HOUSE OF COMMONS

Business, Energy and Industrial Strategy Committee

Oral evidence: Leaving the EU: implications for the pharmaceutical industry, HC 382.

Tuesday 5 December 2017

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Watch the meeting

Members present: Rachel Reeves (Chair); Vernon Coaker; Drew Hendry; Stephen Kerr; Peter Kyle; Rachel Maclean; Albert Owen; Mark Pawsey; Antoinette Sandbach.

Questions 1 - 136

Witnesses

I: Mike Thompson, Chief Executive, Association of the British Pharmaceutical Industry; John Smith, Chief Executive, Propriety Association of Great Britain; Paul Fleming, Technical Director, British Generic Manufacturers Association.

II: Mark Hicken, Managing Director, UK & Ireland for Janssen, Pharmaceutical Companies of Johnson & Johnson; Peter Ballard, Managing Director, Xiromed.

Written evidence from witnesses:

- Association of the British Pharmaceutical Industry;
- British Generic Manufacturers Association;
- Pharmaceutical Companies of Johnson & Johnson.

Examination of witnesses

Witnesses: Mike Thompson, John Smith and Paul Fleming.

Q1 **Chair:** Thank you very much for coming to give evidence to our Select Committee today about the impact of Brexit on the pharmaceutical sector. We appreciate you coming in to see us. It might be helpful if you start by introducing yourself and who you represent, and then we will crack on with the questions.

John Smith: I am John Smith, the Chief Executive of the Proprietary Association of Great Britain. We represent branded manufacturers of consumer healthcare products in the UK—products that you would buy in a supermarket or a pharmacy.

Mike Thompson: Mike Thompson, CEO of the Association of the British Pharmaceutical Industry. We represent the research-based pharmaceutical companies and supply the NHS with about 80% of the branded medicines. We have a similar percentage of all of the medicines that are in development around the world. We also have the responsibility for the industry's code of practice and the responsibility to negotiate with Government over arrangements.

Paul Fleming: Good morning. My name is Paul Fleming, and I am the technical director for the BGMA, which is the British Generic Manufacturers Association. We manufacture unbranded generic medicines, which become available after the patents for the original versions of the drugs are over. In the NHS, that constitutes the great majority of the volume of medicines that are used: we constitute about 75% of the medicines that are actually used day to day by the NHS.

Q2 **Vernon Coaker:** Good morning, everyone. As a general start, what would you say the reaction of the different sectors of your industry has been so far to Brexit? What has the general reaction been to it?

Mike Thompson: On the day of Brexit, we made an announcement to say that we accepted the voice of the British people and we would work to find the best solutions for them. We have been doing that. We agreed with the Government to set up joint working parties with George Freeman, who was then the Life Sciences Minister. We set up a working party and we involved everybody that we could, including people like MHRA. We had six work streams; we did something like 60 hours of workshops. We had 200 global experts—some of the areas are incredibly specialist, so we were able to reach into our organisations. We came out with a meeting with the Government in September, with four key areas that we felt were vital: regulation, trade, people and investment in the science base. Those four areas have remained the key areas of focus. They have been amplified by the Government and they have essentially set how we have worked now to find a way forward to get the best result for patients and public health as an outcome of these negotiations.

Q3 **Vernon Coaker:** Other members of the Committee are looking in more detail at some of the things that you have mentioned there, but can I just get a general comment, please?

John Smith: I am absolutely aligned with Mike and what he is saying. We are also looking at ways that we can make sure that this happens in the best way possible. Making sure that we have a continuous supply of consumer healthcare products on the marketplace is key for us. We are working very closely with our trade associations—Mike and others—and are also working with our European trade association and the MHRA.

Paul Fleming: It is very much the same for us. We have worked very closely together, both here in the UK—not just within pharmaceuticals but across the life science sector—and in parallel with our colleagues at European level. A lot of that has been around mapping out the scale of potential risks and the timescale. One of the important points for us is to have very well managed change, so that we have visibility on what is likely to happen and are able to ensure that there is no disruption to the supply of medicines to patients in the UK.

Mike Thompson: I should just add that our written evidence was produced jointly with the UK BioIndustry Association, who are not represented today. It would be important for me to mention that, because, as everyone has said, we have worked very closely together on this.

Q4 **Vernon Coaker:** There is a lot of working together, looking at what is happening, and everybody is trying to assess the impact, et cetera. Let us try to look at that a little bit. Paul, you were talking about the register of risk, unless I misheard you. Anybody would say that there is a degree of uncertainty at the moment about what exactly is going to happen. Have you noted any changes in investment decisions or changes in the way any of the people you represent are acting at the moment? What are they factoring in in terms of the future, and when do they need decisions made by?

Paul Fleming: I will try and answer some of that.

Vernon Coaker: Essentially, have you noticed any changes in behaviour as a consequence of Brexit. Can you give any examples, as that is always helpful?

Paul Fleming: Yes, I will be very happy to do that. I will probably ask Mike to add a little bit more on the piece about investment after I have finished answering. Regarding the specific risk factors, one particular one is around quality control testing of medicines. Before any batch of medicines is released for sale in the market, it has to go through quality control testing, which is a wide range of laboratory testing and specification controls. At the moment that is done once and once only, for the whole of Europe, so if there is any risk of duplication on that—if the UK had to repeat that testing, for example—that would have a very significant impact. People are changing their behaviour in planning for

that possibility: either they are thinking about building new facilities, which would be the ultimate approach and the most costly in the long term, or they are moving to alternative facilities, which they either already have access to or are making new commercial arrangements for.

Q5 **Vernon Coaker:** Have you seen anybody do that?

Paul Fleming: Some companies are starting to do that already, because of the time that takes.

Q6 **Vernon Coaker:** This may sound pedantic but what does "already done it" mean? Have they have already moved to another country, have they already built a bigger facility, or what?

Paul Fleming: They are starting the process of doing that, because it is a very lengthy activity. It takes at least 12 months, typically 18 and up to 24 months, so that is one of the physical activities that does take a long time to perform. Due to the timescale that we are on running up to March 2019, to do something that takes 18 months, you have to have started now or be starting very soon.

Q7 **Vernon Coaker:** So you need certainty quite quickly.

Paul Fleming: That is right.

Mike Thompson: I am seeing different players making different decisions. If we start with individuals, AstraZeneca, in their evidence to a Lords Committee, said that they were having difficulty attracting some people to take up jobs in the UK. It is understandable that if you are coming from the continent, at this moment in time it does not seem like a good idea to move your family when there is a period of uncertainty. They are having difficulty filling some of the jobs that they have open at the moment.

Q8 **Vernon Coaker:** Already?

Mike Thompson: Already.

Q9 **Vernon Coaker:** Do you know the numbers for that? Do you have any figures?

Mike Thompson: No, we do not have any numbers for that. You then see some different decisions, which may be confusing to people from the outside. There are some people who have decisions to make now in their cycle who have either made a decision to delay making that decision, or, as some smaller companies are reputed to have done, made choices about going to Switzerland as opposed to going here. On the other side, you will have seen that there have been some major announcements of companies that have planned to invest in the UK.

Pulling these things apart, there are different reasons for those decisions, and therefore there is not a simple answer that you can take across the whole piece.

Q10 **Vernon Coaker:** Is there evidence that there is a difference between some of the decisions being made by smaller companies as opposed to bigger companies?

Mike Thompson: I would not say that. I do not think it is as simple as to say that. Tomorrow we are expecting to see Sir John Bell announce the next phase of the life sciences sector deal, and I think we are going to see a significant number of investments from companies of all sizes. You have to look at each individual company and you have to look at the reasons behind their decisions.

John Smith: Very similar to Paul, we are seeing our companies considering about where batches are released; if the UK has a hard exit, we would have to have a release in both countries. They are thinking about putting positions into Europe.

If you also look at medical devices, which we also look after, you have notified bodies. Notified bodies have to be part of the EU, so they are looking at having offices in the UK but probably also having offices in Europe so that they can cover both sides.

The last thing for us is we are seeing some of our members thinking about how they deal with the MHRA, because if they are a reference member state and they have a process that is going to go past the EU exit date, they are looking at going to other reference member states rather than the MHRA.

Q11 **Vernon Coaker:** So people are starting to hedge, in a sense, against what may happen.

John Smith: Yes, because the whole process is not going to be quick. Once we know what is happening it is still going to take quite a while to do that, so they are going to have to start hedging now. The most important thing for us is certainty going forward, so that the companies can start planning. If we have no certainty they have to start hedging now to be in a position at the date.

Vernon Coaker: As Paul was saying, if you are going to change something, there are a couple of years, with the transition period and how long that is, et cetera. We will come on to that.

Mike Thompson: I would say "hedging" is an umbrella word, and I do not think it is quite accurate enough for the decisions that are being taken. As John said, GSK has publicly announced that it is going to build some batch release sites on the continent because there is a requirement under EU law for batch release to be done in an EU state for those medicines that are going to be distributed to the EU. Therefore, although there is a possibility that the outcome of the negotiations is mutual recognition, so that decision would not be needed, essentially GSK would not be able to supply its medicines manufactured in this country to other EU states if it did not have that facility built. They are going to spend tens of millions of pounds to set up that capability.

Q12 **Vernon Coaker:** GSK is going to spend tens of millions of pounds setting up a facility in another European country.

Mike Thompson: Correct, because the EU regulations, as they stand, say that you need to have batch release from an EU member state. At the moment, the guidance from the EMA is that the UK will be a third country. The issue of whether there will be some mutual recognition is something which is not going to get clearly resolved for a long time, and therefore companies have got to make sensible contingency decisions. Our overriding concern is to make sure that we can continue to supply medicines to patients across Europe.

Vernon Coaker: That is interesting. GSK, AstraZeneca—and a small business moving to Switzerland.

Mike Thompson: I am not saying that GSK and AstraZeneca are moving to Switzerland.

Vernon Coaker: No, I am saying GSK and AstraZeneca are doing something, and then you mentioned a smaller business moving to Switzerland.

Mike Thompson: Yes.

Q13 **Chair:** I want to put the other side, because, as you have said, Mike Thompson, tomorrow the Government will be announcing parts of the industrial strategy and the sector deal with the pharmaceutical sector. We had the announcement, on the day that the industrial strategy was launched, of new investment coming into this country. We also had the letter from the Secretary of State for Health, along with the Secretary of State for Business, Energy and Industrial Strategy, to the *Financial Times* in July setting out the Government's objectives with regard to the sector and to have that close co-operation.

Some of that seems to be working; investment is still coming into this country despite the worries that you have spoken about, so what explains that? Some companies are saying, "We need to do more in the European Union," and others are saying, "We still want to come to the UK." Are they different companies reading things in different ways, or are they doing different things?

Mike Thompson: I recognise that it can look confusing from the outside. It is a good question. If we look at the MSD announcement, it is an announcement into early phase discovery, and I think the UK is recognised as being the third best centre globally for early stage research. After the east and west coasts of America, the UK is predominant. Everybody in this room can feel very proud about the ecosystem that we have developed, with the strength of our universities and medical charities, having built a life sciences business here. In the UK we are fantastic at creating and discovering things; it is something in our psyche and therefore I think it makes a lot of sense. I am absolutely delighted to see MSD's investment in here.

The message to Europe is that Europe benefits from its close association with the UK. There is not another centre on continental Europe that matches the UK and the golden triangle. We are operating in a global business and people make global decisions. I have to tell you that if people are not going to invest here, they are unlikely to be investing in Paris or Berlin; they are much more likely to be investing in the east and west coasts of America, so Europe as a whole benefits enormously from the strengths that we have here. Therefore, we were delighted with the letter that Secretaries of State Hunt and Clark wrote, which said, "Actually, the UK's aim out of this is close co-operation with Europe, which we believe is in the best interests of the UK but also in the best interests of Europe."

What we have been able to do is ensure that that across our industry and across the whole of Europe, we are completely aligned. We have a single set of messaging that everybody in the industry is using when we talk to Governments across the whole of Europe, and it is the same thing: that we are better together in Europe, and that Europe benefits as much as the UK from us working together in this space.

Q14 **Chair:** To follow up again with you, Mike Thompson, something like 40% of the jobs in the pharmaceutical sector in this country are in research; many of the others will be in manufacture. Are you saying that in the future it might be easier to attract the R&D jobs—or that will not change because we have such strength there—but it is the manufacture and testing of the drugs that might move overseas because of Brexit? Is one type of job sort of okay, and the other more at risk?

Mike Thompson: We have seen that a large amount of the manufacturing has actually already moved overseas. The work that we have been doing through the Medicines Manufacturing Innovation Partnership is essentially to say, "Can we now jump a generation of medicines, and can the UK be effective as a manufacturing base for the next generation that is coming along?" We have, in a way, lost the battle in some of the previous generations. You will have seen in the Budget quite a bit of money being put into manufacturing. That is because the nature of manufacturing for new medicines is changing, and some of the very large-scale manufacturing plants that were required for the previous generations of manufacturing medicines will not look the same in the future. They are much more likely to be back-ended into research bases and therefore they can be much smaller—you can use a much smaller plant to produce the same volume of medicines.

Q15 **Chair:** My question is about whether Brexit affects those sorts of jobs more? The answer to Mr Coaker's question was that AstraZeneca, GSK and others are going overseas, and yet at the same time you are acknowledging that there are jobs coming to this country.

Mike Thompson: I think there is the potential, but clearly if there were trade barriers, then those trade barriers would then make people think twice about those investments. That takes us into the area of trade, and

clearly we are saying that one of the critical things—and I think one of the most important things for people to understand—is that frictionless trade is really critical in this area. This is an important conversation for us to have.

Q16 **Chair:** We will come to that in a minute. In terms of the Government's aims, as stated in the letter from the two Secretaries of State to the *Financial Times* and then also in the industrial strategy, is there anything in the aims of the Government on pharmaceuticals that you disagree with? If, as I expect, you agree with the objectives of the Government, how realistic are they for that close co-operation in the future?

Mike Thompson: First of all, you are absolutely right: we are delighted with the UK Government's response on all four areas. We have seen a series of announcements on all four key issues that have been really aligned with the work that we have been doing together. I think it is no surprise that when you work together, you come to solutions that everybody can buy into. It has been a very effective process.

As a result of that letter, our European organisation wrote a joint letter to both Barnier and Davis saying, "This is what we are looking for." As you know, the issue for us has been that the negotiations with the EU have been stuck in phase 1, and the message back from Barnier's team was, first of all, "This is a really interesting letter that has been published in the *Financial Times*. We really note its significance and it is very welcome, but, by the way, we cannot talk about it, because our brief from our member states is only to talk about three things until we get to the end of phase 1."

One of the challenges for us is that, if I may say, it is not unusual for politicians to think that you do not need to do a deal until the absolute last minute, but businesspeople need to be able to plan ahead. The fact that we have not had the time to plan ahead has meant that companies are having to make these contingency decisions, which is costing them an enormous amount of money. We have been pushing hard. If there is any disagreement, it is to say, "Can you please get into phase 2 as quickly as possible, because we need to have some decisions so that we can plan to ensure the continued supply of medicines to patients across Europe?"

Chair: That is very helpful. If either of you want to come in then please do, but we are going to cover some of these issues in more detail.

John Smith: I think we are completely aligned.

Q17 **Mark Pawsey:** I would like to pursue the issue of trade that you spoke about. Can you help us by giving us some numbers in terms of the value of the trade, both imports and exports? Could you also give us some guidance as to what proportion of the trade that is happening in pharmaceuticals is between the UK and the EU, and between the UK and the rest of the world? How important is the EU in the industry generally?

Mike Thompson: We export about £30 billion a year and we import about £30 billion a year. To make that a bit more tangible, there are 45 million packs of medicines that leave the UK every month and go to Europe, and there are 37 million packs of medicines that leave the continent and come to the UK. The reason for that is that, in a sense, this industry has taken the most from being in a single market and we have a very integrated supply chain across the whole of the continent. That obviously gives us some more problems at the moment. I think about 44% of our exports go to the EU. Those are the numbers.

In trade there are two issues, as you will know. There is a tariffs issue and then there is a process and paperwork delay issue. Candidly, both of those issues are important, but for us the most critical issue at this moment in time is the delay issue, particularly for the sorts of newer medicines that are being produced. The production process has a number of steps; typically it can be up to eight different steps before you get to a final medicine. The way we have developed our supply chain is that often those are done in different manufacturing plants, because it is not sensible to build the same process in each country; you tend to have one for a region. As you make a medicine these things get moved around, and they can go across borders multiple times. That is just in the production of them.

The other issue is that quite a lot of them are temperature-controlled. If you do not manage to do it within a certain time period, you are out of spec and you have to throw it away. There is a very real issue for us here. We do absolutely everything we can to get medicines to patients; I have seen us charter planes and people work thorough weekends. We do whatever we need to do to get a medicine to a patient. If we legally cannot get through borders or we are delayed in getting through, there is nothing we can do about it. We have been imploring people to understand that medicines are different.

Quite frankly, if a car is held up at Dover it is obviously unfortunate but it is not life-threatening. If medicines cannot get through, it is life-threatening. What is important is that people need to understand that this is not an issue about UK patients versus EU patients. This is about patients across the whole of Europe, so everybody is going to lose out here. At one level we say, "Surely everybody is going to understand that and we will not end up in that position", but sometimes you can see that the scale of challenge that is facing those who are negotiating arrangements is such that somehow these things could get missed, the officials cannot cope with it, and we could end up in a situation where we cannot supply.

Q18 **Mark Pawsey:** Can that process delay not be dealt with by simply holding more stock?

Mike Thompson: It is not possible for us. First of all, some medicines will only have a shelf life of 12 to 18 months. At this stage we would not

be able to ramp up all of what is required to produce the sort of stock holding that is required to be able to manage this effectively.

Q19 **Mark Pawsey:** So you are suggesting that the process issues are rather more important than the tariff issues. What impact would it have if we do a hard Brexit, tariffs are imposed and we go to WTO rules? Would that be marginal?

Mike Thompson: I think it will depend. First of all, if you are making future manufacturing decisions, you will then clearly look at tax and tariffs, and you will make some decisions looking at the total fiscal weight that you have. It will make a difference in the long run. From our perspective, the delay factor at this moment in time is the more important factor. The others will start to play out in time, but that is for us.

It obviously depends on the margin you have available in a product. I will perhaps ask John and Paul to talk, because it will have different impacts for different people.

Q20 **Mark Pawsey:** Perhaps the others might like to contribute. If there are tariffs or process delays, why can we not simply manufacture more of what we need ourselves? Why do we need to rely so much on products that are manufactured overseas? Why can it not come back?

Mike Thompson: We do not have the process capability in the UK to manufacture all medicines in the UK. We do not have the plants. These plants cost tens, sometimes hundreds, of millions of pounds to invest in. Nobody is going to build it in the UK; at current values, with the devaluation of the pound, the UK is 2.3% of the global market. People are not going to build manufacturing plants to supply all of the medicines for the UK.

Q21 **Mark Pawsey:** Not all of them, but maybe at the margin. Would it not make more sense to manufacture in the UK more of the medicines that are needed in the UK?

Mike Thompson: I think that will not make economic sense.

Q22 **Mark Pawsey:** So the cost of medicines would go up, essentially. We would end up with the cost of the process and the cost of the tariffs.

Mike Thompson: First, I do not think it is practical, but it would also mean that the costs would have to go up dramatically.

Q23 **Mark Pawsey:** In terms of trade, if we are going to do less business with the EU—you said that 40% of our exports were to the EU—why can we not be more aggressive in other markets outside the EU and pick up more business? Why can we not grow that 60% in emerging economies? Why are we so dependent on our 40% of exports into EU countries?

Mike Thompson: Remember that this is a global business. At the moment, those other economies receive the same medicines out of

regional supply chains in their areas, whether it is the US or the Far East. There are already manufacturing capabilities to do that, so I do not think it is the fact that they have not got these medicines and we can therefore sell them. There are supply routes that are already regionally based.

Q24 **Mark Pawsey:** What about the relationships that we have? We have trade envoys and we are starting to talk to countries as a UK producer rather than part of the EU team. Are you discounting that?

Mike Thompson: No, I am saying the same medicine is already being produced in a different regional supply chain. We tend to have regional supply chains, so it is not that it is only produced in the UK for the whole of the world. It will be produced in the UK for Europe, but then there will be a plant in the US producing for the US and there will be a plant in Singapore producing for the Far East. Those supply chains are already established, in the main.

Q25 **Albert Owen:** Can I just follow up on the WTO rules? Mr Thompson, you said pharmaceuticals should be zero tariff. You also pointed out that there are 1,000 finished products and an additional 700 component products awaiting introduction to the list. In your opening remarks, you also talked about your relationship with the Government. Have the Government indicated that they are acting on this? Is there going to be a standardisation in the timeframe?

Mike Thompson: Regarding WTO rules, as you rightly say the last round was in 2010. In the main, we expect a sort of "zero for zero" will play out. However, there are a large number of ingredients that are not on the list. At the moment, as you will know better than I do, there appear to be geopolitical reasons why a renegotiation of the WTO rules is unlikely to happen. It should have been updated every three years but there seem to be some reasons why other major countries are not interested in updating the WTO rules. It is not in the gift of the UK to say, "We want to update them so let us just update them." There are very significant other issues that would need to be addressed to do that.

There are challenges there. As I said, the result of those challenges is that those elements will probably have a 6.5% tariff laid on them. If you have stuff that is going across borders three or four times before you actually get to it, that mounts up to quite a lot of money. Those things will then start to play on people in terms of making the decisions as to where they will manufacture in future. Of course it is a very big issue, but I am just saying that for us the other issue about delay is a much bigger issue at this moment in time.

Q26 **Albert Owen:** Regarding the delay, in a previous answer you talked about the sensitive nature of the products and the temperature sensitivity if there were delays in ports. You have just indicated that two or three stops may add problems. How much of your trade, as an industry, is with the Republic of Ireland, and how much of a land bridge is the UK to the rest of Europe? In my constituency, much of the trade coming through

the Port of Holyhead goes to central Europe and to the rest of the EU.

Mike Thompson: I do not have specific figures for that. As you know, the Republic of Ireland has built a tax regime that has resulted in a very strong manufacturing base. There will be quite a lot of intermediates which come from the UK to the Republic of Ireland, and therefore a resolution of that will be of as much interest to the Republic of Ireland as it is to the UK.

Q27 **Albert Owen:** Absolutely, and we heard what happened yesterday, but my point is, as somebody who worked in trade with Ireland, you could have R&D in the UK, manufacturing in Ireland, and then transportation from the Republic of Ireland via the United Kingdom back into a European market, and that is complex.

Mike Thompson: That would be a very typical supply chain today.

Albert Owen: I will leave it at that.

Q28 **Antoinette Sandbach:** I wanted to talk to you about the regulatory aspects and, in particular, regulatory alignment. How important is regulatory alignment for your industry?

Mike Thompson: We think it is critical. I wonder if I should describe the solution that we have proposed, which we think is acceptable to both parties. In the regulatory process, as you know, the first stage of the process and the most important stage is what is called scientific review. The MHRA, which is the UK regulator, has played a very big part in being a leader of that scientific review, which is called a rapporteur. Essentially, they then make a recommendation; there is a committee that signs it off, and it moves to a second stage, which is that that recommendation from the scientific review goes to Brussels for a decision.

Q29 **Antoinette Sandbach:** Can I just check, because you said MHRA. What role does the EMA have in this process?

Mike Thompson: The EMA runs the process but, essentially, it subcontracts the work to the national regulatory authorities. By the way, we should be very proud of the MHRA. They are an absolutely outstanding agency: they have really good recognition around the world and their influence across Europe is huge. This has been a very successful agency from our perspective. I have to say that, for the rest of Europe, not having the MHRA involved will be a really significant loss to the totality of the effectiveness of Europe.

The point, however, is that, if, at the point of decision, the decision train is split in two, and one half goes to Brussels and one half goes to London, the advantage would be that London would be able to say that we have total control over what we license as medicines for UK citizens, and Europe would be able to say, "We control what we license." The benefit for the UK is that that decision would not be beholden to the ECJ but the result would be that the medicines that are used across Europe would be identical. Since the EMA was set up, there are only one or two cases

where there has been any challenge to that decision, and I have to say that that has normally been for political reasons and, in the end, it has got worked out.

That was a very neat solution that we know is acceptable to the UK Government, and we believe that that will be acceptable to the Europeans as well. We have a solution on regulation that I think is a very neat solution. That regulatory co-operation would also fit the Irish question as well, because that would meet some of the requirements that people are looking for there, so this is a very good outcome.

Q30 **Antoinette Sandbach:** I think my colleague Rachel Maclean will pursue that regulation issue further, but I am going to pick up on the MHRA. You said it is a huge benefit to us, and that that expertise is a huge benefit to Europe and that Europe will lose out, in effect, if there is separation in terms of the EMA now moving, as we know it is. Do you think the UK will lose its influence over those regulatory standards because the EMA is no longer in the UK, or do you think that they will still take into account MHRA decisions?

Mike Thompson: If the outcome is that the MHRA is still involved in the EMA, which is the proposal that the industry is making across Europe, then I believe that the quality of its capability and its expertise will still have a huge influence, regardless of the final decision about whether they have a vote or not. Votes tend to be taken by consensus. This is a scientific debate and it is more about being at the table than being able to influence the decision that is important. I think everyone would benefit by the expertise of the MHRA participating.

Q31 **Antoinette Sandbach:** Effectively, if the MHRA is not part of the EMA going forward, in whatever status it has, that would potentially be a big problem and the UK would—

Mike Thompson: They have been fairly open to say that they would look to try to build alliances with other stringent regulatory authorities elsewhere in the world. In our industry, 75% of the value of the medicines is in the US and within Europe. If you are not participating in those two parts, then you are inevitably diminished in terms of your influence.

John Smith: Can I just come in on the regulatory process? For consumer healthcare, the big issue is what is already registered. There will be a process for batch release, and a batch release will take place in Europe for the UK as well. If we do not stay aligned with that, it would mean that we would have to have a batch release in Europe and a batch release in the UK. That adds significant complication and costs to our industry and you have got to be in two places, and that just does not make any sense. When you look at a cost perspective, it is going to add millions of pounds to the whole process. Delay is important for us, but I think the whole regulatory process of making sure there is not divergence and making

sure that we are together and that we can have one batch release for everything that is produced is important for us going forward.

Q32 **Antoinette Sandbach:** Your evidence suggested that companies are moving away from the MHRA as being their EU-wide reference agency. Is that a trend across the industry, do you think, and what does that mean for the UK?

John Smith: Like Mike said, you should be very proud of the MHRA. I think they are very pragmatic and forward-thinking in getting access to medicines to people who can get access without going via a prescription. Members companies are now saying—and the advice coming out of Europe is—that if you have a process that is going to go beyond the date, you need to think very seriously about whether you use the MHRA or not.

Q33 **Antoinette Sandbach:** Beyond the date of March 2019?

Mike Thompson: Yes, the exit date. They are saying that, if the process goes beyond that, by then the MHRA will not be part of Europe and, therefore, you should not be using the MHRA. A lot of companies, although they do not want to, are starting to think about using other regulatory agencies for their processes.

Q34 **Antoinette Sandbach:** How soon would it need to be clear, in terms of transition and following processes and so on, to stop that? What is your lead time?

John Smith: It is now. If you look at how long things take to change the process, you have to start making decisions very soon. Companies are trying to hang on to try to understand whether there is going to be some sort of guidance: either there is going to be a transition period or we are going to have some sort of statement from the Government saying that there will not be a divergence. However, they need to start making those decisions now and at least by the first quarter; otherwise, companies will have to make those decisions.

Paul Fleming: For generic medicines, we collect a lot of data on how long things take to do. Registering a new generic medicine within the current system takes an average of 15 months, so we are right on that decision point now. MHRA, as colleagues have said, have been very good in terms of their performance in adhering to those timelines, so they have managed to run a very predictable process—very consistent and with very good standards of scientific assessment, rigour and visibility on that.

That 15 months, start to finish, has been something that the industry has been able to plan for with great reliability over the last decade, so anything that puts a risk factor over that does bring into play whether people are going to change their choices, particularly for generic medicines, because of the large number of products that are involved. Some of our bigger companies will have more than 500 products in their portfolio, so the scale and the engagement with the regulatory process is huge and continuous. The link between the regulatory process and what

that means for when medicines become available and how companies have to sequence their planning is a very big part of the thinking and scenarios that companies are working through at the moment.

Q35 **Antoinette Sandbach:** Can I ask very briefly about IP, which is very important in your industry? What is your view in terms of the possible divergence from the EU on IP rights? Is it something that you would welcome and think creates an opportunity in terms of Brexit or, again, is this an area where regulatory alignment is really important for you?

Paul Fleming: Certainly, we want to maintain regulatory alignment. Our view is that this is not the time and place to be talking about those different elements around IP.

John Smith: I would be aligned with a lot of what Paul was saying.

Q36 **Antoinette Sandbach:** You must have cheered yesterday when the Government were talking about regulatory alignment, only to groan when the signature was not on the dotted line.

Mike Thompson: I think we are encouraged.

Antoinette Sandbach: You are encouraged. I am glad to hear that. Thank you very much.

Q37 **Rachel Maclean:** We have touched on the EMA and we have probed into that, but I just wanted to come back on one point. You mentioned the judgments. Are you referring to the ECJ judgments with respect to that, which you mentioned previously?

Mike Thompson: Yes. The regulatory process in Europe is ultimately governed, through dispute, by the ECJ.

Q38 **Rachel Maclean:** You said some of the judgments were made for political reasons. I think those were your words.

Mike Thompson: I am just saying that 99.9% of all recommendations from scientific review have been accepted. The only time when there have been questions is when they have been controversial—for example the first time Viagra came forward. If you like, it was not that the scientific pronouncement or recommendation was being challenged; it was because there were other factors. I am saying that we can feel very confident that, if the solution that is being proposed and is acceptable to the UK Government is adopted, we will end up with, essentially, the same medicine being prescribed across the whole of Europe and the UK, which I think is beneficial and would be the outcome we would be looking for. Medicine is becoming increasingly globalised. Having doctors who are liable to be talking to each other at conferences about medical issues having medicines that are the same helps that dialogue, so there are all sorts of reasons why I think there are benefits.

Q39 **Rachel Maclean:** In terms of those judgments, were there any times when those judgments were against the interests of the UK that you have

seen, in your experience?

Mike Thompson: I do not believe so. I have to say that I do not know the detail. We are talking about over 10 years. It is such a rare exception. I only mentioned it to explain that it almost does not come into account.

Q40 **Rachel Maclean:** How many cases would that be, roughly?

Mike Thompson: I think there were two in the whole period.

Q41 **Rachel Maclean:** You touched on the Hunt and Clark letter, and you have talked about how important what was set out in that is. Does that mean, in effect, anything other than being part of the EMA, in practice? You said that you were encouraged by the aspirations that were set out in that letter and the assurances that were given to the industry, so does that mean, in practice, anything other than remaining part of the EMA, or can that be achieved outside the EMA?

Mike Thompson: No. It is clear that the preference is to remain part of the EMA.

Q42 **Rachel Maclean:** That is the preference but, if that was not possible, would there be an alternative way to achieve those aspirations outside the EMA?

Mike Thompson: The MHRA is understandably working on fall-back scenarios in terms of what that would look like. Even within the EMA, the MHRA is already a rapporteur for a disproportionate amount of medicines that are reviewed. Essentially, however, it is a distributed model, so everybody clubs together to do it; the MHRA does not need to build the capability and the number of people to review all of the medicines that need to be reviewed, and that is a very cost-effective way of doing it. The challenge is that, if the UK, which is 2.3% of the value of the global market, has a regulator on its own, it is just going to find it very difficult to build the resources. 80% of the fees of the MHRA are paid by the industry in terms of fees for review of medicines. It is very clear that we would not be able to sustain the levels of fees required for them to build up an authority that could review all medicines.

We have discussed options about taking decisions from other stringent regulators, which could still be the EMA or the FDA, and getting the MHRA to, essentially, do a very small process to look at them and then adopt them, because we need to find a way to get these medicines to British patients. There are fall-back options that we would have to work on with Government to work through.

Q43 **Rachel Maclean:** Clearly, however, that will involve some degree of cost, as you have identified in your evidence, as a common theme.

Mike Thompson: It absolutely will do.

John Smith: Just to add, we absolutely support that. We believe that regulatory convergence should be the priority. If there is not, there needs to be a decent transition period that allows member companies to find a way through the new system. Lastly, if we do diverge, any costs will outweigh any benefits. Although there will be some benefits, we believe strongly that the costs associated with not being part of the EU will absolutely outweigh any benefits, so our strong viewpoint is that we need to make sure that we stay part of that system going forward.

Q44 **Rachel Maclean:** In terms of the British Generic Manufacturers Association, do you see any advantages in terms of cost reductions for your type of business from being outside this regime at all?

Paul Fleming: It is very hard to identify cost benefits. The risks, as we have talked about this morning, are significant, particularly if we end up in a regime where there is duplication. If we look at global regulatory trends over the last few years, there has been an increasing move to more mutual reliance, working more closely with authorities and agencies, working to the same standards and building confidence in each other's decision-making. There is a possibility that that could be strengthened if the UK looks more broadly in terms of building its relationships and information-sharing.

Examples of where that has worked very successfully so far include areas around drug safety or pharmacovigilance, where there is a lot of data that is shared globally. That is a very good example for us to think about because, if we were disconnected from the European system—something called EudraVigilance—where there is very rapid sharing of safety signals, and if we did not have access to that and were relying on a more fragmented approach, that would cast a potential risk over the safety monitoring of medicines for patients immediately.

John Smith: I just have one other small point from a consumer viewpoint. We also represent medical devices, and there is the new European Medical Device Regulation going forward. That is a gold standard that we strongly believe needs to be implemented, and the UK has been part of all the negotiations to get that. We strongly believe that that should be part of this maintaining as part of Europe.

Q45 **Rachel Maclean:** Are the reassurances that you have received that it would be covered? Have you received those assurances?

John Smith: We have not had assurances that it would be covered. While we are part of Europe, it remains part of it, but it is in the process and, in 2020, there is another part of it that needs to be implemented. We strongly advise that that continues, because of the UK being part of the discussion going forward. It is a gold standard and it is the right way forward for us.

Q46 **Chair:** I just want to pick up on this briefly, because I think the evidence that the Committee has received in this area was perhaps the most

worrying. AstraZeneca has said that, although the costs of duties are not attractive, more important is the extra administration and delays. It went on to say that "it could undermine our ability to conduct and run clinical-trial programmes in and from the UK", and it has suggested that a three-year transition would be needed, if additional testing needed to take place to bring drugs to market. The BMA has said it could take two more years to get new drugs if our regulatory system diverges, and the American Pharmaceutical Group says that a no-deal scenario would have a detrimental impact on the UK economy and threaten access to medicines.

If there is a divergence and if the EMA will not recognise testing in this country, those are the risks. Do you think that any of that is overdone in that evidence, Mike Thompson, or do you think that, if there was a divergence in regulations, that could delay access to drugs in this country for British patients?

Mike Thompson: I do not think it is overdone. Can I use clinical trials as an example? I think that has been a very big source of debate. The reason that there has been debate is because members have rightly picked up that, historically, there was a lot of criticism about the European Clinical Trials Directive. It was seen to be over-bureaucratic and not really fitting with industry's needs, and I think that was correct. What has happened is that the UK Government, UK industry and the MHRA have done a really good job of amending that, and the updated Clinical Trials Directive, which I would expect is going to come in in 2020, which will be after we have withdrawn, is now pretty good.

The issue for us is that, if we are doing clinical trials, particularly towards the later stages of drug development, you end up needing so many patients that you do them in multiple centres. If you are a company that needs to do 8,000 patients in a trial and, therefore, are going to need 40 centres to recruit those patients, if you have to go through two systems of approval, it is quite possible that you are going to say, "I cannot be bothered to do that. I can do it through one. Why would I take the extra costs? Why would I take the extra complexity?"

If there is not complete alignment, it could be the that the EU would say, "We are not going to accept the results from the UK centres because they are not being governed by exactly the same legislation and, therefore, we will not take those patients into account in a licensing decision in Europe," and companies would not take that risk. Therefore, it is quite likely that the UK would miss out. NHS hospitals gain enormously from the money they make from clinical trials. Patients benefit from the free drug. Our doctors benefit from using the latest medicines. All of these things are a virtuous circle that improve the ecosystem we have in the UK.

It really would not make any sense for us to have something where we had a divergent regulation. What is true, just to give you a balanced perspective on this, is that, possibly in phase one, where you have very

small numbers of patients, you could do things a bit more quickly. We believe, however, that the trade-off between potentially being able to do things a bit more quickly is outweighed by the fact that, in the majority of trials, the results potentially would not be applicable and would cause the other problems that I think. Those are the reasons why we think that participating in one system is in the best interests of everybody.

Q47 **Vernon Coaker:** Can I just ask on this whole area of testing of drugs and medicine? It is really for information for the Committee and to have a greater understanding of this. What does that mean in terms of the use of animals in that testing process? How is that regulated? Will that change and where is that going?

Mike Thompson: I have to say that that is not my area of expertise but, essentially, use of animals would be very early in drug development. The testing we were talking about, which is batch release, is, essentially, when you have got your finished product and you are making sure that that finished product that has come through the manufacturing process is consistent with the standards and the licence that you have been given.

Q48 **Vernon Coaker:** Some of the companies that you represent will be involved in trials that are testing out various drugs and medicines. To be honest, I am not sure how that is regulated at the moment.

Mike Thompson: There are very stringent regulations. The UK can be enormously proud of having some of the highest standards, if not the highest standards, in the world. The fact that we have got such high standards means, I have to say, that it is highly likely that other countries would accept those. There is just always a problem that, if we have a divergence in regulation, and even though the standards are great, the EU may decide, because it is a different set of regulations and if we do not have some sort of mutual recognition, not to allow tests that have been done in the UK to count towards the process of licensing of medicines. That is the nightmare scenario. I have to say you almost cannot believe that we would end up in that position but you have to accept that there is a scenario where, if that happens, that is a very difficult position for us.

Q49 **Vernon Coaker:** There is also the movement of the animals as well.

Mike Thompson: All of those things are governed by regulations.

Q50 **Vernon Coaker:** It is just an interesting aside. I wonder, Chair, whether there could be a note from anybody. You say it is not exactly your field but is there somebody within your—

Mike Thompson: We have an expert in ABPI. I would be happy to supply a note on that, if that would be helpful.

Vernon Coaker: Yes, that would be really helpful, thank you.

Q51 **Peter Kyle:** Mike, my job is now to test your argument with your colleagues. If I could ask John and Paul, when it comes to the possibility,

if Brexit goes ahead, of a divergent regulatory environment for IP, are there any circumstances in which this provides a positive opportunity for your sectors?

John Smith: If you look at divergence, there are always going to be opportunities, but our strong view is that, if we go down that route, the benefits will be outweighed by the costs involved. I go back to having two different systems. We would have to have two different batch releases; we would have to have two different regulatory processes, which would add significant costs to our overall business in terms of millions of pounds. Any opportunities are completely outweighed by the costs involved.

Q52 **Peter Kyle:** Is that simply because the British market is not big enough?

John Smith: Absolutely. Look at the European market and however many million people you have got there compared to the UK market. It is just that you have to have two systems. If they were the same system, then great. If they both agree that they accept each other, that is absolutely possible. At the moment, however, the way it is going—hard exit—could mean we would have to have two systems. Everything batch-released is checking back to what has been registered and we would have to have that done once for the EU and once for the UK market.

Paul Fleming: All I would add on that is that we have done a little bit of work looking at what this costs. For each batch of generic medicine that is released into the market, we think that costs about £1,500 a time, so that would be a straight additional cost if that had to be duplicated on top of the infrastructure costs of setting up a new lab or—

Q53 **Peter Kyle:** How many batches, sorry?

Paul Fleming: In terms of the number of batches, it would be lining up with the figures that Mike gave at the beginning. This is just an incremental cost per batch of about £1,500 for each one.

John Smith: I would just add that we have looked at one-off costs being over £7 million. We have just taken a sample from our members and extrapolated out for the total market. Ongoing costs would be in the region of £12 million, so that would add £20 million.

Q54 **Peter Kyle:** That is quite significant. What we are doing is turning over some rocks and finding some pretty big numbers underneath them, with all the different sectors that we are meeting. In your written evidence, you have suggested that there is the potential for increased self-regulation in areas of your business. What would that look like?

Paul Fleming: I will make a start on that. Within the regulatory regime, we have talked about some of the bits already about the early-stage work, clinical trials and getting the products to market. Once the products are on the market for the rest of their lifecycle, there are routine regulatory activities that have to be fulfilled. A lot of those are largely

administrative. They are very important and they need to be collated, particularly, as I touched on earlier, safety data and making regular reports on that.

There is some room to streamline these and we have already had some discussions with the MHRA, who are looking at their IT infrastructure, making that more flexible and adaptable, and perhaps including some more self-certification elements of that, which would then still have the same level of regulatory scrutiny through things like periodic audits and self-assessment reporting.

John Smith: We do self-regulate the industry. All the advertising that you see out there on the TV and in the newspapers for our members has already been approved by us. We follow strict codes and we work very closely with the MHRA in making sure that we self-regulate the industry. There are opportunities, I am sure, as we look forward, to do more self-regulation. Could it be on packaging or could we take some work away from the MHRA and make it more streamlined? Again, I am going to say that the benefits are completely outweighed by the costs involved from the regulatory and trade, where we have got to do all this additional testing with the additional costs involved.

Q55 **Peter Kyle:** Thanks. You have made that very clear. Finally from me, we have had written evidence from StopAids that says that a weaker IP regulatory environment here in the UK could lead to a lowering of pricing for AIDS/HIV drugs. Do you want to respond to this piece of evidence that we have had?

Mike Thompson: What they are talking about is, essentially, opening up the IP protection for the whole of the market. In this country, this industry is based on effective IP. What I would say to you is that, if you look at the deal that we did with the Government on prices of medicines, for the 80% of the medicines that we supply through the PPRS, the average price over the last five years has declined in real terms by half a percent. I know that those facts are not normally understood well, but the control of medicines overall in the UK is really well controlled. I think a better way than that approach is to look at the overall costs of medicines, rather than trying to undermine something like IP, which would fundamentally undermine the model.

You need to remember that the pharmaceutical industry is, essentially, based on a model where you discover something and then you have an average of 10 years to get your money back. It then goes off-patent. We are delighted then that Paul's members are able to make money, but it is a huge risk business. It has, however, been enormously beneficial. We have all worked together. You know that, since 1960, the average life expectancy in this country alone has increased by over a decade; that it is one of the most productive figures of any industry that has been created. This is a very effective model and we should never take a risk by undermining IP, because IP is the only thing that holds this together.

Q56 **Stephen Kerr:** You mentioned people as one of your four areas, as well as skills. We have received written evidence to suggest that there are skills gaps, particularly in some areas such as translational medicines and pharmacology. What are your members doing to recruit and train more British workers?

Mike Thompson: We are doing that. We were delighted with some of the measures in the Budget, in terms of things like investment in maths and that sort of thing. There are absolutely things that we can do and we work with universities to think about what types of courses could be developed to develop people with the skills. That is on an ongoing basis.

I would take it a level up and say that this is a global business. As I said, the UK is the third best centre for science and research anywhere in the world. How do we achieve that? We achieve that by attracting to the UK global experts to come and work here. This is not just in industry; you will hear this if you talk with the Crick or if you talk with some of our leading medical charities. Pretty much, if you look at the Crick or those charities, about 40% of the talent that they have has come from outside the UK. In our industry, in the research base, something like 17% to 40% of the people we have come from outside. If we cannot attract the global leading experts, then we will not remain as a global centre. It is all about people, as always, and it is all about the intellectual capital that is created. We are brilliant at it but, if we are not able to bring those experts in, then that would undermine our position.

Q57 **Stephen Kerr:** Which points to having a suitable and appropriate immigration system.

Mike Thompson: It does, and I have to say that the UK Government have been very good at making it clear that these are the sorts of skilled jobs they want to continue to attract here. There are opportunities. The current process for bringing people in is quite bureaucratic. Most companies have to employ specialists to work their way through the system, so certainly our hope is that, when a new proposal comes forward, it will be less bureaucratic and we will be a step forward from where we are today.

Q58 **Stephen Kerr:** The UK industry is an attractive industry to want to come to live and work in.

Mike Thompson: The UK is an enormously attractive place to come and live. If you come with your families, families have a wonderful time here. The culture is great. Whether it is men or women, people feel comfortable and safe in our society. There are all sorts of reasons that attract people to come to the UK and we need to leverage that.

Q59 **Stephen Kerr:** In connection with that, it has been suggested that, as the EMA relocates, up to a quarter of their staff will not want to leave the UK. Is there an opportunity for businesses to attract those people into their ranks?

Mike Thompson: I think there will be some opportunity at the margin. What I would say, though—and it is an important fact—is that, at the moment, we all know that there is a negotiation going on and there is some hardball being played. We now need to get to being very pragmatic. The EMA moved not so long ago, in 2011, and it took four years to move from Nine Elms to Canary Wharf. That took four years—and, by the way, it was pretty difficult.

We are now trying to move 950 people from Canary Wharf to Amsterdam. Already, 200 have said they will not go, so that is already a 20% problem. The property market in Amsterdam grew by 15% last year; it is one of the hottest property markets. There are 600 kids in the EMA who will need to be found international schools. I have to tell you that there will be very serious issues in effecting that sort of transfer. We all know that, where there is one parent working in an organisation who is offered a job overseas, if you cannot get your kids into school, people make some choices based on family needs, not on professional needs.

At the moment, no one is really being honest about the challenges of this transfer. I hope that, as we get into phase 2, there can be some real pragmatism here. There is a long lease on Canary Wharf. There will be a number of people who will not choose to move. We need to have a pragmatic agreement. We need to be generous. However, we need to have a number of people who continue to work from the EMA out of Canary Wharf; otherwise, quite frankly, the EMA will not be able to fulfil all of its duties. As soon as we are out of the heavy negotiation, we need to get into something that is much more pragmatic.

Chair: That is very interesting and is something that I have heard before: the possibility of some EMA staff staying in London for those very practical reasons. If that could be achieved, I think that would be a very good outcome for the sector and for the industry across Europe. Thank you.

Q60 **Mark Pawsey:** Probably to conclude, you have given us a pretty challenging picture around Brexit with issues on the regulatory process, trade and, just now, about attracting talent. Are there any niche areas where Brexit offers an opportunity to specific companies? You all represent a very large number of companies in your sectors; are there any that see our leaving the EU as an opportunity, whether it is going for new markets or developing products on our own terms?

Mike Thompson: We have found it very difficult. As I said, we had a lot of people working, and one of the questions we asked is, "What is the upside?" I have to tell you that we really did not come up with very much. There are times when Europe is slow and bureaucratic because, if you need to get 29 people to sign up to something, the processes are slower. If, at the outcome of this, we were in a different scenario, we would have to look at speed and agility as something to try to take advantage of, and that is where I think we would focus.

Q61 **Mark Pawsey:** Do you think we could set something up that would enable us to do that?

Mike Thompson: We would have to set something up but, as I have explained, there are some very significant challenges that we would have to overcome here.

Q62 **Mark Pawsey:** Do either of your colleagues want to add anything?

Paul Fleming: The one point I would add is one I touched on a little bit earlier, which is working more closely with global regulators who work to the same standards as us and in Europe. There are a lot of platforms where people are sharing scientific and regulatory expertise. There are opportunities to make those more formalised and stronger going forward. Collectively, we think that that is probably the clearest opportunity. It is something that is already there that could be reinforced in working more closely with other global standards.

Q63 **Mark Pawsey:** Mr Smith, are there any upsides for any of your members?

John Smith: Like Mike, we have struggled to find real upsides, and the downsides far outweigh them. Certainly, speed and agility of what the MHRA could deliver in terms of the registration of products could be something we could be looking at, but it is the downside of all the additional costs of the regulatory process and having to do things twice. My concern is some of the smaller companies. The big companies will be able to cope with whatever happens. The smaller guys have not got all these big systems and understanding of what is happening, and my worry is that they are as well prepared as they could be. If we do end up with a really hard end date, it could be very severe for some of the smaller guys.

Chair: Thank you very much, all three of you, for coming to give evidence to the Committee today. It is very useful.

Examination of witnesses

Witnesses: Mark Hicken and Peter Ballard.

Q64 **Chair:** Thank you very much, both of you, for coming to give evidence to our Select Committee today. I think you have heard the earlier evidence session but we are very keen to hear from you, representing the businesses that you work for. It would be good if you could just start by introducing yourselves, and then we will go straight into the questions.

Mark Hicken: I am Mark Hicken. I am Managing Director of the pharmaceutical business of Johnson & Johnson, but I am also Vice-Chair of the American Pharmaceutical Group, and it is on behalf of the

American Pharmaceutical Group that I am here today. We want to thank you for the opportunity to give evidence.

APG represents 10 companies of various sizes and with different priorities, working across a range of different specialisms in many of the world's leading challenges from a medical point of view. We collectively invest in excess of £1 billion into the UK, supporting 14,000 jobs directly. If you look at the general economic impact of inward investment, you can probably multiply that number of jobs by three, if you look at the number of companies that partner with us. Over 3,000 of those work in research and development. We do an awful lot of work partnering with smaller businesses and also the NHS and academic centres, conducting more than 500 clinical trials involving over 20,000 patients.

Peter Ballard: I am Peter Ballard. I have been in the pharmaceutical industry for 20 years. I am here today employed by Xiromed but more representing the BGMA, who Paul was representing earlier as well. I have had a number of key jobs in the pharmaceutical industry over the 20 years. I was MD of a pan-European, quasi-global company. I also worked for an Israeli company that was exporting product into the UK, and also an Indian manufacturer, Accord, that bought the business of Actavis UK & Ireland, so the acquisition of a factory in Devon. I have experience of various different elements that I think are relevant to this discussion.

Q65 **Vernon Coaker:** Good morning and thank you for coming in. As a Committee, we are looking at Brexit and the impact on various sectors. Mark started off saying a little bit about this, but both from yourself, Mark, and you, Peter, it would be interesting if you could just say a little bit more about the focus of your companies, what you do, and the importance of different markets to you. What is your size in the United Kingdom and what is the importance of that market? What is the importance of the EU and the rest of the world, so that we get a sense of how all of those impact on each other and the importance of those different parts of your business in terms of those different markets?

Peter Ballard: The UK is a very important business for generic manufacturers because of the high usage of generics. As Paul mentioned earlier on, over 75% of the consumption of all drugs by the NHS is generic packs. Of the 1 billion packs, roughly, that are consumed by the NHS per year, three-quarters of those are generics, but we only account for something a bit less than 25% of the cost of drugs overall, so it is very good value for the NHS. It is estimated that, were there to be no generics, it would increase costs to the NHS by £13.5 billion a year. If all of the drugs were at the original prices pre patent expiry, that would increase the costs by £13.5 billion a year. The current drugs bill is £16.7 billion and the current cost of generics is a little less than £4 billion, so we have a disproportionate impact. Because of the volume that can be produced and sold in the UK, that creates efficiencies for the rest of Europe. As Mike was saying earlier, we are important to each other: the UK is important to Europe, and Europe is important to the EU.

Q66 **Vernon Coaker:** It is almost like a cross-subsidy—"subsidy" is the wrong word but a crossover.

Peter Ballard: Yes. The business has developed over the last 20 years, to my certain knowledge, with cross-border trade. We depend upon each other. The key risk in Brexit is that, as the panel indicated quite clearly before, any friction, any increase in complexity or any differences in regulation will undoubtedly cause additional costs. That may cause delay and, ultimately, the worst thing from our point of view is that patients may not get the medicines that they need, and that is to be avoided.

Q67 **Vernon Coaker:** Other members will come on to a bit more of that in a minute. Peter, you mentioned the UK and the focus on that, and the benefits that that brings to the EU. What about the rest of the world?

Peter Ballard: For the same sorts of reasons.

Q68 **Vernon Coaker:** Presumably you have big commercial activities there as well?

Peter Ballard: Of course, but in terms of looking at the entire European market, the UK is perhaps disproportionately important in terms of the volume consumption that then drives efficiencies.

Q69 **Vernon Coaker:** I see. Your most important market is the UK, then the EU and then the rest of the world, is it?

Peter Ballard: For European-centric companies, yes, that is true.

Mark Hicken: You have already heard a lot, but just to add some things that may be helpful, the UK constitutes less than 3% of the global pharmaceuticals market in terms of sales of product. It typically attracts more than 5% of the research and development spending—the inward investment. The place of the UK in our sector is really in the research end. That is where, typically, the UK has been very successful. Mike talked earlier about the great universities and the NHS. It has also been a country that has encouraged small and medium-sized businesses to grow, and that whole ecosystem has worked well, attracting further inward investment. The place of the UK, however, is really in the basic science; that is the great thing that the UK does.

Vernon Coaker: The Chair was referring to that earlier on: the importance of research and development, and maybe keeping that focus more. That is under less threat, perhaps, than some of the manufacturing areas.

Q70 **Mark Pawsey:** I want to ask you about the trade aspects of your specific businesses. I am interested in knowing the proportion of the products that you manufacture that are exported, what you import and what you need for your supply chain. What is the balance there? We heard in the previous evidence session that it was roughly 50:50, so is that the case with you?

Peter Ballard: Quoting the ABPI's figures, overall it is 45 million packs a month produced in Europe that come to the UK, and 37 million that are manufactured here and exported. In terms of total consumption of generics, it is between 10% and 20% that are manufactured in the UK and consumed in the UK.

Q71 **Mark Pawsey:** For generics, 10% consumed in the UK is manufactured in the UK?

Peter Ballard: Correct.

Q72 **Mark Pawsey:** 90% is imported.

Peter Ballard: Correct.

Q73 **Mark Pawsey:** It is very significant.

Peter Ballard: Yes. Going back to the testing points made several times earlier, if everything had to be retested separately in the UK, that would have a very significant impact.

Q74 **Mark Pawsey:** Is the same stat in Johnson & Johnson?

Mark Hicken: For the American Pharmaceutical Group, the proportions that you heard from Mike earlier for the overall industry are very similar, so they are a good indication.

Q75 **Mark Pawsey:** With 90% being imported, why can we not make more of those here in the UK? If we end up coming out of Europe, why can we not stimulate a bigger and stronger domestic manufacturing sector?

Peter Ballard: With five to 10 years, I am sure we could, but the cost, the time required to put up a factory, the training required and the staff, the cost of machinery, the regulatory requirement to test that everything is working properly and the validation of the inspections take a very significant amount of time. I would love to see more being manufactured in the UK. It would be very hard, in any event, ever to be able to make it as cheaply as other countries seem to be able to manufacture medicines. There would be a cost implication, even if you had the time to be able to do it. From day one, however, there simply is not the capacity there to be able to do that.

Q76 **Mark Pawsey:** Mr Hicken, do you share Mr Ballard's view that we could do it but it would be disproportionate in cost and too time-consuming, or is it a complete non-starter?

Peter Ballard: I would refer back to the answer that Mike gave earlier about the ability to manufacture to new processes. We are seeing new manufacturing processes emerge. Investments in capital are long-term investments.

Q77 **Mark Pawsey:** You said to us that we are great at the R&D, so why are we great at the R&D but unable to follow it through to capitalise on that skill in our production processes here?

Mark Hicken: They are two very different activities. The basic science and research is grounded and really comes from the great academic institutions that we have, some of the research centres that we have and those partnerships between academia and the NHS, particularly in the golden triangle of Oxford, Cambridge and London, where we see a lot of collaboration. That is quite different to large-scale manufacturing investments or large-scale manufacturing decisions, and the skills, the environment, the tax incentives and all of those things that go into making those decisions.

The way that we would make decisions in terms of where we research is we go where the best science is and also where we see healthcare systems routinely up-taking the new innovations. Where we are looking to make investments on manufacturing, we look at access to skills, the availability of infrastructure, the fiscal incentives and the tax incentives, and other considerations, as well as access to labour.

Q78 **Mark Pawsey:** Is it your assessment that those are currently lacking in the UK?

Mark Hicken: Certainly, other countries have been more successful. As Mike mentioned earlier, Ireland in particular has been very successful at attracting investment, particularly in the manufacture of pharmaceuticals.

Q79 **Albert Owen:** Could I just follow up on that question? You heard me put it to the previous panel. What would the impact of customs delays be on your businesses? Again, you mentioned you have an American connection. The Canadian-American border has been cited by Government as an example, and also the Sweden-Norway border. Do you have experience from other markets? What is the impact? I will let you answer.

Mark Hicken: Again, I think the answer that Mike gave was representative of the view of the American companies as well. If there are additional borders, we have the risk that costs rise for us in the business in terms of being able to trade in the UK and use the UK as a base from which to trade with other countries. Either we accept that the costs go up or we make an alternative decision, so it is pretty clear that where we are going to see additional bureaucracy and delays—and we talked a lot about the regulatory situation as well—that is going to make the UK a less attractive place to come and invest.

Q80 **Albert Owen:** You operate in other markets, so can you give examples where you have this issue and you have been able to mitigate it somehow?

Mark Hicken: The key here for the UK post Brexit will be the negotiation of the trade agreements in place. Where we have had successes, there will be trade agreements in place that allow for tariff-free trade. Under the WTO arrangements that Mike mentioned, there is already a zero tariff. Where we have zero-tariff arrangements and where we minimise

the bureaucracy, we are going to see more successfully the flow of trade between those countries.

Q81 **Albert Owen:** Mr Ballard, do you want to respond to this? You heard the previous panel talking about delays for sensitive drugs as well. They need refrigeration and they need warehousing and that kind of thing, that the company would have to have additional costs.

Peter Ballard: Yes. Any delay, by definition, is not going to be a good thing. Any friction that causes delay or causes any increase in cost or any increase in regulatory burden is not a good thing.

Q82 **Albert Owen:** Are you having this discussion with Government? Is there openness by Government to talk about these things and to give you indications, so that you can prepare for it?

Peter Ballard: What we have requested and where we have got to so far in the discussion has been, "Please can we keep everything as similar, if not the same, as currently?" because it works so well. It is a system that has developed over many years.

Q83 **Albert Owen:** You are also developing contingency plans and you need to talk those through.

Peter Ballard: Yes. The contingencies, as was mentioned earlier, are that companies are looking to build additional testing laboratories in Europe because they will have to do that as a separate, duplicated exercise.

Q84 **Albert Owen:** How important is the Irish dimension? Yesterday's politics were dominated by the serious one about us being the land bridge between Ireland and the continent, and the delays could be R&D in Britain, manufacturing and then coming into mainland Europe. Do you see that as a huge challenge?

Peter Ballard: Yes. Somebody said earlier that we must have cheered yesterday when we heard the news that we were close to an agreement there.

Q85 **Albert Owen:** That was in the morning, not in the afternoon.

Peter Ballard: Yes, and then groan in the afternoon, and I did precisely that. I cheered at lunchtime, hearing the lunchtime news, and then groaned later.

Q86 **Albert Owen:** Did you cheer because you thought Northern Ireland was a special case and that you could move goods from the Republic of Ireland to Northern Ireland and then maybe into the UK?

Peter Ballard: No. I think I felt that, if Northern Ireland would be adopting that sort of system, it would necessarily apply then to everybody else, which would be—

Albert Owen: Single-market alignment.

Peter Ballard: That is our very clear preference.

Q87 **Albert Owen:** Mr Hicken, just on the point—the Irish dimension—do you feel that there is a way around it by us having, as Mr Ballard indicated, a special relationship with them?

Mark Hicken: I am probably not best qualified to comment specifically on the Ireland situation, but what I would say is that we would expect the treatment of the border and the trade agreements to be consistent with any of the other European member countries, and we would want to see the trade as free as possible of tariffs and bureaucracy and so forth.

Q88 **Rachel Maclean:** We have heard about the importance of the EMA and the relationship with the EMA and the MHRA, and specifically that it facilitates access to a market of 500 million people, bringing new therapies to patients. In a scenario where we were not able to retain our membership of the EMA and we had to mirror that work ourselves, what would be the cost to your businesses to do that?

Mark Hicken: I honestly do not have the specifics of costs. Clearly, what it would do is add work to be done. The other potential consequence, of course, is that we have limited resource in our organisations, in the American pharmaceutical organisations. Typically, what happens in terms of the process of making priority decisions on where you make your regulatory submissions is you go to the larger markets first. The EMA and the US are the two largest markets. If the UK were to be considered a separate market entirely, at less than 3% of the global potential, and if the process were different, it would slip down the priority list, and that would be the bigger worry. Would we spend more money? Probably. I cannot give you an exact number. The bigger worry, however, for patients in the UK and for the NHS is it would slow access to new treatment.

Q89 **Rachel Maclean:** You would, by necessity, prioritise those large markets over the UK.

Mark Hicken: Yes.

Q90 **Rachel Maclean:** Can you give us any ballpark figure for what percentage it would add to your cost base?

Mark Hicken: No, I honestly cannot. I do not want to misrepresent facts.

Q91 **Rachel Maclean:** Has your company done any contingency planning on this specific issue?

Mark Hicken: We are contingency-planning but I have to say that our assumption is that it would not make an awful lot of sense for a decision to be taken to run a sovereign regulatory process. There should be opportunities, as Mike laid out, to remain members of the EMA, or at least the CHMP, and, at the point at which the CHMP decision is adopted, you can then break off and do it a little more quickly in the UK. That would not add any additional bureaucracy, and there is a chance for the

UK to get ahead of Europe, but it would be an odd decision to have a sovereign regulatory system.

Q92 **Rachel Maclean:** Peter Ballard, has your company done any contingency planning about the costs?

Peter Ballard: No. It is one of those questions that you cannot answer because there is not the cost of a licence fee for Europe, in terms of what the alternative would be. If one imagined, however, that they were broadly similar, the cost of maintaining a licence is £10,000 to £15,000 a year. The cost of a new application is in the region of £30,000 to £50,000, depending on the number of different strengths of a product. If one were to have to replicate all of the licences that one currently has, 85% of which have been applied through European pathways, and replace them with UK standalone-only, that would be thousands of licences at £10,000 to £50,000 for each one, for a significant number of companies. Those are very big numbers.

Rachel Maclean: Yes, they are.

Mark Hicken: There were a couple of questions. Have we done the work on the regulatory burden? No, in terms of files and submissions. Have we done the work on batch releases, so if we did not have a single licence? Yes, we have done that work. For Johnson & Johnson, we estimate that is an additional 50,000 tests at an incremental cost of about £1 million a year.

Q93 **Rachel Maclean:** Is that for one drug?

Mark Hicken: No, that is one company—50,000 tests and about £1 million. We are less than 5% of the market, so you could probably scale that to give you a sense. That is only the batch releases for supply of product; that is not all of the additional costs, which I think you should question.

Peter Ballard: Another way to come at that one would be to say, of 1 billion packs of medication, if one were to assume an average batch size of 50,000 packs per batch, and £1,000 to £1,500 per batch test, that would be the additional cost. They are big numbers as well. If all of that work had to be duplicated and done separately for Europe and separately for the UK, that is the dimension of just the testing incremental cost.

Q94 **Rachel Maclean:** The other angle is also recruiting the necessary qualified person as well. Would you be confident that you could recruit that person in the UK, if you had to do so?

Peter Ballard: No. Good QPs have been at a premium for many years, to my certain knowledge, having tried to recruit replacements when people have retired. I have worked with some decidedly superannuated QPs who have carried on, out of goodwill, into their 70s. We had one chap who was absolutely first class but we just could not replace him, so he stayed on. It is already difficult to recruit good QPs. I am not aware of

any sudden increase in the rate of production, so that is something that is going to get more and more difficult as time goes on.

Q95 **Rachel Maclean:** If I may, Chair, we talked about the possibility of delayed access to drugs. Are there any common products that would cease to be available in the UK, were we to encounter the situation that we have discussed—products that it just simply would not be viable to have in the UK, on the NHS, for example?

Peter Ballard: I do not think we can say that. There would be some for which you could probably say it does not surprise me that would become very difficult, and also that there would be some complete shocks—some products that are inexpensive and widely available but may suddenly become unavailable. I do not think you could say that. It is too broad and diverse an industry.

Mark Hicken: I am not aware of any examples. We would need to understand what the future state is that you are talking about, and I do not think we know the detail yet. It would be highly unlikely, however, that you would cease to make medicines available in the UK. In the event that it was a challenge, then we would have to have a conversation about the nature of the challenge with the NHS, if that was where we need to have that discussion, and then we would make plans, but it would not be in the interests of patients. We have to make sure, in the first instance, that patients get the medications they need.

Peter Ballard: May I very briefly add a point? I think there has already been some impact from the vote in that there are more medicines that are in shortage now, because, when companies have been reviewing their portfolios and build-up to the Falsified Medicines Directive, which is introduced a little bit before March 2019, with the exchange rate, some costs have increased. It is no longer viable to produce some medicines and we are beginning to see some impacts of the vote already. The damage may not be too great, if we have tariff-free and friction-free trade, but it could be quite significant if there are tariffs or significant regulatory changes.

Q96 **Antoinette Sandbach:** I am going to ask about the MHRA but, just before that, do you have medicines that are of limited lifespan, if there are delays at borders? For example, I am going to ask about vaccines that may or may not be considered that, but are there what I call live-culture medicines that are being imported from the EU that would be potentially affected by delays at borders if there was a hard Brexit?

Mark Hicken: It depends on the nature of the delay. Certainly, one of the things that is quite common in the distribution of pharmaceutical products is cold chain. Where you experience delays, clearly you increase the risk of a disruption. Where we have a temperature excursion in cold chain, that can result in, effectively, the product being written off and having to be resupplied, so there is a risk, where you have extensive delays at borders, that that could happen. As it relates to the shelf-life, if

you like, of your product from when it is manufactured, Mike has mentioned that, typically, the shelf-life of a product is 12 to 18 months, so it would have to be quite a substantial delay.

Antoinette Sandbach: Hopefully, there will not.

Mark Hicken: Hopefully. However, things are certainly moving forward. In terms of the manufacture of monoclonal antibodies and more of the personalised medicine, the future would be perhaps a situation where that could create a challenge but, at the moment, I do not see that as a major risk.

Q97 **Antoinette Sandbach:** I think you were both in the room and heard the evidence concerning the MHRA from the earlier panel. As companies, are you concerned about the UK losing influence over the EMA or being able to influence the rules of the EMA?

Mark Hicken: Again, it depends on which scenario we talk about, but clearly, as the evidence earlier suggested, the MHRA has certainly been punching above its weight in terms of its influence in the European Medicines Agency. It has shouldered a large burden of work and has been a major influencer, so if we were to lose a place in that group in the EMA, then of course we are going to lose influence. If, however, the system that we have proposed is adopted, which is that we maintain membership or a close alliance with the EMA, and we maintain a status as a rapporteur or co-rapporteur in those scientific evaluations, then we should be able to maintain the degree of influence that we have had.

Peter Ballard: I would agree. We are very proud of the MHRA and it would be a tragedy for the influence to be weakened.

Q98 **Antoinette Sandbach:** What influence do you feel, as companies, you have on regulatory standards at the moment? Do you find the MHRA approachable? Is it a process that you have influence on, even if it is an influence through research rather than other influences?

Peter Ballard: I would probably say, as generic manufacturers, we would not dare to think that we really have any influence, and nor should we. I think they have such a sound reputation for good science that it is easy to understand why they make the decisions they do. It is fair, unbiased, sensible and pragmatic, and we support that. I would not say that we could have any influence on them.

Mark Hicken: I would say we would characterise it as a good collaboration. I would agree that the extent to which you should be able to influence an independent scientific body is not something that anyone would be comfortable with. We have a good collaboration and, over many years, have built a strong working partnership, which is in the best interests of patients and research.

Q99 **Antoinette Sandbach:** Again on the previous panel, we heard evidence, particularly from the PAGB, that some companies were moving away

from using the MHRA as their European reference agency. For example, with Johnson & Johnson and, indeed, with your own company, is that true? Are you seeing that in the sector? Is that something that you are actively looking at at the moment, given the lack of clarity around regulatory alignment and rapporteur status within the EMA?

Mark Hicken: From a pharmaceuticals view, for the American Pharmaceuticals Group, we do not have a choice. We are highly regulated and everything goes through the EMA and MHRA. At the moment, that is not an option for us.

Q100 **Antoinette Sandbach:** "Not an option" meaning you are automatically doing it?

Mark Hicken: We are automatically doing it, yes.

Q101 **Antoinette Sandbach:** So you are now moving over to Europe to ensure that your pharmaceuticals have European-wide—

Mark Hicken: They already do. Everything goes through the EMA, so we do not have a choice. There is not an opt-out for us in terms of who we would work with.

Peter Ballard: In terms of licensing new products, exactly as the gentleman from PAGB stated, companies are now looking at using alternatives to London as the reference member, so are registering through alternative sites. I believe there is a capacity issue, so the work that was being done in London is now being sent elsewhere, and there are not always available slots, which is causing some delays already. There was another point you made.

Q102 **Antoinette Sandbach:** I asked about your companies.

Peter Ballard: Yes, my company. Interestingly, I was on a call yesterday where a decision to license a product from a UK source has been held off, and they are looking to find a European source, so there are examples where decisions are not being made, because of the risk that that will introduce further cost and delay.

Q103 **Antoinette Sandbach:** Will that have an impact on that company based in the UK in terms of its turnover?

Peter Ballard: Potentially, yes. The deal would have been to license a product that would have been sold in a dozen or so European countries.

Q104 **Antoinette Sandbach:** Having said that yesterday you cheered at lunchtime and groaned in the afternoon, are you hoping that you will be cheering again?

Peter Ballard: Very much so.

Q105 **Peter Kyle:** Just to follow up on intellectual property and divergence again, is there any case to be made that divergence could be a positive for this country in terms of intellectual property?

Peter Ballard: In terms of IP, I genuinely cannot think of one. In terms of the innovative industry developing new products and the date of patent expiry being linked, the first patent expiry across the whole of Europe is linked to the date of issue of the supplementary protection certificate. Were there to be a change there, then there would be downsides for the NHS in terms of cost reduction and, ultimately, patient benefit.

Q106 **Peter Kyle:** Even if we strengthened IP regulation and did so in a way that made our market perhaps more attractive for people to invest in R&D here and in innovation, is it the case that our market just simply is not big enough to make it attractive enough?

Peter Ballard: I am not quite sure how that would work. Would you grant a longer period of patent protection for a drug?

Q107 **Peter Kyle:** I presume that would be one of the ways that you could strengthen IP.

Peter Ballard: The NHS would continue to pay a higher price for longer, therefore denying the NHS the potential to save money at the same point.

Q108 **Peter Kyle:** This is why we are trying to test with you what the scenarios could be and whether there are positive cases, because we need to make sure we give a balanced view going forward. What you are saying is that you do not see a case that Britain could become a more attractive market in terms of IP, should we divert from the EU.

Peter Ballard: No. I think the downsides to British patients would outweigh any potential gains for an individual company.

Q109 **Peter Kyle:** Mark, do you concur?

Mark Hicken: I do. I think what is more important is maintaining the consistency. The intertwined regulatory and IP laws mean that unpicking and trying to do something special on IP would just add complexity.

Q110 **Stephen Kerr:** I have some questions about people and skills. What proportion of your employees in the UK are from the EU and from the rest of the world?

Peter Ballard: I believe it is 12%, based on a recent survey that we undertook to find out exactly this question. About 12% are non-UK EEA citizens in the generics industry.

Mark Hicken: For J&J, it is 10%. For the life sciences sector, it is a little lower, at maybe 7% or 8%.

Q111 **Stephen Kerr:** That is from the EU. What about the rest of the world?

Mark Hicken: In the UK, I do not have that information to hand. I am afraid I will have to come back to you.

Q112 **Stephen Kerr:** Did you have a rest-of-the-world number?

Peter Ballard: I do not.

Q113 **Stephen Kerr:** Have you noticed any discernible shifts in recruitment issues since the referendum?

Peter Ballard: Anecdotally, I think there are some employees who have tended to go back home once their contract was up, and it has been a little more difficult to replace them. Typically, they are in skilled scientific and technical jobs such as testing, where we hire in European workers, and also intracompany for people's career prospects, where they move around and experience different markets. I believe it is a little more difficult than it was.

Q114 **Stephen Kerr:** Are there specific jobs that EU nationals do for which it is hard to find UK equivalents?

Peter Ballard: Yes.

Q115 **Stephen Kerr:** Can you elaborate?

Peter Ballard: In certain scientific testing environments.

Q116 **Stephen Kerr:** Why is that?

Peter Ballard: Sorry, I cannot answer that question. I do not know.

Q117 **Stephen Kerr:** Is there anything that your company is doing to encourage UK workers to be able to do those sorts of tasks?

Peter Ballard: Yes. In terms of training in previous companies, we have always tried to home-grow talent wherever possible but, sometimes, it just is not possible. Staff may not necessarily want to do that work.

Q118 **Stephen Kerr:** Johnson & Johnson: any change in the pattern of recruitment?

Mark Hicken: Nothing so far. If I speak, first, for all the American Pharmaceuticals Group, each company will have its own priorities and have its own experiences. We are seeing a recent announcement for one of our companies, Merck Sharp & Dohme, who have decided to make a big investment in the UK, bringing new scientists and new skilled people to the UK. This is a pretty powerful signal about the faith in our ability to maintain the UK as a great place to come and do basic science. That view is consistent across almost all of the companies.

In terms of what we do to grow talent, we have a commitment as a sector, and certainly many member companies of the American Pharmaceuticals Group work with schools and universities, encouraging people to come through STEM subjects. We have programmes where we reach out into local communities. We support further study through PhDs and so forth. Growing the talent here is something that we are heavily invested in, and that continues through the scientific collaborations with universities.

Q119 **Stephen Kerr:** Are there any roles, in your experience, where it is difficult to replace EU nationals with UK workers?

Mark Hicken: Nothing specifically. I could not give you a type.

Q120 **Stephen Kerr:** One last question: how important is it for your businesses to have an appropriate immigration system that recognises the need for talent?

Mark Hicken: Yes, very.

Stephen Kerr: I am leading the witness, almost, by asking that question. "No, it is not important". It is important.

Mark Hicken: One of the things that enables large global organisations to be successful is the ability to move talent around the organisation and experience different markets, and the fact that we can draw from talent pools all across the globe, including Europe, is critical to the success of our organisation.

Q121 **Mark Pawsey:** Just a quick last question: are there any positives to come out of this process—opportunities in the UK market or perhaps niche areas? Is there anything that you have not told us about that we can take as something that will be good for the UK as a consequence of the Brexit process?

Mark Hicken: I would be very cautious about saying that there are opportunities. Our view is that Brexit would not be good for our industry generally; however, one of the things that we have seen, with the recent publication of the life sciences industrial strategy, is that there is an opportunity for the UK really to sharpen its pencil on what its offering is to global investors. That work has been done, so I would refer you to the recommendations in the life sciences industrial strategy. There is a great opportunity for the UK to be a beacon for early discovery science and for the uptake of new innovation, and to re-advertise itself to the world, because everybody is watching.

Peter Ballard: I would agree but I would almost say that that is something that we are good at already and that we will continue to be good at. We will almost, as my colleague from the earlier panel said, be unaffected by Brexit.

Q122 **Mark Pawsey:** That sector is not going to cause any harm. Our innovation and our research, in your view, are going to continue to progress in the way that they have done and be a beacon for the rest of the world.

Peter Ballard: Correct. In terms of the ongoing routine supply of effective, low-cost medications for the NHS, I cannot really see any good news, and there is potential for significant bad news if we do not have more of the same, please. If that simply is not possible, then it must be the longest transition period—absolute minimum of two years. Anything less than two years would be catastrophic; three to five would be

tolerable. However, bear in mind that any regulatory divergence would cause increasing cost.

Q123 **Drew Hendry:** Given your previous answers, I am not certain that this is a question that you would like to contemplate, but if negotiations are not concluded until October 2018 or even just before March 2019, what is it reasonable for you to expect from the UK Government in terms of detail about what will be happening?

Peter Ballard: We have heard the expression, "Nothing is agreed until everything is agreed." In our dark moments, we expect not to know the certainty until really very late in the day. As we have said already, it is already having an impact on decisions that companies are making.

Q124 **Drew Hendry:** You spoke earlier about the need to gear up for about five to 10 years. The Prime Minister proposed a strictly time-limited transition period in her Florence speech. If there is no possibility to say, "Just take as long as you need," what is the minimum amount of time that you would need for a transition?

Peter Ballard: Two years. Anything less than two years, I believe, would be catastrophic.

Q125 **Drew Hendry:** One final question: you talked about medicines being in shortage, and testing laboratories being set up in other parts of Europe. Are investment decisions being delayed in the industry for the UK just now? If so, what other behaviours are your members seeing?

Peter Ballard: I believe decisions are being affected. It is contemplating the unknown, so that is slowing down the decision-making process anyway, and companies are trying to second-guess what might happen, with the most obvious one being that, in the worst-case scenario, there would need to be a separate, parallel, initially aligned but divergent-over-time system of regulation.

Mark Hicken: Can I just come back to your question on time? Of course, what we need is the appropriate amount of time to contingency-plan and ensure continuity of business. Importantly for us, that means continuity of supply of medicines and the delivery of new innovations, which is where we play a large part, into the NHS. Those temporary arrangements, however, should not replace or defer the conversations on trade agreements between the UK and other countries. The US—and we are from US companies—particularly has a very strong trading relationship with the UK and we would need to make sure that the plans are in place to make sure that that continues. Enough time, then, but not so much that we are not getting into the conversations on those longer-term trade agreements.

Q126 **Drew Hendry:** You mentioned the Government's life sciences sector deal. What does that offer your companies and are there new measures that you feel will mitigate Brexit?

Peter Ballard: I am not sure I am sufficiently familiar with it to be able to comment.

Mark Hicken: I can. On the sector deal, we are waiting to see the detail. There are going to be a series of announcements; I think we have seen a couple. What is clear is that the Government are giving serious consideration and we are encouraged by the conversations we have had in the response to the recommendations made by Sir John Bell. American companies and British companies were involved in advising the Government on what needs to happen in order for the UK to continue to be successful, so we will see what comes of it. One of the things that I think is very encouraging is that we are hearing that Government see that the NHS being positioned more as an engine for innovation, attracting new investment by adopting and diffusing the latest technologies, is going to be central to the success of the deployment of the life sciences strategy.

Q127 **Drew Hendry:** I suppose, given the mixed answer there, how well do you think the Government engaged with the industry during this time? Do you feel it was sufficient at an industry level?

Mark Hicken: Yes. I would say absolutely. Over an extended period, starting with the Accelerated Access Review, which Sir John Bell had led, there was extensive consultation across industry, and that has continued with the life sciences industrial strategy, from all parts of the life sciences sector and all kinds of companies—not just pharmaceutical companies but devices, med-tech, smaller companies and larger companies. What has come out is a recommendation that quite strongly endorses the need to do more for small and medium-sized businesses and to grow more local business in the UK. I think they have done a great job and they understand the ecosystem very well.

Q128 **Drew Hendry:** Mr Ballard, is that reflected in your experience?

Peter Ballard: Yes, I think so. I am aware that there has been significant engagement, and there has been very useful dialogue both ways. One example that I can think of, where the dialogue has been helpful, is in repurposing old medicines and creating innovation from new uses of existing medicines. This is something that we have done a significant amount of work on. However, it is more applicable for the R&D sector than the generics sector, so I do apologise.

Q129 **Drew Hendry:** For R&D, it is good for medicines but it has not really made any impact. Is that correct?

Peter Ballard: It is not that it is not good; it is just that I do not think it is as helpful.

Q130 **Vernon Coaker:** Just to finish, you will correct me I get this wrong, but just to summarise: a hard Brexit would be bad, full stop, for your industry and for pharmaceuticals in general, but you are making contingency plans for every outcome, whether it be a hard Brexit and no

deal to a soft Brexit. There is contingency planning going on with respect to all of that. Is that right?

Mark Hicken: It is fair to say that everybody is going through the necessary considerations. The extent to which people are prepared would vary across organisations and may vary depending on what they believe the outcome of the negotiations might be.

Vernon Coaker: There is an act of faith going on as well here.

Mark Hicken: There may be in some organisations although I cannot speak for all.

Q131 **Vernon Coaker:** Has there been any estimate of what the costs of all of that may be?

Mark Hicken: No. We have given you some illustrative examples but, as to a total cost, one of the things that is very difficult to predict is that there is a swing in currency that also impacts significantly part of our business and can be one of the largest influences in the business. It also depends as to whether you look at the short, medium or longer term, so it would be difficult to give you a total number.

Q132 **Vernon Coaker:** In terms of the impact already, did you say earlier on, Peter, that there is already a shortage of some medicines? Again, correct me if I have misheard you.

Peter Ballard: Correct. Yes, there are. Every month, the concessions list is published, and that typically has 10 to 15 medicines on it that are in short supply, for whatever reason. I think last month—and we will correct this if it proves to be incorrect—there were 65 medicines on the concessions list. That is 65 products where pharmacies are experiencing difficulties and an increasing cost in sourcing the medicine.

Q133 **Vernon Coaker:** As a result of the uncertainty?

Peter Ballard: Not entirely, but the uncertainty and that the vote has happened. It is a difference between then and now, if that makes sense. It is not the only reason but I do believe it is a contributory factor. In terms of uncertainty, there may have been some destocking—not destocking, but some companies commercially deciding that it is no longer worth producing certain medicines. There has also been a manufacturer that has had production issues, which will also play into that. It is not the only reason but it is, I believe, a factor of why there are more shortages now than there were before. Certainly, a significant factor will be the exchange rate, because that has increased costs, as we have discussed already. A big chunk of product comes in from Europe, so all of those prices have gone up.

Q134 **Vernon Coaker:** That is fine. I was just trying to understand what you had said and not misinterpret it.

Peter Ballard: I certainly did not want to mislead you in any way.

Q135 **Chair:** Mark, in the evidence from Johnson & Johnson, you said that you might have to carry out an additional 50,000 extra tests of medicines at a cost to your business of £1 million. One of the other members of the APG—Lilly—say that the additional costs for them would be between £1.2 million and £2.2 million for additional testing. APG is 10 different companies. Is Johnson & Johnson 10% of APG or a bigger proportion?

Mark Hicken: We are slightly complicated because Johnson & Johnson is medical devices, pharmaceuticals and consumer products.

Q136 **Chair:** What I want to know is whether you could multiply that £1 million by 10, roughly, to get the whole cost for the APG. We have bits of information, and Johnson & Johnson and Lilly have given their estimates of the increased costs of testing. It might be you will be able to come back to me, Mark, and tell me roughly, for the APG, what the additional costs of testing would be, so that we do not have just fragments of information.

Mark Hicken: Yes, let me do that.

Chair: Thank you. I think the evidence session today has been incredibly useful. We have heard from everybody giving evidence that there is a very strong preference to remain part of the EMA and to keep the relationships as close as possible to what we have today. We also heard concerns about customs, particularly from the APBI, about the risks of medicines being held up at customs points. Most of all, however, we have heard about the importance of regulatory convergence for the sector and the risks of either medicines not being available or additional costs associated with that.

We have also heard a welcome for the Government's language around close relationships in the future, and I think the issue now is about putting those into practice with our European partners, so that we can maintain those relationships to ensure both access to drugs at a low cost and ensuring those high quality, high skilled jobs remain in our country. Thank you very much, both of you, for giving evidence today. We appreciate your time.