



Industry and Regulators Committee

Corrected oral evidence: UK regulators

Tuesday 14 November 2023

10.30 am

Watch the meeting

Members present: Lord Hollick (The Chair); Lord Agnew of Oulton; Baroness Bowles of Berkhamsted; Lord Burns; Viscount Chandos; Lord Clement-Jones; Lord Cromwell; Lord Gilbert of Panteg; Baroness O'Grady of Upper Holloway; Lord Reay.

Evidence Session No. 3

Heard in Public

Questions 21 - 29

Witnesses

[I](#): Michael Gibbons, Senior Non-Executive Director, Bluefield Solar Income Fund; Filippo Pollara, Senior Policy Adviser, Federation of Small Businesses; Virginia Acha, Associate Vice-President, Global Regulatory Policy, MSD.

Examination of witnesses

Michael Gibbons, Filippo Pollara and Virginia Acha.

Q21 **The Chair:** Good morning. Welcome to the Industry and Regulators Committee and our inquiry into UK regulators.

I am very pleased to welcome three witnesses today. Michael Gibbons is senior independent director at Bluefield Solar Income Fund. He used to be the chair of the Carbon Capture and Storage Association and had a big involvement with the Better Regulation Commission and as chairman with the Regulatory Policy Committee. I would also like to welcome Ginny Acha, who is currently associate vice-president for global regulatory policy at Merck Sharp & Dohme and has been involved in pharmaceutical regulation for a decade or more. Finally, we have Filippo Pollara, who is senior public affairs adviser for the Federation of Small Businesses. In 2021 he contributed a report on the UK regulatory environment for small businesses. All three of you have very extensive experience of regulation, which is good, because that is the topic of our inquiry.

Can I start by asking all three of you to tell us about your interaction with regulators? What is your current view of that, at the highest level? We will go into more detail later. It would be interesting to know the particular issues that crop up in your work with regulators and that we should be taking note of. Filippo, would you like to start?

Filippo Pollara: Good morning, everyone. It is nice to be here.

Day-to-day experience of regulators varies for a small business. There is an array of regulators that they experience on a day-to-day basis. If you put yourself in the mind of a small business, such as a pub, you see that there are lots of different things coming its way, with limited bandwidth. There are things on the tax side, with HMRC, and with staff. There is the business rates bill, with the VOA. There may be things with the ICO, with data. There may be food standards provisions and Food Standards Agency certification. There is the length and breadth of different things and different requirements that a small business wants to adhere to.

The main thing to take into account is that, when dealing with regulators, small firms just want to know what they need to do in very clear terms. That is what they would like to see, customer facing, from a regulator.

Consistency across those different areas is also important. It is tricky. You have one on the tax side. You have some that might be on the consumer protection side, which we may have seen on the energy side in most recent months. Then you have more on the accreditation side. A regulator that puts itself in the mind of a small business and understands the daily burdens of what regulation is imposing on that business is one that is quite healthy for an SME environment. Different types of regulators have different requirements, but SMEs welcome consistency and clarity.

The Chair: Do I infer from what you are saying that there is a problem

with the opaqueness of regulations? They are not set out as clearly and succinctly as you would like.

Filippo Pollara: There is variation across the board. Over the years, with oversight from government, through some of the things it has done with the Better Regulation Executive and so forth, many regulators have understood the need to set out more clearly what a small business needs to do. Sometimes regulators can be quite outcomes-focused in achieving their strategic objectives. A bit of ambiguity at times might be all right for a larger firm that might have a dedicated person who is liaising with the regulator. They might have that regulatory position, whereas in a micro-business with under 10 staff there will not be someone dedicated to that, so absolute clarity is something that we welcome, and we see movement towards that a bit more frequently now.

The Chair: Ginny, let us go to the other end of the scale. You are a large employer in the UK and other countries.

Virginia Acha: Indeed.

The Chair: It would be interesting to hear about both your experience here and what you have seen and experienced elsewhere.

Virginia Acha: I am happy to talk about that. Thank you very much for taking this topic on. I do not think that many committees globally focus on regulation anywhere near enough. People tend to think of regulation as red tape: the less you hear about it, the better.

In our view, particularly for medicines regulation, it is the opposite situation. Regulation is the basis on which we establish the appropriate terms on which we can innovate. You will hear that consistency, predictability and clarity are watchwords, whether you are a very large company or a very small company. As innovators, you need to know what the expectations are and what you can predict in terms of your effort. If I do this, what will the outcome be?

Globally, the leading regulators have focused very much on that, not just within themselves but internationally. In medicines regulation in particular, there is quite a lot of international alignment. For example, we have the international conference on the harmonisation of standards, ICH, which was established primarily to do that—to create a basis for the standards that are applied by one regulator to be considered acceptable to another—because the way in which we develop medicines is not specific to any one nation or population; you have to develop globally. This is the enabling role that is critical to regulators, besides being clear and consistent for us.

The other piece that is very important to this committee is the purpose of a regulator. It is not here to make my life easy. It is here to make sure that the patient is going to get a medicine or medical device that has met the quality, safety and efficacy terms that we have established in science and clinical practice. The regulator has to balance support for the

developer in its broader remit of delivering on the basis of patient gain and for the benefit of society. The best of the regulators globally manage that balance very well, but it is a dynamic one, particularly where you have very novel technologies that are still a little untried or still to be seen. I am sure that we will come back to it in the discussion, but you had a very beautiful example of that in Covid-19, where that was paramount.

In our experience with regulation, it is very fair to say that in medicines we probably have one of the longest-standing regulatory establishments outside tax and patents. We have over 100 years' experience in medicines regulation, so it is quite mature as a regulator compared with other areas. For that reason, there may be some lessons to be learned about what works and what does not work. I am sure that we can come back to that.

The Chair: Thank you. Michael?

Michael Gibbons: It is also a pleasure for me to be here. A little more flesh on my CV might help to explain where I am coming from on a number of these questions. I was with ICI, PowerGen and Elexon, which operates the central wholesale systems in electricity, for most of my business career, so it was very energy intensive. As you said, I have worked for three better regulation institutions for government over the last 20 or so years—in particular, the Regulatory Policy Committee—so I think I have a decent perspective and balance between an industry view and the regulators' view.

I guess that is where I would like to start. When I was on the RPC, we had a lot of international visitors, and we travelled overseas to some extent. Wherever we went, there was a very high measure of respect, if not approval, for the regulatory frameworks that operate in the UK. I am thinking not just of energy but across the board in that respect. I think we need to have a balanced discussion. Businesses rarely give credit to regulators for things that they have done well. You tend to hear from them when they highlight the things where they have not enjoyed regulators, but it is important to get both things right. I can think of some great examples of good regulatory behaviour and some not so good ones. As I say, we need to get the balance right.

Filippo made comments about a multiplicity of objectives and therefore, perhaps, some confusion in the mainstream purposes of regulations. I would add that complexity in general often leads to delays. Lack of timeliness, for sure, is one of the issues that businesses have trouble with. There is also a skills constraint on a number of regulators, certainly in energy and, I am sure, beyond. I hope that helps as an introduction.

The Chair: I have one little follow-up question. When you worked on the Better Regulation Task Force, were you listened to by the Government?

Michael Gibbons: Yes, I think we were, not least because our conclusions at that time—we are thinking about 20 years ago, of course—

were inevitably very valid. There was a lack of appraisal of costs and benefits of proposed regulations. If you look back on it 20 years ago, you will conclude that many government departments and regulators did not assess in any formal sense the impacts of their proposed policies and regulations. Therefore, they really did not know the costs or benefits to anybody of such a high proportion of regulatory activity; they had not really been monetised. Looking back on it, that is pretty amazing and pretty alarming. I think that there was a very strong case for making the case for regulation and trying to simplify it to make it more fit for purpose, as people saw it at the time. I think that we were listened to.

Q22 Lord Gilbert of Panteg: Michael, you helpfully pre-empted my question when you talked about the importance of clarity in regulatory objectives. You have all talked about what you are looking for from regulation and regulatory behaviour, but can we go back to the objectives that are set for regulators? How important is it that, from the outset, regulators are given clear, consistent and discrete objectives, and maybe a review process to make sure that they remain relevant? In the UK regulatory estate, are we very good at setting those clear objectives? Shall we start with you, Michael?

Michael Gibbons: It is fairly self-evident, is it not, that for any company, organisation or institution it is quite important to have clear objectives? The difficulty is that quite often government believes, understandably and rightly, that there is more than one objective. The trouble is that when you start putting in layers of objectives, one on top of the other, they have a nasty habit of implying a number of trade-offs. When you add to that potential problem the fact that, in my experience, Governments have not been able to prioritise one objective over another, you certainly have the potential for inconsistency and even confusion.

Ofgem is the case that I know best. It has a page full of statutory objectives. It must also have regard to a strategy and policy statement from government. It has recently had a net-zero objective added, under the recent Energy Act. Nobody would disagree with that, although I think that it was doing quite a bit about net zero beforehand. It could also pick up a growth duty, which has been consulted on. That already seems very complex to me.

As I say, having too many layers does not help. Not only does it not help the regulator's thinking processes but it adds costs to its performance. In particular, coming back to one of the things I highlighted at the beginning, the more objectives there are and the more processes that regulators have to go through to reach conclusions, the more delays there will inevitably be in addressing the problem.

Lord Gilbert of Panteg: Understood. Virginia?

Virginia Acha: That is an important clarification also for medicine. It has perhaps been resolved a bit better within the medicines and medical devices regulation with the key purposes, but I still think that the point stands. If the regulators' expectations go beyond assessing the quality,

safety and efficacy of these products and assuring that their safe use in practice is observed, and they get additional requirements that have been set by government, that can complicate how they are free to act.

One point that you did not ask about but that is really important, given the comments on Ofgem and other regulators, is the question of independence. There are not many examples globally of medicines and medical devices regulators that are fully independent, but the degree of independence is usually a good marker for the maturity and stability of a regulator. The closer it is tied into a government agenda, the less likely it is that it will be clear, predictable or consistent. Independence, particularly in medicines regulation, is key. We need to have the science guiding the practice. That sort of discretion allows the regulator to have flexibility to act where technologies and circumstances change.

I gave the example of Covid-19. It should be recognised by this committee that the MHRA was the first international regulator to issue a flexibility during the pandemic. If I remember correctly, it came out at the end of April or the beginning of May 2020. It was very quick. We were facing phenomenal problems with clinical research. How do you undertake clinical research in a lockdown? The MHRA had to think on the quick. It was actually the first to come through with a proposal, followed by FDA and, later, EMA. Those flexibilities were essential. We would not have been able to continue the work in clinical, our filings or our manufacturing. All would have stalled if that regulator had not had the opportunity to operate as it felt fit. That is an important factor for success in any regulatory agency.

Filippo Pollara: I agree with Michael's points in particular, because it can be multifaceted. The example of Ofgem that Michael used is difficult. There are some specific objectives that a regulator has for the market, let us say. Then there tend to be some broader ecosystem objectives, which might blur lines a bit.

I caveat that by saying that strategic objectives being strong and clear make a robust regulator, but your average SME will not go in and look at a regulator's strategic objectives. Contact will be quite late stage and customer facing. You might get a letter through the post outlining fees or something that you need to comply with, so it is a slightly different experience. But if objectives change, which can sometimes happen underneath the jurisdiction of a government department, that can lead to confusion. That confusion can lead to a drift from what an SME needs to do.

Lord Gilbert of Panteg: I get the picture that what we tend to see is objectives being added to, slightly updated or changed. Something topical may come along, and the Government may write to a regulator to ask it to have regard to an issue, but they are never comprehensively reviewed on a systemic basis. We never say, "Are these objectives really up to date and relevant for now?"—is that fair?

Michael Gibbons: If I can butt in, quite often the objectives are of the “take into account” nature. That is not really a clear objective. You have a lack of clarity at the beginning. You do not have anything very measurable or any prioritisation, generally. That makes the regulator’s job quite challenging.

Virginia Acha: I have seen that periodically, every five years, strategic mandates are reviewed. That is pretty typical. What is throwing the challenges is technology and environmental change. You will have seen that artificial intelligence is now becoming more of a cross-cutting theme. It certainly affects medicines and medical devices. To some regulators, that may pose the question: how do these things come together? The MHRA helpfully combines both medicines and medical devices under one roof. That is not consistent globally. EMA, for example, does not deal with devices. That is problematic when you are trying to work on a combined product. These sorts of changes suggest that, over time, the structure and mandate of regulators probably need to think about how the scope of their focus has been evolving outwith their own efforts.

Filippo Pollara: I agree. Government and Parliament have tried this, with stuff like the Red Tape Challenge and one in, three out. It is a question of having a review point after a bit, to look back at the regulatory burden and see whether some things that have been added to the regulator’s purview are perhaps a bit burdensome and have not had any effect. It has probably been subject to subconscious addition, which can happen sometimes with regulatory requirements in a regulator that wants to do the right thing but naturally grows and grows in its remit and wants to do more to create a level playing field. That review point would be healthy to always give a bit of a temperature or sense check.

Lord Gilbert of Panteg: Thank you. I should note for the record that I am a member of the board of the Electoral Commission.

Q23 **Lord Agnew of Oulton:** Good morning. I am interested to know of any regulators that work particularly well, from your experience, either here or abroad. I am a great believer in trying to learn from best practice. Ginny, would you like to open the batting?

Virginia Acha: Sure. I recognise that some regulators globally for medicines and medical devices are very mature and have been the scope for future development. When we as a company or an innovator are working together on new technologies, we tend to engage with the leading regulators early on because their guidance, particularly on the expectations around evidence, is key.

At the minute, FDA is a very important voice in our regulatory science. Historically, the MHRA has also been a very strong contributor to the science. It has been going through some changes in the past few years, which has meant that it has had to rejoin some activities such as ICH and ICMRA. EMA has also aligned very closely with FDA and PMDA, the Japanese regulator, to try to co-ordinate advances in technology.

These agencies all have different practices. Some of them are bound in law. Some of the FDA's activities are just based on its constitutional formats. At present, what cuts across all the very strong regulators is that they have good scientific staff. They are sufficiently resourced and have good capabilities themselves. They have open communication with developers. I can establish regular meetings, as needed, for a filing. Occasionally they have innovation units that will help to support very early-stage discussions. Some of those are directed very particularly to the SMEs. PMDA, for example, is opening an office in the US because it is trying to appeal to the US biotech. They are open and engaging with the science debates.

Those tend to be the agencies that have the ability to really partner with us. The analogy that I would like to share is a bit prosaic, but it is like having a referee on a football pitch. If your referee cannot keep up with the match, it is not going to be a very fair game. I need a referee who can keep up with the ball. That requires investment and support, both from the Government and through the funding arrangements that are made in due course. If I could see all these differences, for me, that seems to be the leitmotiv of a very strong regulator.

Michael Gibbons: I am not sure that I am able to single out particularly outstanding regulators. I can certainly single out episodes of regulation that have gone very well. For example, in utilities generally, and in energy in particular, the response of regulatory functions to lockdown was very good indeed. If you think about it, an awful lot of activity that had previously taken place in offices and on the ground around the country had to be operated completely differently when, essentially, people were staying at home. The adaptation, the compromises and the modifications that were made to deliver a working industry, which we all needed at that time, were quite considerable.

In energy, you would have to say that the transition from coal to virtually doing without coal in this country has gone very well indeed.

Lord Agnew of Oulton: To that point, what about the regulator's role, or not, in getting the grid capacity to be developed to handle the huge backlog of solar and wind power? We are hearing about a 10 to 15-year backlog. Is that not a regulatory failure?

Michael Gibbons: It certainly is. Bluefield Solar Income Fund is a FTSE 250-listed company. We are one of the biggest operators of solar and wind in the country. We have a lot of opportunities and a lot in our pipeline, but we have very real problems with our planning consent, which is a regulatory matter, and, of course, with getting grid connections. As you rightly imply, sometimes the bigger solar installations, in particular, take over 10 years simply to get a grid connection agreement.

The Winsor proposals, for those who know about this subject, have suggested some considerable streamlining and improvements, which would bring the hoped-for outturn down to about half of that. That is still

too long. A solar farm can be put up very quickly. I remind you that solar is probably the lowest-cost energy that this country could have access to. It can be fitted in months, when and where there is a grid connection available.

Lord Agnew of Oulton: Why is it taking so long? Five years seems ludicrous to me, let alone 10. Where are the blockages? They are regulatory blockages, are they not?

Michael Gibbons: Yes, they are. The blockages are in the queue. It is the pipeline to get connections. There are a lot of people who get in that pipeline. Some of them have more realistic projects that can be delivered earlier than others, but they are all in the pipeline, in a sequence. The sequence takes a very long time to get through.

Lord Agnew of Oulton: Are you suggesting that the regulator should have the power to decide who gets to the front of the queue, judged by their credibility or their balance sheet?

Michael Gibbons: I certainly think that there is something in that. I suspect that I am inferring from the question that there could be more resources devoted to this. After all, this is a regulated activity. The regulator could require more resources and skills. Perhaps more expertise could be brought in.

Lord Agnew of Oulton: Wearing your hat as Bluefield Solar, would you be prepared to pay for that extra resource with the regulators?

Michael Gibbons: I think that industry in general would like to see some of its own resource injected into the regulator, by secondment or other means. To generalise this, I think that both with Ofgem and with the future system operator—currently, the electricity system operator—there are occasionally gaps in their organisation. I can go into the reasons why that might be the case with regulators in general, if you wish.

The way to solve this is partly to get more expertise from the industry into regulators. The industry should be more prepared to offer secondments in, for example. Another approach that the energy industry seems to have used quite well over the years is to recognise that, when expert people come to retirement age, they are simply lost to the organisation. I would have thought that regulators of this kind, in particular, might consider more use of part-time or advisory roles so that that expertise is retained and they are able to bring forward these projects more quickly.

Lord Agnew of Oulton: Can these secondments be managed without conflicts of interest? That is what people in government get obsessed by.

Michael Gibbons: That is a perfectly fair challenge and, sometimes, an issue. In my experience, they can. You can ensure that the secondment in is to an area that is not in conflict with the company that is doing the seconding, or you can take other steps to ring-fence the activity. It is a

perfectly fair challenge, but I think there are ways to deal with it and we should find them.

Filippo Pollara: I echo some of those points. Resource, communications and scrutiny are pretty key and pretty welcome. I would not like to single out regulators, but one that has conducted best practice is the Health and Safety Executive. We have just mentioned Covid and back-to-work regulations on working safely, with social distancing. Even more broadly beyond that, with building safety, the HSE is an example of a very communicative regulator. It has regular business burdens sessions to look at reviewing what it is doing and whether it is being a transparent, compassionate regulator.

The ICO has a small business advisory service, which means that business owners can go on to see whether their data protection usage means that they have to register for a fee, so that they know exactly what they are doing. Those are examples of regulators that are engaging and are quite clear about what a small business needs to do or not to do.

Lord Agnew of Oulton: What about the ones that are not?

Filippo Pollara: The ones that are not are those where you are faced with the bill straightaway or you have to pay fees but do not really understand why it has got there.

In the past, communications have not been clear. A few years ago, I met ICO about a letter that was not on the enforcement side but was informing someone that they had to pay a fee. I think the direction of travel has been that it has understood the limited bandwidth of a small business owner, their limited capacity and their need to understand what they need to do when they are having to do lots of different things. We have seen that with ICO and other regulators.

There are regulators that have shone through and done quite well, from a slightly lower-back position. Michael mentioned Ofgem. The energy price shock was quite a tricky scenario. We saw a bit of constant juggling between Ofgem and the energy suppliers, but it came through and worked in the interest of small firms.

Lord Agnew of Oulton: Would your members be prepared to pay to provide more resource to the regulator so that they could get quicker and clearer decisions?

Filippo Pollara: I would argue that regulators should have enough resources—

Lord Agnew of Oulton: They do not. Let us get into the real world. Could you just answer my question?

Filippo Pollara: I think that there may be other ways in which they could be resourced, perhaps from government.

Lord Agnew of Oulton: Your members would not be prepared to pay for

a better, quicker service.

Filippo Pollara: The feedback I get from members is that they pay enough fees for regulators.

Q24 **Viscount Chandos:** I would like to follow up Lord Gilbert's line of questioning. Where businesses find themselves in conflict with regulators, sometimes that may be businesses just chafing at rules, but if objectively that seems a fair conflict, where does responsibility lie? Is it with the Government or the regulator? Are regulators being asked to address political and distributional questions without sufficient guidance?

Virginia Acha: I think it depends on the nature of the conflict. Sometimes we have disagreements over decisions that have been made over filings or submissions in clinical trials. Those are usually questions of scientific argument. Does the regulator accept your evidence and point of view? If not, the regulator decides. Occasionally, we have disappointed developers who get a bad outcome for their file and they have to take it away and do something with it. The challenge arises where the problem is more about the means by which that decision was arrived at. It is a question not so much of the decision but of the practice itself. If there is some sort of concern that the process has not been fair, or there is something missing in the process that needs to be revised, that is where it is important to be able to have open communication and continuing dialogue.

We have regular touchpoints not as companies but through our trade associations where we meet with the MHRA or other regulators regularly to discuss these issues and how things are performing. Are the performance metrics achieving the goals that have been set out? Certainly, within the MHRA that has been a concern in recent years. We have had considerable delays in clinical trial applications. We had a number of exchanges through our trade bodies where we were able to represent the challenges and say, "It's taking eight months to get clinical trial approval and that is really off the expectation". The MHRA was able to come back with a proposal for how it could be resolved. Again, it was down to challenges of resources within the agency. It has lost a number of staff in recent years and is working a little under numbers, so it was able to agree a programme to get back on track. That kind of productive dialogue is very valuable—indeed, essential.

On your question about whether expectations are put on the MHRA or similar regulators that go beyond that, occasionally this is definitely true. In other countries it does occur, particularly in developing countries where regulators are used as a sort of first decision around access that can sometimes be an inappropriate use of a scientific and clinically based decision. In the UK, the bigger question is whether the MHRA is not always included in the conversations when it should be. In some questions on the use of medicines, the conversation is more with the HTA body, with NICE, and the MHRA is not really in the mix. In some respects it is probably the case that, at least in the MHRA setting, it has not

always been included in the very conversations it should be, but for the most part that is the range of experience we would have had.

Michael Gibbons: I want to comment particularly on the early part of your question where you were asking who bears the real responsibility for a problem. Is it the regulator itself or the Government? That is an interesting question. I suppose that, in very strict theoretical terms, ultimately the Government and Parliament are responsible because they have set up the organisation and provided the framework for it, unless there is a problem of process within the regulator.

That causes me to want to comment on those episodes where there are differences of view between government and regulator on interesting policy issues. The price cap was mentioned as possibly being one. I well remember the 2016 CMA inquiry into the energy markets. It concluded that it was concerned about the lack of a formal mechanism by which Ofgem could express its views on policy proposals. It also concluded that there was a lack of effective co-ordination between government and regulator in implementing key policies, and it recommended a requirement on regulators to publish their views on policies and for government and regulator to publish joint implementation plans.

Seven years on, I think I have seen some joint plans by government and regulators planning for a particular policy objective between them, which is great. I might have missed them, but I do not think I have seen any letters or correspondence from regulators commenting on the underlying policy objective and any difficulty they have with it. This may be because, in the end, the threat of being able to do so brought the parties together sufficiently and there was not then a need, in which case it was a positive requirement. I have a great deal of sympathy with that approach to resolving difficulties. Expose the difficulty—make it transparent and possible for everybody to comment on it—with the effect that there will be correspondence showing the difference of opinion between an independent regulator and government.

Viscount Chandos: That point very much resonates with what we found in our recent inquiry into the Office for Students. In a sense, that goes to the heart of it. There is no point in having a regulator if it is not independent. I think we have agreed that there needs to be clarity in terms of objectives. How prescriptive do you think those objectives should be and the prioritisation between them? Is there not a case for saying that the balance—the trade-offs—may be different case by case and, therefore, an independent regulator should have a fair degree of discretion?

Michael Gibbons: Yes, I agree with that. I think I agree with all parts of the question, particularly on the clarity of objectives, making them as simple as possible and, where possible, prioritising them. I am entirely with you on that.

Viscount Chandos: Virginia, do you have anything to add?

Virginia Acha: I think your point about being independent and having clarity is critical. If you do not have that, I would be very concerned. It is fine where there is a strong, representative Government with a very established democratic process, but there are parts of the world where, if you do not have an independent regulator, you will not have clarity and consistency, and you will be at the whims of whatever the latest priority should be. There has to be discretion and a well-resourced regulator that has the capability to deliver on those objectives with a very clearly established remit, which is fine, but it needs to be able to work within that. You need to be able to count on your regulator to make those independent points of view, because the world moves too quickly. If you had to prescribe everything, I guarantee it would be in bottleneck before it could help.

Michael Gibbons: On the point about independence, it is quite an interesting topic to explore, in that many regulators are naturally staffed by civil servants from Whitehall. If there was a high proportion of such civil servants, you might think that their willingness to be independent and hold a different view from that of the departments they have come from would be constrained. I honestly have not seen any evidence of that. By the way, that is an argument for a lot of diversity in the regulators as well. In most organisations I have been associated with, the culture and tone are normally set from the top, in particular by the chair and chief executive. Therefore, those appointments need to ensure that the independence of such organisations is underpinned. I know that a few years ago there was concern registered in the public appointments process about the political independence of candidacy. I think that is an issue on which we need to keep a very strong watching brief.

Q25 **Lord Reay:** From your experience, do you find that the roles and remits of the different regulators you have encountered are sufficiently discrete, or is there overlap and duplication in their responsibilities? What is the impact of this on business?

Filippo Pollara: Where there might be mergers of regulations or a bit of overlap, that maybe lends itself to a slight drift in confusion. When a small firm is quite confused as to the overlapping remits and what fits into which regulator, that confusion can lead to what we call gold-plating, which has been researched at Newcastle University. It found small business owners with limited bandwidth trying to over-comply and using up resource and time. That is where some confusion can lead to an overcompliance culture that is to the detriment of a small business.

We have touched on this before. I was going to make a point about independence and government having oversight. We have regulators working a little bit together. I think we have seen that with the growth duty and the Digital Regulation Cooperation Forum. I think Ofgem and Ofwat have been added to that as well. We have seen it with the FCA in terms of having a consistent form of communication and dialogue by regulators on online platforms. That simplification process creates an easier demarcation line as to which responsibility falls under which body.

Lord Reay: Can you give examples of the confusion that is sowed?

Filippo Pollara: I suppose that with HMRC there is always a little bit of confusion in tax and employment areas, as well as Companies House with filing requirements. You have to file HMRC accounts, and staff and national insurance go to HMRC too, so there are very different things with employment, staff and tax. Sometimes there is quite a lot of regulation in different areas.

Lord Reay: Michael?

Michael Gibbons: I have a good example. When I was chair of the CCSA—the Carbon Capture and Storage Association—I was associated with a carbon capture and storage project. That came to an end in about 2018, about five years ago, but I have no reason to suppose that the fundamental problem is different. By the way, I would like to take the opportunity to say that carbon capture and storage is recognised as a necessary, not an optional, route for delivering net zero, so it is really rather important that we do it.

In carbon capture and storage, developers had a major problem in navigating through a multiplicity of regulators. In no particular order—it is certainly not a complete list—there was Ofgem for various fossil fuel requirements. There was the National Grid for the planning and consenting arrangements that we talked about before, shortly to be the future system operator. By the way, I note that the future system operator has responsibility for gas pipelines that might go into a carbon capture and storage power station but not the CO₂ pipelines that would come out at the other side of a carbon capture plant. The Crown Estate has responsibility for seabed licensing. NSTA has responsibility for carbon licensing and safety licensing. The MMO has nature preservation responsibilities. The Environment Agency has other responsibilities, and there are others from whom you need a licence.

The problem is not just multiplicity. It seems to me that in carbon capture and storage you have a problem where a number of those regulators are concerned with things onshore and a number of them are concerned only with things offshore, and they are not really brought together well. If you are looking for a good example of difficulty in navigating overlapping regulations, there is one there for carbon capture and storage clusters that go from onshore to offshore. It is a real issue.

Virginia Acha: We have already talked about the overlap from a global perspective and how that is being managed with technological ones. I want to focus on an interesting example where there may be inspiration to think about how this could work differently.

Decisions are taken about a medicine, medical device or combination by the MHRA, but that is not the only time a decision is made. Of course, it has to be assessed by the health technology assessment body and eventually the NHS and the clinician who might be prescribing it. Finally, there is a judgment by the patient. The process of evaluating treatment

throughout the process, or a vaccine in a different setting, has been the subject of a lot of government inquiry in the past decade. The result has been through a number of initiatives. There has been an attempt to combine these a little better, and the current proposal is through the Innovative Licensing and Access Pathway. It is perhaps not working to its full capacity yet; it probably needs better resourcing and strategic direction, but the intention is to support a developer, whether it is a small biotech, a start-up or a large company, to help it navigate how that is going to be assessed at all the different stages.

One thing we have seen very plainly is that you can get your licence approved by the MHRA and then stall for many months before the next-level decision is taken. Meanwhile, patients are rightly challenging us and saying, "Where is it? You promised that this was on its way". If we can tee these up a little better to make a more streamlined process, you get to the benefits much more effectively. It is not working perfectly yet, but I think the intention is the right one. It is not unique to the UK; we are seeing it echoed also in Europe, Canada, Australia, Japan and many other parts of the world, even the US, where they are thinking, "How do you work on the focus from the patient or the user rather than just the different stage gates that a developer has to go through?". I think that is powerful.

Lord Reay: How effectively do the regulators co-operate with each other?

Virginia Acha: Increasingly.

Lord Reay: How can we improve this?

Virginia Acha: Historically, the MHRA has played a really important role. A group called the International Coalition of Medicines Regulatory Authorities has been combining the leading regulators globally for the past 10 years. The MHRA was one of the founding members—in fact, it held the chair at the beginning—and is still party to it, but it needs to be resourced to play in the premier division on the regulatory front. It is important to allow regulators the chance to integrate and co-operate with their international partners effectively. If they are resource constrained and do not have enough staff or are overworked, they do not go anywhere. That has to be a priority, as we need to make sure our regulators are well connected and have the wherewithal to attend and participate in the fullest way possible.

Michael Gibbons: I can think of another example where there is perhaps a more extreme and radical solution to the problem: the energy business in general. Sir Dieter Helm, in various of his papers and his cost of energy review some years ago, famously pointed out that there is not only a very long list of energy interventions in the market, which frankly nobody could think up themselves—he had to publish it for people to be aware of them all—but a very large number of regulatory bodies that oversee them. Clearly, he felt—and I have great sympathy with this—that there was a great case, to avoid the kind of duplication, overlapping,

unintended consequences and extra layers of cost issue that you are hinting at, for merging at least some, if not many, of them. Where you have overlapping regulators with different objectives and they appear to cause some trouble in the market, why should the extreme option of merging them not be considered?

Lord Reay: Do you have any examples in mind?

Michael Gibbons: In energy, I would like to go away and send a note on the ones that I think might be combined, but there is a very long list of them in Dieter Helm's work.

Lord Reay: Filippo, would you like to add anything?

Filippo Pollara: I think a closer working relationship between regulators helps standardise some of the working processes and languages and, in turn, the demarcation lines between what responsibility falls under whom. I think that would lend itself to a clearer customer-facing framework for an SME.

The Chair: Michael, can I just check that you will write to us with that information? It will be very helpful.

Michael Gibbons: I will.

Q26 **Baroness Bowles of Berkhamsted:** What impact do you think Parliament and the Government can have on regulators through scrutiny and accountability? Is that obvious and appreciated by businesses? What improvements could be made through parliamentary scrutiny that would impact regulatory performance?

Filippo Pollara: I think Parliament plays an important role in scrutinising a regulator and its processes, particularly on things such as impact assessments. That is an important role for things such as this committee. On many occasions the committees look at the working practices of a department and the work of Ministers and their responsibilities. I think the same principles apply to the workings of a regulator, maybe not looking just at strategic objectives but at whether it is outward facing and consultative and has good engagement with the people it regulates. I think that is an important role for Parliament.

As for government, the regulators are set up by legislation and are arm's-length bodies of departments. We have regular consultations that are measured against the Better Regulation Framework and so forth, so there is a lot of progress there, in particular with the Government's current smarter regulation agenda where they seek to regulate as a last resort. I think that tallies well with our view that a good regulator is one that does not look to impose burdens on an SME unless absolutely necessary.

Virginia Acha: That is a very good basis as a health check within regulators to make sure that they are performing in the best way possible. There should be routine monitoring. A critical role for both Parliament and government to play is to do that routine assessment to

understand whether the strategic direction is right. Are there sufficient resources for the regulator to comply in the best possible way? There is also the importance of stakeholder feedback on a routine basis. I guess my plea is that it is more important to Parliament than just as a health check. I am sure my colleagues will agree for their industries, but for life sciences I cannot think of a single place in the world where you have a thriving life sciences cluster and you do not have a world-leading regulator, because there is a symbiosis. They are not just avoiding burden on the start-ups; they are creating that scope, focus and support to enable that international leadership. It is the investment and foundation that any strong economy needs.

Michael Gibbons: Accountability is a very important issue, but it is not an easy one to grapple with. My analysis is that regulators, in general, get scrutinised by their sponsoring departments as a consequence of the framework agreements. That tends to be rather budget oriented and finance oriented, but, when you think about it, for a regulator that is intended to be genuinely independent of government, when necessary, to be scrutinised and held accountable only like that is not very satisfactory. The only practical solution is for these regulators to be accountable to Parliament. That is the correct answer. I cannot think of a different or better one; that is the right answer. The trouble is that, with all respect, for a regulator to appear for a committee session now and again is not really effective accountability and scrutiny; it needs more than that.

The challenge is: how do we fix this problem? There are a number of options. Clearly, Parliament and bodies such as this could spend more time more frequently seeing the chief executive and chair of the relevant regulator. They could also appoint some sort of subgroup to do it on a standing basis. The idea that I quite like—but you would expect me to say this as the former chair of the RPC—is that there should be an independent body to assist and inform Parliament in this way. An independent body would bring in genuine evaluation expertise and give non-political, objective advice to parliamentarians on what to do here.

I add the KPI problem that I briefly mentioned before. In any good business you have meaningful KPIs and as a result that business is capable of being held to account against those KPIs. Most KPIs I see in regulators are, frankly, a bit low level for that; they are a bit in the weeds and do not really give you an opportunity to judge whether their performance is up to standard.

Finally, the role of industry in this respect is quite interesting. Obviously, I do not propose that regulators are responsible and accountable to the people they are regulating, but the people they regulate know whether they are dealing with a good, competent, professional regulator that has the understanding, skill and time driver to deliver a good outcome.

Ofgem operates quite an interesting approach. It calls for industry views in assessing the performance of the electricity system operator, shortly to become the future system operator. I think that process works quite well to make sure that the views of the regulated are properly taken into

account. I think that would be another important ingredient in getting to the bottom of the accountability challenge.

Q27 Lord Cromwell: Just to comment on the foregoing discussion, systematic monitoring is clearly common sense. The trouble is that with 80-plus regulators out there the reality is that they get dragged in when there is a problem or crisis, not on a systematic basis. I am afraid it is resource driven.

My question feeds into what Michael just said. How transparent or otherwise are the regulators about giving a balanced assessment of their own performance? How easy is it for businesses to know anyway whether their regulator's performance is good, bad or indifferent, and how do they give feedback? Who do they go to with their views?

Filippo Pollara: To pick up the end of your question, probably the point at which they realise whether a regulator is good or bad is when they get some form of enforcement in the post.

Lord Cromwell: Is that a good or bad sign?

Filippo Pollara: It is a bad sign because it usually means there may not have been communication beforehand in understanding why a regulator has gone in a certain direction or the reason for enforcement. That sort of enforcement in an aggressive way is quite rare. An example of a good regulator is when it takes steps to explain why a small business has to adhere to that regulation, why it needs to take those steps and for what reason, and why it has come to a certain decision. That transparency is welcome, but I want to stress that it is at a very late stage. It is true because they do not have much working capacity, so it is one of those cases where they just want to make sure that what they are doing is right in the limited time they have. So the regulator is at arm's length and stays away so they can get on with it.

Virginia Acha: In medicines, they have been remarkably open on transparency, in particular in the time it takes for filing or review schedules. The MHRA has agreed with ABPI, the research-based pharmaceutical industry, to go through a process of performance indicators, some of which do not show it up in a very good light but it is still happy to publish them, which we very much appreciate because then you can do something about it. If you do not know, you cannot do anything about it.

There is also work at a higher level. There is an organisation based here in the UK called the Centre for Innovation in Regulatory Science. It undertakes benchmarking of the major regulators globally. That is published every year. Increasingly, it is evaluating more and more regulators. So we have a third party that is doing it independently. Finally, as companies, it is almost like a simulation across several settings. We file in many jurisdictions and get a feel for what sort of decision processes these different regulators are pursuing and how quickly, and that is a collective view. As I said, if it is down to your particular file or circumstance it may just be you, but if 20 people are

suffering the same problem it is probably something more systemic. We use our engagement in our trade groups to bring things forward, but I have to give credit; most of the medicines regulators are pretty open and transparent with their performance.

Lord Cromwell: That is very interesting. Before I come to Michael, what is in the back of my mind is the Post Office issue. As an SME you were told consistently that you were the only person who had this problem when, in fact, that was patently not the case. I just could not resist dropping that in.

Michael Gibbons: It is a good point. I said at the beginning that I felt we needed to have a balanced conversation on this. I am one of those people who thinks that good consultation lies at the heart of good regulation so that, whatever the regulator decides to do, it has at least understood the problem and the views of those who are regulated before it reaches a conclusion. Regulators have developed and advanced in leaps and bounds over the past 20 years. I now see not only good consultation but—and here is the point—good responses to consultation, which in my view summarise very fairly what the consultees are saying and then make a decision. I think I can say from what I remember that the decision notices themselves are always well argued, well presented and well set out. The bigger problem is that it may take a very long time to get there, which is partly because of gaps in the organisation and partly about skills, but in general they are much better in explaining their position than ever they were.

Lord Cromwell: I have run small businesses. What you want to get mainly is a letter on file from the regulator saying that you are correct. This sort of macro-level assessment is all very well, but how often does an SME form a view that the people regulating it are fair and proper and are doing a good job, as opposed to simply going through the red tape exercise? If SMEs have concerns, who do they go to?

Filippo Pollara: On the first part of your question, the perception of a small business owner is that regulators should make communications with clear advice, be consultative and generally regulate business into doing more business rather than regulating them out of the business, so to speak, in terms of the things with which they need to comply and making sure they are compliant and are registered so that they can trade, let us say with the Food Standards Agency and so forth. Obviously, they can come to us with feedback on the regulators. We can talk a bit more about some of the strategic, high-level objectives in how the regulator works. There are other ones. There is the Financial Ombudsman Service and things related to the FCA, with some variation of course. I see your facial expression, but there are some frameworks there.

I go back to those three key things: being consultative, transparent and having an attitude of wanting to bring businesses into the business fold, via being regulated properly, rather than the other way around, which can sometimes happen to a micro-business and can seem a bit intimidating.

Q28 Baroness O'Grady of Upper Holloway: I should formally record my membership of the Court of the Bank of England and interest as a former leader of the TUC. I have two questions.

First, do the regulators you have encountered have the necessary skills, culture, resources and incentives to carry out their functions? I was particularly struck by Ginny's observation about potentially operating in a much more volatile world with big challenges such as AI, pandemics, the need for agility and speed, and so on. Secondly, do regulators have the ability, candidly and publicly, to speak truth to government power, including when those truths might be profoundly inconvenient? Do you have any examples that would be interesting to hear?

Virginia Acha: I can kick off, especially on skill sets. Candidly, we are a little concerned that the MHRA is lacking in resources at present. It is slowly rebuilding expertise. It has lost a lot of scientific and experiential expertise over the past few years and it is rebuilding. That is already a challenge but, when you add the novelty in the science and AI, it is a challenge to recruit. When you are fighting for some of the most sought-after recruits in computer programming AI specialism, it is difficult to meet those salary aims. Even as a large company, we struggle to get them because there are bigger companies and wealthier industries, and those are scarce resources. It is definitely a concern not just here in the UK but globally. It has encouraged some Governments, including the US, to take their regulators off the traditional government spine for salary to allow them a little more flexibility to attract the staff that they need. That should always be an option.

On the question of speaking truth to power, there have been some important examples where a regulator sometimes has had to say no to something that may be politically very attractive, particularly to a Government in power, on whether it is right to try policies to face the science. For that reason, that is where independence really comes into this space. You need to have the scientific credibility to be able to make the decision as appropriate. I have not seen a case where I think the MHRA has not been able to speak that truth. It is more the case that I do not think anybody asks it to speak. I think it could be asked to speak a bit more.

Michael Gibbons: I have a couple of comments on this, first on the skills background. I think I have already made clear that there are frequently significant gaps in the skills and resources of regulators, such as Ofgem and the FSO prospectively. Both those growing organisations, I note, are likely to experience that challenge. There is almost a systemic reason for it. As I said before, a number of Whitehall civil servants have an interesting career path into regulators, and when they get into regulators and acquire some expertise in regulation of the relevant industries, they are faced with industry parties who will often offer better salaries, bonuses and in-work benefits. There is a regular and not very equal transfer of skills out of the regulators. So there will always be those gaps. Hence we had a brief discussion earlier on about how to deal with it. To some extent it was an unsatisfactory discussion because it was not a

sure-fire resolution of the issue; it is an ongoing issue unless there can be some flexibility in salaries, and I doubt that is the case across the board.

As for the willingness and ability to speak truth to power, I guess you have to know the individuals concerned. I have known the Ofgem chairs and chief executives for the past 10 years or so. In all cases, I have no doubt that they were the kind of individuals who would wish to have such frank conversations, but they take place behind closed doors—and that is probably as it should be.

Filippo Pollara: I think regulators who succeed in what they are doing in terms of culture and resources are able to put themselves in the mind of the pub example I alluded to earlier: someone who has a lot of different things they need to do with limited staff capacity. They put themselves in the mindset of an SME and look at the burdens an SME might face with limited resources and limited time, without a dedicated person to correspond with the regulator. I think the best practice examples are ones such as the ICO and the HSE, which take that into account and embed that sort of SME culture, which is why you see consultative round tables on how they are performing and how they are engaging with their SME customers or, in the case of the ICO, the small business advisory service that gives guidance on where they need to be compliant and so forth on the data protection front. That is the sort of cultural thing I would embed.

As for speaking truth to power, it is quite an intimidating question. Michael has probably touched on the main elements of it.

Q29 Lord Gilbert of Panteg: I want to come back to Michael on the issue of skills and talent. Earlier you spoke about the degree of regulatory overlap and went through that list of bodies. Presumably, quite often they are employing the same set of skills or looking for the same set of skills and competing with each other. Not only do you have a deep-pocketed industry taking people out of the regulatory landscape; you have regulators competing with each other. We have talked about regulatory co-operation. Have you seen any examples of regulators working together to create skill or expertise centres where they can share expert staff across their brief? Would that work?

Michael Gibbons: There is certainly something in it and it is well worth trying. I guess the UK Regulators Network—the UKRN—does attempt to do that. I attended a couple of meetings of it, including when I was with the RPC. I felt it was a body that probably ought to be beefed up to give it a better chance. Maybe more regulators should be in attendance, certainly with a bigger staff than the rather skeletal organisation it has been for a while. It is well worth attempting.

I was smiling while you were asking the question only because in Elexon, which I chaired until last year, there is a code body. The energy industry is governed by, I think, 10 different codes operated by six different bodies. It has its own troubles. Occasionally I would reflect that the skill

set required to be a code expert is to some extent transferable. The trouble is that people will bid. There will be a spiral bidding for the best people in this area, which is to nobody's advantage because the industry pays in the end. I recognise the problem, but it is a problem that is even greater for the regulators because their salary level is almost inevitably lower.

Virginia Acha: You must be thinking, "Okay, you can't really do that with medicines regulators; you can't switch them around". Internationally, you can. One thing that the UK has participated in—this is interesting for regulators—is work sharing, again because we have global projects. Instead of you taking your project to the MHRA, Health Canada, TGA in Australia, Singapore and Switzerland, they do it together. They now have a consortium called the Access Consortium. By work sharing, they can make more efficient use of their own resources. We have been very supportive of that. It takes a little running in to get used to the procedures, but nobody has infinite resources. If there is a way to pool internationally on these things—it will not work for every regulator—these creative approaches are very valuable.

Filippo Pollara: In terms of skill sets and consistency, I think the Government have deployed what they call a growth duty where they talk about understanding the business environment, minimising burdens on productivity, proportionate regulation and so forth. If those principles are applied to staff working in different regulators, that gets added to the skill set and makes it a more holistic skill for regulators, and in turn it means closer co-operation. That is a positive step forward.

The Chair: Michael, can I come back to the point about speaking truth to power in private? It seems to be rather undemocratic. I wonder whether it is very effective because people hear what they want to hear, whereas if you are a regulator you have a public duty to look after the well-being of the people in that particular industry or sector. Let us take energy. This is one that we have looked at recently. Is it not important that if you see 20 years of underinvestment in the sewage and water system you should call it out publicly? A quiet word to the chairman, surely, is not really in line with what the public and Parliament should expect.

Why is it that Ofgem, for instance, has not made a song and dance about the failure to invest in the grid and has not pointed out that the recent auction in the North Sea was bound to fail because it is way under the price that is necessary? By failing to do that, it fails to point out to Parliament, the public and the Government that action needs to be taken if we are to hit the targets that have been set so that sewage will not run through the rivers. You mentioned earlier that chairmen and chief executives have a particular responsibility to set the culture for this. Is it not important that they speak publicly on these matters?

Michael Gibbons: I cannot disagree with your analysis at all. I think what I was saying was that in most of these situations the sequence would have been for the chair or chief executive to talk first to the department or the relevant Minister and make it very clear where they

are coming from. As I said before, I hope and think that where there is still a difference after that conversation, or set of conversations, they should by correspondence make it absolutely clear what their position is. What I am saying is that, in practical terms, it is a far more effective process to have the conversation first and be absolutely clear with the Minister, eyeball to eyeball, where you are coming from, and the likely outcome of such a conversation, in order to give him or her the opportunity to respond and modify their view. If they modify their view, so much the better; if not, then a note from the regulator will be published, as you say, for the benefit of the economy and the sector.

The Chair: It is a yellow card in private and then a red card if you are mute on these matters.

Michael Gibbons: If you like, yes.

The Chair: Thank you very much indeed for this very helpful session.