators to really think through how we do the regulation of medical devices.

I do not want to prejudge it entirely, but I think we will see three big changes. The first is that we need to better weigh the risk of regulatory inaction with the risk of action. It is quite easy for a regulator to say, "If we approve this product and something happens, we can see the direct risk". Increasingly, health systems need to be transformed and can be transformed by the use of technology. We need to weigh the risk of holding that technology back, because at the moment the NHS is at risk of being behind the curve in technology adoption compared with other advanced systems.

The second big change is a big shift of emphasis from pre-market authorisation to post-market surveillance. Of course, there must be a barrier before a product gets into market, a pre-market authorisation process, but software will continue to evolve in the way you describe, or adapt—drift, you could say, if you were taking a negative view—post market. We need to have multiple, iterative checkpoints. Of course, these products by their nature have chips in them. They can give you real-time data in a way that medicines cannot, so there will be a much greater emphasis on what is happening with products post market.

The third big change that we will need to see is context-specific regulation, where we look at not only the product itself but the professional using that product and whether they understand the product and its intended use; the healthcare organisation that is using it and whether it can control for drift and change; the product developer and whether it will maintain its product post market and report safety signals responsibly; and then whether the whole system is proportioned. I think those will be three big changes in how we regulate AI.

Lord Winston: I am a radiologist with a plug-and-play piece of software that I can plug into my machine, and it works very well to detect, let us say, prostate cancer. It does not work terribly well at

all for, let us say, other issues in the pelvis; it does not work at all for breast cancer. How do you regulate that?

Lawrence Tallon: The crucial part of that is the intended use. We need to be really clear with AI software what it is intended to be used for and that the product, at the point of authorisation and then subsequently, if it continues to change or drift, is performing against that intended use. The risky thing is when products are used for purposes that are not part of the intended use. You may find new intended uses because it is really good at doing something you did not originally know, and then you go back through the licensing process to expand its intended use. The key thing is being clear on the intended use at the outset, and then what we call predetermined change control plans, which are essentially the parameters that would allow for learning and improvement, but control for drift as well.

Lord Winston: I do not think that really helps me because, surely, software like this is constantly evolving. It would be perfectly reasonable. Is it actually happening where your software evolves itself?

Lawrence Tallon: Yes.

Lord Winston: How do you deal with that? Do you start regulating that again when you have fed in new AI to change the way it works slightly? How is it regulated?

Lawrence Tallon: I perhaps did not explain myself well in the previous answer. The key component of how that is regulated is what we call a predetermined change control plan, which is an internationally recognised form of regulation that says, "This piece of software is approved; it was licensed to be used for these intended purposes at this time", and the parameters of how much change is acceptable are codified at that point. You can get the benefit of what AI does, which is learn and improve, but you can also control for change that is outside the original expectation. The predetermined change control plan essentially says how much change is acceptable before you have to go back through the regulatory loop.

Lord Winston: That is helpful. Thank you. How many software products have you licensed?

Lawrence Tallon: This will perhaps come as something of a surprise to the committee. At the moment the MHRA does not have the power to regulate medical devices, including software as a medical device, in the UK. We have the power to regulate

medicines, of course, but after Brexit we inherited the former European model. The European model says that for medicines you go through the national regulator—in our case the MHRA, of course—but for devices there is a system that in Europe is called notified bodies. In the UK we call those approved bodies, but they are the same thing. These are private companies that are essentially an outsource assessment that you have to go to. As a device manufacturer, you will go to an approved body in the UK. It will do your conformity assessment and then it will report to us. The MHRA does not believe that is the optimal way of regulating medical devices, and so we are—I sense you want to come back in with a question. Do you want me to carry on?

Lord Winston: What you are saying is very interesting. Yesterday I went to see an exhibition of radiologists. They are using these devices in the NHS highly successfully. Are you telling me that they are not regulated?

Lawrence Tallon: No. If I continue the answer, they will almost certainly have a CE marking. They will have been approved by a notified body in Europe and probably will have a CE marking. That is the most likely route to be used. The majority of these products at the moment are in radiology or another form of image recognition, which is the first generation of AI in healthcare. It is predominantly, about three-quarters, radiology and other forms of image recognition, but that will change very significantly in the years to come with LLMs and LMMs.

The MHRA is seeking to have that power within the agency—just as we do for medicines—so that we can then have greater control and set the appropriate risk tolerance for the AI products that are approved to go into the UK market. At the moment that is essentially coming through the old European system.

Lord Winston: That is very interesting, but it goes beyond radiology, does it not? Let us say that as an embryologist I can now use AI to decide whether an embryo is more likely to implant in the mother's uterus. I could also use AI to suggest to me that this is much more likely to be a male than a female. I could possibly use it as well to look at its genomic sensitivities. How do you regulate that? Do you, or would you? Are there plans to?

Lawrence Tallon: Some of that will be in the MHRA and some will be in the human fertilisation regulator, I suspect.

I will slightly broaden to much more complex uses of AI than image recognition. There are many more complex things that we will be able to do with AI in the years ahead than we currently do with the

majority of the regulated products, which basically say, "Can we spot a tumour or some other image on a scan?" We are getting into a world with LLMs and LMMs, large medical models, which will have multiple complex uses, including the interface with genomics, as you say.

How we regulate it is that there is an internationally recognised classification system with a class 1, class 2a, class 2b or class 3 type of medical device. The level of scrutiny applied is proportionate to those risks. The kind of AI that you are describing would certainly be at the highest risk—the class 3 level—which would have much more scrutiny than class 1.

Lord Winston: How does that work, for example, with private practice in medicine? Clearly a lot of AI is being used with private practice. Is that regulated by the MHRA?

Lawrence Tallon: All medical devices—including software as a medical device—that are used in this country need to be regulated, whether private or public, and the MHRA regulates every product agnostic of whether it is in private or public use. If AI is being used as a medical device in this country, it will need either a UKCA mark, which is the equivalent to the European CE, or a European CE mark. The reality is that the majority at the moment have the European CE mark, but over time—as we take the power directly within the MHRA and build a system of regulation that is much more expert in AI—we will see more coming through the UK conformity assessment route.

Lord Winston: How do you police that?

Lawrence Tallon: We have a system that is multilayered. A product cannot be sold in the UK market as a medical device unless it has either a conformity assessment for the UK or a CE. If we have information or intelligence through our multilayered datasets—including the yellow card system and other forms of reporting—that a product is being sold outside that, we will intervene and inspect. We have an inspectorate, an enforcement unit that will check that those products have appropriate certification.

The Chair: Baroness Willis, do you want to continue on this line?

Baroness Willis of Summertown: Yes, very briefly. We have been very much hearing about medical technologies, but what about the day-to-day use of things such as ChatGPT by clinicians? Do you regulate those, or how can you? Do you think we might end up with a dual system where you have good regulation going on for

the new medical innovations but then you have ChatGPT being used in other ways?

Lawrence Tallon: It comes back to the crucial point about intended use. If an AI purports to have a medical use or a diagnostic use, it must be regulated as a medical device to be sold in that capacity in this country. Of course, we know that people will use some of these LLMs outside their intended purpose. In that case we would have to ensure that ChatGPT was not marketing itself and selling its product for a medically intended use in this country.

However, in the real world, we know that people will continue to test the boundaries of these things. It comes back to my earlier point in response to Lord Ranger's question. As a regulator, we have a responsibility to make sure that if there is a suite of products coming forward that can support clinicians in this country with better decision-making, we do not have undue regulatory bottlenecks that stop them doing that. If we do, they will end up doing things in an unregulated space. I feel that we should say to people, "You should not be using devices that are not intended for a medical purpose in a medical context". That is not just our responsibility. It is the responsibility of the royal colleges and the professional regulators.

We have to balance that with the responsibility not to hold up the access to proven technology for clinicians, so that they can do their job better, make better diagnoses and respond better to their patients' needs. We have to get the right balance between having the appropriate checks and balances, to make sure that people are not using products inappropriately or outside their intended use, and not being so slow that we essentially force people outside the legitimate regulated processes.

Baroness Willis of Summertown: Can you envisage a situation where for many universities—including my own, Oxford, where we have our own version of ChatGPT—it is effectively protected and is not then used to train other models outside the system? Do you think that would be within your regulatory environment or within the MHRA?

Lawrence Tallon: You certainly can have those sorts of LLMs used in that way. Of course, these product developers are selling their products to companies, corporations, universities and others, and they have to provide that protected space. Often the core LLM would have been trained on much larger datasets. The instance that you have in your university is protected from externals, so

that your data does not go and train the model but the model has been trained on large datasets. If you cannot do that as a product developer, you are not going to sell your product to any organisation because their data will leak.

In our instance, it also comes back to the question: is that for a medically intended purpose? If it is not for a medically intended purpose, it does not need to be regulated as a medical device. There are many things we do in healthcare that are not medically intended devices. For example, a summarisation of a clinic consultation, where the clinician then checks the letter and signs out the letter, is essentially just speeding up a process that used to be done by—

Baroness Willis of Summertown: It is an administration cost, yes.

Lawrence Tallon: It is administration, so we would not necessarily need that to be a medical device. In the example that Lord Winston gave, that clearly would be a very complex, sophisticated medical device with high potential, but also high risk.

Lord Winston: Can I come back for just a second, because it is a really intriguing issue? A large number of clinics around Britain are privately run. In fact, the majority of this particular technology is used in the private practice, and it is often used privately in the NHS as well, so it is rather complicated. A number of clinics are now taking on an American custom of taking one or more cells from a human embryo that is invisible to the naked eye, running a genomic study and then saying, "This embryo will have certain attributes". The implication is that you might have a cleverer child, for example, among other things. This is actually happening. It is not just going on in theory, and it is being effectively advertised, even if it is not advertised strictly legally. How do we deal with that? It will increasingly be a problem as more private medicine fills in where the NHS does not or cannot cope.

Lawrence Tallon: This is a really complex question and one that I think I would need to jointly answer with the human fertilisation body, because the ethics of what is allowed in human fertilisation are, of course, not the responsibility of the MHRA. It is a good question and one that I will take away and talk to it about. How do we make sure that the ethical framework, around what is and is not acceptable within human fertilisation, is being delivered through technology? At the moment I do not have a clear position to describe to you on that without having discussed it with the human fertilisation body, whose responsibility it is.

Lord Winston: Would you care to write to us about that?

Lawrence Tallon: I will need to jointly write to you with the human fertilisation body because that domain of regulation is its domain, not mine.

Lord Willis of Knaresborough: Can I ask you a brief question? When you were answering Lord Winston about regulation, you talked about regulation in the EU as a basis. Given that most stuff is coming from the US, why do we not accept the US regulation?

Lawrence Tallon: We are going to do that, and there is a statutory instrument that will do that being laid before Parliament. I beg your pardon—it is in consultation with the World Trade Organization and, subject to that consultation, it will be laid before Parliament.

Lord Willis of Knaresborough: Would you be happy with that?

Lawrence Tallon: Yes, absolutely. If we look at where AI products have been developed, overwhelmingly by far the largest number is in the US. If we want to make sure that our population have access to the latest technology, the best way to do that is to allow a transatlantic bridge from the US to the UK. Of course, we will apply our own checks but will have what we call recognition and reliance, which is a fast pass from a US-approved product into the UK.

We will do what I described earlier with regulatory reciprocity between the US FDA and the UK with embedded liaison offices, so that we can make sure that is all flowing appropriately in the best interests of the UK as well as the US, definitely the flow of products from the US to the UK but also, crucially, from the UK to the US. I know that you will have heard from many innovators in the UK that as soon as their company reaches a certain stage, their investors will tell them they have to go to the US.

The crucial part of the reciprocal relationship between the FDA and the UK, which is part of the recent UK-US economic prosperity deal, is that it means we will be able to say to innovators in this country, increasingly over time, that products developed here will have a much faster route to accessing the US. That will allow companies to grow in this country and be able to access the US market without having to decamp from the UK to the US.

Q232 **The Chair:** As you know, our inquiry has had a significant focus on the exciting developments in personalised medicine, where treatments might be developed that are unique to a person's individual condition, such as cell and gene therapies. You spoke

earlier about personalised medicine. Obviously, it poses a challenge to traditional regulation based on large-scale, traditional, randomised controlled trials across big populations. How is the MHRA approaching regulating personalised medicines, which might vary significantly in efficacy from person to person? What exceptions are you able to make, particularly for the sort of one-off curative therapies or proposed treatments for rare diseases where there may be no alternative? Can you comment on that?

Lawrence Tallon: I can. This is an area where, as a country, we have a particularly important advantage because of our very strong science in cell and gene therapies and the datasets that we described earlier, including our genomic datasets. The MHRA recently published a new rare disease regulatory framework, which is currently out for consultation and, subject to that consultation, will be finalised in the autumn. I will make sure we share that with the committee after this session.

It is fair to say that this has been received—particularly by the rare disease community—as one of the biggest steps forward in the regulation of rare diseases for a long time. As we see it, the key problem is that there is a very large unmet need, particularly around rare diseases. Something like 300 million people around the world and 3.5 million people in this country have one or more rare diseases. Fewer than 5% of those rare diseases have an established, effective treatment because it has not been seen as commercially viable to do that. Part of the reason it has not been seen as commercially viable is because of the regulatory and reimbursement pathways.

As you say, Lord Mair, the regulatory pathway has been built largely for higher-prevalence diseases with the classic phase 1, phase 2, phase 3 trials and then into marketing authorisation. That works well if you have a large population to work on, but where you have very small populations, sometimes individual populations, clearly that does not work. Almost by definition in those cases—or many of those cases—these are often very severe genetic diseases that present in childhood, things such as Duchenne and spinal muscular atrophy where, sadly, quite often a patient will not make it to their teenage years, let alone adulthood. So the benefit-risk calculation has to be quite significantly different from what it would be in the case of a prophylactic vaccine against a minor respiratory virus.

We hear from the rare disease community, who we have been working with extensively over the last year and more, that where there is a compelling case that a medicine or a therapy could be

effective—and where, frankly, you have a child who is probably going to die—we need to be much more proportionate about the benefit and the risk. That is not to say that we will bring forward therapies that we know are unsafe or anything like that, but where there is a reasonable hypothesis of efficacy, we can collapse down that phase 1, 2, 3 and marketing authorisation into a much shorter process.

We have brought in the idea within the rare disease framework of an investigational marketing authorisation, which says that where there is a very high unmet need and a very severe disease—and when we are talking about rare diseases we are talking about fewer than one in 50,000, so genuinely very rare, sometimes individual—and where we have a technology or a therapy that can be tailored to the individual, with a reasonable or compelling chance of success, and where that benefit-risk is understood by the treating clinician and the patient, or quite often the patient's parents in these cases, we will have a much faster route to approval.

We have started to do some of these things already. There was a protocol, a world first, about a treatment, an antisense oligonucleotide synthetic DNA that allowed for children at Great Ormond Street to be treated under what we call a platform approval, where the core treatment was approved but the individual tailoring to the 10 different children was different. This uses a thing that we call either platform approvals or prior knowledge, when we know that the core of a treatment is safe and effective but the individual component is tailored to the patient.

A little like the answer I gave earlier on predetermined change control plans, when you talk about a platform technology, you need to agree with the trial sponsor how wide a variation is permissible before you start to create a whole new treatment. You do not need to go right back to the start for every individualised treatment. We think that holds significant potential for the UK to be a real standout country for the treatment of rare genetic disease.

The Chair: You mentioned risk. Last October the MHRA commissioned Sir David Spiegelhalter, who wrote a very interesting and significant paper highlighting exactly what you have been saying. When you have highly individual rare diseases, examples where the potential benefits and the potential harms are essentially a risk-based decision process, what you have just been saying is that you take account of that.

Lawrence Tallon: Absolutely. It is two ends of the spectrum. If we take a large population vaccination against a respiratory virus,

where the counterfactual for a young person is that they will get a runny nose for a week and then get better, of course we are going to apply an incredibly high barrier for safety to use that vaccine in that young person. There might be a slightly different one for an older person with underlying conditions. If we take the same young person who has a severe genetic disease such as Duchenne, who may not be able to walk by the time they are five and may not be alive to make it to adulthood, and we have a way of treating that disease, we will of course apply very different benefit-risk calculations in scientific terms, the methodology, but also in choice terms.

Very often we hear from parents of children with rare diseases that they know from the treating clinician there is a possible treatment but the barrier of regulation and reimbursement is preventing them having that treatment. I talk a lot, and I have talked after my conversations with Professor Sir David Spiegelhalter, about the regulator not being paternalistic but framing the reasonable parameters of choice, which is of course to say—and Sir David would say the same thing—that the job of the regulator is to take out of the equation something that is an unacceptable choice, because it is either unsafe or ineffective. At the other end of the equation, when we have something that has proven to be effective, that is the standard of care. In between those two poles there is what Sir David describes as the preference zone, where a patient or a patient's parent should be given a reasonable span of choice where the benefit-risk calculation is acceptable to the likely outcome of their disease.

The Chair: Thank you. My last question is about the draft guidelines for cancer vaccines, which you have been consulting on in the last year. When do you expect those to be finalised?

Lawrence Tallon: Certainly by the end of this calendar year, ideally in the autumn. This is an example of where we are increasingly able to tailor treatments to the individual. We seem to be further ahead on that process in cancer—not just in this country but in general—than we are with rare disease, but we are applying some of the methodology for the personalisation of cancer therapies to the application of rare disease.

Q233 **Baroness Willis of Summertown:** This builds on what we have been talking about. Moving away from rare diseases and cancers, more generally we have heard concerns throughout the inquiry that the UK's approach to clinical trials is too slow and is falling behind international competitors. This was raised by the O'Shaughnessy review, and recent reforms to guidelines have been put in place to

help address this. Could you explain what the MHRA is doing for the NHS to become the competitive test bed for clinical trials?

Lawrence Tallon: This is incredibly important to us as a regulator, as a country and for patients up and down the country. There is fair criticism that the number of patients we have in clinical trials in this country is too low compared with the number we could have. We must improve that number. If you ask me for the best way we could improve the health outcomes of the population in this country—in medical terms, obviously; there are many other things outside medicine—and increase inward investment to help grow the economy, without spending taxpayer money, I often say to people it would be by significantly driving up the number of people we have in clinical trials in this country.

If we go back a few years to when Lord O'Shaughnessy did his review, unquestionably regulation at that point was one of the problems, probably the biggest problem. I am happy to say that that has moved on very significantly now. We have brought down our clinical trial approval timelines significantly, working closely with the Health Research Authority, a separate body that does the ethics. Our turnaround time went down from 91 days to 41 days now, and we continue to drive that down.

If you permit me, I will read a quote from James O'Shaughnessy that he put in our annual report, which I will circulate to you: "The progress made since I published my review in 2023 has been remarkable. The MHRA is now delivering consistently good approval times while introducing further reforms that are adding speed and flexibility to the process. The MHRA is once again taking a global lead, which is helping to attract more clinical trials to the UK". I will not do that again, I promise, but I thought it was worth sharing that.

Baroness Willis of Summertown: It is useful to have that.

Lawrence Tallon: Regulation definitely was a problem. We have really brought that down. However, I am ambitious that we go much further still, because this is such a competitive environment globally. We have announced a package of reforms that came in from April just gone. One is that we will guarantee a first appraisal of a phase 1 clinical trial within 14 days, which is seen as highly competitive against pretty much all the world, although China is a different case.

The second thing we are going to introduce is what we call a notifiable route. This applies to about a fifth of the clinical trials we assess, where it is a minor change or variation and low risk. We are

saying we will not require those to wait for a central approval. Sponsors will be able to tell us what they are doing, and if we have not said anything within 14 days, they can go ahead. That is similar to the way the Australian model works at the moment. The Australian model, as you probably know, has come in for a lot of attention because many people are taking their phase 1 clinical trials to Australia.

The third big change we are making at the MHRA is greater acceptance of multiple data sources. Crucially, this includes what we call real-world data. Essentially, instead of having to have the data within the confines of a clinical trial, you can use real-world data, which is particularly helpful for rare disease where there are fewer patients to compare. We will also include in silico data—computational modelling—and data derived from other regulatory jurisdictions that we recognise. It will become easier for trial sponsors to use those multiple data sources in their clinical trial approaches. We have already seen an increase in clinical trials last year—I am going to say 5%, but I will check my notes on that. Everything we are hearing is that the change in turnaround we have seen in clinical trials performance on the regulatory side means that figure is likely to go up.

There are still significant problems with clinical trial uptake across the country. These issues have moved from the earlier phase, which was around regulation, to the uptake within the NHS. That is the bit we really need to focus on. The Government have done a sensible thing in bringing in an end-to-end target. Rather than measuring research, ethics and uptake separately, there is an end-to-end target of 150 days from clinical trial application to first patient. We are now delivering that as a country in about 122 days on average, but we still need to keep driving that down. We also need to focus not only on first patient but on last patient—that is, trials closed.

This is less about the MHRA and more about what the Government are doing overall, though it all goes to the same story. Better use of single national contracting is crucial. We have a single-payer system in the NHS, but a clinical trial sponsor has to go to each individual site separately and agree a contract. That is not making use of the opportunity we have for single national contracting. Advertising clinical trials through the NHS app is another important step. Because we had such growth in use of the NHS app around Covid, we now have an opportunity to reach patients directly. There also needs to be broad accountability for clinical trials uptake. From having sat on NHS trust boards, I know that the focus of discussion—particularly because of the way our health

system works in a quite top-down way—is on other important things, such as waiting time targets. Those are clearly very important, but we need to focus much more attention on R&D, because that is how we can improve outcomes.

Crucially, the financial flows in research have become too complex and too muddled, as I am sure you will know from university conversations. If you are running a clinical department in a hospital trust, you want to know that when you recruit patients and encourage your clinical team to drive up patient recruitment, there is a financial reward for doing that and similarly a financial penalty if you do not. That has all become too opaque, and we need to better align incentives with trial uptake.

Baroness Willis of Summertown: Thank you. I think you have answered a lot of the second part of my question, but I have one more question related to speeding up the process. We have the director of UKRI coming in a couple of weeks. To be able to set up these clinical trials, the research funding itself—from the point that an academic or a medic puts in a grant application through to when the money is awarded—can take up to a year. That is presumably not within your remit, but presumably it is a really important part of speeding up the process. Are there things the MHRA can do to speed up that part of the process?

Lawrence Tallon: I will answer your question. May I first correct the record? I said that clinical trial volumes have gone up by 5%, and I have just checked my notes. I should have said that the percentage of clinical trial applications increased by 11.5% last year, not 5%. That is quite a significant error that I am happy to correct.

Baroness Willis of Summertown: That is very nice to hear and very positive news.

Lawrence Tallon: On the allocation of research funding, I do not immediately see the MHRA's role in research funding, but your crucial point is that the end-to-end process needs to operate as an end-to-end—

Baroness Willis of Summertown: The point is not the funding; it is the process of speeding it up.

Lawrence Tallon: The whole process from end to end is too long and too disjointed. If, as a country, we do not become really ambitious about how quickly we are going to fix this, we will see other countries moving ahead of us. That is our target and our opportunity.

Baroness Willis of Summertown: Where my thought process was coming from is that at the beginning of this session you talked about highlighting where there are gaps between toxicology and so on. Is there a way that that process can feed into the research funding calls and be speeded up that way?

Lawrence Tallon: Yes, certainly. Looking at the way in which AI will impact drug development—which we are still learning about because it is so new, but it is happening very quickly—the opportunity of the data I described earlier in response to Lord Willis's question is that you can use AI to speed up drug development only if you have the data. Looking at drug development at the moment, some 90% to 95% of candidate molecules fail to make it all the way through to a successful end. There is a huge amount of waste and leakage through the drug development process. Partly that is because the preclinical work that we look at in the MHRA is highly unreliable. Preclinical work done in animals is not a very reliable indicator of eventual success in humans. That means that in our clinical trials process we are likely discarding a lot of molecules that could actually be successful medicines, because of inaccurate preclinical work.

Baroness Willis of Summertown: I will stop you there because I want to hand over to Lord Stern, who needs to go soon. I think he is asking the same sort of question.

Q234 **Lord Stern of Brentford:** My question is about the way in which AI affects the nature of clinical trials. We have a standardised picture of a drug and the RCT and so on. There are three things. The first is what you have just referred to: you may be overwhelmed because AI can produce drug after drug very quickly so there is the volume of stuff coming your way as a result of AI. The second is that AI can look very quickly beyond the RCT and bring all sorts of other relevant information to bear, which you would hope has some role to play in decision-making, although of course it is not the gold standard of the RCT. It is a question of how you combine the broad search that AI can do with RCT data. The third is AI itself as a device, which you have elaborated on, and Lord Winston gave a number of examples. Those are three ways in which AI will test out the standard RCT model as the simple gold standard that dominates everything else. Can you comment on that?

Lawrence Tallon: Yes, I can. I have discussed AI as a medical device so I will focus on the other two, although I am more than happy to come back to that. I will definitely recommend that we share with the committee clerk the outputs of the work we have

done so far with AI as a medical device, the research and evaluation, and also the final report in September, which I am sure you will find very interesting.

On AI in drug development—I was just starting on this theme—we know that 90% to 95% of drugs fail to make it through the process. There is a huge amount of waste and leakage in that process, often because the early preclinical work in animals is an inaccurate predictor for humans. That is where we believe, and certainly industry believes, there is huge opportunity to use AI to better predict efficacy and also the side-effects of molecules. We have recently announced a regulatory sandbox called AI for ADMET, which is essentially using our data to help drug developers make better predictions of the efficacy of those molecules at an early stage. This is at a very early stage of evolution, but there is an opportunity to have more medicines coming through and to eliminate vast amounts of waste, either successful molecules being discarded on the basis of inaccurate animal studies or molecules that have side-effects being spotted much earlier and not making it so far through the process. Of course, one of the reasons that medicines cost so much to produce is because of all the inaccuracy that comes from animal models, and we as a regulator, and the industry at large, think that AI has a huge opportunity—

Lord Stern of Brentford: AI could cut either way for the number of drugs coming your way. There are two forces there.

Lawrence Tallon: It could. It would be a good problem to have if loads of effective medicines were coming through. As well as AI being used to develop medicines, we can also use AI to interpret large files. We have a programme called ARISE—AI for regulatory insight on safety and effectiveness; academics love their acronyms—which is using AI to initially interpret clinical trial applications. As you can imagine, clinical trial applications are very large files of information in highly structured formats where we can define the structure. This is amenable to agentic AI to help package that file up for our scientific assessors to read and assess. To be very clear, we are definitely not at the stage where AI will make a decision—the human scientific assessor will make the decision.

At the moment, the process of scientific assessment is quite laborious and administrative, involving pulling relevant precedents from other places and case law. That can all be supported by agentic AI. First estimates from beta testing of that product show that we can save about 30% of a scientific assessor's time and therefore increase the output. Once we are confident in the reliability of that product, we also want to make it available to

developers externally. Rather than having a clinical trial application submitted to us, we do a load of analysis and send back a list of gaps and problems, we should be able to make that available to developers so that they can see what the scientific assessor will see before they submit it to us. That helps them address gaps that the AI has identified, which is better for them and better for us because it means less rework with the trial sponsor.

I emphasise that, for the foreseeable future, it will always be a human making the final decision. But AI can speed up our assessment and speed up product development.

The Chair: You have answered many of our questions. We have only one final question for you, which Lord Duncan is going to ask.

Q235 **Lord Duncan of Springbank:** In truth, you have answered the question. Mine is a summary question to try to get you to focus on what recommendations you would have us make to government. You have already touched on a number of these, but if you want to refocus or re-emphasise them, they will form part of our thinking when we come to our engagement with the Minister.

Lawrence Tallon: Thank you, Lord Duncan. There are three things, and I am going to focus mainly on one because I have already touched on two of them. Since I have been in this role for a year and a quarter or so, I feel that all the Government Ministers I have dealt with have been incredibly supportive and receptive to what we are trying to do at the MHRA. I feel we have had the support we need along the way.

The three things I will mention are things I have discussed with Government and feel we have support on, but I do not want us to take our eye off the ball. The first is the one I mentioned earlier, particularly in response to the questions about software as a medical device: we need to have the ability as a regulator to approve medical devices and software as a medical device that go on to the UK market. That allows us to define the risk appetite, the architecture and the requirements for software as a medical device ourselves, rather than only being able to go through approved bodies or notified bodies. I know the Government plan to legislate on that, and we are very keen to support that.

The second is that, as everywhere else, we need to invest in technology. There is so much we can do to respond to the technology opportunity and challenge by having top-rate technology ourselves. At the moment, we do not have the technology stack that we need. We have a terrific new appointment—the former chief information officer at the US CDC—

who has joined us in the equivalent role. We have great leadership, but we are going to need to invest in the technology the agency needs to meet the challenge ahead. That is no surprise.

The third, which I have not yet touched on, is very significant. Running through a number of the questions today is a theme about whether we as a regulator have sufficient capacity and expertise to do the job we are going to need to do in the future, recognising that the job is growing and changing in the level of expertise needed in personalised medicine and in AI. My answer is that there is no reason why we should not be able to do it, because the majority of our funding is not taxpayer funding. We provide regulatory services—sometimes ones that are welcome, sometimes less so—and industry has to pay for the regulatory services we provide, which is very similar to all our peer regulators around the world. We know that the prices for our regulatory services are very low compared with our peers in, for example, the FDA, the EMA and other countries.

We do not want our prices to inhibit industry from wanting to bring its services to the UK, but in the main that is not the case. We do an annual or biennial inflationary uplift and are about to go through that process again, which is another parliamentary statutory instrument. However, for a small number of our services—such as scientific advice and marketing authorisation—we know from industry that what it really wants is speed and predictability. The price is not really an issue, because these prices are in the tens of thousands of pounds; if you can take a month off someone's drug development process, you have just saved them millions of pounds. What they want from us is speed and predictability; within reasonable parameters, they are not bothered about the price.

We propose to increase our fee structure for a small number of our high-value services in exchange for guaranteed performance standards, so that industry pays more only if it knows it will get the performance we have promised. If we do not hit that performance, we will rebate the increase. If that can take months out of a drug development process and save millions of pounds, the incidental couple of tens of thousands is neither here nor there. We have done lots of work with industry to check that its understanding of this is correct. We have benchmarked our fees against peers and will be bringing that forward, working with a trusted advisory group of industry.

I think that is the way in which we can grow our capacity in relation to demand and make sure we can invest in the right level of expertise in areas such as AI and personalised medicines.

The Chair: Mr Tallon, you have been splendid in answering so many questions for so long. Thank you very much. It has been very informative. We will now close the session. Thank you very much.