HOUSE OF LORDS

Industry and Regulators Committee

Corrected oral evidence: Regulators and growth

Tuesday 6 January 2026

10.05 am

Watch the meeting

Members present: Baroness Taylor of Bolton (The Chair); Lord Best; Viscount Chandos; Baroness Drake; Lord Gilbert of Panteg; Baroness Harding of Winscombe; Baroness Nichols of Selby; Lord Teverson; Viscount Thurso; Viscount Trenchard; Lord Udny-Lister; Baroness Valentine.

Evidence Session No. 6 Heard in Public Questions 68 - 80

Witnesses

I: Dr Scott Steedman CBE, Director-General, British Standards Institution; Georgina Fleet, Chief Compliance Officer, Zurich UK; Caroline Allen, Senior Vice-President for Regulatory Affairs, Smith and Nephew.

Examination of witnesses

Dr Scott Steedman, Georgina Fleet and Caroline Allen.

Q68 **The Chair:** Good morning. This is a public evidence session of the Industry and Regulators Committee of the House of Lords. We are looking at the relationship between regulators and the Government's growth agenda. Our witnesses this morning are Dr Scott Steedman, who is director-general of standards at the British Standards Institution; Georgina Fleet, who is chief compliance officer at Zurich UK; and Caroline Allen, who is senior vice-president for regulatory affairs at Smith and Nephew.

Before we start asking specific questions, it would be helpful if you could give a brief introduction of your business and the key regulators you deal with on an ongoing basis.

Georgina Fleet: Thank you very much, Chair, for the invitation to come here today. It is a pleasure to be here and to be involved in this topic, which is of close interest to Zurich in the UK and globally. I am representing Zurich Insurance and, as the name suggests, we are headquartered in Switzerland. We are a major Swiss multiline insurer offering property, casualty, life and related insurance products and services. Founded in 1872, we operate in over 180 countries and territories, serving millions of customers. We employ tens of thousands of employees globally and are publicly traded on the Swiss stock exchange.

In the UK, we have a well-established business, with operations headquartered in London and elsewhere across the UK, including Birmingham, Farnborough, Glasgow, Swindon and Whiteley. We employ approximately 4,500 to 5,000 people in the UK, and we provide a broad suite of insurance products, including general insurance, life and protection, pensions and savings, and public sector and charity insurance solutions. As a foreign-headquartered but operationally significant UK insurer, we primarily engage with the PRA—the Prudential Regulatory Authority—and the FCA, the Financial Conduct Authority. There are other regulators, but those are the most significant to us. I will stop there and pass on to my colleagues.

Caroline Allen: My name is Caroline Allen, and I work for Smith and Nephew, a portfolio medical technology company which was founded in Hull in 1856. We serve over 100 countries—we are a global company serving those countries. We have three global business units: orthopaedics and robotics; sports medicine and ear, nose and throat; and advanced wound management, which is headquartered in Hull in the UK. We serve over 14 million patients each year with our products.

As a medtech company, all our products are regulated. The over-100 markets that we serve are all regulated individually, and we take a choice when we enter those markets based on the specific regulation within those particular fields. In the UK, we work very closely with the Medicines and Healthcare products Regulatory Agency (MHRA), which is the

regulator, and with the National Institute for Health and Care Excellence (NICE). We have a transparent and open relationship with both those parties and welcome the continuation of that going forward.

Dr Scott Steedman: Good morning, Chair. I am Dr Scott Steedman, Director-General at the British Standards Institution—the BSI—where I have primary responsibility for the national standards body. In contrast to the other two witnesses, I suggest that the BSI is part of the regulatory landscape. Our role is really to support the work of regulators, industry, government and consumers, all in the public interest. We have a significant commercial operation as a royal charter organisation, which we manage ourselves and which is active in areas of industry, business certification and regulatory approvals.

In many ways, industry would see us as part of the regulatory structure; we would see ourselves as part of the interface that is helping to support the industry to deliver its products and services. We are a notified body in the European system and an approved body in the United Kingdom, and our certification teams are accredited by the United Kingdom Accreditation Service, UKAS. We are very intermingled with the regulators.

From a standards perspective, which is what I would like to talk most about today, we work very closely with a wide range of regulators, including the MHRA, of course; the Office for Product Safety and Standards, which is part of the Department for Business and Trade; the Building Safety Regulator; as well as the FCA, the Competition and Markets Authority and others. We are very involved and active in trying to support the work of regulators and to act to deliver their ambitions, as well as in trying to support industry to deliver the products and services in as innovative and cost-effective a way as possible.

Q69 **The Chair:** Thank you. Scott, you are in a very different position from our other witnesses. You have talked a bit about the regulators and mentioned transparency in how you operate. If you could sum it up in just a few words, when you think of regulators and your relationship with them, what are the first few words that come to mind—good, bad, indifferent or too involved?

Georgina Fleet: I would say that it is relatively good. We have a healthy respect for each other, and we believe that the regulators have the best interests at heart. I could go on, but I will let my colleagues speak.

Caroline Allen: I have similar comments. We also feel that good regulation protects patients and creates a level of consistency and trust within the market, by producing consistent products in the market. I think that the relationship with the regulators helps support that—certainly for us—on a global basis.

Dr Scott Steedman: I would suggest, particularly from the national and international standards perspective, that we have a very good relationship with regulators, but they may not all have a good

understanding of how standards are used by industry and how to use standards most effectively to support their work. I think that there is a lot of opportunity to develop and improve the understanding of the market governance system as a whole, rather than just thinking of standards and regulations as alternates.

The Chair: Thank you. I think we will want to pursue some of those points. Baroness Harding?

Q70 **Baroness Harding of Winscombe:** Thank you, Chair. I want to explore in a bit more detail what you see as the impact of regulation on your two businesses and how the British Standards Institution interfaces with those regulators. Georgina and Caroline, could you start by setting out what burdens regulation places on your businesses and what benefits you see regulation bringing them?

Georgina Fleet: As an insurer in the financial services environment, there is a huge burden and impact. That is not necessarily a bad thing, but to give a bit of context—I am sure you will be aware of this—just to be able to provide business and undertake what we want to do in the market, we have to be authorised to do so. There is a level of burden there just to enter the market.

If you are in a position of authority, like me, you have to be authorised to do that too, and you have criminal liability if you get those things wrong. There is a level of authorisation, as a starting point, just to be able to provide your business. On a day-to-day basis, there is lots of process, frameworks and compliance.

My function deals with compliance and regulation day in, day out. There is governance, thresholds and a whole handbook of regulation we have to comply with. For the most part, the intention of that is good: it drives good standards and high quality, and it means that we have good standing, transparency and solvency. That cannot be a bad thing for consumers and policyholders, or for us in delivering high standards and taking regulation very seriously.

The other side of this is that we have a layered approach to regulation—many rules build up over time—which means that understanding what you have to comply with can be very difficult. You need advisers—you can sometimes need an army of them to get through that regulation. When new regulation is provided, it is not often done with a cost-benefit analysis, so you are left trying to implement regulation without really understanding whether there is true benefit to it and whether it will be incredibly costly to you.

An example, which I am sure you have heard of before, is the consumer duty. It is principles-based and outcomes-based regulation, its intention is fair and clear, and it wants to do good. However, because it is very high-level principles-based, we are left with an industry trying to understand how to implement that.

Each firm will have done that differently, and the FCA will try to manage to standards which become gold-plated because we all end up being judged and managed to the highest standards. We have all spent a lot of time and cost in trying to get to what good looks like, without really understanding what good looks like until you get to enforcement activity, or what bad looks like, later down the line.

There is a kind of ying and yang to this. We recognise that regulation is good; it is important and creates predictability when done well. But when there is too much complexity, it is hard to wade through it and get to a practical approach.

Caroline Allen: Good regulation is underpinning patient safety, et cetera. From a company standpoint, we welcome that; from a good regulation standpoint, this is welcomed. We work in a regulated field, and we would not want to move away from that; we are used to that environment. From a medical technology company standpoint, the burden grows when it is overly duplicative, and we work with many regulations that have to mesh together for the products that we place on the market, both from a local standpoint and then also from a global standpoint as well.

We would like to avoid any kind of duplicative efforts there. If we look at an example here with the new European regulation that was put in place a few years ago, that is now going through a revision to remove some of that duplicative burden. Also, within regulation, it is really important not to have overly broad rules. We work with various different products from a medical technology standpoint—from, say, wound care products through to pacemakers, hip replacements and even aids for daily living. The rules need to be flexible enough that they can have successful and safe product regulation, but they also need to be applicable to different devices that are placed on the market.

Baroness Harding of Winscombe: Scott, I appreciate you are in a slightly different position, but could you just double click a bit on the detail of the relationship you have with regulators, and what benefits and burden that presents to your mission?

Dr Scott Steedman: Yes. Georgina has given the perfect example, in her opening comments there, about an excellent piece of work in the principles-based regulation that she referred to, but no understanding of what good looks like. Where we work with regulators most effectively—I could give you some particular examples; connected and autonomous mobility is one—the regulators and the industry work together to say, "If this is the principles-based regulation a risk based approach, and light touch, what would good look like? Can we agree on that together?" Then those two approaches work as a system. And the dynamic of the standards environment is stakeholder-driven. All the stakeholders are involved and all in the room, including the regulator, industry, the consumers and the environmental sector—whoever needs to be in the room, we put them in the room. Our job in BSI is simply to make sure that good governance—strict governance—is followed, and that there is

neutral, independent representation of all the interests that are going to work out, exactly as Caroline said, what good looks like in this situation, so that the regulator can have confidence that that can proceed.

In this country, we have a very effective system of designated standards. We use designated standards for product safety across a large part of the market. The designated standards provide a presumption of conformity to the business that, if they use that standard, they are more likely than not to be compliant and they can claim compliance with the regulation. That does not absolve them of the responsibility of meeting the regulation, but it is a very clear indication of what good looks like. That system is very effective, working with principles-based regulation.

The toy safety regulations are an excellent example of that. They say very simply that toys shall not pose a risk of strangulation—they do not say how—and that a means of compliance is this standard. That standard is managed in a neutral, independent way under the national standards body as one of our 1,500 committees. All the stakeholders sit in that room and all are managing that "what good looks like" standard in perpetuity, as long as the market needs it. They will be changing it and responding to different technologies or different policy requirements as required in a much more agile way than the regulation itself. The combination of principles regulation really needs a standards support structure as well.

Baroness Harding of Winscombe: Very interesting. This is probably a very stupid question, but is there any distinction between a designated standard and a voluntary standard?

Dr Scott Steedman: No. "Voluntary standards" is an interesting term. Voluntary standards are standards that are defining, from a stakeholder perspective, a particular consensus on a particular issue. It could be absolutely anything from suicide awareness to a test method. It is whatever that group needs to agree. Then, in the sense that it is voluntary, it is not regulated, so there are alternative ways. If a company wants to comply with the regulation in its own way, it is entirely free to do that. But if it wishes to claim a presumption of conformity, then it can use the designated standards.

That is a system that operates throughout the European region and continues to operate, of course, in the UK, and is a very powerful mechanism. But there are other mechanisms to support that. Earned recognition is something we do not do enough of. There are examples in the UK of earned recognition where there is a regulation—for example, environmental management—and, if companies are certified to use a particular international standard, then they will achieve earned recognition. That will enable the regulator to have more confidence that they are complying with the law, and they may not be inspected so often. There are many opportunities.

Baroness Harding of Winscombe: To what extent does the regulation that Georgina and Caroline have described come from the regulators you

have mentioned or from the Government directly? I am just trying to understand.

Georgina Fleet: That is a good question, because it has to be acknowledged that both the regulators we work with obviously have pressure from the Government to behave in a certain way and devise regulation in a certain way. They have pressure from society and consumers to do a certain thing, and pressure from industry to do a certain thing. I think regulators are trying to strike a balance between the two so, even if it does not come directly from the Government, there is probably pressure to do something a certain way.

I will give a good example of the recent captive insurance regime which the Government have announced. There is a new regime which is supposed to be in force by 2027 to allow a captive insurance regime in the UK. I draw on that because it is an area which we believe would be of great investment to us and allow more flexibility in terms of how risk is managed by groups. The regulator has to define how it is going to enforce that and make sure it does so by 2027. So there is a collaboration between the two parties to get to where we want to get to, but I would not say there is one or the other which is a greater burden, because everywhere is impacted by each party.

Caroline Allen: If I speak about a global basis as well, it differs quite significantly, but in most cases the regulation is coming directly from the Government. However, different global bodies—for example, the US Food and Drug Administration—use guidance documents to support manufacturers on how to practically implement that specific point of regulation. It was a similar approach in Europe before the new EU Medical Device Regulation, and it is a balance between the two of those exactly how that is enforced.

Q71 **Lord Best:** I want to probe a bit more on the balance between the regulatory predictability and stability, and regulatory flexibility—this dilemma between the two. The regulatory predictability gives you certainty and allows people to plan ahead. Everyone knows where they stand. On the other hand, flexibility allows you to adapt to changing circumstances. Things change. You need to move on and innovate. Where does the balance lie? Where would you like to see a change in the balance?

Georgina Fleet: That is a really good question, because I completely understand that dilemma, but I do not think they are mutually exclusive. As my colleague was saying, if you have principles-based regulation, that does allow for evolution and flexibility, but it can lead to complexity and opaqueness, and that can reject investment because you do not get certainty. However, if you have good collaboration and good communication with your regulator, and you have predictability in how your regulator is going to behave, what it is going to do, how it is going to do it and you have standards which uphold that, I do not think you need to have any additional rules that go into place to enforce it. So there are ways of creating the predictability that you want to achieve

without it having to be specifically rules-based. That requires all parties to come to the table and be reasonably open and transparent.

Caroline Allen: From Smith and Nephew's perspective and a predictability standpoint, we would welcome that for well-established technologies and for products that have been on the market for a considerable period. That gives the manufacturer a specific assurance, and it also offers support from a market-access perspective.

The UK has a unique opportunity here to develop and leverage some innovative pathways for new devices that are entering the market, and to become an expert in those areas too. Again, they are not mutually exclusive; there is an opportunity to create both. Predictability, clarity and transparency are probably the most important factors for whatever framework happens.

Lord Best: Dr Steedman, how do you view it from your perspective, looking at the scene as a whole?

Dr Scott Steedman: Lord Best, it is a balance. The question is all about risk and what the opportunity is to create a system where the burden of responsibility lies in the right place. In a prescriptive system, where the Government and the regulator precisely define what is required—let us think of the speed limit, which is my favourite example—they have to police it because they will set the definition of safety.

However, in a principles-based system, the burden of responsibility remains on the manufacturer. Therefore, there is more of an opportunity for a conversation about what good looks like and how we can be agile in this situation to deliver the outcome that is in the public interest and that Government, industry and consumers want.

There is a very big conversation there about this sliding scale. What do we actually require the regulator to police? If they set it, they will have to police it—so where do we want the burden of responsibility to lie? Can we let industry have more scope to innovate and be agile? Sitting in the national standards body, our role is to work with all those parties to develop a system that is as agile and flexible as required and that meets the requirements for public safety and environmental protection.

Lord Best: You would negotiate on a case-by-case basis?

Dr Scott Steedman: Yes.

Caroline Allen: I will build on that point. From a voluntary standards perspective, this is a useful way for manufacturers to have some flexibility, where they are used as part of a conformity assessment or for specific products within the marketplace. They can be used in a good way so that regulators can have trusted confidence in certain products. It is important from a UK perspective that they maintain international relevance and that they do not diverge from any international standards. That is really important for global manufacturers.

Lord Best: That is really important.

Q72 **Baroness Valentine:** I think you have covered a lot of my question, but I suggest that you dive into one aspect of it. There is a tension between prescriptive regulation, with clear rules and guidance, and principles-based regulation, where outcomes are clearer but companies have more flexibility on how they get there. You have mainly answered this question, but how would you define the regulation you work with, and what are the benefits and challenges of each type?

Focusing a little on the rules-based regulation, can you give examples of where that is actually a good thing? What are the challenges? I think you have already talked about the latter.

Georgina Fleet: We have talked about principles-based regulation and the challenges of that. For rules-based regulation, the challenges are obvious from a theoretical perspective because you are benchmarked very clearly. In our life insurance business, the benefit of hard and fast rules is that you know that you are protecting your customers, and they have predictability over their products. For example, pensioners will know what to expect in terms of what they receive by way of documentation and what they can invest their assets in. It is clear what they can receive and what they might get at the end of that.

However, it does not allow for flexibility, so you have to issue more and more rules to get to where society might have moved to, in order to allow for the flexibility that you want to achieve. That builds layers and layers of regulation, which makes it harder, in the long run, to understand what you are trying to achieve. In some of the older industries where we are dealing with older rules, we will see prescriptive regulation, and that has not really moved with the times.

Baroness Valentine: Is your point about the need to amend the old rules, as opposed to the idea of having rules being a bad thing?

Georgina Fleet: Yes, I suppose so; it depends on what you are talking about. As we have discussed, there are some areas where you might need some fundamental rules to make sure that there is a starting point and that everyone is in the same position. However, there are other rules where you might need to be flexible because of the way that products and society develop—and having very strict rules does not allow that. Amendment is difficult because we would build on the regulation and because we do not have a consolidation of the rules happening.

Two things are going on here. First, building on rules is difficult because you have to understand them. Secondly, it would be great if our regulators would issue a consolidation from time to time to say, "These are the current standards of rules that we're dealing with", without having to hark back to things from the 1970s, for example. For principles-based regulation, there needs to be the ability to have a negotiation and discussion about what good looks like, so that we all understand, in the broad ballpark, where we are trying to get to.

Caroline Allen: I will use a specific example to help. Most regulation requires that a manufacturer should have a quality management system. There is a recognised international standard here that shows what good looks like—although I do not need to give the specific number, it is ISO 13485. That is harmonised with the European regulation, but it is also a voluntary standard used globally as a good measure of what a good quality system looks like. So principles-based regulation can work well, as long as exactly how that should be implemented is tied in with some specific guidance or rules.

Again, predictability is important for well-established technologies. It is important that we have that clarity for manufacturing, so that the rules and goalposts are not shifting significantly from one year to the next as we are placing well-established technologies on the market. There definitely has to be some room for things to evolve. The medical technology field has evolved vastly in the past 10 years. Now as we move towards the big buzzword of AI, we need to have a flexible regulation that enables manufacturers to place safe products on the market and to understand the rules of the game.

Dr Scott Steedman: I will build on that, because the example of AI in healthcare is a good one. We started working with the MHRA, as well as the FDA in America and the American standards body AAMI (the Association for the Advancement of Medical Instrumentation), to develop White Papers on how we could manage this fast-moving technology in an environment where regulations simply could not keep up—and they have not to this day. From a standards perspective, we have had to work as an industry, with the support of the MHRA, to try to create an international system that is flexible and agile enough to allow us to see these products, which bring great benefits to patients, come on to the market, while at the same time doing our level best to manage the risks that the new technology clearly brings.

There are very different structures in different countries. The idea of prescriptive regulations is very common in developing countries, in countries such as India, which is heavily regulated. This leads to an awful lot of confusion in the industry, because you end up with regulations referring to old standards, yet the industry wants to use new standards or even the new revision of the old standard. So which is used? We also see this in the US. There is heavily prescriptive regulation and that ends up inevitably referring to the industry standards that the industry is trying to use, because they cannot write them all into the regulation. We have an industry standards system. We have around 50,000 British standards that are almost all international standards—we cannot write that all into the regulation.

There is an interface here. If the regulation is too prescriptive and the standard is changing, we end up with a regulation that is contrary to industry practice.

Baroness Valentine: Can you give an example of good prescriptive regulation, because you all seem to be suggesting that it is bad?

Caroline Allen: There are some really good things about the new European regulation, which I know is world-renowned. It went from about 60 pages and several guidance documents to over 200 pages of regulation. That created consistency in the marketplace.

However, it has some negative pieces too, because it has now become overly burdensome. I talked briefly before about applying a very broad brush over the different products that we are regulating. Now, in certain circumstances, we have to go back and look at where that has become too prescriptive in certain cases—putting far too much burden with no real clear patient safety outcome at the end. The European regulation is probably a good example, now that it is applied consistently throughout Europe, which was the goal of the new regulation versus a directive. However, there is a bit of a "watch out" there.

China also is a good example of very prescriptive regulation. It is extremely difficult, and well renowned for how difficult it is, to get a product on to the market in China. It often has very specific national standards that are not at all in line with international standards and without a clear benefit—for example, they are not increasing patient safety there. China is probably a good example that is overly bureaucratic. If you look at the portfolio base in China, it is, generationally, approximately 10 to 15 years behind devices on the market from international manufacturers, which is not where we want to go from a UK perspective. It is important to have that balance: clear rules of the game but with the flexibility built in. There are a couple of examples.

Georgina Fleet: Building on that, if you are asking for good examples, it is quite hard to find them when you think about how you are currently—

Dr Scott Steedman: I have one.

Georgina Fleet: You have one. But I was thinking about the route to market—authorisation, capitalisation and what insurers have to do to get into an entrance position. That is clear. What you need to do and what capital you need to hold is relatively prescriptive. I think that that helps anyone understand what they need to do and comply with. I am not saying that it is right, but it creates clarity, and anything more opaque might be harder, because you would not know what your starting point was. I think that is a good place to be. What was your example?

Dr Scott Steedman: I think you need to look up the risk ladder. I would say nuclear safety was an example which was very successful—it was expensive and heavy duty, but it has clearly worked. It is a very successful global industry there. They quietly get on with it. There is a lot of effort there and a massive amount of detail. In my previous career, I was involved in various nuclear engineering projects. I have to say that it is a very robust system that has worked very well for a long time. I do not know enough about the detail; you may wish to pursue that separately.

Georgina Fleet: Can I check that? I guess what you are saying is: the riskier the area you are in, the more prescriptive you might need to be.

Dr Scott Steedman: Yes, and the more effective the system needs to be with industry in it.

Q73 **Baroness Drake:** We have talked a lot about the balance between rules-based and principles-based. I suspect most of my questions have already been covered, so I will take it down to the more specific and ask this question. In your respective areas where you are operating, where specifically would you like to see the regulators taking a more open approach to new products, services or forms of delivery? If you could, make it more specific, even if these increase the level of risk for consumers or the environment, and illustrate that with practical action that you would like to see from your regulator to operate in a more risk-open way. Georgina, you mentioned the PRA as an example of good prescriptive regulation, but that is systemic risk, is it not? That is very big. Could you start on that question, taking it more specifically into your area?

Georgina Fleet: We have a large general insurance business in the UK and a very large commercial insurance business, but the rules that are prescribed often do not differentiate enough between the two. A retail customer would need protection. If you are buying an insurance policy, particularly something to cover your home or your house, you need to make sure that it is clear, easy to read, and understood, and that it will pay out and the claim will be easy to manage. They do not have the benefit of advice most of the time, so they are dealing with things on their own, and it is their own pockets they are drawing from.

In the commercial insurance industry, it is completely different. We cover a large portfolio of corporate clients internationally, and they have insurance buyers in house. They will have advisers, brokers and an ability to negotiate their price and terms. This has roughly £3.9 billion, in GDP terms, of worth to us in the UK. The industry in total has 50,000 jobs in the UK, 74% of which are in London, and the overall share of that market is now at 0.3%. In recent years, that grew by 32% in London but by 59% elsewhere in the world; I think some providers have considered exiting the market because the regulation is too prescriptive and difficult.

To draw in some specifics, in the consumer duty, we have the recent advent of the fair value assessment, which looks at your products and says whether they are achieving fair value and achieving what you have designed them to do. For the most part, that is great for retail customers, because we have to maintain and hold our distributors to account to make sure that the value is what we think it should be.

Some of that is also placed on our commercial insurance policies, because you may cover a group policy which has end beneficiaries. That does not make any sense to me. It is expensive, it is costly, and it does not actually benefit those who would need it. The companies receiving those policies have the ability to negotiate them and to change the terms, so

trying to provide a value assessment every year or every three years now is a great expense for no value.

To draw on that even further, in this industry, you have MGAs—managing general agents—who act like quasi-insurers. They have specialist advisers and specialist underwriters, and they are in control of the market and the price, but the insurer is really giving them their underwriting capacity. But the MGAs themselves have to provide a fair value assessment, as does the insurer, neither of which provides necessarily value to the end customer but creates additional cost and burden on both parties. You could simplify that by removing it or allowing one of those parties to do it in a more simple way.

Regulation could more easily differentiate between the two types of customer; I know that the FCA recently issued some reforms to try to get to this point, but it does not go far enough because it only defines the commercial customer in a very narrow way which does not necessarily help the customers or us. That is the way in which regulation does not help us, is not flexible and does not drive at where the risk really lies.

Dr Scott Steedman: I might refer to three areas. One example is battery technology, where some very good work has been going on about the alignment of standards development and regulatory development for the safe manufacturing of batteries. That is a very good example of where that has all worked out very successfully.

Another is the work we have been doing with the Centre for Connected and Autonomous Vehicles on rules for testing innovative products such as connected and autonomous mobility, which are clearly high risk on the roads, and how we can do that safely and effectively to deliver safety outcomes in the UK but also international advantage globally. By pioneering that work in an approach with the regulators, the industry and the standards community—the stakeholders—engaged in that, we end up with the right balance.

An important topic that we are deeply engaged with right now is the construction product regulation and how prescriptive or principles-based you should make that, as we want to add additional requirements to define what safe construction products are. How do we do that without creating barriers to trade with our European colleagues and counterparts? There are a lot of areas of work going on there. In our work there with the Ministry of Housing, Communities and Local Government (MHCLG) and Minister Samantha Dixon, we have had very good conversations about how we can support that evolution of better regulation in a very important area.

Caroline Allen: To reiterate some of the points made before, I think it is important for well-established technologies to have that predictability level there. But from an innovation standpoint, if you ask about the risk appetite, I think MHRA in the UK have a unique opportunity there to explore some of those pathways. From a manufacturing standpoint globally, most key regulators have green pathways or fast-lane pathways

which support a flexible way to enter new products on to the market, where it is probably quite difficult to have a rigid regulatory base. To explore that would be a way to have that. It is important to say that regulation should always be science-led and not excessively burdensome in either of the pathways I have spoken about there.

Baroness Drake: Basically, are you all three arguing that the regulator needs to start with a greater differentiation in the risk it is trying to manage when deciding where it is on the continuum of principle or prescriptive, and overlay that with an assessment of the ability of the consumer to manage that risk?

Georgina Fleet: Going back to one of the points you made earlier, it is possible to make an assessment of the company providing those services or products as to whether they themselves are managing risk effectively and have got a history of good behaviour, good culture, lack of enforcement et cetera, so that could be treated with a bit more recognition or leniency; I do not know what you would call it. We have a similar recognition with HM Revenue and Customs; we have a low-risk status, so we are trusted to get on with what we want to get on with. We do not have any concerns. We have a lighter touch in how they react to us. There is every reason why other regulators could do the same thing, having understood how we operate and how we take our regulation very seriously. That would be very helpful from our perspective too.

Dr Scott Steedman: May I build on that? We have talked a lot about industry and regulators as stakeholders, but the consumer stakeholders are extremely important. In my team, the national standards body, we host the Consumer & Public Interest Network, so we have a community of people who represent the consumer independently and who are offered the opportunity—we train them and invite them to participate—to shape the standards. They will bring that voice into that discussion and ensure that the voice of the consumer, or the environmental issue, is represented in the conversation between the industry and the regulator about what that good practice might look like.

I think these are examples where there is opportunity and there are well-informed regulators. But I also suggest that there is quite a large area where regulators dive for the instinctive, heavy handle of regulation, because that is what they know and that really is what their job is. Their instinct is to write regulation, but to pause and think about the outcome that is needed in the national interest is really crucial. When you want to discuss the outcome, then you want to get everyone in the room and say, "Okay, so what is it that we actually have to regulate, and how do we do that?", instead of diving in and saying, "Well, I know—I am the regulator. I shall decide. This is what has been handed to me by the Government".

Georgina Fleet: Can I build on that, because it is a good example of how we have collaborated with the regulator? In our industry, bereavement claims are notoriously long and hard to get through; going from death to paying out an insurance policy can be a very long period of time, and we probably have all had sad experience of that. The insurance

industry has been asked to look at that and its processes and controls, and whether it can use AI to do things differently.

We recently had a call with the FCA—I hope they will not mind me explaining this—saying that it wants to try to find a way to help shorten that timeframe. Recognising that, in the chain of command from death to payouts, there are GPs, hospitals and medical issues involved, the FCA is trying to find out more from the industry and is having various calls to see what it can do to produce anything different for that outcome or to try to innovate. That is really welcome. That is a good innovation from a regulator. More of that along the same lines of what we are saying would be really welcomed, because it is a recognition that there are lots of contributors to this—it is not just one party with all the responsibility.

Q74 **Lord Teverson:** I always thought, actually, when you are dead, you are dead, but I am fascinated that it takes so long to work it out. There we are.

One of the things you will be very aware of is that the Government had an action plan in March last year; I think it had about 60 measures in it, and it was updated in October. What I am trying to understand on that is whether you were excited by that announcement and thought, "Hey, the world's going to change"? Did it? Was it a call that you genuinely welcomed, and what changes have you actually seen since then? I think the FCA and the PRA to a degree had been pushed in that direction prior to that. I am going to start with Caroline on that.

Caroline Allen: We see the action plan as an opportunity to ensure that the regulators are properly resourced and internationally aligned. That was the real takeaway piece that we felt as a result of that action plan. It is really important for the UK as a sovereign regulator to rebuild that competence and explore some of the different ways that we can have things like innovation pathways, green lanes or fast lanes. There is a lot of opportunity with that action plan, and we really welcomed that.

Dr Scott Steedman: I welcome it as well, because it is time that we put the 20th century behind us and started thinking about regulation in the United Kingdom as a system—a market governance system. We have talked a lot about standards and regulation, but we have not actually used the phrase "quality infrastructure", which is the invisible layer. We have talked briefly about conformity assessment. A series of functions have to happen for industry to succeed in delivering products and services safely into the market competitively. It is not just standards and regulation; it is how those products are policed in the market. Market surveillance, conformity assessment, accreditation, intellectual property and standards and regulation all have to work together as a system. The call to action that I read into the action plan, which I am very excited about, is that we will start having these broader conversations, making sure that everybody is well informed about the tools available to deliver a more successful and productive economy.

Georgina Fleet: It is probably quite well documented; we welcome the calls for reform and the action plan, and the aim to reduce the administrative burden. The Mansion House reforms in particular have been very welcomed but, actually, if we look at the detail, they probably do not go as far as we would like them to. The consultation papers that we responded to probably provide the evidence. In particular, we welcome reforms around the Financial Ombudsman Service, because it has been quite unpredictable and has been acting as a quasi-regulator. Having an ability to be more predictable about that is fantastic, but there is more to be done. I am hoping in future that there is more collaboration with industry to get to a point where what is released is of real benefit to industry and consumers alike—not, as you might have alluded to earlier, just a regulation that tries to do something but does not necessarily design the benefit that it is trying to get to.

Lord Teverson: Can I check with the three of you whether you have actually seen a real change of attitude since that action plan and the revision have come out? Have you noticed a cultural change within the regulators that you deal with?

Caroline Allen: From an international recognition standpoint, there is a huge intention from the MHRA to really explore that pathway. There is a unique opportunity here for the MHRA to do that. There are other regulators globally—for example, in Canada and Australia—that successfully implement international recognition. They are really open to this. Smith and Nephew has also supported, together with the MHRA and other members of industry, to help grow and shape that.

One of the challenges that we have seen around it is that there are not clear timelines exactly for when this is going to be ready. Then there are the fundamental specifics to move from this overly burdensome regulation and to actually define an international regulator. Some points were made earlier around trusted regulators—really trusting them and signing up to the fact that you will accept the work that they do. It is definitely an excellent intention from the MHRA, and we have certainly had really open and transparent dialogue with them from a Smith and Nephew perspective. But we would look forward to absolutely concrete timelines and then some specific actions around there.

Dr Scott Steedman: I am not sure I can point to a causal relationship, but you do see an increasing interest in new ways of doing things.

Lord Teverson: That sounds like damning by faint praise, to be honest.

Dr Scott Steedman: Other trends have been happening at the same time. The Organisation for Economic Cooperation and Development (OECD) has been working very hard on this for some years and produced an excellent report in September on the use of quality infrastructure regulation and standards being more effective. It also scores countries regularly, and its report last year will show where the UK stands in that.

There is an interest at that level in understanding and sharing practices between countries about how we can improve regulation and standards. Then there is also the whole question of digitalisation—digital trade, digital services and digital product passports. All of that is also driving interest in how you use the digital transformation—not just AI, but the whole concept of digital information in products and services—to improve the way that you are policing and regulating subjects. So there is a series of other pressures that is also supporting this.

Georgina Fleet: I would say, yes, we have seen change in culture, and I have used the bereavement claim call as one example of that. When the call came through, we were probably worried it was going to be some kind of, "What have you done that is wrong and what can we do to improve it?" But, in fact, it was a really welcome and refreshing change to look at the collaboration between the two parties. I was also recently at a Confederation of British Industry round table, which was all about regulators and growth. That had HM Treasury, the PRA and the FCA sitting around the table taking comments from members of the industry about what they would like to see done better. I have not seen anything come out at the end of that, but that is a welcome innovation to try to create more collaboration.

We also had a recent call on unit-linked products as a result of the thematic review. Again, we were worried that it would ask pointed questions about what we ought to do better, but, in fact, it seemed more explorative; it was trying to draw comparisons with others in the industry to see what could be done better. I would suggest that that demonstrates green shoots of collaboration and a change in approach that is less parent-child, which was where we have been, to a more—I do not know what to call it—sisterly one.

Dr Scott Steedman: Collaborative.

Georgina Fleet: Yes, it would be a collaborative approach to regulation. I hope that that continues.

Lord Teverson: That is an interesting description of the relationship. I will briefly come back to a comment you made about the nuclear industry and nuclear regulation. You said that it has been very successful; indeed, we have had no examples like Three Mile Island or Fukushima here. However, you could argue very strongly—could you not?—that the nuclear industry has become completely uncompetitive, that build times are three or four times longer than expected and that costs double because of changes in regulation. If the industry has not been quite destroyed, then it is resurrecting. Is that an argument too?

Dr Scott Steedman: Yes, I am sure that that is an argument. There is a whole political conversation there about small modular reactors (SMRs) and what the future should be—central generation versus SMRs, and so on.

I will expand on the thought about outcomes. There is a very interesting school of thought around Outcome-Based Collaborative Regulation, which is all about closing the loop between regulation, the marketplace, and redress, solution and improvement. That is also gaining traction. There are some experts working in that field too, so I think it is worth exploring.

The Chair: One of our colleagues is online. Lord Gilbert, in coming to you, I hope that the technology works.

Q75 **Lord Gilbert of Panteg:** Thank you, Chair. The action plan commits to cut administrative costs for business by 25% by the end of the Parliament. That sounds quite significant, but I wonder whether it is. How material is that ambition, in terms of the impact either on your business model or on the ability of businesses to contribute to the growth agenda? Is 25% of administrative costs that material?

Georgina Fleet: Yes, it is material; it is a great ambition. It is a tricky question, because I am not quite sure how we are measuring that—it will be different depending on who you are talking to. I am also not quite sure how you determine whether or not it has been achieved. So one of my worries is that it is defined by a regulator that is also determining the outcome. Having management information or Key Performance Indicators, or whatever it might be, to try to explain that would be very helpful.

I would prefer the main focus of attention to be on the clarity of the rules—which would have the by-product of cutting administrative costs—not on the cutting of administrative costs itself. In terms of our own burden of regulation—maybe we will come on to that—there is a high cost that we have to comply with on a regular basis. That is increasing because of the complexity of regulation and because of the way that we have been moving in recent years.

Caroline Allen: I have similar comments to that. Concrete actions are needed around that 25%. I think it is a little opaque, certainly from a medical technology standpoint, when we look at that target. However, in principle, it is a great ambition to have to reduce that burden. Again, I definitely would support a focus on the patient safety and efficacy elements rather than the administrative checkboxes.

Dr Scott Steedman: Lord Gilbert, I would welcome the ambition too. I think it is material. In terms of the impact on the national standards body, it will increase our workload because we will be required to do more work to support the regulators—as we should do—and we look forward to that.

Lord Gilbert of Panteg: I know that Lord Udny-Lister wants to unpack where the burdens and costs are, but first I would like to go back to the materiality of the 25% of administrative costs. Georgina and Caroline, I wonder whether you have done any assessment of what that means in terms of the sums that you would save in your respective businesses, to demonstrate to us that that would have some material impact on your

bottom line or your business model.

Georgina Fleet: That is a very good question, because a questionnaire was recently done by the Association of British Insurers to look at our costs of regulation. We found that it is quite hard to put a figure on it because it is so endemic throughout the organisation—from fair value assessments, which are built into business processes, to reporting and having to pay fees and fines to the regulator.

However, it is significant. Some of the figures are quite alarming. TheCityUK's report highlighted that 84% of compliance leaders have seen costs increase over the past five years, with regulatory compliance being at roughly 13% of operating costs, amounting to approximately £33.9 billion annually for the largest firms. That 13% is probably around the right number in terms of complying with regulation, but it could be higher depending on the year that you are working in and what has happened.

Personally, I would like to put a better figure on it and to be clearer about that, but that requires lots of good data, good inputs and collaboration across the industry, so it is quite hard to be definitive about it.

Caroline Allen: I can comment from an arbitrary standpoint. In general, in medtech, it is around 10% of your sales volume. That is roughly the cost of quality compliance—but of course that is global quality compliance in general. As I have said, the international piece is really important for us, as a global company, in order to be able to harmonise, where possible, to ensure that, while we have market-specific or country-specific requirements, they can be applied globally too. However, it is roughly around 10% of revenue. For Smith and Nephew, that is roughly about £600 million per year—the cost of compliance—but that is to serve global markets. We may be able to provide you with some specific information; I can write to the Chair afterwards.

Lord Gilbert of Panteg: That would be useful. I think Lord Udny-Lister probably wants to unpack some of that a little.

The Chair: I am sure he does.

Q76 **Lord Udny-Lister:** Thank you for that lead-in. We have been told—you will love this—that the administrative burden of regulation may be small compared to the cost of complying with the regulation, including the cost of demonstrating compliance with standards, the opportunity costs of senior management, the amount of time they are spending on regulation, et cetera. You started to talk about this, but how would you set out these costs and how do they affect your business? Caroline, this might be a good point for you to respond, as I do not think that that £600 million is the sort of number that the regulators had in mind when they were making their claims.

Caroline Allen: That is the total cost of compliance. That includes, in general, all the quality management systems that we need to employ, the certification that we need and the staff—there is generally a high number of staff. I am happy to come back and write to the Chair with some

specifics and give you some examples as well. Lots of research has been done. I think McKinsey does lots of research here.

In general, manufacturers are spending roughly 5% to 10% of their revenue to support the cost of compliance. The administrative burden there—what I would describe as the non-value-add elements of that—would probably be a much smaller number, if I came back to you with that. I am happy to give you some of that context.

The Chair: That is probably very difficult to do, but we would welcome any attempt at that.

Georgina Fleet: Similarly, we have done some work on this, but providing meaningful data is quite difficult when everything is peppered with compliance with regulation. My function covers around 50 people. That includes consultations, interpreting regulation, providing board reports and looking at governance assurance work. Some of that is really helpful, but some of it is just tick-box exercises. There is also the way that we provide products to markets. I could go on, as I am sure you are aware. Financial services are particularly heavily-regulated—often for good reason.

Let me see whether I can come back to you with something more meaningful that sets out some of the buckets of costs. That might give you a better flavour of where the real burden sits.

The Chair: Any comments, Dr Steedman?

Dr Scott Steedman: No, I do not think that I can add to that.

Q77 **Baroness Nichols of Selby:** I hardly dare ask this question, listening to the billions and the £600 million, but I will anyway. We have had information for people about a fast-route approach to regulators for quicker approvals, but there is obviously a cost to that. Given what you have just said, do you think that that would be useful to you as organisations in the various sectors? What do you think would be the advantages and the potential disadvantages?

Georgina Fleet: First, we have seen a change. If I look, the timeframe to certify or authorise an individual through the Senior Managers Certification Regime (SMCR) used to be 12 weeks. Our most recent figures are two to four weeks, and that is great. That is, in part, recognition that an organisation such as Zurich takes regulation very seriously and has no concerns about how we operate. But it is also because the regulator probably recognises that, in trying to authorise or assess a lot of timeframe or obstacles to get over, it is in fact kind of approving the people internally, which is not great for a regulator to be doing; we should really be having that burden and taking that responsibility ourselves. Nevertheless, we have seen that improvement, and we would like to see similar improvements happen for authorisation of firms.

When it comes to paying for fast tracking—I think that is one of the questions—it is really tricky. I can see how it might be anti-competitive if you allow those who can afford it to fast-track applications or people, leaving those who cannot afford it with a slower timeframe. I am not sure that there is an answer to that, but if it were transparent and proportionate and there were ways of doing it that were competitive and promoted competition, we would be happy to consider it. I think we would be happy to pay for that fast track if it was necessary, or to have certainty over the timeframe; I just would not want others to be disadvantaged because we could afford something and they could not.

Caroline Allen: It is probably a similar comment for Smith and Nephew. We have experience of this, and we utilise these fast lanes globally, especially if we have a very specific, important market launch going into a specific regulatory field. I think that is common. Again, it can be a disadvantage for Small and Medium-sized Enterprises (SMEs). Some of the global regulators look at different ways to set these criteria and fast lanes. With products that they want to see within their marketplace, they attribute them to a specific need within the specific market. It is not necessarily an extra fee base but having a designated team that are working and then narrow the criteria that would qualify for that. There are different ways to do it. It does not necessarily have to be, from a tech standpoint, more financial burden, but just restricting the products that you allow through that, because it is a specific product that is required for a specific market or that the UK specifically wants to see more of within the frame. That can also help.

Baroness Nichols of Selby: I am hearing that it is something you would consider, but you want the fairness and openness so that it does not impact on probably much smaller companies, et cetera. You would possibly be interested in the fast-track approach and maybe having to pay more—although when you go from 12 weeks on average to between two and four, I can see that there is obviously an improvement.

Georgina Fleet: Yes, and we are already there. It is really good. That must be a result of recent reports, which we have been discussing today.

Q78 **Viscount Trenchard:** Good morning. My question relates to regulatory sandboxes. As you know, the Government have, in recent years, extended their use. The FCA, the Food Standards Agency, Ofgem and others have used them, and the Care Quality Commission set up a sandbox to explore use of AI in screening and diagnostics. Do you participate in regulatory sandboxes, and how helpful do you think they are?

Georgina Fleet: We do not; we have not used them in the past. From our perspective, a lot of these initiatives are to benefit new entrants, such as fintechs (financial technology firms) that want to explore new markets or want reduced complexity in initial authorisations and more flexible governance, which lead to lower up-front costs. Existing insurers such as us will already have complex regulation to comply with. We have a broad suite of products. We do not see the need at the moment to go

and do that. We do not have any desire to do so, but we can completely see how useful it could be for others in the market. It might be of more interest to other industries.

Caroline Allen: Smith and Nephew are also not participating in any regulatory sandbox at the moment, but we do see a benefit there, especially in relation, for example, to medical technology and exploring how conditional approvals or something like that could happen, again to support this risk-and-burden approach. There are definitely some big advantages there. We would happily participate and would welcome participating, but we are not currently doing so.

Viscount Trenchard: You say you are not participating at present, but have you participated?

Caroline Allen: We have not.

Viscount Trenchard: You never have?

Caroline Allen: No.

Dr Scott Steedman: From a general perspective, I think it is an excellent idea. They are really important. Especially in fast-moving, high-technology areas and innovation, it is a really powerful tool. On the standards side, to complement that, we have created very fast-track processes for reaching consensus. The Flex process, which we now use quite a lot in new technology, has a four-week cycle time. A group of companies working with a regulator can sit in a sandbox and say, "Okay, let's see what good looks like. Let's try this in a bit of a sprint". They go off after four weeks and try it out, see if it works and come back. It is all quite constrained and tight. There is a huge opportunity there to try to build understanding and trust between the regulators, the new entrants, the industry, the new technology and the consumer community—try it out, see if it works—and then begin to hone the regulation as well as the standards, so you get a really optimal system. We could give you examples of that.

The Chair: Examples would be extremely useful and welcome.

Q79 **Viscount Thurso:** Good morning. Part of the Government's plan is to increase accountability, or to have greater accountability, of regulators. One of the mechanisms for this will be by having more frequently published key performance indicators (KPIs). I want to ask you what you think about that as an approach and how we should go about defining those, given that if you measure something, you can manage it and, if you do that, that tends to be the outcome you get. Setting KPIs can end up defining what you do, irrespective of whether it is the right or wrong thing. Earlier in the discussions today, you talked about the fact that people do not really know what good looks like. Are these KPIs purely on the process, which may or may not be helpful, or about the outcome, which could be very helpful? What are your views around that?

Georgina Fleet: That is a good question, because we have outcomes-based principles regulations, so it would be helpful to have KPIs that look at the outcomes too. We have given some thought to this. Perhaps for something such as shareholder investments, if there are a large number of foreign shareholders, this could show that the competition objective is being met. There is the resource breakdown between the second objective as part of the overall spending, the amount of capital released when compared with the cost of regulation, and the number of scams and fraudulent activity that have been prevented—and, where prevention led to improved trust within the industry, you could have a KPI that showed that. There is also the speed at which new applications have been approved. While the regulators asserted that they met the regulatory deadlines in 98% of applications, we should also consider whether those deadlines were appropriate and whether those deadlines are set in the right format. Generally speaking, there has not been enough evidence of regulators being publicly and transparently held to account for this. I would welcome anything that gives us something to go on, but I think they probably have to be outcomes-based to show that what has been designed has been achieved rather than that the process has been ticked.

Caroline Allen: It is possible to do some international benchmarking here. Some of the regulators publish at least target timelines, if not very predictable timelines. I think the Food and Drug Administration is probably the most famous one: it has a very strict clock. It is also about the risk appetite and how that fits in with the general regulatory framework. The most important from a medical technology standpoint is predictability and reliability, and focusing on that international recognition piece to leverage those international product regulations and to build that within the framework. It is definitely predictability and reliability for us, rather than a specific hard and fast 50 days, for example. That is what we would look to.

Dr Scott Steedman: I can give you an example of a situation we resolved a few years ago now, which is coming through now. The new Building Safety Regulator is tasked with the introduction of new regulation around competence in the built environment post Grenfell. The idea of new regulated roles for building safety was completely new. That challenge—the speed at which that could happen and the number of competent people who, we needed in the country within a certain timeframe—could easily be seen as a metric of the success of that solution, involving legislation, regulation, industry participation, standards, accreditation, ministry and department all working together. That took a long time to get off the ground because all the different parts did not talk to each other. The regulator was not actually appointed at the time but, even then, they said, "Well, I don't know what I'm going to regulate, so, until you tell me what my scope is, how can I do this?" Everybody was dancing around the problem.

Coming back to your comment, Georgina, what is the outcome? The outcome we wanted was qualified, competent individuals in these roles within X years, and we needed 1,000 of them. Right—who is involved in

all that, and what is the role of the regulator? I could easily see outcome-driven KPIs supporting the accountability ofnregulators but, for me, the crucial piece is the stakeholder involvement. Regulators cannot act in isolation.

Viscount Thurso: That was going to be my next question. To what extent should government and consumer stakeholders be involved in setting this framework?

Dr Scott Steedman: They need to be involved from the very outset. In fact, the most successful examples are where the stakeholder community is convened—almost a town hall model—right at the outset and we all say, "We recognise that there is a problem here. We want to solve it. Consumers are in the room. What's the timeframe, what's the scale and who has to do what?" The regulators are only part of the system that I tried to describe earlier. You could have a successful regulator, but you do not have a testing structure in the country to deliver the tests that the regulator is trying to police. All the bits of the jigsaw have to fit together or you will not have any accountability. Full stakeholder engagement is crucial early on.

Georgina Fleet: To build on that, it is important that industry views should inform but never determine the assessments. We are well placed to comment on clarity of rules and supervisory communications, consistency of regulation decision-making, proportionality of supervisory intensity, operational effectiveness—timelines, duplications, et cetera—and predictability of outcomes and guidance, but I do not think we should be looking at whether those objectives should be pursued. For example, we should not determine regulators' risk appetite, the stringency of consumer protection, the trade-off between competition stability or enforcement priorities versus sanctions philosophy. There are things that are firmly reserved elsewhere but it would be useful to be involved in the former. I agree that collaboration is key to this.

Viscount Thurso: There is a slightly jolly dance that goes on between the chair of a regulator and the relevant official in the sponsoring body, where the annual letter of guidance contains the KPIs that have been negotiated before and the chair makes sure that they are the ones it can meet. Breaking out of that loop is what is required, is it not?

Georgina Fleet: Yes. It goes back to the point around this 25%. If you are defining how that 25% is made up and then how you determine whether it has been met, it does not necessarily mean much to those to whom you are delivering it.

Q80 **Viscount Chandos:** I would like to pick up on something you have alluded to already. In looking at successful regulators and prescriptive terms, you talked about the nuclear industry. What can regulators learn, from both other regulators in the UK and regulators internationally? Is there something systematic that could be done to promote that—for instance, should the Regulatory Innovation Office see that as part of its brief?

Dr Scott Steedman: We work very closely with the Regulatory Innovation Office—with Lord Willetts, who is doing an excellent job—and we have a lot of conversations about the opportunity to increase collaboration between regulatory innovation and consensus stakeholder standards. We see that community as the wider stakeholder conversation that is happening outside the regulatory bubble, and we enable that to take place. There is a big opportunity there.

Fundamentally, I come back to a point that I tried to make earlier on about the depth and breadth of understanding across this complex system. The digital world is here, public concern is very genuine and international pressures are very real. It is a complex world of standards regulation, conformity assessment, intellectual property, market surveillance, accreditation, certification and a lot of language that people do not often manage to get their heads around.

There is a very important function here around making sure that the key people in the community are apprised, are aware and understand both the tools they can deploy and how to deploy them most effectively. We are not a very large country—it should not be that difficult in the United Kingdom to make sure that we can have a conversation around issues we need to address—but we do have a bit of a silo mentality. I would strongly argue that the Regulatory Innovation Office has a big opportunity to work with a range of regulators, both large and small—there are many regulators in the market—to look at ways to open up the bubble and to make sure that the regulators are exposed to other ways of doing things that may make their work more successful.

Caroline Allen: From a medtech standpoint, there are groups such as the International Medical Device Regulators Forum (IMDRF), which is a good resource to benchmark and talk from regulator to regulator to understand the different risk profiles and elements there. Although international benchmarking is there and is very important, these frameworks have been developed globally with different levels of risk appetite. It is important that the UK determines its risk appetite then uses and references that global and international information, together with forums such as the IMDRF; and, where possible, that it uses international recognition where we believe this is a trusted regulator and we have a good security within that specific regulatory environment. We should not overdevelop a UK system just to be special and on its own; it is a balance between those two things. The IMDRF is a really good forum to reference back there.

Georgina Fleet: The PRA and the FCA are very well respected internationally, but our US and European counterparts are slightly nervous about doing business here because of the costs of regulation and of capital. We have an eye on other regulators internationally; we have to assess our products and services accordingly because we are we are selling them to different markets. Learning from others would be a great initiative if it leads to improvements, and diversity of thought can never be a bad thing. I would say that most regulators seem to have the same

overarching requirements for their industry and its customers. We need to be careful not to stray too far beyond what we are doing now, because we have to conform to a certain extent to other markets—certainly Europe. If you are a global organisation, you do not want to be completely siloed apart from that.

The two I would point to would be regulators that already have a statutory international competitiveness objective. That includes Bermuda and Switzerland, which both have full Solvency II equivalents.[1] That said, they also have their own disadvantages, so I do not have a good example of something you can draw on, but any collaborative discussion will be useful.

Viscount Chandos: In a previous inquiry that the committee undertook, again looking across the board at the regulatory environment in the UK overall, a number of witnesses stressed the extent to which the UK regulatory system was admired and respected internationally. Do you agree that it is? Does that have implications for what we can learn from elsewhere?

Georgina Fleet: Yes, I agree that it is, because it creates the certainty that there is a protective regulator and you will not get charlatans entering the market. There is a certain transparency in how things will be provided, and what customers can expect is certain. But that comes with the concern that it is slow to change, react and get to the position you want to get to. A couple of years ago, our Brexit transaction Part VII Transfer—where we transferred business from one side of the company to another because of Brexit, it took a long time to achieve. Lots of questions were asked, some of them very pointed and necessary. But, essentially, the risk was not really changing for us or our customers, and to get to that high degree seemed to be very painful when it did not need to be. That leads to a bit of distrust from our counterparties in the organisation, which think, "This is going to be too much hard work. Do we really need to do it?"

Dr Scott Steedman: I certainly agree with that. That whole conversation we had earlier around principles and prescriptive regulation illustrates that we have a very progressive system of market regulation across a large body of our markets. There are tricky areas that are highly regulated—financial services, medical devices, nuclear and all those—but the vast majority of our system is very progressive and pro innovation, and that is absolutely as it is with the European region, where we have the same system, which has evolved over some decades. So, as we move into a future world—the digital economy, AI and so on—we are on the edge of that. Having this conversation is really important because we are pioneering new ways of doing things that other countries may, in the end, seek to follow.

[1] Solvency II is the European Union's prudential regulatory framework for insurance and reinsurance companies, which was also implemented in the UK before it left the EU.

As I said earlier, 95% of the work we do in the national standards body is on international standards. We hardly make any British standards any more. Why would we? The stakeholders do not want them. Being progressive in the use of international standards not only gives the UK advantage for ourselves but allows us to export a model of doing things to the rest of the world, which will enable the UK to be more competitive and successful globally.

Georgina Fleet: I agree. Looking at how our UK entity deals with problems or tries to find new ways of innovating, we tend to be much more able to do that—we are much more agile and considered in that approach. That is because we have had to be creative: there is a huge market where there is lots of diversity and change. So we have the ability to move as we want to, whereas maybe our European or American colleagues do not have the same ability. That is that is a good place to be; I completely agree.

Caroline Allen: Historically, the MHRA is certainly one of the lead regulators in Europe with an absolutely fantastic reputation globally. Again, post Brexit, it almost lost a seat at the table a little, but now it is able to regain that seat as part of this new unique opportunity. There is a huge opportunity here to gain that seat. But in general, from a UK market standpoint, there is a perception of high regulation and good regulation.

Viscount Chandos: If the position is that positive—pro innovation and hence pro growth—why have not just this Government but Governments over the last 10 years or so talked so much about the need to change the regulatory environment to promote growth?

Georgina Fleet: From my perspective, it is all the preceding things we have talked about today. We could do more and could find more agile ways of innovating. Taking the commercial insurance example again, we would love to find ways of doing more international business, encourage more employment and expand that business, but it is very difficult to do so when you have to comply with rules that do not necessarily make sense. So I am not saying the whole thing is broken; I am saying that we have been regulating for risk rather than for growth. So you end up regulating to the zero-risk denominator: "How can we protect everybody in this environment?" That leads you to a point where you have to do more to get over the hurdle, rather than say, "We are trying to grow. How do we move to this position, and how can we assess that with a risk-based approach?"

Dr Scott Steedman: I would suggest that it is because there has been a presumption that markets are driven by regulation alone. There is not a deep enough understanding of the way markets actually work, which involves a lot of other tools in the toolbox. So there is a simplistic view of the problem—"It must be the regulation, because that is what we do"—without the broader understanding. You might look at a number of other countries where they have taken a broader approach to their

understanding of how the market is governed, and that has allowed them to do things slightly differently.

Caroline Allen: From a medical technology standpoint, there are two key elements at play here: the regulatory part, which is the licence to sell that you work together with MHRA on, and a fundamental medical technology part in the UK about the paying element of it and then the work, together with NICE and other agencies, to get that product into the market. There have been some good improvements, and we would continue to promote how those two systems are fundamentally working together. That is probably from a medical technology standpoint, but, on the growth element, the two are not matching together and not necessarily fully aligned.

The Chair: Coming from such different areas, it has been interesting to see the amount of agreement in your approach and analysis of where we are. Certainly, common themes came through from what you said about risk and predictability. Your idea of regulating for risk or regulating for growth comes into this particular field significantly. Thank you for being so efficient in how you gave your evidence this morning.