Science and Technology Committee

Oral evidence: Impact of EU regulation on the UK life sciences, HC 904

Tuesday 19 April 2016

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Written evidence from witnesses:

- Association of Medical Research Charities
- Department for Business, Innovation and Skills

Watch the meeting

Members present: Nicola Blackwood (Chair); Jim Dowd; Chris Green; Dr Tania Mathias; Derek Thomas

Questions 95-195

Witnesses: **Emma Greenwood**, Head of Policy Development, Cancer Research UK, gave evidence.

Q95 Chair: I welcome you all to our second session on EU regulation and life sciences. Ms Greenwood, thank you for coming to give evidence to us today. Can I ask you at the outset, as we are asking all our witnesses, to declare whether you receive, as an organisation, any funding from the EU?

> ***Emma Greenwood***: As an organisation we do not directly receive any EU funding. However, we are a large funder of medical research and so, as with other funding streams from the UK, quite a lot of the research that we fund we might fund in partnership with EU funding streams, or indeed we might fund in a university that also benefits from that wider investment.

Q96 Chair: What do you feel are the main ways, beneficial or not, that EU regulations have a general impact on the medical charity sector? At the moment we hear a lot of scare stories, but you will have particular insight. Do you think that EU regulation is hindering or helping the life sciences in the UK?

> ***Emma Greenwood***: Maybe I will frame this around what we are trying to do as an organisation, which is driven through our medical research activities but is all about cancer patients and delivering changes and benefits for them. Thinking about it through that prism, we want to be involved in the sorts of research studies that are going to deliver

the biggest impact for cancer patients in the UK. We have a strategic approach to that, which says we want to focus on cancers where currently survival rates are not as good as they could or should be for UK patients. Where this really comes into play in the European environment is that we want to fund the sorts of studies—clinical trials are a really good example—where to get the number of patients involved for the study to be valid we have to work with other countries on the international stage, many of which are European countries. We have seen, certainly in the last 10 years, a real desire to be able to work in that European framework so that we can set up studies quickly and make sure that patients in this country can take advantage of those sorts of opportunities. A really good example is paediatric trials. That is absolutely an area where we know that if we want patients in this country to be involved in those studies, which are a legitimate route for a lot of people to explore treatment options, we need to be doing it as part of European-wide studies. That is absolutely essential for us as an organisation, and the legislative framework to enable us to do it is therefore really important. We want and need to see harmonisation as much as possible across all the countries with whom we are seeking to be involved in studies.

Q97 Chair: The importance of harmonisation for research to find bigger cohorts for clinical trials is something we discussed a lot in our first session, but so was the problem that arose with the clinical trials directive. It is a problem that I think has taken about two decades to put right. It looks like that is coming to an end with the new European clinical trials regulation. That is not coming into force until 2018. Is this indicative of the length of time it takes, in your experience, to put right a bad regulation for life sciences, and is that kind of error what normally happens?

Emma Greenwood: The experience with the clinical trials directive was in many ways quite unique, from the perspective of Cancer Research UK and, more broadly, the academic research community in this country and indeed across Europe. The thing to remember is that, when imagined in the first instance, the clinical trials directive was the first time that we were seeking to legislate across all sorts of clinical trial activity, so it was the first time we were looking to include academic studies under that framework, seeking to improve patient safety and standards overall. The first thing to say is that the aim of that piece of legislation was absolutely the right one. Because of the nature of clinical studies and just how challenging they are, and the fact that they happen within the health service, which is different across member states, it was always going to mean that it was quite a complex and complicated piece of legislation to design. Having said that, there were some missed opportunities early on when coming up with the clinical trials directive to properly engage with the right parts of the sector to understand what was needed. We as a country were quite slow to establish what the impact of that directive was when it came in, so we perhaps took longer than we could have to establish that there were problems. As a country, and certainly at European level, once there was acknowledgment that there was a problem and there was an opportunity to look at it again and the consultation process kicked in, the length of time that it took to address that was appropriate, given the complexity and the need to get it right second time around. Although it took a number of years to consult through the various problems, that was done in a robust way; everybody in the representative sectors was properly listened to and we are now in a position where we are in a much stronger place to make sure that the new regulation is rolled out across countries in a much more proportionate manner.

Q98 Chair: It took them a long time to recognise there was a problem, but, once they did, they had to go through a process of consultation, and you think that that was a sensible timeframe. How long did it take from when they recognised that there was a problem to introducing the new regulation?

Emma Greenwood: I do not have the time period and dates to hand. It is certainly something we could provide you with. The formal consultation period, once it kicked in, as in an actual consultation document published, was when we saw that the process was going through the right stages and we were able to submit the right types of evidence to inform how the directive needed to be revised; so I could not really identify any opportunities to shift that. That is a process that has to happen and you have to take a certain amount of time over it. The challenge leading up to the point of issuing that formal consultation—this was from both parties—was that there was perhaps a lack of understanding from the academic sector, certainly in the UK, as to what sort of evidence it would be useful to provide to demonstrate the impact of the directive. That was something from which we certainly learned quite a lot, as an organisation, about how to work with our research community to better generate that evidence and provide it in a way that was useful both for the UK representatives and for the Commission more broadly. It was the first time that we had been in that scenario, so now if we are in a similar situation, as we have been with things like the EU data protection regulation, we are able to generate evidence much more quickly and to have conversations in a meaningful way, such that we get to the point of formal consultation much more quickly.

Q99 Chair: Although you said that you do not get EU funding directly, I understand that AMRC member charities received over £260 million of EU funding covering different disease areas. How important would you say EU funding is to medical charities in the UK, and were there to be an "out" vote on 23 June, how confident would you be about that funding being replaced in its absence?

Emma Greenwood: I am not able to comment on other member charities. Routes of funding back into the UK are important for a variety of reasons, and we have to consider how that route of funding plays a part in the wider ecosystem in the research environment in the UK. We would need to make sure that we were taking into consideration all the sources of funding that make up the picture of the UK science environment, including funding from industry, medical research charities and the UK Government, making sure that we had a solution that meant that we were still able to operate at the very ambitious level we have set in terms of what we want to be doing as a UK research environment. I do not have the details of the member charities and what that would mean directly for them. It is important that it is taken into consideration in the round. Every research funder has a slightly different model, and that absolutely needs to be taken into consideration.

Q100 Jim Dowd: Are you aware of any putative EU regulations or legislation coming down the track that might have an adverse effect on UK research?

Emma Greenwood: So—

Jim Dowd: If so—it sounds as if you are going to say yes—what can we do to ameliorate any disadvantage?

Emma Greenwood: A few months ago, I would have said that EU data protection regulation was absolutely an area that we were very concerned about as an organisation and represented the challenge that potentially all legislators have, which is that it was trying to look at several different sectors in regard to the regulation of data and there was a missed opportunity to think about—I suppose, as a principle—health in all policies. We saw as a research community that, despite best intentions, there had not been proper consideration of the potential unintended consequences of that legislation on the research sector. Once we were able to identify and highlight that, there was a conversation and, finally, we have got to a point where all parties understand how important that is and we have a resolution.

The learning there is being able to think about all the sectors that could be impacted at the point of legislative development. The area that I think could be a potential missed opportunity is that the better regulation initiative means that there is, quite rightly, a desire not to legislate unless it is necessary, and that means that the opportunity to sometimes review or open up legislation could be missed. Specifically for us, the area we are really interested in at the moment is paediatrics, which I have already mentioned. There is a paediatric regulation at EU level and we would very much like to see that regulation looked at again, because we think that, as currently drafted, it means that drug development in the area of paediatrics is not as supported as it could be. Essentially, that is because the way it is drafted means that companies only have to take into consideration whether a drug in one indication could also be applicable in the same indication but in children. It does not take into consideration mode of action, so you might have a molecular target that works in a certain drug in adults that is a similar molecular target in a different type of cancer in children, and, as it is currently drafted, there is not an incentive or a requirement for companies to think about that. That is a tangible opportunity, but because of a wider initiative around not seeking to regulate too much, which is quite right, we may miss the opportunity to have proper dialogue and conversation about that. That is the sort of area that we are thinking about and are concerned about.

Q101 Jim Dowd: But you feel that you have adequate avenues to draw attention to potential defects.

Emma Greenwood: Yes. We specifically link to UK representation on that issue, and interests from UK MEPs and people within the EU. It is a classic case where an initiative in one part of the organisation can potentially have unintended consequences. We are just making sure that we talk to everybody who could have a route to influence there, including scientific advice and so on.

Q102 Jim Dowd: What about existing regulations that have defects from your point of view: how able do you feel to get amendments to those?

Emma Greenwood: Our most recent experience was on data protection, and then, I suppose, clinical trials regulation. Certainly our experience, increasingly, is that, as a UK-based organisation, the best mechanism for being able to have the proper dialogue

with decision makers is, where possible, to work in collaboration with others in the medical research sector in the UK—that works really effectively—but also to identify people and organisations that represent pan-European interests, so we have equivalent cancer groups that work across the whole of the EU, as another vehicle to make sure that we have a unified message and approach. Increasingly, those avenues are open to us. Initially, the desire to speak directly just to a UK organisation is not always there, but if you can demonstrate that you are part of a wider conversation, it tends to mean that doors open.

Q103 Chris Green: How can medical charities, especially small ones, be better helped to navigate the EU regulatory landscape?

Emma Greenwood: I have been thinking about that question. It comes back to the point I have just made. There is a really important role that larger organisations can have in horizon scanning, understanding the processes at European level and working with smaller organisations to share that information. That is certainly something that, as a larger organisation, Cancer Research UK is keen to do and it has set up cross-UK groups just to facilitate that sharing of information. Potentially, there is more of a role for the UK Government on that front. Again, to use the example of the data protection regulation, horizon scanning for pieces of regulation that are not obviously within the life sciences domain but could have a potential impact is important and will be increasingly important. If there was some sort of more formal horizon-scanning mechanism that could signpost those possibilities, it would help smaller organisations.

Q104 Chris Green: You highlighted at the beginning of your reply the relationship between the European Union and small organisations being mediated, to some extent, and that Cancer Research is an intermediary in that. Is that because the nature of the EU does not lend itself to work with small organisations, so they need to piggyback or work with larger organisations?

Emma Greenwood: I am talking predominantly about the charity medical research sector. I think it is more about resource within a charity to be able to understand all the possible issues that have an implication at European level, and, fundamentally, some charities are better resourced to do that than others. The point is more about organisations, regardless of size, that are predominantly based in the UK using UK sector-wide initiatives to have a shared voice—that has more impact than individual organisations going in, all making the same point—and for UK organisations, where possible, to partner with pan-European organisations to demonstrate shared concerns or shared perspectives across the EU membership. I do not know if research is unique in this area, but certainly it feels that, by and large, there is a shared view of legislation across member states; and working together you can identify where there might be differences in approach such that the conversations you have at European level are much more fruitful.

Q105 Chris Green: You appreciate that when dealing with any large organisation a small organisation finds it a bit challenging, and getting together is quite a good idea. In that regard, do you think the guidance given by Government or regulatory agencies, such as the MHRA, is as it should be? Is it good enough, or do you think there are any improvements that can and should be made?

Emma Greenwood: With an issue like the clinical trials regulation, we feel that the role of the MHRA has been key, both their direct role in influencing and negotiating at European level and their role in translating that and working with the sector back in the UK. We have seen a noticeable shift in the way that medical research charities and the sector more broadly are able to work with the MHRA on things like the clinical trials regulation, both in influencing how it was drafted and now working through what that means specifically for the UK. Working with the MHRA, we have held training sessions where we unpick the legislation, and we have clear guidance and a steer from them as to what we need to be thinking about. Increasingly, it feels like collaboration and working together.

Q106 Chris Green: It works quite well at the moment; there is no particular change you would like to see.

Emma Greenwood: I think it works really well at the moment. There is always the process within the UK and then a parallel process that is happening across the member states where people are trying to work out what they are doing with the legislation. Cancer Research UK is always at the table in those conversations. Perhaps the only potential gap is real clarity from the MHRA about what stage they are at in their thinking. Some countries have lots of thinking to do with regard to certain elements of the legislation and actually, probably because we are so far ahead on elements of it, we do not need to be doing that; it is just articulating that and being clear in communications that we do not need to worry about this piece of the jigsaw because we already have it sorted. I have no concerns that we have not done the necessary thinking, that we are not involved when we need to be and that the MHRA is not keeping us up to date on things that we need to have sight of. Again, it is back to that small organisation point: regular communication of that is helpful and needs to continue.

Q107 Dr Mathias: Can you give us an idea—an example—of any EU regulation that might appear from the medical charities' point of view to be unnecessarily complex, if there is one?

Emma Greenwood: I cannot, to be honest, because the nature of medical research is very complex. Again, to reiterate, every country operates in a slightly different health service, and a lot of life sciences work has to happen within the health service. Because of the complexity of research, we need an approach that takes all that complexity into consideration and, where possible, tries to apply a proportionate approach. At face value, something like the clinical trials regulation can seem quite a complicated piece of legislation. However, I think that demonstrates that it has taken a more proportionate approach and has taken into consideration the nuances across different member states.

Q108 Dr Mathias: The clinical trials regulation is okay from a British medical charity's point of view.

Emma Greenwood: Yes, I think so. Obviously, the devil is always in the detail of how these things are implemented, and even though it is a regulation there is still some scope for slightly different approaches to elements within different countries, so that is something you always have to watch out for, but our—

Q109 Dr Mathias: Can you give an example?

Emma Greenwood: The approach to ethics committees is a good example where we have a system that works really well in this country. Other member states may be in slightly different places, so they are—

Q110 Dr Mathias: Who? Would you say we are top or that what we do in ethics is top?

Emma Greenwood: I do not know that you could describe it as who is best or who is not. The system we have in place has taken a number of years to get to a way of working that is as effective as it can be. It was one of the things we sought to protect when negotiating the new regulation. Other member states are in different places for different reasons and are seeking to get to a similar level so that there is a similar approach across all member states. Again, I do not think there is any one model that should be applied across the board.

Q111 Dr Mathias: You are not saying we have better ethics than other EU states.

Emma Greenwood: I could not comment on them.

Q112 Dr Mathias: But you are saying our system is fine for us.

Emma Greenwood: Our system works really well for us as a country, given how complex our health system is, and so on.

Q113 Dr Mathias: But you cannot roll it out to other member states. Is that what you are saying?

Emma Greenwood: I am saying that you might be able to apply some of the principles from it and make them work in other member states, but what we need to see at this stage of implementation is a conversation across all member states, so that the model that each country chooses to take makes sense in the broader framework, because we are trying to have a more unified approach. It is the balance between as much unity as possible while also taking into consideration what works in each country.

Q114 Dr Mathias: But it is not possible—

Emma Greenwood: I do not think you could apply the same model in each country because of the nature of health services and how they work.

Q115 Chair: I cannot quite believe that none of the EU regulations at this point could be in any way improved or simplified for the life sciences sector. The clinical trials directive had significant problems and is now being replaced with a regulation that people are largely happy with. The data protection regulation has just got to a place where researchers seem to

be happy, but are you telling me seriously that there is no other regulation that does not need improvement at this point?

Emma Greenwood: The paediatrics regulation that I mentioned earlier, absolutely, we think needs to be looked at again. We think, as currently operating, that it is not necessarily doing what it sets out to, which is to ensure that we are, as a life sciences industry, always thinking about the opportunity for paediatric drug development. That is absolutely a piece of legislation that we want looked at.

Q116 Chair: What about any others?

Emma Greenwood: From our perspective as Cancer Research UK, that is our priority.

Q117 Chair: Just one.

Emma Greenwood: That is just coming at this from the prism of cancer patients and having the most impact; that is where we have drawn the line, but the rest of the medical research sector, which is perhaps interested in other areas of disease, might have different priorities.

Q118 Chair: Okay. Is it your impression that EU regulation tends to start off too bureaucratic and finds its way to the right place with heavy lobbying or that it starts more or less right and just needs a few tweaks here and there? What is your impression of the tendency?

Emma Greenwood: I always subscribe generally to the ambition and the intent of legislation. I think perhaps there is a lack of engagement or less engagement than is desirable with scientific advice and expertise very early in the process, so you can end up in a situation where you feel you are having to rectify an existing piece of legislation that has been drafted, rather than necessarily informing it in the early development stage. That is where there is the greatest scope for improvement. That is based on two main examples: clinical trials, which is obviously a very long time ago, and the data protection regulation more recently. There is definitely an opportunity to embed that scientific advice; by that, I mean not just the latest science but speaking to people who are delivering and trying to run those studies. In something like clinical trials it is about how you set up a clinical trial, so that is where there is still the greatest opportunity to shift where in the process that level of engagement is happening.

Q119 Derek Thomas: How would you say smaller businesses and charities can get more readily involved in shaping relevant EU regulations in a timely manner? It is an enormous project. Is there an opportunity for small companies or charities to get involved in helping the development?

Emma Greenwood: Yes, absolutely. Understanding the asset you have as an organisation to bring to the discussions is critical. If you are a charity, you obviously have access to patients who are supporters and to the general public, and you can understand from them a sense of how important some of the issues are. We quite regularly talk to patients about

something like data protection, about which, on the face of it, you would not necessarily think they would express a strong opinion, but you can talk through the implications. There is a role that small organisations can have in demonstrating the potential impact from their constituents' perspective, and if you are a funder of research, in going out to the people you fund and having a frank conversation about the impact of regulation on them day to day. Again, we did that with clinical trials. We went to trials units and visibly saw the difference in paperwork from one year to the next once the clinical trials directive had been implemented; it was very visual. Understanding what you can bring to the table is very important, and then finding mechanisms to work with others in the sector to bring that expertise to life in a unified manner, as I have described.

Q120 Derek Thomas: Thank you. That is good. What additional scope is there for early identification of issues—horizon scanning, if you like—to enable timely intervention in subsequent policy development? Does that make sense to you?

Emma Greenwood: Yes. Horizon scanning is always a challenge, and that is where small organisations rely more on large organisations that have the resource to do it. The sector group that we have on medical research in the UK has people like the MHRA around the table, so everybody with the right expertise comes to that horizon-scanning conversation. I come back to the point about health in all policies, or maybe it should be life sciences in all policies for this issue: perhaps there could be wider consideration across UK Government Departments thinking about that. With the data protection regulation, once we flagged the problem to the MOJ, who were leading on it from a UK perspective, they were quick to respond and to liaise with colleagues in the Department of Health and so on, but it was slightly concerning that it had not necessarily been in their horizon-scanning process and that it took an outside organisation to flag it.

Q121 Derek Thomas: Finally, and it might pick up on what you just said, what do our Government need to do to encourage more timely horizon scanning, and can you give any examples of where you have been taken by surprise in relation to any new EU directive?

Emma Greenwood: I do not think I can give a current example of that. The clinical trials directive provided an opportunity for the life sciences sector to understand the process and understand how to work better together, and as a result, across charities, across big medical research funders, regulatory bodies and Government Departments, we are generally, as a sector, much more aware of the possible impact of legislation. Ten years ago there was massive scope to shift that, but we are now in a place where it is something that we are thinking about much more regularly.

Q122 Jim Dowd: You mentioned in response to a previous question what you felt to be a generally satisfactory relationship with the MHRA, for example. What about the Government more broadly? How do you regard your relationship with the Government in determining EU policy development as regards life sciences?

Emma Greenwood: The data protection regulation is a good example of where, as soon as it was something that we identified as a challenge, the ability to have the right conversations with the right people in the Department of Health and BIS, and to try to help

them identify what they needed to do to work with other colleagues across Government Departments, seemed to work quite effectively. Again, the nature of being a UK-based charity is that a lot is about existing relationships on UK matters; there is value in being able to go to people you regularly talk to about the UK domestic agenda to raise issues on that platform. There is still some consideration around better understanding sometimes of what is needed from an evidence perspective.

Q123 Jim Dowd: Better understanding on whose part?

Emma Greenwood: On the Government's part in terms of what they need from us as a sector. This is not unique to the role in influencing EU legislation, but there is a lot of value that the research charities can bring to those conversations, because of the way we work and the interactions we have. It is about breaking down that relationship so that it is not just seen as us highlighting a problem but understanding that we can be part of the solution, and that we can work in collaboration with people in UK Government Departments to help unlock the case that needs to be made at European level to shift those issues on. Potentially, there is scope for a bit more of a collaborative working relationship. That is the place we have got to with the MHRA; it does not feel that we are just pushing them to raise certain issues. It feels like they are coming to us to ask our opinion on the solutions, as well as helping to identify the problems, and I would like us to be able to get to that point more broadly across Government.

Q124 Jim Dowd: The general feeling about your channels of communication with Government, Government agencies and other key opinion formers is that it is broadly acceptable and there are no great problems with it.

Emma Greenwood: Yes, absolutely. For the issues that we need to work on, they are very open to engaging with and hearing from us. It is just about that slight shift in focus—we are not just here to tell you what the problems are; we are also here to help co-develop solutions and we have access to a huge medical research footprint of people who can help shape them.

Q125 Jim Dowd: Do you feel it is a bilateral relationship in the sense that it is not just you reacting all the time to perceived difficulties that you then take to Government, but they come to you in the first instance for responses to issues that they have identified?

Emma Greenwood: I do not have examples in recent years of that happening, to be honest, because the big live issue has been the clinical trials regulation, and that has an established way of working. On data protection, because it was with a Government Department that we do not strongly work with that often as Cancer Research UK, there was an element of having to develop those relationships, and go to them. Because data did not automatically highlight to people that it needed to be a life sciences issue, that meant that there was a very different approach from Government and not one that we were used to, or I suppose that they were used to. No, by and large, it still feels like us raising the issues in the first instance, which is why I would like to see a bit more of a horizon-scanning role from the UK Government.

Q126 Jim Dowd: Sure. Is it your impression—I appreciate it will only be an impression—that the Government have a UK-wide view of life sciences and its priorities as regards to EU regulation?

Emma Greenwood: That would certainly be my interpretation and impression. Again, it is mainly based on the clinical trials regulation, but certainly the main regulators we have worked with always consider impact across all four nations. It comes back to that health services point; all four nations approach it slightly differently, and I have always felt that that is front of mind when considering something, so that we are not just coming up with a solution that works for England. The regulators very much consider UK-wide.

Q127 Chair: Our witnesses in the last session proposed that it would be helpful for the science advisers in the European Parliament, the Commission and other places to have a life sciences horizon-scanning group there to foresee areas where regulation would be needed and where problems would arise with different pieces of proposed legislation. You have proposed that for the UK. Do you think that is something that should be happening in the European legislature?

Emma Greenwood: Yes, it sounds like a very sensible idea given the current state of scientific advice at that level. There has recently been a change, and, given that it is quite early on in that change, there is an opportunity to really think about how it works. Currently, there is not an expert with life sciences expertise on the new scientific advice group. You would want to make sure that that was being channelled somewhere within that process and, yes, if setting up a group seems like the best mechanism to do that, it is absolutely something we would support. The only thing I would say about scientific advice is that it is not just about the role of those individuals and that group. We would want to make sure that they were bringing in advice and expertise more broadly and that it did not shut down the route for influence directly to decision makers, so it did not mean that scientific advice could only be channelled via that route and that there was still willingness to engage more broadly with organisations outside that formal mechanism.

Q128 Chair: Thank you very much for taking the time to give us evidence today. You have given very helpful and full evidence. However, we are likely still to have some more questions, because this is a complex area of policy and one that we want to look into with enough depth and rigour to contribute a serious comment, so I hope that you will be kind and write back to us if we send you any follow-up questions.

Emma Greenwood: Absolutely.

Chair: For now, thank you very much.

Examination of Witnesses

Witnesses: **Dr Ian Hudson**, Chief Executive, **Jonathan Mogford**, Director of Policy, and **John Wilkinson**, Director of Devices, Medicines and Healthcare products Regulatory Agency, gave evidence.

Q129 Chair: Welcome, and thank you for coming to give evidence today. We have been asking all our witnesses to declare whether they receive any EU funds. Can you tell the Committee how the MHRA is funded and whether it receives any EU funding?

Dr Hudson: Sure. In fact, we receive around £10.3 million a year from the European Medicines Agency, a fee for service; we do assessment work on behalf of the European Medicines Agency, where we bid for that work, if we are granted it. It amounts to that sort of sum each year. In addition, we received around £2 million—just over—last year from the innovative medicines initiative for things like a project relating to strengthening pharmacovigilance and medicines across the European Union and developing technologies like an app for reporting adverse drug reactions.

Q130 Chair: Thank you. That takes me neatly to my first question. Can you please explain to the Committee how the MHRA interacts with the EMA?

Dr Hudson: Sure. The EMA has certain responsibilities relating to medicines. For example, most new drugs—almost all new active substances, new drugs—go through the European Medicines Agency. The European Medicines Agency then contracts that to individual member states through its scientific committees, one of which is the committee for human medicinal products, composed of members from the different member states of the European Union. A person is appointed to lead that assessment and there is another person—there are two teams appointed. They take it back to their national agencies and they do the work. We provide a lot of scientific expertise to the system. The pharmacovigilance committee similarly is composed of people from the individual member states, and the MHRA, again, provides expertise in those committees. The EMA also has a co-ordinating role in other activities on the medicine side across the member states. I and the individual member states are also part of the management board of the European Medicines Agency. There are five main scientific committees in the European Medicines Agency. They elect a chair. Two of the five are actually chaired by representatives from the MHRA—the scientific advice working party and the pharmacovigilance committee. It operates very much as a single network, with the EMA co-ordinating activities and the member states providing a lot of resource to the system, so that there is a single decision-making process for areas within the EMA's competence. That is new drugs and changes to variations to new drugs—pharmacovigilance.

Q131 Chair: Do we accrue any particular practical benefits—our life sciences sector, our researches—from having the EMA based in London, so proximal?

Dr Hudson: Yes, I think we do. The MHRA is one of the bigger agencies across the European Union and puts a lot of resource into the EMA, but having the EMA based in London helps enormously, in that we take a lead in the greatest number of assessment works, whether new assessments, pharmacovigilance or scientific advice. It helps reinforce the UK as a strong place for the pharmaceuticals sector to have a strong national

agency, very much open to dialogue, together with the European Medicines Agency based in London as well.

Q132 Chair: You were sitting in for our previous witness and will have heard her evidence that, except for the regulation on paediatric drugs, which I think is coming up for review, Cancer Research UK is pretty happy with the regulatory framework in the EU at the moment. Does the MHRA feel that there are any particular areas of EU regulation that need reform or any areas of legislation that it would like to see come forward, given the innovation landscape?

Dr Hudson: We have had quite a lot of changes in EU regulations and directives over recent years, and the priority now is to make sure that they are taken forward and embedded properly. You asked the previous witness about the clinical trial regulation. To make sure that it is now taken forward and implemented appropriately, we are in the process of negotiating the devices regulation, to finalise the negotiation of the devices regulation and make sure that they continue to maintain the right balance of supporting innovation or allowing innovation and protecting public health. There are new things on the horizon, like the finance and operation of the system that the Commission is going to be looking at, and we need to work with our European partners and the Commission in relation to the review that will take place and the whole agenda of making sure that regulation remains fit for purpose. It needs to continue and, where possible, take elements out, and indeed reduce the burden where possible, but regulation itself is quite flexible in many ways.

We have seen a shift in emphasis, rightly so, to perhaps exploiting more of the opportunities in existing legislation. There are all sorts of flexibilities in things like conditional approval and licensing under exceptional circumstances, so the focus for me would be much more about planning to use those, and some of the recent initiatives like adaptive licensing or the European Medicines Agency PRIME initiative—the promising innovative medicines initiative. It is about trying to make the most of existing legislation and really support developing products, particularly in novel areas. The focus for me would be to make sure that the existing things that we know are coming are implemented appropriately and then to support the new initiatives that we have been very heavily involved with, like adaptive pathways, adaptive licensing and PRIME.

Q133 Dr Mathias: Are you aware of how EU regulation affects UK business in the life sciences sector and if there are advantages and disadvantages?

Dr Hudson: We have to recognise that the UK is about 3% of the global market for pharmaceuticals and a similar figure for devices, but it is hugely expensive to develop new medicines. Companies aim to do a single global development plan, as far as possible. Having a single set of rules across Europe is enormously helpful, with single decision making for medicines and devices, and access to the whole of the European Union as a consequence, rather than each country doing its own thing, which I think—we have to be realistic, at 3% of the global market—would be challenging for companies, particularly if it is a series of different countries.

Q134 Dr Mathias: Are there any drawbacks from your point of view?

Dr Hudson: Clearly this works very well, but it means that we have to work very closely with our European colleagues to make it work effectively. I think it does work very effectively at the end of the day, but it means we cannot take different decisions. In reality, we work very closely with our European colleagues. We lead in an awful lot of the assessments done in Europe, so I do not see that as a problem, but where something is a common system, you cannot do your own thing.

Q135 Dr Mathias: When you say 3% of the global market, is there another European country that dominates more than the UK in that way?

Dr Hudson: In terms of size of market, I could not quote other countries. I think Europe is about 27% collectively, but I do not know.

Q136 Dr Mathias: You would not want national regulation. The EU regulation works in your favour. Is there extra cost for you in complying with EU regulations?

Dr Hudson: National regulation would be difficult if each member state was repeating a national regulation. That in itself would impose a cost, both directly, with fees for individual agencies, and the industry cost of putting dossiers together and potentially doing different development plans. That would be very challenging.

Q137 Dr Mathias: Would you want to change any of the EU regulations?

Dr Hudson: I do not think there is anything that I would want to change now. We have talked about the clinical trials directive and the clinical trials regulation, and I think the clinical trials regulation is correcting some of the faults of the clinical trials directive. Although the clinical trials directive achieved a certain amount, it also had its faults. To me, the focus is going to be making sure about the areas that I mentioned: complete the devices regulations, implement the clinical trials regulation appropriately—make sure that that happens—and then continue to make sure that regulation is fit for purpose. As I mentioned, the regulation is quite flexible and a lot of things are now in guidance, which is much easier to change, but we should make sure that guidance continues to be updated and is fit for purpose in new areas coming forward.

Q138 Chris Green: We have been told by the BioIndustry Association that the application of chemicals regulation—the so-called REACH, or the registration, evaluation, authorisation and restriction of chemicals regulation—was compromising the development of medicines. Can you see a way through the problems that exist at the moment?

Dr Hudson: REACH is under the responsibility of DEFRA, but I am aware of the issues that have been raised, and I saw the evidence that was presented by the BioIndustry Association. If there are examples where REACH will have an impact on medicines, we would work very closely with DEFRA to find a way forward to make sure, particularly, that essential medicines could continue to be manufactured appropriately and supplied to

the market to meet the unmet needs that are there. Absolutely, if there is an issue, we will work with other Government Departments to make sure it is addressed.

Q139 Chris Green: There was a recent Government report on identification of barriers to innovation. In some of the evidence taken there, a company said that it had to recruit four people—2% of the workforce—just to work on REACH compliance. That sounds like a huge burden for a small business.

Dr Hudson: I am not an expert on REACH and I think DEFRA would have to address some of the issues on that. Certainly I would approach it, from MHRA, from a public health point of view, in that clearly REACH has been put in place for reasons of trying to protect in relation to various chemicals, but there is also a need to make sure that medicines are brought to patients for the benefit of public health. Absolutely, from the public health point of view, from the medicines point of view, if there are issues relating to supply of medicines as a consequence of this, we would work with other Government Departments on it.

Q140 Chris Green: If you are not getting the right chemicals, the right drugs, to market, that is a public health concern, if there are delays. If businesses find there are huge constraints and are having to increase their workforce by 2% just to deal with REACH legislation, I would think that is quite a burden. Would you say that of SMEs? I realise it is not your specialist area—

Dr Hudson: It would be an area for DEFRA.

Q141 Chris Green: Would you say that SMEs are hit disproportionately hard?

Dr Hudson: It is an area that DEFRA would need to address, as it is a regulation that is under their responsibility. Active pharmaceutical ingredients in the final product medicine are exempt from that process. It is about chemicals used along the way, such as solvents and so on. If there are issues relating to production of medicines that are having a consequence on essential medicine, absolutely, we would want to get engaged in discussing that with other Government Departments.

Q142 Chris Green: The Government report highlighted that small firms have been advised by trade associations not to grow, to remain below certain thresholds to avoid some of the impacts of REACH. Are you aware of that?

Dr Hudson: It is a question that would need to be addressed by DEFRA as it is their regulations. It is not something that we get involved with.

Q143 Chris Green: How do you alert yourselves to regulatory proposals in other sectors that may have unforeseen consequences for medical and life science research?

Dr Hudson: We have responsibility in the medicines and devices area, but we work closely with other parts of Government. If there are other things coming along through

Government, we discuss with other parts of Government the potential impact of that. We talked about the data protection legislation earlier on. That would have potentially had an impact on our work, but my understanding is that it has reached a satisfactory position. Here we certainly worked with the Department of Health and we worked with the Ministry of Justice in relation to the UK position to make our views and position known. Yes, we work with other parts of Government to make sure that we are aware. As the previous witness mentioned, we work closely with stakeholders outside the agency, in other parts of Government, with industry, the charities and the academic community as well, such that if they have any concerns they can bring them to our attention.

Q144 Chris Green: Overall, the communications work sufficiently well to identify and resolve potential regulatory conflicts.

Dr Hudson: Yes, I think they do, but clearly we need to continue to make sure that we do this and make sure that we are aware of other things that are coming that could have a potential impact on us.

Q145 Derek Thomas: Can I talk briefly about the Transatlantic Trade and Investment Partnership? MPs know a lot about this, but we probably do not know very much; it is constantly raised by constituents. Negotiations are continuing between the EU and the US and have been for some time. In your view, is that partnership likely to help or hinder the development and approval of new medicines and the research that underpins them? Is it likely to dampen down research because both the US and the EU regulatory bodies will have to consider new products, or do you think it will create greater markets and more investment because of the two continents?

Dr Hudson: I think it will help our work in a number of areas. Priority areas for us are sharing information between ourselves and our counterpart, the FDA, certainly when it comes to inspection. Moving to mutual recognition, if you like, on inspections would be extremely helpful. At the moment, we inspect in the United States, and the United States sends inspectors over to factories in the UK. To get to a situation where we rely on each other to do that for us would be extremely helpful. It can only help to harmonise requirements.

Q146 Derek Thomas: You feel that investment may even improve or increase, do you?

Dr Hudson: I think it could reduce burdens on companies by having, for example, fewer inspections. It can have a better public health outcome through much more open sharing of information. There may be other areas that could come out of this: for example, being able to recognise each other's studies that are used as comparators and so on. I think it could help reduce burdens.

Q147 Derek Thomas: What input has the MHRA had in the negotiations around TTIP? Have you had any input on that?

Dr Hudson: We have had discussions. We have seen the priorities that have been raised through the Commission, and indeed discussed those and fed back to them, but maybe I could turn to my colleague Jonathan Mogford, who is our director of policy, who may want to add a bit to that.

Jonathan Mogford: There are two key routes. First, within the UK Government processes we have been engaging with BIS, who are in the lead in terms of influencing the Commission's position, as clearly this piece of work, the negotiation itself, is being led at Commission level because it is international trade. There have also been a number of conversations, and discussions have been taking place, between us as regulators, particularly in the global context. One initiative that we have been strongly supporting is the International Coalition of Medicines Regulatory Authorities, precisely on some of the issues about building confidence in information sharing and how we address some of the concerns, particularly on the US side, about confidentiality and the constraints they have there. There have essentially been two routes where that discussion has been developing.

Q148 Jim Dowd: Dr Hudson, in reply to an earlier question, I cannot remember if you said we had 3% of the global market in medicines and devices or we were 3% as a consumer. Which is which?

Dr Hudson: I think the UK represents about 3% of the global market for new drugs.

Q149 Jim Dowd: I see, so it is from the consumer point of view, not the provider. My main question is: how do you feel the MHRA can more effectively influence the development of EU policy?

Dr Hudson: We do pretty well on that and I can think of something at all levels really. First, in terms of some of the regulations that have been put in place, the variations regulation that changed a few years ago was based on work that we had done within the UK to simplify some of the processes and reduce some of the burdens. For the clinical trials regulation, in the interim between the directive and some of the issues with the directive, we have been doing a lot of work to make our assessments more risk proportionate and have been supporting and promoting the voluntary harmonisation procedure, which is a way of sharing assessment across the European Union rather than duplicating it. Those elements, for example, were the basis for the clinical trials regulation going forward.

When it comes to more operational elements in the work of the European Medicines Agency—certainly the policy on adaptive pathways, adaptive licensing—people from the MHRA were very much involved in setting that up. On PRIME, the promising innovative medicines initiative, which supports new medicines in unmet need areas, we have been very instrumental in supporting that and chairing the sessions that have been taking place in relation to it. I mentioned earlier that we chair two of the five scientific committees. There is the European Medicines Agency and there are others: we co-chair the clinical trials facilitation group; we have the vice-chair of the committee for medicinal products; the CMDh—mutual recognition and decentralised procedures, the non-centralised application; and my colleague John Wilkinson chairs the management group of the competent authorities for medical devices. We have a lot of influential slots and we put a

lot of effort into making sure that the European system is risk proportionate, that we have appropriate regulation and that it operates smoothly. We put a lot of effort into ensuring that we get the right answers from a public health point of view.

Q150 Jim Dowd: You mentioned that you feel it is risk proportionate. It has been suggested elsewhere that the application of the so-called precautionary principle is rather inflexible and that it is a deterrent to research. Is that not your experience?

Dr Hudson: It has not been my experience. My experience has been that the European regulatory system, whether medicines or devices, is one that looks at the risk benefit, certainly, for example, for medicines, but the same applies for devices; the risks you are prepared to take for the licensing of a new medicine will very much take into account the nature of the disease you are treating and the options available to the patient. Clearly, if you have a malignancy for which there are no other treatment options, we would accept a much higher degree of risk. If it is a vaccine, of course, that is a completely different issue; being given to normal people, we would want a very safe product, but if it is an oncology product, for example, we would expect to see and perhaps accept significant toxicity.

Q151 Jim Dowd: It is not a rigid application.

Dr Hudson: No, absolutely not. That has been my experience, and I think John, from the devices point of view, would give the same response.

John Wilkinson: The devices legislation is risk stratified. Medical devices are anything from walking sticks to heart valves and MRI scanners, so it is clearly inappropriate to apply simple single rules to each of those categories. Even within categories, the risk-benefit equation can be quite variable. An intervention for somebody who is unable to have a surgical intervention and would otherwise die clearly has a different threshold from somebody who may be able to tolerate a surgical intervention, which might be the best way of doing things. It is, generally speaking, flexible and there are dangers in going down a path where the legislation is too prescriptive.

Q152 Jim Dowd: Do you have any formal or informal relationships with other national EU regulators?

Dr Hudson: Yes, we do. We meet them regularly. It is an informal relationship. For example, all the heads of medicines agencies get together on a quarterly basis and make sure that the system operates well collectively. We speak to each other all the time, yes, whether on the medicine or indeed the devices side.

Q153 Jim Dowd: Does that translate into a recognised collective representation to EU institutions, or do you still do it as a national agency?

Dr Hudson: The network getting together as the heads of agencies is more of an informal group, but it adds weight to it if we are collectively having the same view formally feeding into things coming through the national agencies.

Q154 Chair: You spoke about your engagement with the medicines directives and the devices directives as being a risk-benefit analysis that was applied. Did you have any engagement with the data directive?

Dr Hudson: Do you mean with the European data protection regulation?

Chair: Yes.

Dr Hudson: Yes. We have an interest in this, because we also house the clinical practice research datalink within the agency—data for research purposes. We discussed with the Department of Health, who discussed with the Ministry of Justice our concerns, if you like, about some of the proposed amendments, but I think we have ended up in a place that will continue to allow and facilitate clinical research. So, absolutely, we did—

Q155 Chair: With medicines and devices you say that your experience has been that a risk-benefit analysis was applied. Did you find the same sort of attitude with data? Do you think it is the same across sectors, or are life sciences particularly enlightened?

Dr Hudson: The position we have ended up with reflects a balance between the benefits and the risks. It obviously had a difficult passage and, had some of the proposed amendments succeeded, it perhaps would have been a bit risk averse.

Q156 Chair: What I am trying to get to is: do you think there is a different attitude in that area from that in medicines and devices?

Jonathan Mogford: If I may, it was actually that there was a different dynamic playing out at EU level affecting negotiations in that area. That is particularly the tension on data privacy and very strongly held views in certain other member states. That was what was playing out in the context of that particular negotiation. It was the levels of privacy to apply to data and data protection, whereas the risk-benefit approach is a particular feature of the medicines and devices legislation.

Q157 Derek Thomas: What are your organisation and the EMA able to do to help businesses, particularly SMEs, to navigate and influence the regulatory landscape and, more importantly, foster innovation?

Dr Hudson: We see it as one of our key tasks as a national agency to foster innovation to enable new products to get to the market for the benefit of public health. Certainly, that has been a major thrust of ours over the last few years. We do it in a number of ways. We have established an innovation office, where we are very happy to support maybe academics and SMEs, or it may be bigger companies—those developing novel products who are less familiar with the regulatory pathways—to help them navigate the regulatory pathways. We offer scientific advice to whoever wants it, whether companies, academics or whoever would like to take it, in terms of helping them with their development programme. We have quite a lot of guidance available to help people. We have helplines available—a clinical trials helpline, for example. We do workshops. The clinical trials unit has done workshops with some people in the academic community who work in advanced

therapies. We put a lot of effort into supporting the innovation agenda such that new products can be brought through for the benefit of public health. The EMA does similar sorts of things. It has an innovation task force; it has an SME office to support SMEs; it offers scientific advice and, again, is very willing to engage those who are developing novel products, to support them as much as possible to understand what is required of them.

Q158 Derek Thomas: Are you fairly pleased with the way SMEs engage in that and take up your service?

Dr Hudson: Yes, particularly the innovation office, where SMEs and small academic groups have engaged with us. That is working well.

Chair: Thank you. We are, unfortunately, a little tight for time, so we are going to have to move on to take evidence from the Minister, who has been sitting listening to the end of your evidence. Thank you very much for the evidence you have given us. It has been extremely helpful. However, we may have to write to you for a couple of points of clarification or to follow up for some more detail. As we have said, this is a complex area and we want to make sure that we get any commentary right, so I hope you will indulge us and write back to us so that we can make sure that we put out a timely comment. Thank you so much for your time today.

Examination of Witness

Witness: **George Freeman MP**, Parliamentary Under-Secretary of State for Life Sciences, Department for Business, Innovation and Skills and the Department of Health, gave evidence.

Q159 Chair: Minister, thank you very much for taking the time to come to speak to us today. We have had lukewarm evidence from different witnesses giving a sort of approval to the current situation in the EU for life sciences, with some comments about how things are working and about the focus on the need to implement existing regulation, but there have been some comments about how things could be improved. There has been quite a lot of mention of the tension between consistency and flexibility, especially in such an innovative landscape as life sciences. There has been quite a lot of concern about the need to get scientific advice embedded early enough in the legislative process, and concern that there is not enough horizon scanning at EU level to make sure that reforms and new legislation come in early enough. There has been particular comment about lack of responsiveness at a time of accelerating innovation. I know these are issues you picked up on yourself in your speech at the Commission, when you called for the EU to adopt an "enlightened regulatory system on the side of innovation." What does that mean, and what do you think is wrong with the system as it stands?

George Freeman: Chair, thank you for the chance to be cross-examined by your Committee. As your Committee is well aware, we are in a very exciting time for bioscience and for what I call the bio-economy, the appliance of science in three principal

markets—food, medicine and energy. Some of the most exciting technologies are in the convergence space where industrial biotech are tackling the problems and creating new markets and new opportunities; for example, there is use of the microbiome to break down agricultural waste and turn it into low carbon fuel, or the merger of food and medicine. Some extraordinarily exciting markets and opportunities are being opened up by the pace of biomedical science, which creates an economic opportunity for Europe and for the globe, and I rightly believe that this Government and the last Government are serious about investing in our ability to be part of and to contribute to that. But it challenges all our traditional regulatory silos.

This is not a unique problem in Europe or the UK. I was with the FDA last year, whose regulatory framework makes—let me put it this way: the FDA has an entire campus, with a whole street of buildings devoted to devices, to diagnostics, to drugs. When I asked them how they grapple with the extraordinary convergence of technology—we now have digital pills that monitor their own absorption and devices that release a drug in site-specific ways, in tissue-specific ways; these are merging and challenging all the traditional regulatory silos—the FDA agreed that this is a big challenge for us all in this sector. I believe Europe is a science powerhouse in the globe—you do not need to take it from me; the scientific evidence suggests it—and within that the UK is a science powerhouse. Potentially, these are very big markets for us, helping the world to feed, fuel and heal emerging and exploding populations. Europe has been a powerhouse in terms of regulation in much of the medical side, particularly in devices where, unusually, we have had a more competitive environment than the Americans and much support for it.

My warning to the Commission was triggered by two or three things. First is the rise of some interesting coalitions across the European political system, which is more given to coalitions, including some quite strident anti-capital, anti-science, anti-big science and big business coalitions. We have seen early signs of some quite radical anti-science thinking and I expressed some concern that if Europe wants to generate new jobs and new economies we need to be aware of that. Specifically in agriculture, on GM, when a company the size of BASF, a great German industrial major, closes its agricultural research plant and moves to America because of German opposition to the appliance of GM, it is a warning wake-up call to the European community.

I have been warning about some of these convergent technologies creating new markets, which we need to anticipate and be ahead of. It is an ongoing challenge, and it would be, of course, if we were outside the European Union; we would have to tackle the regulatory landscape. You have heard in all your evidence that ideally we want to be in a single market; I think everybody who has come to you has said that. Nobody wants to go to a fragmented, duplicatory and repatriated regulatory framework, which is what we had before the European Union. The UK is very influential in this field, in medicine and in agricultural science and technology; in medicine, as you have just heard from the MHRA, the European Medicines Agency is based in London, and the European Patent Office is in London. We have had some victories. There are some issues that we are dealing with right now and there are some that I am signalling are coming down the pipe that we need to prepare for. I would not pretend that this is easy—it is not—but I do not think it would be easy if we were out of the European Union and able to regulate for ourselves. The truth is that the 500 million consumer market in pharmaceuticals alone represents 55%-odd of our pharmaceutical exports, but if you look at digital health, genomics and the new

technologies that are emerging we could be—the UK in Europe—a powerhouse globally for those technologies. We need to be very alert.

I close by saying there is some good news. President Juncker has prioritised innovation and the importance not just of investing in science but applying that science for the creation of new products, companies and wealth. Commissioner Moedas has been very good to deal with. I went quickly to see him after his election and appointment to say, "Look, you really need to grip this," and all the signs are that it is steady as she goes; indeed in the February Council meeting there was some important deregulatory progress. There are ongoing battles, and I will happily talk you through some of those other battles if that is helpful.

Q160 Chair: You have pointed to some very entrenched cultural attitudes. You started with GM, which is a decades-long issue, but we have just been through data and privacy, which I do not think are put to bed. How confident are you that these sorts of problems and other systemic issues are things that we are going to be able to address at a pace that will keep up with the innovation that we are seeing already in the UK? It is accelerating exponentially. How confident are you, as life sciences Minister, in your engagement with the EU that we are going to be able to have the clout that we need in order to get the EU regulation that will enable that innovation rather than stifle it?

George Freeman: That is an excellent question. We all face this challenge internationally, so it is not just a UK-EU issue. The FDA in America is grappling with this and wondering how to respond to the pace of progress. My experience is short. I have only been in post for 18 months, with responsibility for agri-tech for nine months, in which time I have had three meetings with the Commission and with MEPs. My experience is that we are a much more pro-science country than, I think, every other, and we are recognised as a science leader, both on regulation and policy. A lot of the other countries look to us for a lead in this area, not least because of our regulatory expertise in the MHRA; we are also the only member state that has a chief scientific adviser in every Department and a Government science office of the sort that we have, so we are highly respected. That said, the European political structure moves quite slowly and, as you highlighted, it is a different mechanism with quite a lot of opportunity for lobbying to influence legislation very early in the process. It tends to incubate legislation. It does not have the clarity of our system, where the largest party in the Parliament of the day arrives with a mandate and gets to work, for better or worse, implementing it; it is a different model. In this area, we are influential because we are able to feed in very early. The economic pressure in Europe will drive politicians, and is driving them, to realise that this very fast growing sector can create the jobs of tomorrow, not just in Germany or in London, but in Italy, in Spain and across Europe. I have certainly experienced a lot of support from other countries for our message of enlightened regulation for 21st century European leadership, but I do not pretend it is easy; it is quite slow. The real challenge is the pace at which the technology is moving. We need to make sure that we are not just investing in science, which we do—this country gets back more than it puts into science—but converting that science into companies, growth and competitiveness. There are good signs, but we need to move faster.

Q161 Chair: What examples do you have of areas, regulatory or otherwise, where you are particularly frustrated, and you think there needs to be a change and you are working on that, and where do you think the EU are getting it right and we are going to support them in that and implement it well?

George Freeman: Where we would consider we have had some successes—I think your previous witnesses paid testament to this in their written and oral submissions—is on the data protection regulations, which were way off where we needed them to be; we have had quite a lot of wins and brought them back to a place where we think we can make them work. On the PRIME regulations, the EU accelerated approvals of medicines, which, as you know, is a subject close to my heart, we have been very influential in getting European progress, as we have on the co-ordination of national agencies. People are not talking about it down the Dog and Duck, but it is quite important stuff in terms of process.

There are two areas about which I am really concerned, which I signalled in my earlier report as a Back Bencher and have continued to pursue in government. One is in agriculture, particularly the trait-based genetic technologies in agriculture, which, for the benefit of those not on the Committee who are looking in from the outside, is using naturally occurring genetic mechanisms in plants and animals. They are perfectly natural; they occur naturally—this is not GM, moving a gene across a species. We are beginning to understand how we can up-regulate or down-regulate a naturally occurring genetic characteristic, so we can make a plant naturally more drought resistant than it otherwise is, or naturally more disease resistant. There is a massive danger, if that is regulated as GM—as genetic modification—that it would be taking a sledgehammer to crack a nut. Of course it needs to be properly regulated, but that would be a disaster for our competitiveness, and most of the agricultural industry is now looking at trait science as far more exciting than the old, crude, blunt GM. It will be a disaster if Europe does not anticipate that change. That is one I am really worried about.

The other area is genetic testing. As you know, we in this country have led the world in creating the genomics programme, the 100,000 genomes project. We are sequencing 100,000 entire genomes of NHS volunteers—patients—combining that with hospital data to form what I refer to as the NASA of genomic medicine. It will be the first at-scale database that allows us to start to understand how different genetic variations predispose us to disease and how we respond to drugs. Ultimately, that leads us to a place where we can give a newly born child a very quick genetic test and help the parents to adapt diet and lifestyle and avoid risks. In the device directive we are very cautious about, and strongly resisting, some moves. Some of it is religiously driven; it is in principle, a religious concern, not in the context of a medical ethical debate, just a pure religious opposition to using genetics in that way. I think most people in this country would think that helping with the earlier diagnosis of genetic disease was a benign use of genetic science. That is an area where we are absolutely steadfast.

Q162 Chair: I am going to have to let my colleagues grill you next, but I am going to read you some evidence we received from the Shelford Group in response to the comments that you have just made about important areas for innovation. They said: "EU regulations are always intended to protect patients...which is commendable. The drawback is that in doing so they often adopt a very conservative, risk-averse approach which can be particularly

problematic for research that is trying to push the boundaries of what is possible." Is that your experience?

George Freeman: I am working on the same evidence as you are. The science community that I work with and represent strongly want to remain in the European Union, for all the benefits of science investment and the community of science and inquiry, but they support the work we are doing to put in place a more enlightened and uniform regulatory environment. Those problems would not go away if we were to vote to leave the European Union and take control of our own regulations. We are still in a global market, and industry—the people investing the billions that we want to come here—will look at us outside that single market. All the evidence I have had, and industry has announced it loud and clear, is that they want us in that single market, but leading, as we are, on the battle for updated regulations to keep pace with the technology.

Q163 Chair: We have received that same evidence. My question, though, is what do you do to counter that? What is the effective recommendation? We have had recommendations on the need for a life sciences adviser on the science advisory mechanism—there is not one at the moment—and for horizon scanning, a mechanism for early stages. What is your recommendation for countering that risk aversion?

George Freeman: There are two. We need to continue to redouble our efforts and make this an area to which we attach very high priority, and to continue to be very loud in urging Europe at every level to allow us to help frame the regulatory environment. I would not claim to be a long expert on how the European Union works, but I think it works on principles, and I am specifically drawn by those who have said, "Look, Minister, the sensible thing would be to attract some principle, and build into the European Union's competitiveness agenda the principle that it does not just want to invest in science research, but that it has an in-principle aim to use that science to create economic growth." There is a difference between research and innovation. When I first raised the concerns, a number of people said to me, "The European Union invests huge amounts in bioscience," but that is in research. My point is that we also need to be looking at how we turn that science and research into companies, growth and jobs.

Q164 Dr Mathias: I think you may have answered this. I hear what you are saying about wanting the single market, which most scientists do, and it is interesting that you talk about the EU pace and the EU sledgehammers. Correct me—I am going to put words in your mouth—but you seem to be saying on balance that an EU-wide regulatory system is good for life sciences.

George Freeman: Yes.

Q165 Dr Mathias: Okay. Is there any area where national regulation would be better—probably in farming?

George Freeman: On genetics in agriculture, derogating is not ideal. We would much rather have a single market, but if that mainstream single market is going to be hostile,

there is an area where we might say we will at least have the freedom here, but it is far less good than having the whole market.

Chair: We are going to adjourn in order to vote. We will be back in about 15 minutes.

Sitting suspended for a Division in the House.

On resuming—

Chair: Can we resume the meeting? We will be joined by the rest of our members shortly, but in the meantime I call Chris Green.

Q166 Chris Green: Minister, can you provide some examples where the application of the precautionary principle has been inhibiting good practice at EU level?

George Freeman: Mr Green, you have had, in the very specific evidence, quite a lot of detailed examples that I will happily harvest and put in a proper list for you, if that is helpful. I will perhaps start by saying that part of the problem with these principles is that there is a danger they become enshrined and then become a prism that guides the interpretation of all subsequent and secondary measures in connected space. The real danger, if the European Union were to adopt the precautionary principle writ large, is that it is not proportionate. There is a danger that it may not be proportionate to the actual hazards, the risks that are trying to be legislated for. That principle has appeared in various areas, in some of the REACH—agrochemicals regulation—although not, I think, in medical genetics, where the concern is normally religious and ethical rather than really to do with specific medical risks. The issue is proportionality; it is trying to get it clear.

On neonicotinoids, with bees, for example, I do not know anybody, any farmer, anyone who loves the countryside or anybody who would want us to be in a situation where we are using agrochemicals in a way that is damaging to our great and humble bumble bee, which is responsible, by the way, for about £50 billion of value in the agri-chain through its services for pollination. We need to make sure when determining how dangerous that group of chemicals is, and whether they are causing the bee colony collapse, that we do proper science. That is not spraying neonicotinoids at very high dose at a bee in a laboratory; it is looking in the field, in wind and weather conditions in the real world, and seeing whether that chemical is having that effect. If it is, I do not think anyone would have any problem with legislation that rewards the market for coming up with an alternative; it is about the proportionality of the risk and the need to get good science to drive the regulation.

Q167 Chris Green: There are concerns about some decisions made in other parts of Europe. We have taken a different approach in terms of new nuclear, so we are looking forward to increasing our nuclear fleet, whereas Germany, because of the way they have looked at the evidence, the risks and everything else, are closing theirs down. You highlighted BASF closing down research in Germany. That must be suggestive that within the European Union there is too much caution, too much risk aversion. Being part of 28 countries, if other countries take a similar approach, doesn't that risk holding us back as well?

George Freeman: Potentially, but I would make the point that some of this is just democracy. Explaining complex science to a lay electorate is not easy. I genuinely think that, were we to come out of the European Union, we would still have to confront all these issues; we would still have to work out how our great agriculture industry is going to do crop protection; we would still have to work out how we keep our life sciences sector here. You, as a fellow parliamentarian, know that that is not straightforward and the electorate here are not necessarily intrinsically any more seized of the need for this than European electorates.

Q168 Chris Green: Although, as highlighted earlier, different countries across the European Union may have variations on ethics—equally moral—so you could end up with the lowest common denominator in that every nation's risk aversions come together to stop anything.

George Freeman: Yes, that is absolutely right, and I worry, when one looks at some of the protectionism that is beginning to appear in different parts of the world, that there is a real danger, when instinctive protectionism meets legislative activism, that we could easily put ourselves in the situation where the European Union does not become the powerhouse in the bio-economy of the 21st century; it retreats back into fragmented, religiously and culturally driven regulation. That would be terrible for the UK. We are in fact a relatively small consumer, particularly in the life sciences sector; for most of the companies I deal with in drug discovery, it is about 5% of the global market, and we are not, you will be delighted to know, as taxpayers, the highest price payer. The reasons that companies are coming here are partly our science base, the quality of our deep science, but also, increasingly, our regulatory expertise, the role of NICE, the data, the health economics and the genetics. But that is as a gateway into the European single market. I take your point that collectivising the regulatory effort does not solve it, but I do not think that coming out of a collective effort solves it either. It is hard. Certainly the message I have had from both science and industry is that we would strongly want to be in this noble endeavour of slow—sometimes frustratingly slow—regulatory progress rather than enjoying what might be a brief period of a feeling of liberation and then discovering we are still in a global market with a huge global regulatory burden that we have to tackle somehow.

Q169 Chris Green: Of course the global market is going at a pretty rapid pace and this steady approach may not deliver the best results, but what changes, perhaps in a general sense, would you like to see in EU legislation?

George Freeman: As I made clear to Commissioner Moedas in the letters and in the representations that we have been making—I would argue this is one of those areas where the Government's view, and the Cabinet's view, that we are better off in a reformed European Union influencing that reform is nowhere more true than here—there are a number of reforms I would like us to pursue and the European Union to look at seriously. One is a much stronger independent voice for science at the heart of policy making. I was concerned when Anne Glover, the—as it happened—British chief scientific officer was removed. I can accept that a panel of scientific advice could be very powerful, but if Europe is serious about the appliance of science, we need to build scientific advice into the heart of policy making. Every Department here has a chief scientist; every Department has a science office for advice. Secondly, I think this principle of the European Union in the

21st century, as part of the push for competitiveness—globalisation—that President Juncker is leading, has something tangible to say. We do not just want to invest a lot of money in science, powerful and important though that is; we also want to measure and hold ourselves to account on how successful it is in driving economic co-investment, job creation and company creation.

Q170 Chris Green: Something you highlighted earlier is the transition from excellent research to innovation, and there are substantial challenges in that regard. I suppose we do not want to get back on to that. In terms of taking a healthy attitude to risk as opposed to too much precautionary principle, who would you cite—which nations within the EU—as the champions for having a risky, innovative approach?

George Freeman: I would not call it a risky approach, but I think I know what you mean—having a more proportionate approach to risk in its policy framework for innovation. I genuinely think this country leads, and is viewed as leading, partly because of the expertise sitting behind me in the MHRA. We have allies in some of the economies that you would expect. Interestingly, the German industrial sector, despite some of the difficulties of German coalition politics, looks to us as setting a powerful lead, with the Dutch on agriculture and some bits of the French on medicine—very enlightened—particularly on our accelerated access pathway work. We have a lot of allies in Europe and, as ever, it is about working with them and setting a lead. I would just say this. One of the difficulties is that, if we look as though the reform agenda is being driven purely from the point of view of appeasing a certain element of the British electorate, it is harder to win and build consortiums for reform. You will have seen that in my work I have tried to say that I am very ambitious for the UK in Europe and ambitious for Europe in the world, but also impatient. If we reach out across Europe and signal our ambition for the European Union in the globe in this sector, and for Britain in it, we could build quite a powerful alliance and, indeed, if we vote to remain in, there is an opportunity for to us do that through this process.

Q171 Chris Green: On a slightly different note, what is your opinion of the scientific advice available to you, and how does it compare with that available to your counterparts in the other EU member states?

George Freeman: Seeing that it is sitting behind me, you will not be surprised to know that I think it is absolutely first class. Seriously, one of the great privileges of ministerial office in this country is that, if you are so minded, scientific advice is on tap in your Department, and indeed, through the office of the chief scientist and the Prime Minister's Council for Science and Technology, the science voice is very powerful in government.

Q172 Chris Green: Now you have built us up, how does it compare in the EU?

George Freeman: If like me, and I suspect like this Committee, you think science matters, part of what the European Union needs to do is build a copy of our model. It does not have to be an exact copy. If we are serious about science and the appliance of science—harnessing the benefits of science for a 21st century Europe—Europe needs to think, as indeed it is thinking, about how it gets that science voice right at the heart of both the

Commission and the Council. I am less versed in the byways of the European Parliament. Here, of course, Parliament is reasonably well served through the Parliamentary Office of Science and Technology, and I know this Committee has done a lot of work on that, but of course, where people are elected on a religious, ethical or cultural ticket of hostility to big science, no amount of briefing notes is going to change their view. This is an area where we lead. Across Europe, we are viewed as leading in our reliance on science and, despite there being very few qualified scientists, in our House at least—there are many more in the upper House—people have been impressed that on some of the vaccine work, the public health work, the genetics and the ethical debates, this Parliament is generally pretty heavily led by independent non-party political non-scientific advice. That is a challenge for Europe.

Q173 Chris Green: It is a challenge for Europe. You mentioned Professor Anne Glover. She was not sacked, but it is fair to say there was a certain cloud on her continuing in her role, particularly with reference to a certain area of research and developments on genetically modified food, which is a little unsettling if you want good, objective science to be offered at the highest level in the European Union. I appreciate you said before that you are not that familiar with all the details of the structures of scientific advice in Europe, but how do you think—

George Freeman: Within the Parliament.

Q174 Chris Green: In the Parliament, yes, but do you have a view of how the scientific advice mechanism is performing? Do you have a view on that?

George Freeman: Of course, it is being changed and I welcome President Juncker's emphasis on wanting to beef up the scientific advice. We were concerned at first that the reforms, whatever their intention, might have the opposite effect. The jury is out at the moment, but the indications of intent are certainly all in the right direction. There are different models and I hope that the scientific advisory board has a proper role, with teeth, to advise European institutions proactively. It is very important in this field that advice is on stream before something hits the front pages of, in this country, the *Daily Mail*, and in Germany whatever the newspaper is. It is important that parliamentarians and Ministers, and indeed the Commission, are alerted early to the direction of travel—where technology is heading. If you put that together with a principle that says Europe wants to harness the bio-economy for job creation, you would have a structure in which we could have a lot of confidence.

Q175 Chair: Minister, one concern that we had expressed to us was that the scientific advice mechanism has no life sciences expert on it. Is this something that the Government are lobbying to reform?

George Freeman: We have made representations that we think this sector, both life science defined as biomedical science and, as I tend to think of it, as a broader bioscience platform—food, medicine, energy, the industrial application of bioscience—is crucial for Europe's competitiveness, for delivering all the things that the February Council set out in terms of deregulation, competitiveness and globalisation. Yes, we are making

representations that we want to see, and believe it is in Europe's best interests to have, a strong voice in this broader bio-economy space. Indeed, I will be in Warsaw with the Secretary of State for Business this Friday with other Ministers on a summit on the bio-economy—the fourth industrial revolution—so we are actively pursuing it.

Q176 Chair: That voice—should it be someone on the mechanism or something else?

George Freeman: I am sorry, which?

Q177 Chair: Should that voice be getting an expert on to the scientific advice mechanism, somebody to represent that sector on the mechanism, because apparently they are under-represented at the moment?

George Freeman: Certainly through that mechanism. As to whether it has to be somebody with a particular CV, I would not be so worried, but there needs to be a strong voice somewhere in that.

Chair: Someone with experience, okay.

Q178 Jim Dowd: Thank you, Minister, for joining us today. I want to look briefly at the benefits or disbenefits of harmonised EU regulation. You have made it pretty clear already that you feel there are far more pros than cons. I would just say in passing, given what you said about GMOs, that the previous Committee did an inquiry into GMOs at EU level and found it decidedly disharmonious in the way that was dealt with. We got the strong impression that it was not just the science that was leading the conclusion they reached. Do you feel that any of the benefits of EU-wide regulation have come at too high a price for either the EU broadly or the UK in particular?

George Freeman: That is an interesting and very difficult question. How does one value too high a price? One has to try to put a value—a metric—on those intangibles, which is very difficult to do. I do not know, and I do not want to put words in your mouth, but I suppose you are inviting me to speculate about whether maybe in an area like the GM regulations, by derogating back to the UK in order to get the regulatory landscape that we wanted, we paid too high a price in excluding ourselves from the single market. I would say, in an ideal world, yes, that was absolutely very much our last position. It would be far better to have a single market of 500 million consumers with a benign framework than a single market from which we have had to derogate because the regulation does not suit us, which also then undermines our ability to be an attractive location for international investment. As a good example, we have reached a point where—

Q179 Jim Dowd: Does it do that? If what we discovered, or felt we discovered, with the GM experience in the EU was that there were those who were just implacably opposed—it did not matter what the science said as they just were not going to have it—and there were those who, rather like ourselves, wanted more, it may have hobbled our position with regard to the rest of the EU, but perhaps we could have persuaded BASF to come here rather than go to the US.

George Freeman: If you are asking me whether I am ambitious for the UK in Europe, the answer is, yes, absolutely. Indeed, I have told the European Commission as much; I want us to be at the arrowhead of the 21st century bio-economy, the place that companies come to first because of our deep science, our regulatory enlightenment and our progressive pro-science framework, but to use it as a gateway into the European single market. In those core primary markets of food, medicine and energy there is huge opportunity for growth across, particularly, eastern Europe, but the derogation that we have reluctantly had to agree on GM—we were free to do academic field trials anyway, free to do commercial crops, but the UK is a very small market really—has sent a signal that Europe is hostile, and it is far better for us to put in place a framework that can carry credibility across the whole continent. The irony of this, of course, as I discovered when I was chairman of the all-party group on agricultural science, is that around the rest of the world agricultural genetics is exploding and it is not us in Europe who are leading any more; it is countries in Africa and the Latin American countries—Brazil, for example. That references the early point I made about trait science. Actually, the first generation, if you like, GM1.0, was very crude, particularly the original Monsanto monoculture model: "Spray everything that dies apart from the thing we have protected." I do not think anyone thinks that is a particularly progressive way of doing 21st century agriculture, but what we are now seeing is really elegant GM2.0—the very subtle use of naturally occurring traits. That is incredibly exciting science, and somehow we have to find a way through Parliaments and commissions to explain that to electorates and win their trust in an appropriate regulatory framework. It would be quite difficult in this country as well, or not necessarily that much easier.

Q180 Jim Dowd: If I understood you correctly, you implied that the regulatory framework we would have, if it was not for the EU-wide one, would not be radically different from the one we have within the EU. Are there any areas where you think it might be beneficial for it to be different?

George Freeman: I am sorry, I may not have been clear. Ours is quite different. Under this derogation, if the rest of Europe says it does not want to grow any GM crops, we have the freedom to say that we can. My point is that, okay, we have that freedom and we could say that, but I do not see industry queueing up wanting to come and do GM crops here, given that the gateway that we would have been into the European market is now of very little value; the European market is shut. I think you are asking me whether I can think of other areas where, by doing it outside, there is a benefit for us. I genuinely cannot, because, first, as this Committee knows better than anyone, science works through networks of collaborative work across universities and institutes in Europe. We benefit hugely from being part of the framework funding and the 2020 funding streams, things like the innovative medicines initiative—really good initiatives that take the very best across Europe—and, from a deep science point of view, I think you have heard that your scientists would absolutely not want to be in any way semi-detached from those European funding mechanisms, where we get back more than we put in. In terms of the R and D, and the regulatory environment, the truth is that in this rapidly globalising world, we are quite a small market as a consumer market ourselves. For most of the companies I speak to, the strategic significance is us as a gateway into the European single market. As I think you heard in your representations, the challenge is to continue to lead and drive benign regulation in Europe rather than to think that by coming out we suddenly escape that

challenge and liberate ourselves to attract lots of investment. We would actually be a much smaller market.

Q181 Derek Thomas: In a minute, we will talk a bit about whether you think we should stay in the EU or not; I am not sure whether you have been that clear. How influential is the UK Government when it comes to shaping EU policy making for the life sciences? How open to influence by our partners are you?

George Freeman: I missed the last bit.

Q182 Derek Thomas: How open to influence by our EU partners are you to policy making around life sciences?

George Freeman: Very. Which is why, in the relatively short period that I have been in this post, I have been to Copenhagen, Berlin, Brussels, Milan and Geneva to meet both companies and policy makers. It links to the earlier point I made. If we are serious about wanting Europe to be a powerhouse for bioscience in the 21st century, it seems that the right way to negotiate that is to build a coalition of other like-minded scientists, companies and policy makers who support us. In some ways the unfortunate dynamic of the much bigger sovereignty reform in the referendum is that while in some ways it is helpful, because it allows us or me to say, "Look, the British public are about to make a choice about whether this is in their interest, so we need to be able to show that we are making progress," equally it pits us against the rest of Europe, and in this agenda we need to be building coalitions of interest across, which is how, as I see it, influence is developed and wielded in the corridors of the European Union.

Q183 Derek Thomas: This is a question about what you believe is the best future for the UK. To what extent does UK influence depend on its continued membership of the EU? Is it absolutely essential that we remain in the EU in order to have the kind of influence we have now?

George Freeman: I will give you my own view, which is that I absolutely think we are better off in a reformed EU, but your question really is what would happen to our regulatory influence if we were out. It is a very good question. You could ask that question about an awful lot of the issues that the public are being invited on 23 June to think are easy. It is not clear, but given all the issues we have just discussed, in a European political economy in which there is, particularly in Germany and some bits of the Mediterranean countries, some political, ethical and religious concern about biotechnology, it is quite difficult to conceive of Britain, having voted to leave the European Union and the European single market, being invited to have a very strong regulatory input in those markets. I would expect to get a phone call very quickly after 23 June saying, "Thank you for your advice, Minister, on how we might build an enlightened regulatory framework. Now that you have left the European Union, I don't think we need it. Call us if you want to come and launch products here." I genuinely do not underestimate the battle of getting benign regulation inside Europe or, frankly, in this country. Walking into Parliament one day and announcing what I think we are going to have to get to in terms of data and genetics and biosciences is not easy, but I think we would be in a much weaker position,

and I do not believe the rest of the European Union would welcome, appreciate or invite our advice if we had just voted to leave.

Q184 Derek Thomas: Could I expand on that? You may have already answered this. Could the UK exert comparable influence by acting as an exemplar in formulating timely and appropriate regulation in the life sciences? For example, if it is so good now and we are such a good example of how we can progress in good life science regulation, would we be better placed independently to lead the direction and where we want to be?

George Freeman: There are two bits in that. I think "so good now" were your words rather than mine—

Q185 Derek Thomas: Yes. You have been so positive about the whole thing.

George Freeman: I have tried to be realistic as well. Am I happy that the European Union is a perfectly seamless, enlightened and progressive pro-science regulatory body? No, I am not, but you are basically saying, if it is so good now, why could we not build nirvana here ourselves, liberated from the clumsiness of having to negotiate with everyone else? There are two bits to that. The first is whether we could pass the necessary legislation in Parliament—leave aside the complexities of the devolved Assemblies for a minute; the Scots have some interesting views on GM as well, but we will leave aside the tensions in a devolving UK as to quite how that works.

It may seem distant in the corridors of Europe—technocratic, a bit boring and quite dry—but I do not think, in bringing it to the Floor of the House of Commons in a liberated UK outside the EU, that we are suddenly going to find a willing electorate cheering us on, even if excited by the prospects of this miracle of overnight sovereignty. I do not see people out in the streets, even in a relatively pro-science UK. This is quite difficult. Even in our very heavily science-advised Government, and with quite heavy cross-party support for science, the debates in Parliament are not straightforward. I do not think that suddenly the gates would all swing open and we would be able to build easily and quickly a very pro-science regulatory environment. Even if we did, we would pay a huge price—in answer to Mr Dowd's point earlier—because a lot of companies would say that even half of that progress, or a third of it in a European single market, would be far more valuable to them: "Well done, Minister. The UK now looks like a very attractive but very small insular beacon of pro-science regulation. The issue for us is that market that you have just come out of."

That goes, genuinely, to your point earlier, Mr Dowd, about the price to pay. We are in a very global sector, with huge amounts, billions, being invested. It is not a question of a small market with a benign regulatory framework unlocking the money. The global sector needs large markets to justify the huge amounts that are being expended. The average medicine now costs about 15 years and $2 billion. The UK represents 5%, for most of the pharmaceutical companies I talk to, of the global market. Our prices are some of the lowest. I just do not see that a regulatory improvement is suddenly going to make us a very attractive market. It is part of being the gateway into the single market that is very attractive.

Q186 Derek Thomas: I would agree probably with the second bit, but am I right in saying, or right in hearing, that it is better to farm off legislation and regulation to the EU because we know we could not get it passed in our own democratic system here?

George Freeman: No, not at all. The premise of your question was, "If we are so good at this, Minister, and it is slow in the negotiated corridors of Europe, wouldn't it be better to repatriate"—I am paraphrasing—"and then we can form a regulatory nirvana here that would attract billions?" I just make the point that I do not think one or two is easy. I do not think suddenly dealing with the issues that you have heard my colleagues at the MHRA set out on medical devices, genetic testing and data is easy, even in our relatively pro-science country. Secondly, even if we did, I do not see industry saying they would invest billions and come to Britain, because we are still quite a small market.

Q187 Chair: I have never heard anyone call the Houses of Parliament boring or dry. I want to try to understand the value of having one single market where there is harmonisation of research all the way to market, essentially, of the regulatory environment because a lot of the larger life sciences, and even the smaller ones, will want to test their medicines or their products in an environment where they know they are getting the regulations right to be able to market in that environment. If we were to come out and perhaps provide a very pro-science regulatory environment, but a company wanted to market within Europe, what kind of system would that create, do you think?

George Freeman: It would be extremely problematic for certainly two, probably three, reasons. First, as you have heard in evidence on the devices, on some of the genetic testing and some of the issues around medicines approval, the landscape is changing very fast. The old model of drug discovery was long chain—10 or 15 years, $1 billion or $2 billion, one drug, one size fits all; you prove it works, that it is safe and has efficacy, and then it is approved everywhere. Increasingly, we are discovering, because of the speed of the science, that using data, using genetics, we can begin to predict which patients are going to respond and get particular diseases in different ways. Markets are fragmenting. What yesterday was one disease is now becoming a bundle of rare diseases. For all those reasons, there are some very interesting regulatory implications, and reimbursement implications, because we are getting to a point where companies are going to be able to come with a genomic biomarker and some data and say, "We know this drug will work in these patients." We are going to see new models of reimbursement flow from that.

In devices, we are going to see extraordinary technological convergences and these—particularly the stratification, as it is referred to, the personalisation, of medicine—make the size of the market even more important. I have companies coming with a drug for a rare disease —we had one this week—for 150 children. The cost of producing that drug for the UK for 150 children is completely prohibitive. Once you start to look at it over the whole of the European Union—500 million people—it is quite powerful, because then you can start to amortise the cost over a much larger area. If we can start to do genetics together and develop common protocols for what genetic tests look like, for what is a valid genomic biomarker, and for what the data evidence is—you can see where I am heading—those common platforms will allow our citizens to get the benefit of greater investment. By cutting ourselves off, we reduce all our numbers. Our main advantage as a

pharmaceutical market at the moment—we are under quite a lot of pressure—is not the price we pay but the quality of leadership in that new model of reimbursement. To cut ourselves off from the European Union would be to take away a major advantage of people coming to invest here. Many of the companies I speak to say, "We are coming here, Minister, because for us it is the global gateway into the European market, and your influence in terms of regulation and the deep science on this new landscape is very important for us."

Q188 Chair: But, to understand, it is not just access to the market economically; it is access for the company to be able to find the necessary cohort, run the clinical trial, get approval to market to multiple countries within that market in one go and then continue marketing throughout those countries, very simply. That is the point, isn't it?

George Freeman: Exactly, and—

Chair: From end to end, essentially.

George Freeman: Yes. That is why the success we have had on data and on the clinical trials and other areas is really important.

Chair: Thank you.

Q189 Jim Dowd: We heard from an earlier witness, from Cancer Research UK, before you were here, Minister, that, while they had a reasonable working relationship with the Government, they felt it was always them having to make representations to Government about issues they had discovered that would affect their activities adversely, and that the Government were not just not very good, but did not actually come to them at all, in an active sense, and say, "We've got this. This is in the pipeline. What are your views on it?" I assume by extension that, although that was a charity, universities and businesses would probably have a similar experience. Is there more the Government can do to alert those active in the life sciences sector to issues they feel might affect them coming out of—

George Freeman: Were those points with reference to the UK Government or the European Government?

Jim Dowd: The UK Government.

George Freeman: In some ways I am quite surprised, but it speaks to a change that is going on; the creation of this first ministerial post for life sciences is about anticipating that. The reason I say that is that there is a profound change in the way medicines are being developed, and devices and diagnostics. Crudely summarised, it is a shift from a very long and siloed model, from deep science, spin-outs, funding A, B and C rounds and partnering with pharma, through to trials, pre-clinical phase 1, 2, 3 and 4, to develop a product and bring it back to the patient waiting at the end. In the new model, research is becoming much more embedded with patients and in our research hospitals, using tissues, genomics and data to inform right at the beginning. That is why, for example, AstraZeneca recently shifted their brand new old model R and D facility in Cheshire to Cambridge

where they have embedded in the hospital, on the Addenbrooke's campus. That is the big change that is going on in the sector.

What flows from that is that the medical research charities—no one more than CRUK, who have led the way, as has cancer, as a disease area—have led the role of genomics, profiling and data. CRUK has now become a major strategic leader of research and patient voice. It is partly for that reason that I recently went up to open CRUK's new laboratory with AstraZeneca. This is not CRUK sponsoring or giving money for some research; this is them as a strategic co-funder of the laboratory, their staff alongside AZ. They are beginning to set the whole protocol for disease and treatment. It is a quiet revolution that I hugely welcome, and in the short time I have been in this post I have been to the charitable sector, to the AMRC, and said to them that, in this new landscape of 21st century life sciences sector, the charity sector comes to the top table alongside pharma; they are every bit as important. The AMRC—Association of Medical Research Charities—now spends £1.4 billion a year on medical research. They are a really big player in this, and in a landscape where patient consent on tissues and data and research medicine will get more and more important, those charities have a bigger and bigger role. In some ways I am surprised—I do not know who you spoke to at CRUK; I do not mean it like that—and I obviously have to do a bit better to signal to them that I am very much seized of the need for them particularly, and other charities like them, to play an ever bigger role. Indeed, they have been instrumental in the cancer strategy, and in a lot of our work in DH and with NHS England on cancer, and I think we are going to see that more broadly in other disease areas.

Q190 Jim Dowd: You can find out who it was from CRUK from the minutes; they are freely available. I do not think I misinterpreted what was said to us. On the realignment of the approach to the whole subject, the other questions I had were on horizon scanning and the Government's response to scientific advice, or the speed of Government response. Would the new arrangement that you describe, or the new way of assessing matters, impact on both of those areas, on horizon scanning and reacting to scientific advice to Government?

George Freeman: It is a good question. You will be aware that I am putting in place a series of reforms to try to anticipate the way in which technology is changing, the way medical innovation comes to our system and how we assess, adopt and reimburse. That is what the accelerated access review that I have launched is really all about. In some ways it is about harnessing a very unique UK leadership in genomics and informatics. No other country on earth has a single-payer comprehensive healthcare system, with a £1 billion a year National Institute for Health Research clinical infrastructure underpinning it. In some respects it is part of a global response. The FDA has launched its critical path breakthrough designation scheme, and, as we have heard, the European Medicines Agency is looking at accelerating its pathways, working very closely with us. Part of what that will require us to do, and is requiring us to do, is a different form of horizon scanning, as you say. Essentially, the healthcare system goes from being a passive recipient of innovation, waiting for innovators to bring us new devices, diagnostics and drugs, to being a partner able to say to industry, "We know that in this new landscape you need to work with our tissues, with our data and with our patients, and we want to make those facilities available to you as a partner in a new deal, in a new relationship." We are in the process of looking at how we can do it better, looking out at the pipeline, at the innovations that are coming,

instead of what we would normally do, which is waiting for them to come and knock on the door with a price proposal. It is to reach out and say, "Look, come and work with us. Can we partner with you?" That is exactly what the accelerated access review is looking at.

In terms of the European Union, all the evidence is that Europe, the EMA and others are looking at our work on NICE and on accelerated access as leading. I am genuinely excited that this is an area where, if we remain in the European Union, we may be able to strike a blow and make Europe a more attractive market than America, particularly given some of the growing hostility politically towards the pharmaceutical industry in America. We have a chance—with genomics, informatics and a collective infrastructure in Europe—to make Europe again a leader in drug discovery.

Q191 Jim Dowd: Finally, one of the most tired and wearisome clichés attached to matters relating to EU directives is gold-plating. Do you plead guilty to such a charge on the question of life sciences directives?

George Freeman: Not on my watch; I sincerely hope not. If your Committee comes across any examples of unnecessary regulatory activism through my arm's length bodies or agencies, please let me know. As you know, the Government have launched a very serious, enshrined commitment to regulation—one in, three out—and you will be reassured to know that a number of the measures that I am putting through have to go through regulatory impact assessments; things that I thought were completely benign have to be scrutinised, rightly, so there is a new rigour in Government. Certainly I would be very disappointed if there was unnecessary gold-plating in the ALBs in my field.

There are two sides to gold-plating: there are specific and unnecessary measures and then there is delay. One of the truths in this sector is that the most profound cost is the time cost of money, and that is why the central reform I am trying to put in place is to take time, cost and risk out of the development pathway. If we can take time, cost and risk out, we are able to unlock a new deal with industry. The thing that makes drugs so expensive is the phenomenal time, the extraordinary failure rate and the very high cost—sunk cost—of failure that they require to amortise back from a successful product. If we can take time, cost and risk out of the pathway, we will reduce the cost for industry substantially. The thing that I am pushing all the ALBs on is time: can we take time out? I think sometimes, dare I say it, with the great British civil service, and in fact quite lot of our public sector bodies, that we give them a statutory time limit and say they have to do it within 90 days, and quite lot of things get done on day 89. Whereas we have had some stunning examples, for example, the—

Q192 Jim Dowd: Only give them 30 days then.

George Freeman: Or 30, yes. In the Ebola crisis, agencies were able to move really fast. I am not suggesting we can always do that, but we can help take time out of this pathway, which is a form of gold-plating, if you like, because time is money.

Q193 Chair: Minister, we accept your challenge as the official life sciences gold-plating ombudsman, but I have a particular question to put to you. We are hotly anticipating the accelerated access review. We have been told to expect it in April 2016. We are in April 2016. Can you tell me when it might be published? We are on the edge of our seats.

George Freeman: Chair, you and me both. As you know, it is an independent review. I set the terms of reference and, genuinely, am waiting for them to come back to me. They have elicited a phenomenal response from industry, charities and others—I would not use the word "overwhelmed"—and have signalled that, in many ways, the thing has exploded under them. It is not just drugs; it is devices and diagnostics. To cut a long story short, I have signalled to them not to feel rushed by that timetable burden. I want them to do the job properly and come back with properly worked-out recommendations and, to be honest, while everybody here is beginning to focus on other things—23 June—if they take a bit more time to get it in the form they want it in, that is time well spent.

Q194 Chair: You might expect it to be after the referendum.

George Freeman: I am not sure about that. The latest advice I have had is that they are working on a final draft. It may not be the end of April, but it may be May or June. I am certainly keen to get hold of these recommendations quickly, and I think, in many ways, it is an ongoing process. I did not want it to be one final report—job done—but I want them to take the time to make sure it is clear. There is an awful lot hanging on it. The only signal I have given is not to feel bound by its having to be by 27 April, but to get it right.

Q195 Chair: Minister, you have been very generous with your time today. We are very grateful to you. We were held up by a vote, but, nevertheless, you stayed beyond your time. However, we are very excited about the outcomes of the accelerated access review and I hope that you will return to talk to us about that when it is published so that we can understand the true implications and opportunities it will represent.

George Freeman: Honestly, nothing would give me more pleasure.

Chair: Excellent. Thank you very much, Minister. I call this meeting to an end.