

# Exiting the European Union Committee

## Oral evidence: The progress of the UK's negotiations on EU withdrawal, HC 372

Wednesday 19 June 2019

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Members present: Hilary Benn (Chair); Joanna Cherry; Mr Jonathan Djanogly; Wera Hobhouse; Jeremy Lefroy; Craig Mackinlay; Mr Pat McFadden; Mr Jacob Rees-Mogg; Stephen Timms; Mr John Whittingdale; Sammy Wilson.

Questions 4341-4434

### Witnesses

I: Nishma Patel, Chemicals Policy Director, Chemical Industries Association, Steve Bates, Chief Executive, BioIndustry Association, and Martin Sawyer, Executive Director, Healthcare Distribution Association.

II: Vivienne Stern Director, Universities UK International, Dr Beth Thompson MBE, Head of Policy (UK and EU), Wellcome Trust, and Professor Tim Wheeler, International Director, UK Research and Innovation.

## Examination of witnesses

Witnesses: Nishma Patel, Steve Bates and Martin Sawyer.

Q4341 **Chair:** On behalf of the Committee, I thank our first panel of witnesses for coming to give evidence to us this morning. As ever, we have quite a lot of ground to cover, so if answers are as succinct as possible, that will enable us to get through what we need to—we have another panel this morning. I welcome Nishma Patel, chemicals policy director from the Chemical Industries Association, Steve Bates, chief executive of the BioIndustry Association, and Martin Sawyer, executive director of the Healthcare Distribution Association. If you could answer the first question in a sentence, that would be helpful.

As you will be aware, at the moment a debate is going on about what should happen on 31 October. Some of the people who wish to be the next Prime Minister are arguing that, if necessary, we should leave the European Union on 31 October without a deal, on a no-deal Brexit. Could you summarise for us what your reaction is to that suggestion? What would a no-deal Brexit on 31 October mean to the businesses that you represent?

**Nishma Patel:** For the Chemical Industries Association, our messages on a no-deal Brexit have been consistent. It will mean that businesses face continuous price rises and costs. There will be inefficiencies. The chemical industry is a just-in-time industry, so there will be an impact on getting material in and out of the country.

**Steve Bates:** A disorderly no-deal Brexit will negatively impact patients, public health and the life science sector.

**Martin Sawyer:** As a trade association representing the distributors within the UK, we would expect medicine shortages and a lot of price rises for the NHS to happen pretty quickly, and some shortages in most constituencies around the UK for sure.

Q4342 **Chair:** Right, okay. Starting with medicines, because the public has learnt during the last three years a great deal about how cars are made and how the motor industry works—imports with just-in-time, just-in-sequence delivery—it would be helpful if you could briefly describe how medicines are made, supplied and distributed in the UK. I will start with you, Mr Bates.

**Steve Bates:** Since 2016, we have worked with the ABPI on the core policy issues around this. I am going to oversimplify it, so apologies for that. If you think about supply chains for medicines, often they are regionally integrated. You will have a supply chain for America, perhaps one for Asia and one for Europe. You will have an active pharmaceutical ingredient made in one place, perhaps the UK. That will then be formulated—put into a formulation—perhaps in another place, like Germany. That can then be put into a finished product and packed—put in



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a pill packet—in another place. That then goes through a regulated process again of labelling, and will then go to a distribution hub and be distributed out.

There are many stages of manufacture. It is different for biological medicines, which are often used for cancer in hospitals, because they are made very differently, but there are regulatory steps in every single one of those places, and there are trade and tariff implications, short and long term, in each of those spaces. Changing any of this at speed is very difficult, because it is factories that are regulated by international regulators. The idea that new things can be done in the timeframes that we are looking at is impossible.

Q4343 **Chair:** Impossible?

**Steve Bates:** Building a regulated manufacturing process would, and does, take years. We are looking at, I think, 130-odd days until the October deadline. Moving things at that pace is undoable.

**Martin Sawyer:** Once the medicine—the finished product—is in a big warehouse in the UK, that is called pre-wholesaling. The manufacturer still has control and ownership of that product. They then release it to my members. My members are wholesalers and distributors. We represent 10 companies that distribute 2.5 billion packs of medicines a year through the four countries of the UK. The NHS largely pays for this. The 10 companies have 54 warehouses around the UK. The bigger warehouses send products to the smaller warehouses, which are local ones, so they can work in a region or a locality, because 250,000 van deliveries a week go to all the pharmacies, doctors and hospitals in the UK run by the NHS and the private sector. They do that twice a day.

It is a just-in-time service. We are acting as the backroom for the pharmacy, because pharmacies are small. They may have a stock for the patient who walks in, but they need the product again in the afternoon to replenish, so we do deliveries in the afternoon. That is how the system works, and it is an integrated, flexible and resilient supply chain that has survived much, but if we do not get the product into the UK in the first place, then we have only about two weeks' stock in the wholesale sector, just so you know, that can then go to pharmacies and hospitals at any one time.

**Steve Bates:** A final point on scale: 45 million medicines packs are exported from the UK to the EU every month, and 37 million packs move from the EU to the UK.

Q4344 **Chair:** On the 45 million packs that go from the UK to the EU, at the moment you can make something in the UK and test it and, as long as it meets the EU standard, it is free to be distributed throughout. Am I right in thinking that the day after a no-deal Brexit any testing done in the UK would no longer be recognised by the other 27 member states?

**Steve Bates:** The European Medicines Agency's ask of the regulatory position for pharmaceuticals has been to ensure that qualified personal

release is done within the EU27. Because there has been some time on this, most of the products that are on the market for the EU will have a QP legally available in the EU. Much of that has moved.

**Q4345 Chair:** So they have shifted that, but does that include the physical testing?

**Steve Bates:** It doesn't include the physical testing; it is the QP release that the EMA has asked for. I think that that is largely there. The thing that is important to understand is that if those trucks are going through Calais, the question of how Calais works becomes a question, because it is not simply a QP release issue. You may have customs and other checks there. I think that there are big challenges for EU patients. It depends a little on how the EU27 and France choose to operate the border. That would be my concern on that one.

**Q4346 Chair:** Mr Sawyer, you said that there would be medicine shortages. That is a pretty serious statement to make. The Government have said that we have done a lot of no-deal planning. We have asked people to hold six weeks' stock, and so forth. There has been a great deal of focus on medicines that have a very short shelf life, and may need to be held in temperature-controlled conditions. How extensive is that? Might there be shortages in all sorts of medicines?

**Martin Sawyer:** There are a lot of unknowns here. There are currently about 100 or 150 medicines every day that are in short supply. The supply chain works to try to fill those gaps. You might go into a pharmacy and be prescribed a medicine and they will say to come back the next day. We can usually get most medicines within 24 hours. They may be in the wrong place—they may be in Newcastle when they should be in Southampton.

There are a lot of patient conditions where there may only be 2,000 people in the UK who require a medicine—things like motor neurone disease, or there was the EpiPen issue last year, which you probably recall. The other challenge is that there might be a global problem. They may only be manufactured on a couple of sites. There may be a regulatory issue. There may be a fire at a factory, or one may be closed down. We have had a lot of that.

So there is a shortage at any one time anyway, but this is to overlay that. Some products might have a short shelf life and may need to be refrigerated the whole time when they are coming across from the EU—50% of the medicines in our warehouses have touched the EU at some point, even though they may come from other countries outside of the EU. It is about trying to overlay on top of what normally happens.

We would expect some critical shortage probably in the lower volume medicines, not the everyday ones, which are stockpiled very high. A manufacturer may produce only one product, and it may be that product is for a small patient base and has to be managed very carefully. The UK is not an expensive market. It is very cheap. If there is a generic product, not one on patent, we believe they are much more likely to be more volatile, because they are dependent on prices. Unless prices go up, the

medicine might not come to the UK. The manufacturer will sometimes not provide it to the UK if the prices are too low.

**Q4347 Chair:** When you talk to them, do the NHS—NHS England—and the Department of Health and Social Care accept that there will be medicine shortages?

**Martin Sawyer:** I can't criticise the preparation that the Department has done. The Department of Health and Social Care and the NHS have done fantastic planning. We have been talking to them for a year, almost weekly. They have already set up a shortages team within the NHS, since January. Certainly, on the communications and the understanding of what might happen, they are right up there, and I have nothing to complain about. It is just that we don't know.

With EpiPen last year, there was a factory that had a fire and suddenly that was a front-page issue, and it was really serious. In medicines, you have to get it 100% right. It is not like supermarket shelves or car parks. You can delay that. You can't delay it for some critical medicines, so that is our concern.

**Steve Bates:** I echo Martin's points around the preparedness of NHS England. I think they have done a good job. The question that is difficult for us to understand is, beyond the normal level of stock-outs and challenges within the supply chain, how much additional will there be from the Brexit challenge? There are a whole host of new unknowns that sit within that, on top of an existing system, which does work robustly and knows how to cope with things like Christmas, where there are stock-ups and stock-downs, and has worked through the London Olympics and the challenges of road closures and things like that. There is some contingency. The question that is hard to judge is what it would look like on top of that.

**Q4348 Chair:** The Government entered into some ferry contracts to provide additional transport capacity across the Channel, depending on delays. Those have now been finished. We are, as you said, 120 days away or so. How important would new ferry capacity through new contracts be, to try to mitigate the risks that you have just been describing?

**Steve Bates:** They were fundamentally important as part of the planning for the last deadline. Then, the Government wrote to companies 113 days in advance saying that border assumptions were being revised to a worst position and companies were told to expect delays for up to six months on the short straits, therefore stockpiles needed to be supplemented and they were working to ensure that there was sufficient roll-on/roll-off freight capacity. Today, we are 134 days from a possible future deadline. As I understand it, the Conservative leadership contest result isn't due until the week commencing 22 July. That will be 101 days to a possible no deal. We saw the challenges last time in the procurement and supply of additional ferry capacity and additional routes. It is getting very short and we are getting less time this time, but no guidance has yet been published to companies on what the plans are for ferries this time round.



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Q4349 **Chair:** Finally from me, Ms Patel, the Government have done their long-term analysis of leaving the European Union. The manufactured goods sector is estimated to be the most affected sector in a modelled no-deal scenario. The Government said that under that scenario, GVA of the chemicals, pharmaceuticals, rubber and plastics products sector will fall by over 20%, compared with today. Is that an analysis that you as the CIA share?

**Nishma Patel:** Absolutely—

Q4350 **Chair:** You do? Right. A 20% fall in GVA is a pretty substantial amount, is it not?

**Nishma Patel:** It is.

Q4351 **Chair:** So the sector, looking at that and thinking about a no-deal Brexit, says what?

**Nishma Patel:** At the moment, the sector is doing all it can to plan for no deal, but the reality is that, in all that preparedness and readiness in their planning, I don't think it is possible for them to compute how no deal will pan out. They will do what they can to make sure that we have stockpiles in place. Not only do chemical manufacturing and goods go into some of the everyday essentials that Steve and Martin talked about and some of the critical national sectors here in the UK, but it is important to recognise that the industry itself is its own biggest customer. Our goods will go to and from the European Union a number of times before hitting any other sector. Any knock-on effect, whether delays at ports or getting goods across the UK, will have an impact on the sector itself before it has one on the sectors that we provide into.

Q4352 **Chair:** How anxious are the chemical companies about a no-deal Brexit?

**Nishma Patel:** They are very anxious, but they are doing all they can to prepare for no deal. Talking to some of our company members at the moment, they are very much looking at planning for no deal, as much as they possibly can.

**Chair:** Thank you very much indeed.

Q4353 **Jeremy Lefroy:** Following on from that, my question arises from a comment made by someone who gave evidence a couple of weeks ago. They said that in the chemical industry, there are companies that have plants elsewhere, particularly in the Netherlands, that are looking to increase their capacity, because they see opportunities for taking production out of the UK to the Netherlands. Is that something that you have seen or heard of, or is that not something you have come across?

**Nishma Patel:** We have some evidence of offices and plants being opened in other parts of the European Union to facilitate trade in the event of no deal. In terms of no deal, in the way that companies have done their planning, they have pretty much highlighted the areas where they need to take action. Some of those actions are reversible and some aren't. Opening a plant, for example, is pretty much a non-reversible action. The



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more uncertainty we have seen over the last months and the more we head towards a possible no deal in October, those non-reversible actions are the ones that companies start to look to.

Q4354 **Jeremy Lefroy:** Do you have any specific examples of non-reversible actions that have been taken?

**Nishma Patel:** Not with me today, sorry.

Q4355 **Craig Mackinlay:** I declare an interest: my wife is a community pharmacist.

Mr Sawyer, you said some fairly alarming things at the start there—I think you said there would be shortages and price rises that would affect every constituency. I am not entirely sure that you have explained why.

Let me go back to basics briefly. During the maximal fear campaign that was out there a few months ago, insulin was mentioned, and I know that Denmark is a very big manufacturer of insulin. Whatever the insulin-making company in Denmark is—I don't know it, but I understand that it would be a good-sized site—if we have money to spend and are part of the WTO pharmaceutical tariff elimination agreement, which it is not beyond reality that we would be part of, are we to believe that that Danish insulin manufacturer would somehow not want to take our money by selling us the insulin that we need? Are we really to believe that, because I would find that somewhat fantastical? I know that Brussels is a very powerful entity, but I don't think that it would be able to influence that publicly quoted company on which Danish pension funds are reliant, and that the company would somehow be prevented from taking British money for goods that we want to buy.

Also, working the other way, there must be a lot of British pharmaceutical products that are needed by EU citizens. Are we really to believe that, in pursuit of some political ambition, we will enter some sort of nasty battle with each other to deprive each other's patients of what they need? I find that difficult, and a struggle, to believe.

**Martin Sawyer:** I don't think that example is realistic. We have months and months—

Q4356 **Craig Mackinlay:** So that scare factor of insulin was rubbish from day one, was it?

**Martin Sawyer:** I would not say it was rubbish; it was an example and I do not know who used it. It was about manufacturers stockpiling; I know insulin is stockpiled and we have months of it. The examples I mentioned in my introduction were smaller volume medicines that are needed by fewer patients which are cheaper and generic and may be residing in companies on the other side of the world that manufacture for the whole world. It is not a well-known product that is necessarily going to cause these problems, but it will be a problem for some patients. A medicine is personal, as you know. That is the sort of product I am talking about. We do not know where that might lie, I'm afraid. I do not think it will be in the

insulin area, because of exactly the reasons you just gave. All household name companies stockpile.

**Q4357 Craig Mackinlay:** I do but guess, but that fear factor on insulin must have come from one of your—well, where did it come from? It was out there—the BBC lapped it up for some weeks.

**Steve Bates:** Perhaps I can give you the detail on that. The manufacturer is Novo Nordisk; it is not a publicly traded company but is owned by a foundation. It has a strong commitment to patients and to the diabetes community, and I know that is its first priority. The supply chain for insulin, which is a biological medicine, does not at present come through the short strait, so it would not necessarily be affected by some of the challenges we see. Last time around, we were asked as an industry to prepare, as part of our stockpiling, for six weeks additional buffer stock.

The question that was put, and where the story arose, was about indigenous capacity to make insulin and how much of it we have in the UK if we were in a position where we had trade challenges. There is little capacity in the UK to build an insulin factory, and very limited capacity to have the insulin supply that is needed for all type 1 diabetics rapidly developed in the UK. You are confusing a question about trade with a question that was put about the ability to do that in the country, which I think is where that story arose.

Thank you for raising the WTO tariff arrangements. We have asked the Government to ensure that the WTO pharma zero-for-zero tariffs, which is a voluntary agreement, will be maintained. They have not been updated since 2010, so any new products that have been developed or the ingredients for those new products since 2010—nine years ago—are not covered by that agreement. Many elements that go into the manufacture of pharmaceuticals when they are made here, such as bioprocessing bags, are not covered by issues such as the pharmaceutical tariff. The way that biologics are made in the UK is that often you make them in bioreactors that are lined with a very large plastic bag.

You have to get into the detail to understand what operating under WTO would look like. I was concerned when Liam Fox said last week that he could see that urgent and drastic action must be taken to protect the global trading system, and he could see the WTO being in existential crisis by Christmas. We have not yet heard details of how, if we were to be in no deal, it would operate if the appellate court was not operating by the turn of the year.

**Q4358 Craig Mackinlay:** I believe that the temporary tariffs that we published in March cover most of these products.

**Steve Bates:** That is about 6.5% on bioprocessing bags, not 0%.

**Q4359 Craig Mackinlay:** I am not familiar with all the inter-country deals. There must be inter-country deals working around the world.

**Steve Bates:** You are right to go to the question here on rules of origin, because in complex manufacturing processes such as biologics or



pharmaceuticals there is a big step between the rules of origin and how they operate. Trying to break that out from an integrated supply chain where you have different steps and levels of manufacturing complexity leads to an impact on the tariff levels. If the pill packaging is in the Netherlands and perhaps the API is in the UK, the implications of that for tariffs to Indonesia are dependent on the mix of those two things. You are right to get to the detail. Again, for us to operate as businesses and for people to make investments, they need certainty on these things, but there is not clarity on the detailed issues.

**Q4360 Craig Mackinlay:** There must be a lot of inter-country agreements on mutual recognition and licensing. To pluck a country out of the air, Israel is a big pharmaceutical-producing country that is well respected. I am sure the many things that we take on a daily basis originate in Israel. How have they managed to overcome these barriers that you say Britain would have to overcome as a normal independent country? How does Israel manage it? On the other hand, there must be Israeli patients who benefit from EU medicines, UK medicines, US ones, or wherever. They obviously overcome those supply chains, the just-in-time process and all of those complications to supply medicines for their patients. It must be possible to overcome these things via inter-country bilateral deals. Can you explain how that works? I do not expect you to understand the full integration of this in Israel, but it is an example of an advanced manufacturing economy that seems to survive.

**Steve Bates:** We led a very successful trade mission to Israel, as we have to China and the US recently. If you look at the UK biotech sector, it raised a record £2.2 billion. We are out there trading with the world and taking great British innovation to global markets. If you look at Israel as a place for patients, what you see in terms of regulated products is that global companies tend to go to the key markets first: they launch a product in the US first and often in Europe—the two big markets—and increasingly in China and Japan. Israel, although it is a small market, would come several years later, because the way it works is you have one regulatory team for the big ones, and then you come to those in the second division. I believe Israeli patients probably—I am no expert on Israeli regulation; Switzerland I could have a crack at, but Israel less so—come later in the launch sequence, so they will get new products later than NHS patients get them at present in terms of regulation. So that is my point No. 1.

Israeli companies trading operate within a European context. They get their product regulated at European level and they distribute into the European market. The question for us is—we have seen some of this concern from Japanese companies as well as other companies—where would they put the UK outside the EU in their thinking? My view is that it is more likely that the UK would become a second division market—a small market, less than 3% of the world's market by value—so it is likely it would go down the priority list. It is hard to know. We don't know. We will bat for the UK to continue and for patients to get access, but my judgment is that it will probably drop out of that top league, which is America, Europe, China.

**Martin Sawyer:** You choose a good example, because a large Israeli manufacturer has a European distribution hub in this country. If we are not aligned in a regulatory standard for QP release with the rest of the EU, there is a chance that that hub would have to move if we were not part of the EU system.

Q4361 **Craig Mackinlay:** Ms Patel, you talked about a potential loss of 20% GVA of many chemical sales and value added to the country. I am intrigued. Where are the EU going to buy this stuff instead in the short term? The demand for all that stuff does not just disappear. Where will they buy it? Will they substitute buying it from the UK with another non-EU country? They could not scale up overnight to produce this stuff themselves. I find it an odd figure. It comes down to basics: I have something I want to sell. It is the right price and the right quality. Frankly, I don't care where it comes from. That transaction happens. This is where I am struggling with a lot of these arguments that are put forward.

**Nishma Patel:** You are right. There will be key chemicals or key components that perhaps only the UK is supplying or perhaps it is the most competitive supplier at the moment, but the EU has the EU27 member states to look to for alternative sources. We are already seeing some of that, particularly when you look at the regulatory part of the impact that the EU exit is having, and knowing that there will be two duplications of regulations and an additional cost that will come attached to that. There are companies now looking in the EU and saying, "We don't know what's going to happen. There is an uncertainty. Where can we alternatively source products from within the EU or perhaps in the vicinity?" That is the worry—the additional cost that will come with it and the additional time to get products to the EU, along with the documentation, are pushing EU customers to perhaps look elsewhere as an alternative.

Q4362 **Craig Mackinlay:** If a French buyer can buy in Slovakia a similar product to the one they can in the UK, why are they buying it from the UK? Because the quality is right and the price is right. Are we really saying that this is all down to a bureaucratic problem, or is the problem that we are facing one of supply and quality? It seems as though the paperwork and bureaucracy is the barrier here, rather than any common-sense issue.

**Nishma Patel:** It is paperwork and bureaucracy, but it is also the additional cost and the need for certainty about being able to have the product in time for the onward supply. As I mentioned, we are a just-in-time industry. Things come in; they are there for maybe a week or two weeks; and then they move back out. They come in and they move out. If that is affected, these are processes that are ongoing within manufacturing sites and you cannot just put a stop to it; you cannot just press a button and say, "Well, that's it. We won't manufacture because we haven't got our raw materials in," because of the nature of the products that we deal with. That is a big risk to companies and it is a big risk at board level.



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**Steve Bates:** And the paperwork and bureaucracy in medicines is of course there for patient safety purposes. That is the core point of this. We are happy to operate in a regulated industry; we think that we should do no less, because of the security for patients.

Q4363 **Chair:** Mr Bates, you said a moment ago that you thought the UK might, in terms of pharmaceuticals, move into the second division. The example you referred to was Israel. Let's say a new medicine is developed in the States. The company has to decide where to go to get it approved. There will be the European approval process through the EMA; the UK, in a no-deal Brexit, will have to establish its own approval process. The European market is that size and the UK market is this size. Is it your judgment that that means that that new medicine is more likely to get to patients in the 27 member states first, before it comes to patients in the UK second?

**Steve Bates:** Yes. We are working hard for that not to happen, but that is my judgment.

Q4364 **Sammy Wilson:** You were saying that the real cost may be the paperwork and the delays that that would cause because of different regulations; that is what may persuade chemical companies and others to look elsewhere in the European Union for their supplies. But we are asking about a no-deal Brexit and what would happen immediately after 31 October. Given that the regulations that pertain to the UK chemical industry at present are the same as the regulations that pertain in the rest of Europe at present—we adopted all the European regulations when we did the legislation here in Britain—why would there be that additional paperwork? I can understand why there might be additional paperwork once regulations diverge, but why would there be an immediate impact if we had no deal in October?

**Nishma Patel:** One of the big pieces of regulation that affect our industry is the REACH regulation, which is essentially about, in a nutshell, having a licence to market. Most manufacturing or importing companies in the EU complete a registration. It is giving the data on chemicals—whether this is safe to use and so on—and in return, you get a licence to market within the EU; you can manufacture and import.

In a no-deal Brexit, the EU REACH regulation does not apply to UK manufacturers any longer. The UK Government no longer has any access to the European Chemicals Agency database, which holds the information on chemicals, so essentially the UK is pretty much starting from scratch. You are right: we do have provisions in place to have a replicate regulation, a UK REACH; the statutory instruments for that have passed. The problem is that the database is no longer there. The UK chemical industry has no data—well, at the moment it has no data and has not provided this to the UK Government to regulate chemicals and to ensure the safety of consumers and the environment. Transition provisions are in place, but essentially, UK chemical companies will pretty much be starting from scratch to provide that information again to the UK Government to build the database, and a very hefty cost is attached to that.



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**Steve Bates:** Perhaps I can pick up on the similarities in the European Medicines Agency work. There is a reason why the chemicals regulator and the medicines regulator work were put into a particular bucket in the political declaration. The point on data is very important. In our sector, it is about pharmacovigilance data, which is the safety data used if something is perceived as being awry and needs to go to their regulators to make a judgment on the pharmacovigilance issue. Then they have to work out whether they need to put extra warnings on, recall a product or such like. If there were to be a no-deal Brexit, the data flows would stop and the UK judgment could not be based on information that would have formerly come from regulators outside the UK. The UK data, which is excellent in terms of the yellow card system operated by the MHRA, would not be available to Europeans.

If I can take you back a long time, one of the reasons why there was sharing of data developed before the European Union is because of the thalidomide challenge. Problems were spotted in one country, but thalidomide continued to be prescribed for a period of time in another country. It is the sharing of that data that enables patient safety rapidly, enabling judgments to happen quickly. That is something we would not be able to do. It will be a particular challenge if you end up with regulatory divergence north and south across the border on the island of Ireland, where under section 2 of the Belfast agreement you will know there are elements of health—patients go to one place to be treated and then return home, perhaps with prescribed medicines.

**Martin Sawyer:** I can bring that to life. From 9 February this year, every single pack of medicine put on the market in the EU28 countries, including the UK, has to have a unique barcode. If we leave with no deal, we could be unplugged from that system. We believe that medicines in the UK will be less safe, because there is already evidence of organised crime trying to get into the regular prescription market. They have already picked up some packets through this new system in Holland, which often exports to the UK. The system of the falsified medicines directive came into law in this country in February—we could be unplugged from that on 1 November, because we have no access to the EU database. It is based throughout the 28 countries.

**Q4365 Chair:** How would a counterfeit medicine get into the supply chain that you described earlier?

**Martin Sawyer:** Often, they could be stolen products that come from other parts of the world and get into the supply chain through different trading mechanisms. They are picked up through the database because the manufacturer has alerted to the database the fact that the product had been stolen. Since February this year, every medicine has to be scanned before dispensing, because every unique barcode has been put on a Europe-wide database. We would be unplugged from that.

**Q4366 Chair:** So you are differentiating between stolen and substandard.



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**Martin Sawyer:** It could be both, because if you are trying to put a counterfeit into the supply chain, the barcode will not be uploaded in the database. As soon as you try to scan it, it would say it is not recognised and you would not dispense it.

**Steve Bates:** For the system to work, when you scan the barcode in the pharmacy it needs to go back to a database and then get a response from the database system, be it good or not. If you are cut off from that database, the scanning does not do anything.

**Martin Sawyer:** It will say, "Don't dispense."

**Steve Bates:** It has to go into the system to be able to say yay or nay. If you are cut off from the system, all that work that has been done on putting barcodes in—the pharmacies have put the work in on getting this stuff into practice—won't work.

Q4367 **Sammy Wilson:** How could we get cut off from that database when we have that arrangement with the EU and they already know that our data systems are compliant with EU-compliant systems? It would also be in their interest to ensure the safe flow of drugs. Why would they cut us off from that database?

**Martin Sawyer:** The European Commission has advised that we would be treated as a third country in the event of no deal, so there would therefore be no exchange of data, covering all sectors.

Q4368 **Sammy Wilson:** Even though they know that our system of gathering data—we have been part of the whole system up to now—is compliant with the EU system, and even though we already have agreements on data exchange?

**Martin Sawyer:** The data for this particular system is one way: it only comes from the central hub, which is run by the EU. We get the data for the UK from them; we do not generate our own data.

**Steve Bates:** We are strongly of the view that a no-deal Brexit would have significant disadvantages to citizens within the EU27 as well as in the UK, and this is a good example of that one as well.

Q4369 **Jeremy Lefroy:** I was about to ask about that. Presumably, pharmaceuticals manufactured in the UK currently have a universal barcode that is recognised throughout the EU. Would that barcode be recognised if those medicines were exported to the EU?

**Martin Sawyer:** No, they would not. The manufacturer puts the barcodes on a central hub, based on the fact that they are QP-released in the EEA countries, so Norway is included, as are Iceland and Liechtenstein. At the moment we do not know what the relationship will be with the EU in the event of a no-deal, so the manufacturer is cogently irrelevant in this instance.

Q4370 **Jeremy Lefroy:** So would that bring to an end the export of medicines from the UK to the EU and these 45 million packs a month?



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**Martin Sawyer:** No.

Q4371 **Jeremy Lefroy:** In which case, how would they be barcoded?

**Martin Sawyer:** The UK would be treated as a third country. Depending on what the future trading arrangements were, the EU would recognise the UK in a new way. If those products were then to be put on to the EU market, they would still have to have a barcode that the manufacturer, at the point of going into the EU27, would put a code on for the EU27. It would be irrelevant for the UK market, but they would have to apply them—you are quite right—for the EU27.

Q4372 **Jeremy Lefroy:** What I am talking about is 31 October if there is no deal—heaven help us if there is. All the medicines—the 45 million packs a month—that will be going in in November will presumably simply not be recognised in the EU. Therefore, immediately there will be a problem with medicines going into the EU unless, somehow, a new system of barcoding is attached to those from 1 November. Or have I misunderstood?

**Steve Bates:** I am no expert on this area. If I may, I will write to the Chair on this point afterwards.

**Chair:** Will you do that, please?

Q4373 **Jeremy Lefroy:** It strikes me that this is the major point. If those barcodes are no longer recognised both ways, as Mr Bates has rightly said, it is clearly a big problem for us, but also a big problem for the 45 million packs—

**Steve Bates:** My understanding is that the packs that are produced globally that go into the European market, because there will be producers from India, America and others that operate in the European market, are part of the QP release system. The EU are confident that, having moved the QP into the EU27, they will be able to use that to say, “Okay, you have guaranteed that this is a legitimate product against the falsified medicines directive”, and they will use the QP as the point to ensure that. If those QPs are resident within the EU27, and therefore legally liable within the EU27, they will enable that to continue. So I don’t think that that is the case. I think they have done a workaround for that. The challenge for us on this one is that the UK will not be able to draw down the data from within the European Union. That is the concern. It is a one-way challenge. They have already done the piece the other way round. But I will write to you on this.

**Chair:** That would be extremely helpful.

Q4374 **Stephen Timms:** Ms Patel, can I ask you about something you said to the Environmental Audit Committee last December when you said that no deal would have catastrophic effects on the chemicals industry here in the UK? You have not used that phrase this morning. Is that because lots of planning has been done over the last six months and has eased the potential impact on the chemicals industry, or is it still your view that it will be catastrophic?



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**Nishma Patel:** It is one of those cases where you should choose your words carefully. I still think that the no-deal impacts on the industry are likely to have profound effects on the industry. I will mention some of those today. The information available and the preparedness at that time was obviously less than what we have here today. We have had two EU exit leaving dates, so there has been an intensified preparedness leading up to those deadlines. The impact does not change. It is just that the preparedness and the understanding of what no deal will mean, particularly in terms of these complex regulations, has changed. It impacts businesses that perhaps had nothing to do with those regulations. They were not caught up by, for example, the REACH regulation and registration. The awareness is higher. It is about the implications and the impact, which I reckon will still be the same.

Q4375 **Stephen Timms:** It sounds as though you are not now expecting it to be a catastrophe.

**Nishma Patel:** I would say that no deal would have profound impacts on the industry.

Q4376 **Stephen Timms:** A profound impact is not the same as a catastrophic impact. That is why I am trying to understand what you are telling us.

**Nishma Patel:** There will be negative impacts on the industry, particularly in terms of costs.

Q4377 **Stephen Timms:** Your association was initially quite sceptical about REACH when it was being developed, as overly bureaucratic, intrusive and so on. We understand that the industry has got used to it and accepted it, but is there now an appetite in the UK chemicals industry for doing something a bit different from REACH in the future?

**Nishma Patel:** You are right. If we were having this conversation 10 years ago, industry was not very keen on the regulation because of the costs and the administrative burden that it brings. Ten years on, there has been a huge amount of investment, and there are a huge amount of benefits to industry of the regulation and what has been done to date. If we are looking at opportunities, what we hear from our members anecdotally is that if there are any benefits from doing something else they are far outweighed by the disadvantages of doing something differently.

On top of that, if we also look at other global economies, particularly where the chemical industry is quite significant in terms of its footprint, most of those, with the exception of the US I guess, are looking to or already have implemented REACH-like legislation. It would not really make much sense for the UK to diverge or do something different from that.

Q4378 **Stephen Timms:** So there is no real appetite now for doing anything different.

**Nishma Patel:** No.

Q4379 **Stephen Timms:** Okay. You have said previously, and you have touched



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on this already this morning, that with UK REACH, as now proposed, there was a need for more clarity about what the Government had in mind. Has that clarity now been provided?

**Nishma Patel:** Yes, I think the information available from the Government has improved significantly, as has stakeholder engagement with businesses across the board. As I mentioned before, that there is a host of companies out there that have not been involved with the regulation. These are particularly companies that are, say, using mixtures or putting together formulations before they go into additional sectors. Those companies perhaps have no idea that they are going to be stung by the UK REACH regulation and will need to put in a registration that not only takes time but has a big cost implication. That would be my only comment: there needs to be wider stakeholder engagement, to make sure that everybody in the supply chain is aware of their obligations under no deal.

Q4380 **Stephen Timms:** That is potentially a big challenge for quite a lot of companies. How can that be overcome? I do not quite understand how companies making things in the UK do not have access to the registration data for those products.

**Nishma Patel:** How the registration process works is, essentially, at the moment it is one substance, one registration. Whether you are a company in the UK, Germany or France, if you are making or importing the same, or a similar, substance it is one registration. The objective behind that is to minimise testing—particularly animal testing—so you are sharing data. This is all done under commercial negotiations. There is one data holder—perhaps not the UK company. They essentially get a letter of access to use that data for their registration for EU REACH purposes.

With UK REACH in place, there will need to be a further negotiation on the data in order to dissect that data and take it back out, and perhaps a commercial advantage to that EU data holder, or anywhere else in the world. Perhaps they would charge more to the UK company to access that data, and use it to submit under UK REACH for a UK chemicals database.

Q4381 **Stephen Timms:** That could mean that companies just do not have the information that they need in order to register with UK REACH.

**Nishma Patel:** As it stands, no. They will be either starting to look at or re-entering renegotiations where they are already part of a registration. Those companies that rely on the EU suppliers' registration will have to do a complete new registration here in the EU. These are the downstream users, if you like, of chemicals. Those companies will be starting from scratch to negotiate access to that data.

Q4382 **Stephen Timms:** How would each of your sectors be affected if the UK exited the EU without a deal and in particular without a data adequacy determination from the EU, so that we could carry on exchanging personal data as we do at the moment?

**Steve Bates:** We have talked about two particular areas. One is pharmacovigilance data and the importance of that being shared at the

moment through a centralised system. That is about patient safety data and the ability and the speed to be able to make a determination if there are any concerns. That would be significantly compromised and would probably mean much slower decision-making processes. The second area is the falsified medicines directive, which we have talked about.

The third area that has a big lack of clarity is clinical trials and clinical trials databases and how that would operate. Again, those are areas, particularly in rare diseases, where clinical trial data flows to and from a number of clinical trial sites within the EU. We hope that will go into the new database that will be established by the new clinical trials regulation.

Those would be the three areas: pharmacovigilance, falsified medicines and clinical trials.

**Stephen Timms:** Would continued UK participation in European clinical trials require a data adequacy determination from the EU?

**Steve Bates:** I believe so.

**Martin Sawyer:** Pharmacovigilance is important to us because we get information through the MHRA from the EMA about the recall of products that there may be a problem with, for whatever reason. We have to immediately take all products from that particular batch back from all the pharmacies in the UK. That can happen within hours, to avoid them getting to patients. Then we quarantine them and arrange a refund and reimbursement through the manufacturing process. It is very important; that speed saves and helps patients.

The FMD we have already touched on. I would also mention that three largish UK wholesalers and distributors are actually pan-European. I imagine they act in an integrated way on stock issues. The transfer of data about that may well add costs to their business, depending on what the impact is on data flows if we have a no-deal Brexit.

Q4383 **Stephen Timms:** Ms Patel, data issues?

**Nishma Patel:** If we have no data, essentially we lose a marketplace. We need the data to register under UK REACH. If that is not there, we lose the marketplace. Some 70% of our members are globally headquartered. They already have registrations in the EU for the EU27 marketplace. If it is not cost efficient or worth getting for the UK, we lose a marketplace.

Q4384 **Mr McFadden:** We have been talking quite a lot this morning about what might happen. I would like to ask you—particularly Mr Bates and Mr Sawyer—about a decision that has already been made: the loss to the UK of the European Medicines Agency. What has been and what will be the impact of that?

**Steve Bates:** The European Medicines Agency put out management data recently. They estimate that they have lost between 20% and 25% of their overall workforce and will not be able to reach full staffing levels for

some time. As of 1 June, 312 of their 776 staff members are still working from London. Their plan to move to Amsterdam is in process but not complete.

I think the main impact of that is twofold. The first is that it means that the EMA itself has had to jettison some projects and work in order to focus on being able to do the core of its work. That means things that could help the development of the latest innovative projects in which the UK has a lead, such as cell and gene therapy. Some of that work isn't being done, so Europe is going slower as a result of the change. I think we are seeing some sense of global companies looking at the EMA's hub in Amsterdam and the possibility of locating within the EU27—these are slow processes—going into their planning and thinking for 2020-21.

**Martin Sawyer:** Specifically, we as the association work very closely with our regulator, the MHRA, on good distribution practice, which is an EU-wide quality and regulatory system for distribution of medicines. The MHRA had a very close relationship with the EMA in the UK, in Canary Wharf, and was doing a lot of that work. Therefore, I think the relevance of keeping the regulations up to date in the UK and the weight that UK business inputted into those GDP regulations—because of the relationship the MHRA had with the EMA—will decline. Over time, that is quite significant because the MHRA is a very well respected organisation within European regulators, and I guess that they have lost that foothold.

**Steve Bates:** One other point: the EMA has completed the transfer of rapporteurships—the leading decision making on drug files for new drugs—from the MHRA. The UK used to do quite a significant amount of this work, particularly in some of the most novel areas, where the UK's life sciences industry is at the cutting edge, and those dossiers have been transferred, in preparation for Brexit, to other national regulators in other parts of Europe. That means that it is difficult for MHRA staff in those areas to keep up with some of this in the way that they had been leading for a decade.

Q4385 **Mr McFadden:** Turning to something else, last week the *FT* reported on a Government paper from a month or two ago, which set out the state of preparations for a no-deal exit for the chemical and pharmaceutical sectors.

The note said: "The Government needs six to eight months of engagement with the pharmaceutical industry 'to ensure adequate arrangements are in place to build stockpiles of medicines by October 31'." It also said that it would take "at least" four to five months to improve trader readiness for any new border checks that might be required.

What is your view of that paper? What is your view of the state of readiness now, compared with the run-up to 29 March? Are we more certain now? Are we still very uncertain?

**Martin Sawyer:** I will handle the first section about stockpiling in the UK in readiness. We have had that engagement, as preparation started a year



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ago, as I said. From our perspective, I represent some of the pre-wholesalers who store and stockpile a lot of the manufacturers' products currently, because it is under manufacturer ownership, which is important. That is still in place, and has been, and we have been asked to maintain those stockpiles, because of the date moving from March to April and now to October.

I am confident that that preparedness on the stockpiles is being maintained in the large. We will find, I am sure, that there will be several things. The stock needs to be rotated, to ensure it doesn't get out of date. There is a six-month difference, so we need to ensure that the older stock moves out and newer stock comes in. For smaller manufacturers—not the household names—that is going to be a challenge financially. The private sector is paying for all of this, largely anyway, in terms of stockpiling. I am worried about that.

The second thing I am worried about is that October is a time when there is more pressure on warehouse space across different sectors, because Christmas is coming up. For us, it is a very busy time of year because you need more medicines over the Christmas period, so we start our own stock build at that time of year. Other sectors do as well because of Christmas.

The warehousing capacity in the UK will come under pressure in October in a way that it did not in March, for other sectors as well. That is a concern. In terms of keeping our eye on the ball, I know the Department is keen to ensure that monitoring of stockpiles continues, so I am confident that that will happen and that we will be in a reasonable place in the pharma sector for that, with the two other caveats that I have just mentioned.

**Q4386 Mr McFadden:** We have heard this point about Christmas and October from a few different sectors. You are telling us, "Don't think that you can just fast-forward six months and warehousing space is the same in October as it is in March."

**Martin Sawyer:** Very much so, yes. Correct.

**Q4387 Mr McFadden:** Do you think there is also a potential crying wolf effect on preparing for a no-deal Brexit in October? We have heard from other sectors, "Well, we were told to spend a lot of money in the run-up to March and then maybe it was going to be June, and here we go for the third time." Is it your view that the sector will be just as tooled up and keyed up in October as it would have been with the earlier deadlines?

**Martin Sawyer:** I think you are right to identify corporate fatigue as an issue. It is important that I ask Government to keep communications going and make sure they explain and monitor what is going on. I agree, however, that there are some smaller companies that may think, "Third time—why should we carry on? It is such a cost to our business that we will take the risk of not stockpiling or decreasing the stock." I have discovered since the stockpiles were built up that other parts of the world suffered from a lack of medicines because they were all in the UK. Some manufacturers will be taking them out, trying to supply the rest of the

world, and then starting to stockpile again in September, so there is a risk that that might not be there in time.

**Q4388 Mr McFadden:** Can you say a bit more about that—that stockpiling in the UK has caused shortages elsewhere in the world?

**Martin Sawyer:** It has caused manufacturers to be concerned that other parts of the world are not getting medicines quickly enough. I am not saying it is causing shortages, but I know that they have diverted stock—some of them—out of the UK to fulfil other international orders from the stockpiles, but they are hoping to build them up again before October.

**Steve Bates:** Our industry is very cognisant of the fact that patients are at the end of our supply chain, and that, in a sense, has been the defining thinking behind what industry has been working towards for a number of years. We have been working for at least two years on the possibilities of a no-deal Brexit, and last time round, by about August, we had a reasonably clear road map of what might be happening in terms of the regulatory environment and something towards the shape of what might be happening at the borders.

This time, we are much more compressed in the timeframe. It was interesting to see in that *FT* article the new context for us. We work in a number of areas where there are risks—clinical risks, scientific risks, financial risks, political risks. Here, the political risk is up, because it is very uncertain as to what a new Prime Minister or a new Government might want to do in this space, and we are doing that in real time.

The thing that is concerning to me in the story from the *FT* is that you have a number of candidates in the leadership election who are privy to information within Government, and some that are not, yet all are making promises about no deal. I do not know whether they are doing that with the best information. My plea is that that information is put before not only all the leadership candidates, but industry—so that we can tell you what is expected of us and what we can do—and MPs, because at some point the new leader of the Conservative party will seek to form a Government, and that should be based on the best information about what is practicable. I would think that there is a good reason for that to come out.

I wasn't sure at the end whether you said "very uncertain" or "ferry uncertain". I am certainly very uncertain about ferries, which is a real challenge, because that was a crucial part of the planning last time round.

**Q4389 Mr McFadden:** If you think the Government has been burned by the chaos over the ferry contracts that took place in the run-up to March with a company that had no ferries and so on, from your point of view, what needs to be in place that you do not think is in place on that transport issue?

**Steve Bates:** From my perspective, one of the things that we have discovered through the work is the vital importance of the flow rates in the short straits—the Dover-Calais Eurotunnel area—for just-in-time supply.



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The workaround last time was to have alternative routes with ferry capacity on them. There is a big difference between having roll-on/roll-off capacity, where the drivers stay in the trucks and roll them on, and leaving the back of the truck, the container, on and have another cab pull it off at the other end, particularly for temperature-controlled medicines that need to stay within a regulatory framework to make sure that they are compliant, and need to stay within a temperature so they can be actively used.

That is beyond the control of the Department of Health and Social Care. We have seen the retirement of the lead official from the borders delivery group announced recently. Some candidates are saying that it is only responsible to prepare vigorously and seriously for a no-deal Brexit scenario, but with 134 days to go to that possible thing, I am not seeing, in terms of clear direction to industry, clear and visible data.

You mentioned the point about trader readiness. There is quite a lot of work that needs to be done, particularly for supply chains and people who drive trucks—they are big companies and small companies too—to make sure that you have all the paperwork together. If you are going to be flagged and pulled at the border, either in Dover or Calais, because you have not got all your paperwork together, that really has an impact on how quickly the lorries go through. That needs time to bed in, because that is not something that people are going to easily do overnight.

**Q4390 Mr McFadden:** That is because some of this stuff cannot be stockpiled. Mr Sawyer told us that we have warehouses full of drugs, which may be having an impact elsewhere in the world—I don't know. You mentioned the phrase "just-in-time supply", so perhaps you could spell that out for us a bit more. Some of these medicines cannot be stockpiled, can they? It is a case of them going from manufacture to use within a very short period.

**Martin Sawyer:** Correct. An air corridor is established—for example, a lot of radio isotopes come over from Belgium for use in the NHS, and the NHS has done a great job in ensuring expedient ways of dealing with some of the products that have a much shorter shelf life. But you are right: time is of the essence, and if a lorry with refrigerated batches of medicines is held up and cannot get through the port, by the time they get to the UK, some of those medicines may not be usable.

**Steve Bates:** We have learned through understanding with industry colleagues and working with the NHS that often you need to put together a package of things to have an operation. It is unlikely that the drug is the key thing, but you may well need medical devices, bandages, equipment, plastic items and all the rest. If those things do not arrive at the same time, or if the machine that you need has broken down and you need a part to fix it, then those things that are needed for everyday use in the NHS could be a challenge. Although we have talked largely about medicines, the Committee may wish to think about health in a broader sense, and particularly the operations of the NHS.



**Q4391 Mr McFadden:** We have been taking evidence on this for a couple of years, and one of the most vivid quotes I remember was from the Norwegian ambassador to the EU, who told us, “Nothing is in as much of a hurry as a dead fish in the back of a lorry”—that was to illustrate the importance of the just-in-time supply chain.

With the Chair’s indulgence, may I ask you one final question? We took evidence last week from trade bodies involving the automotive industry and manufacturing. They told us that the very talking up of no deal was already a disincentive to investment in the UK. Have you seen any evidence of a disincentive effect on investment in the UK, given the Brexit experience of the past year or two?

**Steve Bates:** I spend my time going round and talking up the UK life science sector. We are doing well and are the clear leader in Europe. There is the life science industrial strategy, R&D, tax credits, and the benefits of the fantastic science base on one side of the scales for an investment decision—and that has led to companies investing in the UK—but on the other side there are the uncertainties around Brexit. Talk of no deal adds another weight to that side of the scales. Is that the thing that, despite all the excellent work we have been doing for generations in UK life sciences, tips the investment decision against the UK?

**Q4392 Mr Djanogly:** We have been talking about stockpiling. How much money have your members spent on stockpiling and other preparations so far?

**Martin Sawyer:** As I said, stockpiling in the UK is paid for by the manufacturers of the medicines. We provide space and will rent it out to them. Our members have had to find extra space and properties, and they have been working with the Department of Health and Social Care to identify those, and some of the extra incremental costs have been paid for by the Department. Other than organising it, however, costs have largely been borne by the manufacturing sector. That is deliberate, to avoid stockpiling downstream. The last thing we want is for wholesalers, pharmacies, doctors and patients to stockpile, because that would generate shortages. The idea is for manufacturers to keep this high up the supply chain, and they are paying for it.

**Steve Bates:** I don’t have a figure from my lot, but it is a cash-flow issue.

**Q4393 Mr Djanogly:** And when you say that drugs and chemicals have to be replaced because they have a limited lifespan, there is a cash-flow issue as a result, but you can’t actually quantify the costs.

**Steve Bates:** No, that falls very differently on small companies compared with large companies, and it therefore must be part of the financial risk element, which is different for a major multinational.

**Q4394 Mr Djanogly:** Working on the back of that, Mr Sawyer said that there could be a problem in October because of Christmas demand. I think you also said that there will be a lack of capacity. Would you prefer it if the October date was delayed? Would that make your life easier? Would there be any extra costs?

**Martin Sawyer:** From the point of view of medicines, March through to September is the quieter period of year for capacity, so yes.

Q4395 **Mr Djanogly:** So October is a good time for you.

**Martin Sawyer:** No, March through to September is a good time; the other times of year are harder—as in October, which is a challenging time, because it is the run-up to Christmas, and we get very full in November, for example. October is the start of the build for Christmas, so it is a difficult month.

Having said that, our main ask is to at least get to a transition period so that we can have some certainty. The challenge of no deal is all the uncertainty, and not knowing what plan B is. We have grown up with the EU, the whole system is integrated and we will be pulled off it. We have no alternative. Business likes certainty, and uncertainty is the big challenge.

Q4396 **Mr Djanogly:** What I am trying to get at is, is no deal at the end of October viewed as a significant risk, and would you prefer it to be pushed back to next March?

**Steve Bates:** No deal at any time carries significant risk. Clearly, a number of devil-in-the-detail questions points, about the data and the borders—we have not talked about the flow of people—are still unanswered. Any of that will require time. None of these things in our supply chains is simple or easy to change, and all of them would have a lead time within them. We have prepared vigorously and seriously for no deal but, to an extent, we need clarity from Government to a level of detail if we are to minimise the short-term impact. I hope we are also making you aware of some of the long-term downstream impacts of a route that goes in this direction.

Q4397 **Mr Djanogly:** I totally understand your desire to have maximum lead-in times for all these timetables. However, looking at what has happened in the past with previous extensions, they have happened at the last minute. I don't think that it would be unfair to suggest that that might be the same in October, if there were to be another extension. That being the case, and understanding the cash-flow point and the fact that you are saying that warehousing would be better in March than in October, are you therefore collectively of the view that you would prefer it to be in March than in October?

**Steve Bates:** My preference would be not to face a no-deal scenario.

**Mr Djanogly:** But if there is a no-deal scenario?

**Martin Sawyer:** It is a good question, because on the one hand, as a member mentioned previously, there is corporate fatigue for doing this. If we move the goalposts again, come next March, what is the preparedness? Yes, on the face of it, there will be more warehouse capacity, but it is about trying to get everyone up to the work, isn't it, and I think that the longer this goes on, potentially the more critical the situation becomes for us on whether we will be able to have enough medicines in the UK at whatever time the no deal happens.

**Nishma Patel:** Related to that, it is also a matter of uncertainty and investment. Projects have been put on hold for a year or two years; it is how long those projects can continue to be put on hold any longer.

**Chair:** Jeremy, you had one more final quick point.

Q4398 **Jeremy Lefroy:** Just to go back to Mr Bates on the MHRA, given that the EMA is no longer in London, the MHRA will obviously have to increase its capacity seriously. Do you not see the opportunity for the MHRA to become in effect the leading national body of its kind within the continent of Europe? Rather than, as now, subcontracting a lot of the work that it would have done to the EMA, it will have to do it itself, or do you think that it will simply rubber-stamp anything that the EMA does? In other words, will it be a serious national regulator, as the national regulator in Canada or the United States is, or will it largely rubber-stamp?

**Steve Bates:** I think that they have been the leading regulator in Europe and have been significant in driving the scientific underpinnings of much of the work of the EMA. On the MHRA, from an industry perspective, we would like to continue in close co-operation in a European system, whatever type of Brexit happens. We would very much like to see that.

The other thing that slightly confuses people is that much of that activity remains an MHRA competence. Much of it has not been centralised into Europe. Remember, the EMA was formed in the John Major era, at a time when Europe was very different. In a sense, there is some differential between devices and future activities.

It is good that the Government have stepped in to provide some financial support to the MHRA. That regulatory expertise is not easy to grow; it is scientific capability and people, and it is great that they are continuing to support that. From our perspective, an influential UK scientific powerhouse that has reach beyond our borders and engagement with the EU27 is something that we would like. If that included a greater community, with Switzerland, Israel and others, that would be fantastic. We have been influential on the global stage as a result of participation in the EMA. We would like to see that continue if possible, because we believe that there are benefits to EU patients and UK patients. Having a single set of harmonised rules, rather than breaking out into more sets of rules and additional red tape, is beneficial to patients and to business.

Q4399 **Jeremy Lefroy:** As a supplement to that, have you seen a permanent increase in the MHRA's budget and a permanent increase in its number of staff, to recognise that it will become a more important organ?

**Steve Bates:** The MHRA has largely supported itself through fees based on industry fees. There has been an understanding that there might be a drop-off of that. I do not think that the long-term budgets of the parts of the DH that are not the NHS England are settled yet, and that will be looked at during the spending review.

Q4400 **Jeremy Lefroy:** But you would want that to be substantially increased to ensure that that work—



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**Steve Bates:** Maintaining the UK's capability in a regulatory capacity to do novel therapies is part of the UK life sciences offer and is fundamental, alongside our great universities, in ensuring that the life sciences sector does very well. We are already leading in Europe; we can do that for the globe. The regulatory capacity is an important part within that.

Q4401 **Jeremy Lefroy:** So taking back control means spending quite a lot more money on that?

**Steve Bates:** Certainly, we will have more costs. Whether there is control, I am not sure.

**Martin Sawyer:** I think that more funding is important. I believe that the funding for the MHRA decreased as a result of the removal of the EMA to Holland, so it will require more funding to do that, as you suggest.

Q4402 **Chair:** A couple of very quick things from me. Reference was made earlier to the leaked Government paper from May 2009 that was published in the *Financial Times*. Have your organisations seen a copy of that document?

**Martin Sawyer:** No, I don't believe so.

**Steve Bates:** No.

**Nishma Patel:** No.

Q4403 **Chair:** Finally, say the new Prime Minister were sat in this chair in a month's time and you were sat in front of him, and he said to you, "I'm thinking about whether I should take the UK out of the EU on 31 October without an agreement. I'm thinking about a no-deal Brexit on 31 October. Should I do it or not?" What one-word answer would you give: yes or no?

**Nishma Patel:** No.

**Steve Bates:** No.

**Martin Sawyer:** No.

**Chair:** Thank you very much indeed. On behalf of the Committee, we are very grateful to you for coming today and for sharing your knowledge and expertise with us in what is, as have come to learn as a Committee, a very complex area. We know more about how your sectors work than when you walked through the door this morning.

## Examination of witnesses

Witnesses: Vivienne Stern, Dr Beth Thompson and Professor Tim Wheeler

**Q4404 Chair:** On behalf of the Committee, I extend a very warm welcome to our witnesses for the second panel this morning.

We are looking at the implications of a no-deal Brexit for the United Kingdom. I welcome Vivienne Stern, director of Universities UK International; Dr Beth Thompson, head of policy at the Wellcome Trust; and Professor Tim Wheeler, international director of UK Research and Innovation. Thank you very much for coming.

As ever with this Committee, as with others, we have a lot of ground to cover, so succinct answers to the questions we are going to put would be much appreciated. I will begin by asking each of you to set out in a sentence the view of the organisation that you represent of the prospect of a no-deal Brexit.

**Vivienne Stern:** It's a creeping horror that something that we thought might happen by accident might actually now be the deliberate policy of Government. That sounds to us like a very bad idea.

**Dr Thompson:** Even with the best preparation, no deal will leave a vacuum in the UK's relationship with our biggest research partner. That is untenable and cannot be allowed to happen.

**Professor Wheeler:** A no-deal scenario will be a significant short-term shock to the research and innovation system in the UK—to the people in and the funding for that system—to which we in UKRI need to prepare as best as we can.

**Q4405 Chair:** Given the answers you have just provided to the Committee, does it puzzle you that some people who want to be the next Prime Minister of this country appear to be contemplating leaving with no deal as a policy for the Government that they would lead? Do you think that they do not hear what you are saying? Are there other considerations? Why have we got into this situation?

**Vivienne Stern:** The consensus last December or in January this year, as it appeared to me, was that the complexities of leaving without a deal made it a really unappealing prospect, and that we would do what we could to avoid that. Those calculations and that consensus seem to have changed, and there now seem to be people willing to say that leaving without honouring our financial obligations and with potentially quite a damaged relationship with our EU partners is a plausible outcome. Time passes, and there is therefore an opportunity for everybody to do work that would have been very difficult to do in the short time between December and March, when this became a real hot topic, both in Government and for us.

Time helps us, but my view is still that there is now a short-term focus where there really needs to be a long-term focus. In leaving the European Union, we need to be as mindful of the relationship that we want in the



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long term as we are about the short-term mechanics of the departure itself. It is disappointing to me personally that the rhetoric seems to have shifted towards this very short-termist discussion about the impact of leaving on a specific date or otherwise.

**Dr Thompson:** I would agree. I cannot answer the question about why our messages have not been heard, but I think the research community as a whole is very clear that no deal would be very damaging, both, as Vivienne says, because of the short-term impacts—Tim mentioned that too—but also because no deal will fracture our relationship with the EU in a way that is going to be very difficult to come back from. The kind of agreement that we would need on research for the future, in terms of the movement of people and researchers, research regulation and also funding, will be very difficult to achieve, if not impossible, in a no-deal scenario.

There has been a short-termist focus on how we could manage and mitigate the short-term impacts of no deal, which would be difficult and challenging and would create an immediate shock and some uncertainty, but without enough consideration of the long-term damage that that will do. I find it deeply concerning that we are in a situation where we are having to consider that.

**Professor Wheeler:** Those who are part of the UK's research and innovation system will be fully aware of the potential risks of a no-deal scenario. Those who are taking a more distant view may well know that the UK is a world-leading research and innovation nation, but some of the subtleties of funding processes from the European Commission and some of the issues about the movement of academic staff and students will not be well known to that constituency. It is our job to make them more aware of the potential risks and the sort of mitigation actions that an organisation such as UKRI can then take to address those by the date of EU exit.

Q4406 **Chair:** Do you think that the Ministers with whom you have talked understand the implications that you have referred to in your evidence thus far?

**Professor Wheeler:** The Minister we most frequently have contact with is, as you would expect, Chris Skidmore. He and his officials are fully aware of the details and the broad issues at play. In UKRI, we are working very closely with his officials on a day-to-day basis in the work and responsibilities that we have to undertake.

**Dr Thompson:** I would agree with that, and think that BEIS, Minister Skidmore and his officials do understand these issues. The challenge I think is that Brexit is an issue that spans multiple Departments, so it is less clear whether there is that same level of understanding and join-up across other Departments.

**Vivienne Stern:** I would also agree. We have a good Minister in Chris Skidmore, and his officials have been working very hard on mitigating the

consequences of a no-deal Brexit, and very collaboratively so. I have nothing but praise for them, actually.

**Q4407 Chair:** What do you think the referendum result and the past three years have done to Britain's reputation in the fields in which you and your organisations work? When people look at us, what do they say?

**Professor Wheeler:** There are clearly mixed views out there. We, in a sense, spend a lot of time talking with those in the UK community, but also Brussels-based counterparts and other research agencies. It is fair to say that there is often a perception that this is the UK's research and innovation expertise shrinking into itself—that it is not looking out in the way that it used to. An important role of UKRI's role in its Brussels-based office is to counter that and to give information where we can. There are community events and the underwriting of funding processes—I am sure we will get on to that—that we are undertaking to try to mitigate the risks, but there will always be a perception from some that this is in a sense the UK science and innovation community moving away from their European counterparts in some way.

**Dr Thompson:** From our perspective at Wellcome, there is no doubt that the UK is a brilliant environment for science. We have world-leading science and research in this country, and that should be celebrated. I do not think that researchers or policy makers elsewhere in the world have yet seen an impact on that research base. The concerns that we see are from researchers from other EU countries, perhaps even from other parts of the world, who now look at the UK and say, "Is this the kind of country that I want to come and live and work in?" Some see it as a challenge to UK values, and that they would not now be welcome as an immigrant to the UK. That is not necessarily backed up by statistics, which show that generally the UK public are supportive of researchers coming in to work in the UK, but there is some sense of reluctance. We have heard from some of our centres and institutes that they are struggling, particularly at more junior levels, to recruit as many EU nationals as they once did. Clearly that is not an impact of anything that has happened as a result of Brexit in terms of changes in law or to the immigration system; it is about how people feel about coming to work here. The uncertainty in terms of what the future funding arrangements will look like is also affecting researchers' decisions. They want to come and work in a place where, as an aspiring young European researcher, you are able to apply for a European Research Council grant, because they are one of the best grants available anywhere in the world. If you don't know whether you can apply for that grant after 31 October, you are inevitably going to feel worried about coming to the UK. We certainly have some people who were offered Wellcome funding and afterwards said, "You know what? I am not going to take your funding. I am going to go to Germany and set up a lab there instead because I know I can apply for European Research Council funding there." So it is having an impact.

**Vivienne Stern:** Just to add to that, I think there have been phases in the sort of conversations we have had with our European counterparts. In the early days post-referendum, there was this enormous spirit of solidarity



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and the main message that we got everywhere we went was, "Look—the UK research and education system is outstandingly strong, we want to continue to work with it, we will find a way, we will be at your side and we can do this." Fundamentally, that attitude is still there, but predominantly I would say that now when I am talking to counterparts across Europe, the major emotion expressed is one of pity. I don't really like that.

I was in Iceland recently talking to the head of their research funding agency. We had a good conversation about the Government underwrite and the statements that Governments have made about preserving relationships, but at the end of the meeting on the way out, he turned to me and he said, "I feel rather sorry for you because you are representing what most people would acknowledge to be one of the best university and research systems in the world and here you are presumably going round Europe a bit like a travelling salesperson."

We have had such influence based on people's respect for our system. We have to really think about how we can preserve the fundamental strength of our university and research system so that we don't end up being an object of pity as we lose ground from a previous position of prestige. That has to be a challenge both for domestic policy and our future UK-EU relationship.

**Q4408 Mr Djanogly:** I have heard that one way that research institutes are looking to still get into the EU funding stream is to do joint projects with EU universities. Is that true? Is it happening? Is it a valid way to go forward in the future and do we have the contacts with the EU universities that we need to do it?

**Vivienne Stern:** Our universities are phenomenally networked so those sort of strategic partnerships exist already. In the last couple of years, we have seen lots of universities setting up a physical presence in Europe, or a new deeper strategic partnership that goes beyond what was there before. The concept behind that is finding ways to ensure that, whatever sort of Brexit we get, there will be a route to continue to collaborate on European projects.

The mechanics of that are not entirely clear to me. Take for example the King's partnership with the TU Dresden. It is focused on clinical medicine. If you think about the breadth of research that King's would undertake with European partners, it seems to me that that initiative is pretty narrow. It might help in one discipline, but what will it do for the broader relationship? I think that is replicated in other fields. Lots of the strategic partnerships have quite a narrow focus. An exception to that might be the Oxford-Berlin partnership, which does seem to be quite broad-based, but if you look at what is actually going on, those institutions are contributing to a common pot so they can run workshops together and so they can pump-prime new research relationships. It is not an alternative to being able to draw on big European research funds. I suspect it is going to be helpful, whatever kind of Brexit we get, but it won't be a solution.

**Q4409 Stephen Timms:** I want to put one very specific question to each of you.



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Do you know of specific impacts in your area if the UK were to leave the EU without a data adequacy determination on the part of the Commission?

**Dr Thompson:** The challenge if we leave with no deal is that immediately as a third country the UK won't have an arrangement in place to enable the free flow of data between the UK and the EU. At the moment, because we are a member state, we have that free flow. As you are saying, it is possible to agree an adequacy deal that enables that free flow to continue between the EU and a third country.

If we left without a deal, we wouldn't have adequacy immediately. It would be likely to take some time to get there. There are other options to legitimise your data flows between the EU and a third country, but they are bureaucratic and difficult to put in place. They often require, for example, additional legal clauses. Particularly for the academic research community—there isn't extensive regulatory support within universities to help with large quantities of paperwork—any additional bureaucracy that you, as a researcher, are going to have to go through in order to transfer your data is going to make your day-to-day life more difficult.

A good example of that is the 1958 Birth Cohort. At the moment, that is a brilliant research resource that we have in the UK. It has collected data on thousands of people, and it is shared between the UK and the EU. We see about 2,500 data transfers from the UK to the EU each year. The data then comes back once the EU researchers have done their work on it to enrich that resource, so it gets better for everyone. That is the kind of thing, where personal data is flowing, on which researchers are going to have to do much more paperwork for it to get through. That is going to be more costly and bureaucratic.

**Vivienne Stern:** One of the things that we have done to try to help universities deal with this problem is develop model clauses that they can use in these contracts. That probably falls into the category of no-deal planning, where you can over time, if you have the time, start to mitigate some of these problems. It has a cost, obviously. Probably in the case of a large university, hundreds if not thousands of individual contracts need to be scrutinised and renegotiated. That, of course, has a cost and will take time, but it is fixable, and universities are by and large doing it.

My sense from many universities is that they don't really know whether they should go at this or not. Up until March, you still found universities that said, "Look, it's never going to happen. We're not going to get a no deal. Thank you for all the work you have done to tell us what we would need to do if this did happen, but we are going to hold our fire." We don't yet know whether we should be saying to universities, "Guys, invoke your no-deal plans. Do the stuff that we said you might have to do." That, I'm sure, is true of lots of other parts of the sector.

**Professor Wheeler:** I can perhaps add one more example, because Beth has outlined the issue very well. For UKRI, the main areas of risk on this basis are in clinical trials support. The Medical Research Council in UKRI has been working with its clinical trials unit at King's College London to try



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to prepare together for the situation where the data adequacy issues have to be negotiated post exit.

Q4410 **Stephen Timms:** What would it require to overcome the problem?

**Professor Wheeler:** My understanding is that it would require negotiations on a case-by-case basis—individual contract by individual contract.

**Dr Thompson:** An important element of that is that it is not just something that the UK can do unilaterally. There has to be a negotiation with the EU partner. Part of the problem is that when UK researchers want to get their hands on personal data from the EU, the burden is on the EU researcher. That is a real challenge.

Q4411 **Joanna Cherry:** We have touched on this a bit already, but I want to ask you a bit more about the impact of no deal on staffing in universities. I am not talking just about the academic staff; I am thinking particularly about post-docs and lab researchers. I have Heriot-Watt and Napier in my constituency, and senior staff have spoken to me about their concerns about the fact that post-docs often earn considerably less than the limit on a tier 2 visa, but are absolutely vital to ongoing research work, particularly in science and STEM subjects, but also in language subjects. I am interested in your view of the impact that a no-deal Brexit would have on staffing levels in universities, taking into account those figures.

**Vivienne Stern:** Perhaps I can start. You are right that it is that early career researcher and the technician-type role that are most likely to be affected by the proposed £30,000 salary threshold. We have argued that the threshold should be reduced to £21,000. We think that would deal with the majority of the issues in our sector. It is something that the Government need to give serious consideration to, because labs do not run if you do not have technicians, and the pipeline of early career researchers is incredibly important to the UK. We have a national ambition to invest 2.4% of GDP in research and development. To do that, you need to have a research workforce that is capable of absorbing that investment; if we are to meet that ambition, we cannot afford to stop the flow of overseas research talent to the UK. That would be a very bad thing to do.

**Professor Wheeler:** Underpinning this issue is that this is a highly specialist and highly mobile community internationally. We know that one in six individuals in the academic community in the UK are from other parts of Europe. Equally, we know that people move around frequently, outwards from and inwards to the UK. Where there are barriers to an individual settling into a new position in a new country, possibly with a family as well, they will have choices elsewhere in terms of where they set up their academic or research career. I very much support what Vivienne said. Research technicians and the specialist staff who support research are absolutely critical, and they potentially will fall below this £30,000 proposed cap.

**Dr Thompson:** We too have concerns about the £30,000 cap. If you look at somewhere like the Francis Crick Institute, which is one of the institutes we fund in central London, around 25% of its technician staff are non-UK EU nationals. The £30,000 cap is a real worry. Like Universities UK, our analysis suggests that a threshold of around £21,000 would avoid some of those problems.

There are also significant issues with the way the rest of the UK visa system works in terms of cost. Even for the 55% of post-docs at the Crick Institute who are likely to be over that salary threshold but come from the EU, there is something like a tenfold difference in the visa costs for the UK compared with somewhere like France. We as the UK have to do all we can to be attractive as a destination for these researchers. It is partly about getting the immigration system right. In the longer term, assuming we get a deal—or potentially in a no-deal situation—looking to negotiate with the EU reciprocal movement for researchers to get around some of those other problems would also be a massive benefit.

Q4412 **Joanna Cherry:** Earlier, when the Chair was asking you questions, Dr Thompson, you mentioned an example of somebody turning down an offer of a Wellcome Trust-funded research position in the United Kingdom because of fears about the consequences of Brexit. Likewise, I hear examples from professors at Napier University of people not wanting to come to a position at Napier because they are afraid to come to the United Kingdom. I wonder whether any of you are aware of any actual research and statistics on the rate of reluctance to come here, even in the period before Brexit actually happens. One hears a lot of anecdotal evidence—I hear colleagues talking about it in Committee and in the Chamber—but I wonder whether anyone has done any research into the rate of people already not wanting to come to the UK because of the current climate on immigration and Brexit.

**Dr Thompson:** We have some stats in terms of Wellcome's funding. We have seen a 20% drop in early career researchers applying for our funding schemes in the last year. That has been consistent. It went up from about 14% in 2017. The Wellcome Sanger Institute saw nearly a 50% drop in applications from EU nationals for their PhD studentships in 2017. It is not perfect data, but we have a few snapshots.

**Professor Wheeler:** It is very hard to take a holistic view of anecdotal evidence but, like you, we have heard examples. The example I have is from the Higher Education Statistics Agency. Their figures show that the number of postgraduate research starters from other parts of Europe who enrolled declined by 4% in 2017-18 compared with 2015-16. This is emerging evidence. It is aggregate evidence, but it is quite hard to get numbers across the sector as a whole.

Q4413 **Joanna Cherry:** What about EU nationals who are already here and are leaving? I am interested in whether you have any statistical evidence about people leaving as a result of the fear of an impending Brexit, whether there is a deal or no deal, and whether you feel that the Government's current reassurances on settled status are sufficient to



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prevent European Union nationals who are staff in universities or research scientists from leaving the UK?

**Professor Wheeler:** I don't think I have the evidence you are looking for. I do not have a number for the sector as a whole; I only have some examples of people who have reported that they have found other positions as a result of uncertainties, potentially from a no-deal exit. Individuals will make decisions on a range of bases that are important to them. I'm afraid I don't have the evidence for the sector.

**Vivienne Stern:** The last time I looked at these figures—I will have to write to the Committee with the data because I do not have it to hand—the net effect was actually pretty stable. Yes, EU nationals were leaving, but recruitment was relatively buoyant. Those figures were produced by the Universities and Colleges Employers Association. I could take back the request to update the Committee on the latest figures.

I was also recently at a conference hosted by the University Human Resources association, and I asked that organisation whether they felt that, net, they were losing more staff than they were gaining. Broadly speaking, the response was, "Yes, people are deciding to go, but we're still managing to successfully recruit." They also offered to do the kind of thing that I think you are suggesting is necessary, which is to provide a more up-to-date and timely picture than the HESA data can give us, because the HESA data is lagging by quite an extent.

Q4414 **Joanna Cherry:** What about the Government's current reassurances on settled status? Do you think that they are sufficient to encourage EU nationals to stay in the UK, or is there a problem with the level of reassurance that has been provided so far?

**Vivienne Stern:** The settled status scheme seems to be working reasonably well. I have not heard very many complaints, other than very early on about the process for applying for settled status. Our bigger concern is about the proposals that the Government have made about European temporary leave to remain in the event of a no-deal Brexit. We are deeply unhappy with the suggestion that European temporary leave to remain would be restricted to three years, because people arriving under that arrangement would not necessarily have confidence that at the end of that period they would be able to secure a visa.

If you are coming to do a PhD or any programme in Scotland that might last longer than three years, it is pretty unappealing if we are saying, "Come. Trust us. You can apply for European temporary leave to remain, but we cannot at this point guarantee you that you'll get a visa at the end of the process."

Q4415 **Joanna Cherry:** Of course, in Scotland the standard honours degree course is four years long.

**Vivienne Stern:** Exactly.

Q4416 **Joanna Cherry:** That appears to have been overlooked by the British Government at present.



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**Vivienne Stern:** I would say that the British Government are well aware that the standard undergraduate programme in Scotland is four years, so it is quite surprising that they have not managed to create a system that accommodates that.

Q4417 **Chair:** On that point, is it your view that the Government need to do more to make it crystal clear to all EU citizens who are in the UK at the point that we leave, with or without a deal, that they will be able to stay and get settled status? Do you think that there is still uncertainty in the event, say, that there was a no-deal Brexit? This Committee has disagreed on some things, but one thing on which we have united is that the UK Government should give a clear and categorical commitment in all circumstances that EU citizens will be able to stay and get their settled status. Do you think that there is doubt in the minds of staff from the EU who are working or thinking of coming about what might happen?

**Vivienne Stern:** The problem is that there is so much uncertainty about absolutely everything. A university could give a very clear and unequivocal message to staff who are already here that the settled status scheme is open, and that they can, and should, apply now. However, even if that message is relatively straightforward and quite reassuring, the maelstrom of uncertainty about everything else undermines the confidence that they might have in that message.

There are two levels. On the one hand, the settled status scheme should be reasonably reassuring. On the other hand, if I were an EU national would I feel pretty uncertain? I certainly would.

Q4418 **Wera Hobhouse:** We have two successful universities in Bath—Bath Spa and the University of Bath. I am in close contact with both—the vice-chancellor and the principal of Bath Spa. They both feel very threatened overall about the university funding situation. There is a consultation out about humanities possibly getting lower tuition fees from students, but also, demographically, I understand in the UK student numbers are falling. They might pick up again in five or six years' time. The threat of Brexit creates a perfect storm and a very challenging funding situation, certainly for my universities, as I understand it. What capacity is there for any universities to go further afield and compensate with overseas students for EU students that we might not be attracting? Is there actually a projection that we can do a lot better and go further afield and compensate in that way or is there no evidence for that?

**Vivienne Stern:** I think we can certainly do better on international student recruitment. In fact there is an opportunity right now before Parliament to make a change that would make a huge difference to our fortunes in attracting international students. We currently have what I would regard as an uncompetitive visa offer for international students. If you are choosing between the US, Canada, Australia and the UK, which are typically the most popular study destinations, each of our competitors offers an opportunity to stay and work for a period after graduation. We don't, really. There is an amendment to the Immigration and Social Security Co-ordination (EU Withdrawal) Bill, standing in Jo Johnson's and

Paul Blomfield's names, which would correct that problem. If that change were made I think you would see a really dramatic shift in UK overseas recruitment.

We also have a Government target to recruit 600,000 international students by 2030. I would like them to be more ambitious, but I think it is brilliant that the Government have now committed explicitly to growth. We will need to do everything we can to attract students from outside Europe if we see an impact on European recruitment as a consequence of Brexit, but I have to sound a note of caution. First of all it is not just about numbers; it is also about quality. We have some absolutely outstanding European students, particularly at postgraduate level. Postgraduate research students from Europe are a very important part of our research infrastructure.

Secondly, I think it is important that we have balanced classrooms, so we have a diverse range of students in our universities. Those of you who have universities in your constituencies will probably be familiar with some of the concerns about over-dependence on a very small number of places for international student recruitment. China is the biggest single source country. Europe is currently responsible for a third of our international student recruitment, so I don't think it is okay to say, "Forget about Europe. We will lose those students. No problem. We will go and find them from elsewhere." I think we have to invest in reassuring EU students that they will be able to come and study in the UK and make ourselves more attractive internationally.

**Professor Wheeler:** I think the part of Bath universities' priorities that falls under UKRI will be more to do with research funding, and the funding that they gain through the European framework programmes—currently the Horizon 2020 programme. There they are looking at, potentially, a situation in a no-deal scenario where we no longer have access to a major source of funding from the European Commission. On aggregate all the UK organisations win about €1 billion per year from this programme, so it is huge. I think it is fair to say that UKRI's major activity in preparing for a no-deal scenario has been to deliver the Government's underwrite guarantee and underwrite guarantee extension, to replace as far as possible that research funding from a UK domestic source.

**Q4419 Wera Hobhouse:** This is hugely important for the University of Bath. When you say the Government is endeavouring to underwrite that, is there absolute 100% certainty or does it also depend on the political climate and possibly the Budget, and is the Treasury already fully committed to that?

**Professor Wheeler:** It is a complex scheme, because it is a large scheme, but it has two broad elements. For those projects where UK organisations are currently successful in securing funding from Horizon 2020 up to the day of EU exit, the underwrite guarantee is there to replace that funding from the point of EU exit onwards. UKRI has been commissioned to deliver that underwrite. The underwrite guarantee [extension]<sup>1</sup> then goes from the point of EU exit to the end of the Horizon



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2020 programme, at the end of 2020. That guarantee covers funding for all of those programmes where the UK can continue to receive funding, essentially as a third country rather than a member state. Again, UKRI's main task has been to organise the delivery of both those two elements—the underwrite guarantee and the underwrite guarantee extension.

**Q4420 Wera Hobhouse:** Just one last quick question. Is there anything beyond Horizon 2020, which is running out quite soon? Universities have been expecting that they might be able to bid into the follow-up programme to Horizon 2020 and continue to get the funding that way. Are you saying that that is all finished and there is no further underwriting guarantee?

**Professor Wheeler:** Those particular underwrites end at the end of the Horizon 2020 programme—the end of 2020. The subsequent programme is termed Horizon Europe; it will run for a seven-year period from the beginning of 2021. That is at advanced planning stage in the EU. The UK's preferred option is to seek full association to the Horizon Europe programme, which would give us the same access to that funding as if we were a member state. It would give us an associated country status. Both the final plans for the Horizon Europe programme and the question of full association are not resolved or finalised yet.

**Q4421 Wera Hobhouse:** Surely, in their view Brexit would threaten that co-operation in a big way, wouldn't it?

**Professor Wheeler:** There is no reason why in a no-deal Brexit the UK cannot still seek association to Horizon Europe, but there will be much larger relationship issues between the UK and the EU that may well influence that as well.

**Q4422 Jeremy Lefroy:** To continue on research funding, you said that UK universities gain approximately €1 billion a year. Is that right?

**Professor Wheeler:** Correct.

**Q4423 Jeremy Lefroy:** Your understanding is that that has been guaranteed, but only for the short term.

**Professor Wheeler:** Those awards that are currently underway and those that are deemed successful at the point of EU exit fall under the underwrite guarantee. UKRI has been tasked with delivering that. In a sense, that has been our main no-deal preparation activity to date.

**Q4424 Jeremy Lefroy:** During the referendum campaign, people campaigning for leave would say that we would be able to continue to provide the same level of research funding out of what we would save on our contributions to the European Union. Have you heard Government now saying that, going forward, we are going to make sure that, whatever happens, we are going to have at least the same level, if not more, in

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<sup>1</sup> Correction by the witness on 26 June 2019: The additional word 'extension' is important as it distinguishes it from the underwrite guarantee described in the previous sentence, which is a different commitment. In short, the underwrite guarantee runs to the date of EU exit and the extension runs from the point of exit to 31 December 2020.



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terms of research funding available for UK universities, so that they can maintain and indeed increase their research effort?

**Professor Wheeler:** It is a complex issue. There are three short points. Traditionally UK research and innovation organisations have won back more through these competitive programmes than, broadly speaking, the UK contributes, although that is very difficult to calculate. The underwrite guarantee seeks to replace funding that has already been won by UK organisations, up to the point of EU exit, and to guarantee to cover those that may be won—like most of the schemes—in the remaining year or so of the Horizon 2020 programme.

Beyond that, it becomes less certain. The terms of association to Horizon Europe from 2021 onwards are not yet finalised and won't be finalised until after the point of EU exit, as it currently stands. Those negotiations are yet to be had. BEIS undertake those negotiations and we provide evidence to them as part of that process.

**Jeremy Lefroy:** Sorry, I should have declared that I am a member of a board of a university in the UK.

**Vivienne Stern:** Tim has talked about the underwrite, and he has mentioned that for the part of the underwrite that applies to our bidding for grants that we have not already secured, there are some things we can participate in as a third country under the current rules. Then there are some very significant things that we will not be able to access as a third country after the date of exit. It so happens that those include the European Research Council. What we have not heard clearly from Government, either from Ministers or officials, is that funding will be made available to replace the bits of the programme that we cannot access as a third country: the ERC and the Marie Skłodowska-Curie Actions. If we had left in March and not been able to access those funding sources, the loss to the UK—based on our previous success—would have been about £1.3 billion just for the end of this bit of the programme. That money has never been guaranteed. Although the Government's underwrite for Horizon 2020 is exceptionally useful, there are still some very big unresolved issues.

The other thing I would say is that we now have to start thinking about the next programme. We might not be in a position to negotiate association with Horizon Europe, the next programme, in a timely manner. That is starting in 2021, and we should be having those negotiations now. This political circumstance means, as Tim said, it is unlikely that we will do that. The Government will have to think about extending the guarantees they have already offered and say to European partners, "If you want a UK university in your consortium for the Horizon Europe bid"—one of those for the next programme—"we will put the money on the table. It is there." Nobody has said that so far, so those consortia that are starting to form in order to make applications under the new programme do not know whether the UK funding will be available. It is really important that the Government are more explicit about how they will support our participation in the bits we can part in, and about what they will do to

replace the bits we cannot take part in. The sum of money is enormous, and the loss to the research system would be enormous.

Q4425 **Jeremy Lefroy:** Have you said that clearly to the Government?

**Vivienne Stern:** Yes, we have.

**Dr Thompson:** Vivienne has picked up a really important short-term point that I am very glad we have covered: the European Research Council. I want to come back to the issue of association with Horizon Europe in the longer term. You are right to say there have been indications that we could perhaps do something domestically with the money that it would take to associate with Horizon Europe. It is very important to flag two things here. First, it is not simply a case of substituting cash from one place to another. The EU programmes are very successful. They are world-leading and provide the UK with a great opportunity to network with other researchers. We therefore cannot be looking at like-for-like cash; we have to look at the other values that you get from those programmes.

Seeking association would be really important. The second thing I wanted to say about that is that we should not underestimate the difficulty of doing that in a no-deal situation. Technically, it should be possible—there are third countries that have associated country status—but I think it would be hugely difficult politically to associate and secure that long-term agreement in a no-deal situation.

Q4426 **Jeremy Lefroy:** One of the criticisms that has been levelled, perhaps unfairly, is that the upper rank of UK universities are quite happy to engage in overseas partnerships right across the world—we mentioned Oxford and Berlin—but they are a little more reluctant when it comes to investing in parts of the UK other than their home city. They might have some outreach programmes here and there, trying to get increased diversity among their student population, but when it comes to hard facts on the ground—putting an Oxford University in Bolton, or a small campus there to help regenerate other parts of the country—we are lacking. I have seen a different approach from other UK universities that go into nearby towns that are perhaps not so well served by higher education, to get involved in education and help start small businesses and so on. I have seen that in other countries as well. I wondered whether you saw a greater appetite from our leading universities to invest in the UK outside of their traditional locations, so as to bring the UK together.

**Vivienne Stern:** I think there is a false dichotomy between universities that see themselves as global institutions, globally engaged in research and education, and universities that are somehow local in their mission. If you look at any of our big, research-intensive, civic universities, they are spending probably millions of pounds on outreach to students from disadvantaged groups or groups that traditionally do not go to university. They are investing in a significant programme of public engagement, to ensure that the research that they are undertaking and the knowledge they are generating is available to communities, not just locally but



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nationally. They are one of the major parts of our nationwide museum infrastructure, for example.

Lord Kerslake has recently chaired a commission, which looked at civic engagement on the part of universities. I think that—for me, although it is not my policy topic of expertise—the contributions that universities make to the fabric of society is something that we should be genuinely proud of. That is before you start thinking about the economic impact of those global relationships. The international students that universities recruit contribute £26 billion to the UK economy, not just in terms of what they give to universities, but the money they spend in taxi firms and small businesses, and the spending of their family and friends who come to visit as tourists.

Then we can think about the companies that decide to bring foreign direct investment to the UK, because they have a research relationship with a university. I have been compiling a list of companies that are setting up here because, for example, the University of Exeter or the University of Glasgow has particular expertise. I can send that to the Committee.

There is no distinction in my mind between a university that is making a national contribution and a university that is globally connected. They are bridges. They are so fundamentally important to our economic fabric. We could possibly do a much better job of explaining that.

**Q4427 Jeremy Lefroy:** I will just make the point that in my town a British university, Staffordshire University, pulled out of an entire campus. That campus is still there; it is being invested in by a Chinese consortium, which I welcome. No UK university was prepared to come in and take over an existing UK campus, which I found a little bit disappointing, given that they were prepared to invest all over the world.

**Vivienne Stern:** We heard a little earlier that there are a number of policy and other factors that are putting quite a lot of financial pressure on institutions. There is the demographic issue, which you mentioned. There are rising pension costs. There is some uncertainty about future income for tuition, as a result of the Augar review. There are rising costs across the board associated with not just Brexit, but general economic conditions.

Institutions cannot afford to get into the kind of financial difficulty that might cause a collapse, because, in many cases, they are too important to local communities to fail. That sometimes means retrenching and doing things that might be really unpopular in terms of cutting provision, but at the end of the day they have to balance their finances.

**Q4428 Mr Whittingdale:** Ms Stern, I am sure you agree that the principal reason why so many overseas students wish to study in the UK is because we have some of the finest universities in the world.

You said that we cannot abandon the third of students from the EU and hope to make it up from the two thirds of students who don't come from the EU. Why is it that the two thirds of students who don't come from the EU have the confidence to do so, because they want to study here,



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without an arrangement that has been reached through the European Union, but the EU students won't want to come to study here without that arrangement continuing?

**Vivienne Stern:** I personally do not believe that we will see a total collapse in EU recruitment post Brexit, even if—we don't know yet—the fee is the same as international fees and we have an immigration regime. I am perhaps more optimistic than some other commentators. For example, Oxford Economics did an analysis and suggested that as many as 57% of EU students might decide to go elsewhere if we went to international fee status. I am probably a bit more optimistic than that.

**Q4429 Mr Whittingdale:** Do you know on what basis they produced that figure?

**Vivienne Stern:** You can model behaviour based on previous policy changes. We know that EU students are quite price sensitive, because we have changed our fee regime for EU students on two occasions in the last 15 years or so, and you can see the effect of moving from a fee-free regime to the £1,000 initially and then the £3,000 and then the £9,000 fee regime. You can extrapolate that.

We also know things such as what proportion of students from different countries take advantage of our loan offer. Generally speaking, it is the case that the richer northern European countries draw less on the loan system that we offer than, for example, the EU13. You can then begin to try to make some judgments about what you think the impact of a change will be.

I would argue, however, because it is my job to promote the university sector around the world, including as a study destination, that we can also make our own weather. You are right to say that, fundamentally, when people choose where to study, the thing that matters is the quality of the education that they are offered, and I believe we have a very strong offer. I also think we have a strong offer on graduate outcomes. We are about to publish a lovely piece of research on that, which shows that there is genuinely a wage premium for those people who study in the UK compared with people who study in other systems.

We can do a lot to mitigate the potential impact of that change, but there will be an impact. It may be short term and it may be lower than Oxford Economics thinks, but there will be an impact. I can tell you that some universities have modelled what I would regard as quite catastrophic decreases in EU enrolments of up to 80%. When you work that through to the bottom line, that means closing courses and pulling back from the kind of things that we were talking about a moment ago.

**Q4430 Mr Whittingdale:** But as you say, the modelling is based on assumptions about what we may choose to do. If we choose to charge EU students a full overseas fee, which they do not currently have to pay, I am sure some will decide not to come here, and equally in terms of eligibility for student loans, but all those things are within our gift. The models assume that the British Government or British universities will adopt a policy that will lead to a disastrous fall in their intake, which



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seems rather unlikely.

**Vivienne Stern:** It is an extremely important point actually. We talked about uncertainty in other things. Our Government announced the fee that EU students will pay if they start in September 2020 only about three or four weeks ago. We are about halfway through the recruitment cycle for 2020. There are students who are now beginning to think about studying in 2021 who do not know whether it will be a UK fee, whether they will be able to access the loan, or whether it will be an international fee.

My prediction, based on the last three years, is that we will get an announcement on fee status somewhere like halfway through the next recruitment cycle. It will be late and I will have emails from Greek counsellors sending me impassioned pleas: "Here I am standing in a recruitment fair. Students are asking me what the fee is and I cannot tell them the answer. What are you going to do about it?" I bet that is where we are going to be this time next year.

That is a real shame because, in the meantime, those students know that they can study at relatively high-quality and lower cost institutions in Germany, France and the Netherlands, often in English. We have competition; we cannot just assume that people will come to us because they have no other choice. The Government should be clear, as soon as possible, what the fee regime for 2021 will be, then we can deal with the facts as they are.

Q4431 **Mr Whittingdale:** Is there anything stopping a British university saying to a new entrant coming in this September that, "We guarantee that you will pay the same level of fees that you are currently paying until you complete your course."

**Vivienne Stern:** They do not need to, because the policy across the UK is that any student entering in 2019 will pay the UK-level fee and have access to finance for the duration of their course. No university has to do anything additional to that.

Q4432 **Mr Whittingdale:** So why is there any uncertainty about people making applications?

**Vivienne Stern:** They are now applying for 2020. We have had an announcement for that. Very soon, they will be thinking about 2021.

Q4433 **Mr Whittingdale:** But you could extend that guarantee, if you chose, to those students.

**Vivienne Stern:** The Government could. The question of whether universities could say to European students, "We will discriminate in your favour in setting the fee", is a question on which we have sought legal advice on a couple of occasions. It is our understanding that you can do it at the moment because UK law says you can. We are also assuming that that law is likely to change post exit, so the law that allows us to discriminate in favour of EU students would have to be changed. If it were changed, however, it would leave any university that would say to a French student, "Your fee will be £9,000," but to a Japanese student, "It's



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going to be £15,000 or £16,000," vulnerable to legal challenge. It is a question for the Government. Like everything in this space, it is something that the sooner the decisions are made, in some respects, the better.

Q4434 **Chair:** One final question from me. Imagine that the new Prime Minister, whoever it is, is sitting in this chair in a month's time. They put a simple question to you about weighing up whether we should leave the EU on 31 October with a deal or without a deal, and they ask, "Should I leave without a deal?" In one word, what answer or advice would you give them?

**Vivienne Stern:** No.

**Dr Thompson:** No.

**Professor Wheeler:** We are prepared for either.

**Chair:** On behalf of the Committee, I thank you very much for coming today. Your evidence has been really useful and we are very grateful.