HOUSE OF COMMONS

Business, Energy and Industrial Strategy Committee

Oral evidence: Leaving the EU: Implications for UK Business, HC 384

Wednesday 28 November 2018

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Watch the meeting

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

Questions 212 - 255

Witnesses

I: Mike Thompson, Chief Executive, Association of the British Pharmaceutical Industry; Mark Hicken, Chair, American Pharmaceutical Group, and Managing Director, Janssen UK; Pinder Sahota, General Manager and Corporate VP, Novo Nordisk UK.

Examination of witnesses

Witnesses: Mike Thompson, Mark Hicken and Pinder Sahota.

Chair: Thank you very much to the three of you for coming in to give evidence to our Select Committee this afternoon. Two of you, Mike Thompson and Mark Hicken, were generous enough to come and give evidence to our Select Committee last year when we looked at Brexit, and we are coming back to revisit some of that evidence now that we have a withdrawal agreement and the political declaration. We are likely to have votes at 3.30 this afternoon, so we are keen to wrap up this session by 3.30, which means that we and you will need to be as brief as possible in our questioning and answering. Antoinette Sandbach will give us a good example of that.

Q212 **Antoinette Sandbach:** Last year, we heard evidence that companies were hedging because of the uncertainty around Brexit. I wondered whether that has continued and whether any of you can cite any examples of where there has been a lack of investment because of the uncertainty around Brexit.

Mike Thompson: Are you talking about financial hedging or strategic hedging?

Antoinette Sandbach: Strategic hedging and financial hedging.

Mike Thompson: Typically, our industry has very long cycles for major infrastructure investment so, in terms of manufacturing or distribution, those things do not happen very often. Inevitably, where there is a period of uncertainty, people will wait until the last minute before they make a decision on that front.

We need to balance that by saying that, at the end of last year, we had a sector deal between the industry and the Government where we announced a whole series of investments that were being made, and we would expect a second sector deal to be announced in early December where we will see some further assessments. There remain elements of the life sciences ecosystem in the UK that are very attractive to companies. Therefore, I would expect to see investment, as well as people sitting on their hands a bit and waiting to see how this plays out for other types of investment.

Q213 **Antoinette Sandbach:** Is that your view as well, Mark?

Mark Hicken: Yes. In the first wave of the sector deal, American companies—our members—had decided to make investments in the UK, and there may well be further announcements in the second wave of sector deals. To the question on the effects of Brexit, it is one of a number of considerations, exactly as Mike says. There are various things that we consider but it adds to a general negative sentiment about the

UK. It is not a helpful cloud to be hanging over us when we are making some big decisions.

Q214 **Antoinette Sandbach:** Mr Sahota, the day after our evidence session your company announced a £115 million 10-year investment into a new diabetes research centre in Oxford. Presumably you had calculated risk factors over Brexit and decided that it was worth investing in anyway.

Pinder Sahota: Indeed. It was a consideration but, because of the Oxford site and the science that we do here in the UK, Novo Nordisk has gone ahead with the investment. To the point made by my colleagues, it will be a bit of a watch-and-wait from a longer-term point of view. As Mark has said, it is one of the factors. The business environment, certainly alluding to uptake of medicines, is another big factor that has a big influence on the mood music in board rooms.

Q215 **Antoinette Sandbach:** We also had evidence from AstraZeneca that it was having difficulty recruiting in some roles. Have any of your members indicated that reluctance of staff to move to the UK? Is that a concern that has been flagged up?

Mike Thompson: We have definitely seen that a small number of smaller companies have paused, or decided to locate in Switzerland or on the continent. We need to recognise that this is not a great time for people to be making investment decisions where there is uncertainty. But, as I said, we make decisions over a long cycle. The sooner we can work our way through this, the less uncertainty there is and the better it will be for everybody.

Pinder Sahota: Our Oxford investment currently employs around 30 people. Fully scaled up, it will employ around 100. Clearly, over the next few years, we will be actively recruiting top science and academic talent into that centre. Clearly, we are keen to ensure that we can attract that talent from Europe and other countries, and that these barriers do not get in the way.

Mark Hicken: It is the same for our members. There have been conversations with employees and prospective employees about the uncertainties and people are understandably concerned. Has it caused a wholesale freeze on hiring into the UK? No.

Q216 **Antoinette Sandbach:** A year ago, GSK was building facilities in Europe to maintain a continuity of supply if there was no mutual recognition of standards. Have other businesses been doing that? Particularly to Mr Sahota and Mark, has your company or have your members had to add facilities in Europe or, as global businesses, are you able to use your existing footprints?

Mike Thompson: AstraZeneca is on record as saying, along with GSK, that it has had to build duplicate laboratories for batch test releasing on the continent. They are clearly very frustrated about that because this is essentially duplicating what is available here. We were very pleased that

the UK Government, as part of the technical notices that came out, said they would, in the event of no deal, recognise medicines that are manufactured on the continent to be available to British patients here. We really welcome that. That was clearly done in the best interests of patients. Without that, we would have been in a very difficult position in terms of being able to supply. That was a really warmly welcomed decision.

That has not been reciprocated on the continent. We call on the EU to continue to think about that because, again, AstraZeneca has been very public that it has had some challenges with the prostate cancer drug. Therefore, as an industry, we are interested in supplying patients across the whole of Europe. That is our main concern and it will make it more difficult to do that until the EU reciprocates.

Antoinette Sandbach: Is it similar for you?

Mark Hicken: It is the same for us. Mike covered it.

Pinder Sahota: I think you have covered it.

Q217 **Antoinette Sandbach:** Finally, have any of the decisions of your members been irrevocable? Are there jobs or investments that have been permanently lost to the UK?

Mike Thompson: We can see, with the movement of the EMA to Amsterdam, that there are undoubtedly some regulatory jobs that have moved there. There are some qualified persons jobs that will be moving there and those are not going to come back to this country. At this stage, those are, in the main, the types of jobs that have moved but, clearly depending on the sort of outcome we get, there will probably be other jobs that will be dependent as decisions come up in the natural cycle.

Mark Hicken: It is the same.

Pinder Sahota: It is the same.

Q218 **Albert Owen:** Mr Thompson, you told the Committee last year, "It is not unusual for politicians to think that you do not need to do a deal until the absolute last minute but businesses need to plan ahead", and that companies were already making contingency plans. What plans have been made for a no-deal scenario?

Mike Thompson: As companies, we have been planning ever since the referendum. As a result of that, I am really pleased to say that I think my members have now all built additional stocks and have responded to the request of the Government. That puts us in a much better position.

Since Chequers, and since the Government announced that they would step up no-deal planning, there has been a noticeable change. We have been working really closely with the Government. We have an EU steering group where we all come together. We also, since Chequers, have set up a specific supply chain group, which has been meeting. It is

pretty much meeting now on a weekly or fortnightly basis, and that has made a real difference in terms of overall planning. That is why you are now starting to see a real consensus across everybody involved that stockpiling is not the answer. It will take us some way there, but there are other things that we will need to do. It is one of those things where, as you get into it, you answer some questions and then other questions come up. You have to have enough time to answer the questions you were not expecting, to ensure that we get to a point.

What is different about our sector is that, whereas in some sectors an 80% solution will be considered good enough, that would be a catastrophe in our sector. We need to make sure that we deliver medicines to 100% of patients, not to 80%. We really have to be advanced. We have made very good progress, certainly since the last time I was here.

Mark Hicken: It is the same for our members in the American Pharmaceutical Group. Clearly, our first priority is to make sure patients can get the medicines they need. We have been planning since before the technical notices but, as Mike said earlier, we were very pleased to receive the technical guidance of what to do in the event of no-deal Brexit. It gave us the certainty we need to make the plans.

Building inventory, as Mike said, is helpful in the near term, but there are more things that need to happen. In some instances, companies have made arrangements for duplications of licences or marketing authorisations to make sure we have the respective licences within and outside of the Union. There have been adjustments made in production lines; in some cases, we have to have UK-specific packaging in order to supply the UK. Some of those changes that have incurred cost have been made in order to prepare us for the worst-case scenario. Clearly, we prefer to have, in the medium term, a more aligned approach.

Pinder Sahota: To build on that, some of the medicines that Novo Nordisk supplies are insulins. We supply half the UK's insulin demand. Like my colleagues, we have to ensure continuity of supply. We have doubled our stockholding over and above the request from DHSC, but there are other factors that could influence that level of stock that are outside of our control. For example, if all patients requested an extra prescription from their doctors and the doctors gave it, four weeks of stock would be wiped out.

The other factor is that companies export products that are brought into the UK. There are 2,000 export licences at the moment. With currency fluctuations, it is more attractive to export. Border delays are an issue as well. As an industry, we are doing everything we can, but there are other factors that the industry needs support on to ensure the stock that we are holding and bringing in remains for UK patients.

Q219 **Albert Owen:** Is there capacity if there were delays at borders? Is there refrigeration, for instance?

Pinder Sahota: You make a great point, which I should have added. Another factor is just the capacity piece. A lot of medicines will need refrigeration, and we are probably at the limit.

Q220 **Albert Owen:** Do the technical notices cover this?

Pinder Sahota: Not at the moment. I am aware there is a tender out, but I do not know the details of further expansion plans. At the moment we are probably near capacity on refrigeration, and that is a key limiting factor.

Q221 **Albert Owen:** Would anyone else like to comment on the capacity to stockpile medicines?

Mike Thompson: We have made progress on that. This is a good example of getting issues out early. As Pinder says, a tender has been issued. That is being worked through at the moment. I feel confident that we have been able to find additional cold-chain refrigeration in other sectors that we are capable of repurposing. That is encouraging because it is clear that it normally takes about 12 months to build a cold-chain warehouse. We are obviously very concerned about that. We do have a solution, which we are working through. Those things help. All of this, of course, is based on us building stockholding to a level of six weeks, but I feel more confident than I did last time that we would be able to find and essentially bring into supply that sort of level by March.

Q222 **Albert Owen:** Are you confident that the technology and, indeed, the resources are in the ports for this to happen? If you are importing and exporting, you will have to have it in close proximity to the ports, particularly for the sensitive insulin and various others.

Mike Thompson: I will talk about this and then maybe Pinder can talk about the challenges with the trucks. There is no cold-chain warehousing at the ports, so we have to do it off that. Still getting things through is one of the key things.

Pinder Sahota: Our cold storage is not near the port. It is in the warehouses that we use at the moment, and those are the facilities that we are accessing for the additional stock. A key bit of detail that needs to be explored and that is a determinant of supply in the UK is how long the border delays will be. Some of the notices we have had say that it could be a number of weeks or so. The thing we need to think through is how long a lorry will be stuck at a border. It can keep ticking over refrigeration for a period of time, but if that period is long—and we need to look at what "long" is—you are into, as I understand from the logistics teams, issues of the number of drivers you might need from a health and safety point of view. Do you need to double up on drivers? There is an exacerbation of issues that can crop up depending on the border delay, which is a complete unknown at the moment.

Albert Owen: It is an unknown. That is interesting.

Q223 **Chair:** Yesterday, the Health Secretary confirmed at the Health Select Committee that the Government are compiling a list of medicines most at risk of shortages in the event of no deal. The Government are proposing six weeks of stockpiling. Is that about right?

Mike Thompson: Six weeks is the guidance given by Government in terms of how long they think it will take to get through a border. It is encouraging that the Government have drawn up a list of essential medicines. Collectively in the group, we are essentially working through medicine by medicine and trying to work out, if we have a problem with this medicine, what the available alternatives are. We are getting into very detailed medicine-by-medicine planning. I am encouraged with the progress on that.

As we have said, stockpiling in itself will not be enough. We need to work through other ways to do things. We have seen the Government lease a number of ferries, so they are trying to take control of other mechanisms to get into the country, and we have seen conversations going on about air freight.

These things are very challenging, and we have to work them through on a medicine-by-medicine basis. Let us take the example of a stem cell medicine. You take a bit of DNA out of a patient. You need to get it to where it is processed. There is one plant in Europe where it is processed. You have to get it there in 24 hours. It is processed and then you have to get it back in 36 to 72 hours to infuse it back into the patient. You cannot take it through an airline because it cannot be X-rayed. Those are the sorts of things for which we have to work out a back-up plan, because you cannot stockpile someone's DNA. That is the sort of level that we are into. I am encouraged to be in that level of detail. We are solving problems, and we are discovering new ones as we work through it.

Q224 **Chair:** How much is all of this costing the industry, Mike Thompson?

Mike Thompson: There is no doubt that all of this just means additional costs. I have talked about the cost for GSK and AstraZeneca. Pfizer is on record saying that it has posted $100 million into its quarterly accounts. We are going to see additional costs from everywhere. To give you a different example, I was talking yesterday to someone from the textiles unions who supplies the cleaning of lab coats, and 39% of people involved in that industry are from the EU. They believe, inevitably, that the costs of cleaning lab coats will therefore go up. All across the piece we will see additional costs, from small things like lab coats to really big things. We may have to duplicate the regulatory processes we go through in the event of no deal. We are going to see additional cost.

Q225 **Chair:** Have you done anything in terms of adding all of that up to what the total cost might be of stockpiling or, overall, of no deal?

Mike Thompson: We have not done that, because it is very difficult and, to be honest, at this very moment our sole focus is on ensuring we can get medicines to patients; we will deal with the costs later.

Q226 **Chair:** What happens to the costs? Will they be borne by the consumers or through lower profit margins?

Mike Thompson: In the short run, they will be borne by the industry because, when we agree a price with the NHS, that is the price we agree, and it only goes downwards during the course of the life of a medicine. In the short run, of course, these things will be borne by the industry but, in the long run, industries cannot stay profitable and find investors to invest in them if their profits are going backwards. In the long run, of course, it has to be borne. One of the benefits we have had from working in a regional environment is that we have been able to take those efficiencies and pass them on.

Q227 **Albert Owen:** You have answered the Chair about the cost, and obviously that impacts on competitiveness and investment in the future, which is a concern. Do you see anything in the withdrawal agreement that gives you greater certainty for the transition period? You talked about the unknowns. We have had this document published now. You have had an opportunity to analyse it. Does it give you any greater certainty?

Mike Thompson: The withdrawal agreement gives us a transition period and therefore, in terms of supply of medicines to patients, it would be hugely significant. Our No. 1 priority is a transition period. We need to recognise, as we go into the transition period, that the MHRA will only have observer status in the EMA. That is obviously a really significant step back for us.

We have the ability to pay to participate in the science programmes but not to design them. If you have world-leading scientists in your universities, as we do, they are not going to stick around if all they can do is essentially be a trial site. They clearly want to be driving the thinking forward. They want to design the programmes of the future. That is also a major challenge for us.

While there will be a huge relief if we get into a transition period, from our perspective, we then have two years of work to do to ensure we can convince people that Europe is going to be much better if it stays integrated. I talk with global CEOs. When they have marginal investment, they are asking, "Do I invest this in America, in China or in Europe?" Europe is currently looking like third in the race. This country is the largest biopharmaceutical research cluster outside the east and west coasts of the United States. That is why companies like Pinder's are investing in Oxford. The continent of Europe does far better in keeping us close together. That is how we do our clinical trials. That is how we do our research.

At the moment, quite frankly, apart from the outline of the future political declaration, where there are a couple of lines about our industry, there has been no statement from the EU about what its vision is for the type of relationship that it wants in this sector. There is increasing

nervousness—I am talking not just from a UK perspective but from a global perspective—because we do not really understand what Europe's ambition is in life sciences, and we think that it would be much greater if it kept together with the UK. We are looking to get a clear signal of that as soon as possible.

Albert Owen: It is encouraging, as you are saying, that you have a transition period, but there is a lot of work to be done, so it is not going to be business as usual over that transition period. Can I bring in some of your colleagues as well?

Mike Thompson: Can I just say this? By the end of December 2020, of course, we might be at the same cliff-edge.

Mark Hicken: I agree with the comments that Mike has made. An agreement or political declaration can give a sense of trying to maintain a degree of collaboration across scientific discovery, which is not the purview of one geography, one university or one organisation but happens across geographies and cultures. The idea of maintaining some harmonisation or close association of the MHRA with the European Medicines Agency is really important when you look at just how influential the MHRA has been in the EMA. Those notions of maintaining closeness, proximity and collaboration are encouraging.

Q228 **Albert Owen:** Is this regulator having an observer status a worry to you?

Mark Hicken: Yes, it is, for the reasons that Mike gives.

Pinder Sahota: Like my colleagues, I welcome the transition period to smooth things through, but the balance here is that a long transition period where we do not have active involvement will not be great for us either.

Q229 **Albert Owen:** Your company gave evidence to us with regards to movement now between the UK and Ireland. It might have been your evidence, Mike, that a lot of research is done in England and Oxfordshire, then it is manufactured in the Republic of Ireland and then it comes back to the UK. Is there anything in the deal that will assist with that or not hamper it?

Mike Thompson: To be honest, Ireland is facing the same challenges as we are. Almost 100% of the medicines that are made outside of Ireland and outside of the UK come in through Dover on roll-on roll-off, and then go to Rosslare from Holyhead. Irish patients are also considerably concerned about their ability to receive medicines if things break down.

Q230 **Albert Owen:** I can assure you there is no room in the port of Holyhead for extra traffic in the way you are envisaging. I really do think that. The research and development is only one part; the manufacturing is another. Is there a risk that the research could move towards the manufacturing, rather than having the additional movements, which might mean

additional delays?

Mike Thompson: Moving sites is a really massive thing to do. You cannot just pick up a site and drop it somewhere. We are such a heavily regulated industry. It takes a very long time to do anything. Any sort of kneejerk reaction is just not possible, I believe, in our industry.

Q231 **Mark Pawsey:** Mr Hicken, Mr Thompson said a little earlier that he is a lot more confident than he was when he appeared before us a year ago. He told us that we had managed to solve many of the problems that we thought existed. Do you think the problems the industry has faced were overstated? Do you think people have been crying wolf a little over the challenges of leaving the EU?

Mark Hicken: No, I do not. While I agree with Mike that progress has been made—particularly the planning in the event of hard Brexit—the general board sentiment in American companies towards the UK is growing more negative rather than positive as a consequence of the uncertainty that surrounds us. Do we know what is going to happen next year and beyond?

Q232 **Mark Pawsey:** Do you disagree with Mr Thompson about feeling more confident than you would have done a year ago?

Mark Hicken: Yes, the board sentiment is not better now than it was a year ago, and that is the critical thing in determining the place of the UK's life sciences sector.

Q233 **Mark Pawsey:** Mr Sahota, are you more confident today than you would have been 12 months ago?

Pinder Sahota: We are confident on our planning and supply issues. The boardroom sentiment is that Brexit is not helping, but it is not just Brexit.

Q234 **Mark Pawsey:** Do you get the sense that it is not the challenge and the massive problem that people painted it as a year ago?

Pinder Sahota: I can only detail that the planning we have to do to ensure supply is a workload that ideally we would not want and entails costs that we would not want either. In the industry association overall, we are very well prepared and are controlling everything that we can control. To Mark's point, the boardroom sentiment in a number of companies is looking at Brexit and the business environment generally, and saying, "It is not as healthy as it used to be". That is having an effect.

Mike Thompson: I am on record as saying that this is the biggest logistical challenge we have ever faced, so I do not want to be characterised as somehow saying that this is not a big deal or a major challenge. I am saying that, since I appeared a year ago, I believe that we have made very good progress and we are working well with Government. Never before have we tried to secure the supply line of 12,000 individual medicines to reach patients in the UK. There will

absolutely be unknown consequences where things do not go right, and those are the things that keep us awake at night in terms of what we need to do. I am saying, though, that I am very confident that people are working on good plans to try to address these. There is a lot more that still needs to be done.

Q235 **Mark Pawsey:** I want to move on to the longer-term future for the industry. As members of the EU, we have been involved in developing the rules. During the transition period, we are going to be a rule-taker rather than a rule-maker. Mr Thompson, you told us about the impact on research and scientific activity here. I wonder whether your colleagues, Mr Hicken and Mr Sahota, can tell us what they think the consequences are of being a rule-taker rather than rule-maker.

Mark Hicken: Mike characterised the example of what happens with medicines regulation and the nature of the challenge, which is that we have a great base of science and great academic institutions here. We are leaders in life sciences, and leaders in life sciences want to be designing studies, designing breakthroughs and designing the way that we approach scientific collaborations. That is the place that the UK wants in the world of scientific discovery. That needs to be reflected in the nature of the relationship we have with the Union.

Q236 **Mark Pawsey:** What will be the future role of the MHRA once we go into the transition period?

Mark Hicken: Mike has already talked about that. At this point, it is difficult to comment on what the future is going to hold because we do not know what the arrangement is that we are talking about. There are many variations and many flavours of Brexit. But it is important that the EMA for the future acts as a rapporteur and an active agency in the process of determining not only the decisions on what happens with medicines but also the processes that are followed. That historically has been the case. The MHRA has been a big shaper, and we would want that to continue.

Q237 **Mark Pawsey:** Mr Sahota, your business is investing in Oxford. Do you think that other businesses will continue to invest in the UK in the same way once we are outside the EU?

Pinder Sahota: I cannot fully answer on what other businesses will do but, as I have said, I think they will wait to see how things settle down post-Brexit. They will wait to see what the environment is like and how easy it is to do business here. They will take that post-Brexit period, alongside the general business environment and uptake of medicines, and come to a view.

Q238 **Mark Pawsey:** But will your company be continuing with its original investment plans?

Pinder Sahota: At the moment, yes. We are recruiting actively and plan to continue with the investment that we have made.

Q239 **Mark Pawsey:** Are there any obstacles to recruitment as a consequence of where the industry is now?

Pinder Sahota: Not at the moment, but we are trying to reassure current staff about their status to stay. Clearly, we hope that in the final deal there will be a movement of talent from within Europe and outside of Europe as well.

Q240 **Mark Pawsey:** I will move on from the transition period to the political declaration, which says that we will explore the possibility of co-operation with the EMA and consider aligning with Union rules. Is that adequate for you?

Mike Thompson: It is clearly a very weak vision.

Mark Pawsey: We know why there is no detail there.

Mike Thompson: We understand that. Jeremy Hunt and Greg Clark wrote a letter to the *Financial Times* in July last year where they laid out the British Government's desire for close co-operation. Since that time, there has not been one sentence issued from the other member states about their vision. It is encouraging to see that line because it is the first time there has been any signal that there would be some form of co-operation, but the exact detail of the co-operation is really critical to define.

There are obviously other things in there around health security, which are important. As we know, in things like pharmacovigilance, the UK delivers 38% of the adverse events that are picked up by doctors across the whole of Europe. At the moment, we will end up in two different databases. That is to the detriment of patients in Europe on infectious disease control. Again, we amalgamate into one European database. Not having the UK part of it when so many people come through Heathrow is a major disadvantage to patients in Europe. In all these things, there is a real benefit in being together and, as yet, there has been no signal as to what that looks like. That is why I say that there is a lot of work to be done.

Q241 **Mark Pawsey:** How difficult will it be for us to align with EMA regulations?

Mike Thompson: We are completely aligned at the moment.

Mark Pawsey: Sure, but, moving forward, will we simply take their rules and will we continue to align, or are there alternative bodies that we might choose to align with?

Mike Thompson: If you are talking about no deal, clearly we will have to make some decisions about the role of the MHRA in that no-deal scenario. There are some incredibly complex discussions to be had about what we would do. We are characterised as a global industry but we operate regionally. Essentially, there are two main regulators in the world: the FDA and the EMA. That is why we have a completely

integrated supply chain across Europe. Many African countries, for instance, will reference either the FDA or EMA because they draw on the rules that have been laid out. For us to step outside the EMA would be a major decision. Obviously, there will be a lot of questions to be asked if the participation being offered is only observer status. It would be very difficult for a Minister to answer a question in the House on safety if, essentially, they were saying, "I am sorry, but it is a decision that is being made by a European body in which we have no ability to have a voice". That makes things very difficult.

Q242 **Mark Pawsey:** Would the option of aligning with the FDA be a possibility, for example?

Mike Thompson: It is very unlikely that the UK would have much of a voice in an FDA process.

Q243 **Stephen Kerr:** In the political declaration, there is a reference to the type of trade in paragraph 23—no tariffs, no quantitative restrictions and charges, and so forth—but it does not actually say "no frictionless trade". In terms of the future, and our future trading relationships with the EU, do you accept that there will be, of necessity, additional costs and delays?

Mark Hicken: Again, it depends on exactly what the end state looks like. Inevitably, if you are dealing in a single market with a single set of regulations, a single approach and a single set of packaging, that is going to be less expensive than if you have to have two sets of packaging, two sets of licences and two sets of regulations to respond to or to obey. The more the market breaks apart, the more expensive and complicated it becomes for any business, inevitably.

Pinder Sahota: I agree with Mark. There will be costs incurred in the areas that Mark has mentioned and, clearly, there is potential for significant costs depending on what happens at the borders. At the moment, we have been given some guidance by DHSC, but we do not have clarity on what that will mean and what infrastructure needs to be built up around that, which will have cost implications. There are a lot of costs that we do not know at the moment.

Mike Thompson: The declaration talks about a "free trade area, combining deep regulatory and customs cooperation". Those are the words. I guess our interpretation of that is that it provides a broader range of possible solutions. If we take the other extreme, under WTO rules most medicines are exempt, but WTO rules have not been updated since 2010. A lot of the ingredients that go into the medicines are not covered. You would typically be looking at 6% or something on a lot of things that would be coming in. We are looking at rules of origin, which, as you know, are just a nightmare to work through, so there is the additional bureaucracy of that. There is the paperwork at customs borders that you would have to go through. Just to give you an idea, a pharmaceutical company in the UK is currently revalidating 15,000 supply

lines to essentially cover all the medicines it produces in the UK. Each one of those has ingredients coming from different areas. You have to do that for every single one of them. The cost involved is massive.

Whatever the wording finally is, it is really clear that we are looking to have as free a trade as possible in everything. That is the outcome that we are asking for.

Stephen Kerr: There is not enough detail at the moment to plan on maintaining existing trading arrangements.

Mike Thompson: Correct.

Q244 **Stephen Kerr:** I will turn to talent. I think it was Mark who mentioned talent earlier. Are you satisfied with what you read in the political declaration around the non-discriminatory nature of a future immigration arrangement that would allow EU nationals and others to come to the UK for business purposes, including short stays?

Mark Hicken: The spirit of what is being communicated and the direction is encouraging but, without having the detail to look at, it is quite difficult to know what the impact would be. In our sector, there is a presumption that we typically have highly skilled scientific roles that we want to fill but, of course, we have a range of skills right across the spectrum of employment. We draw from outside of the Union as well as from within the Union. We draw from across the skillset. We would want the ability to dip into the talent pool right across the EU and from outside the EU, right across that skills base. Without having the detail to respond to, it is difficult but, the easier it is to move talent around, the better it is for business.

Q245 **Stephen Kerr:** Pinder, what clarification would you like to see around the issue of skills and movement of people?

Pinder Sahota: Let me use the analogy of what we do today. When we have movement of talented scientific staff or business staff into the UK, they come in because they are talented and have a role to fill, it is good for their development and there is a gap, with nobody locally doing it. If that can be continued, that is what success looks like for me. If there are barriers saying that they cannot come in even though they are the right person with the right talent level, we have an issue.

Q246 **Stephen Kerr:** In terms of the range of skills, Mark described a whole range of skills, but did you also mean low-skilled people in your description of the spectrum of skills you are looking for?

Mark Hicken: Yes, we have people working in warehouses helping with distribution; we have people literally at the cutting edge of science and everything in the middle.

Q247 **Stephen Kerr:** What are you currently doing to improve recruitment and training of UK nationals in your business, given that there might be some restrictions, from what we understand, around low-skilled migration of

labour?

Mike Thompson: Coming from the industry perspective, we are huge takers-up of the apprenticeship scheme. We have more people in highly skilled apprenticeships than almost any other sector. We are doing what we can. The way to develop great scientists is to move them around different labs. You cannot be world-class by just being developed in one centre. You need to be moved around to have that experience and the cross-collaboration it brings with it.

Stephen Kerr: Internationally.

Mike Thompson: Internationally, yes.

Stephen Kerr: Within the businesses.

Mike Thompson: Absolutely. We are looking to do that. If you could not do that, in the end the science base would leave the UK because that is so fundamentally important to it. It is critical for us to get it right. Typically, it is easier to move people when they are younger because they do not have families, kids in schools and that sort of thing. They might not be paid very much money but you want to move them early in their careers, because it is easier to do that, to give them the breadth of experience.

These are really big issues. We recognise that there are political challenges around them. We are all waiting to see the detail of what comes out. We are encouraged by what the Government have said to us in terms of recognising the needs. We have said to Government that getting people through tier 2 visas is a nightmare at the moment. Most companies have to employ specialist agencies to do it. There is a real opportunity to simplify things here, but we have to get this right.

Q248 **Stephen Kerr:** Taking the lid off, for example, the cap on tier 2 visas for skilled people would be a very positive thing, would it not?

Mike Thompson: And minimising the bureaucracy that goes with it, to simplify everything, would be beneficial.

Q249 **Peter Kyle:** Mike, how soon do you really need the clarity? Do you need every "t" crossed and every "i" dotted on the future relationship? Has that ship now sailed? Are we now in the territory where, if Brexit does go ahead, there is going to be a really turbulent period for your industry?

Mike Thompson: First of all, because we have been planning for a long time, we are in a better state than we would have been. However, we are getting to the point where some big decisions have to be made. To give you one example, I was talking a few days ago with my opposite number in the cardboard industry. Obviously, most of our medicines come in cardboard boxes. Between 60% and 70% of cardboard comes into this country roll-on roll-off, on a six to eight-week timeline, and the rest of it is supplied through Chile or China on a three-month timeline because it comes in through ships. If we need to do something different, and if we

are not triggering things at the turn of the year, accidents are going to happen. There will be unintended things that we work out we have not managed to do.

Second, as well as trying to work through to get finished packs in here, it is much more challenging for the people who are making medicines here to work out whether they have everything they need. In a number of medicines we include glucose. If we try to prioritise glucose, do people know whether it is for medicines or for cakes? There are some things that, when you get into the detail, are enormously challenging because we cannot afford for these supply lines to fall down. We are getting pretty close to really having to move into a change of gear to ensure we are able to do everything we need to do.

Q250 **Peter Kyle:** Pinder, we just heard that we have a matter of weeks. We are really talking about three or four weeks because of the Christmas period and the disruption that that causes to workplaces. Is that your understanding too—three or four weeks before we have exact clarity or else there will be considerable disruption?

Pinder Sahota: It depends what you mean. Is it clarity on the overall details?

Peter Kyle: I mean what can come in, the terms upon which that can come in, the trading environment and the regulatory environment.

Pinder Sahota: In terms of what can come in, we are not waiting for that clarity, which is why we are stockpiling and so on for that contingency. In terms of the regulatory environment, there is a lot of detail that we are all seeking. As an example, we have three major products that will go through regulatory filing in the next couple of years. We need to assess whether they will be part of the EMA and what role the UK will play in that. There are some decisions that the organisation needs to make, and we need that level of clarity to know how to handle the regulatory filing in the next few years.

Mark Hicken: We need the detail as soon as we can get it. It is very difficult to pick a date. Mike gives you a sense of the scale. On some of these products, the manufacturing lead timelines and the supply chains are complex. If we do not have clarity on how to move product around borders, it is going to be very difficult for us to respond.

Q251 **Peter Kyle:** When we did these same sittings a year ago, you were saying exactly the same thing—"We need clarity as soon as possible". When is the cliff-edge? When is it that we are not looking for clarity any more but are just acting? When is that point?

Mike Thompson: Around the turn of the year.

Peter Kyle: Let me ask Mark to answer first.

Mark Hicken: I was going to say the same thing—turn of the year. We

have already started. Are we waiting, holding our breath? No. We have had the technical notices that mean we know we can bring products from other countries into the UK. That is very helpful. Can we supply if we are manufacturing outside of the UK? Yes, we can do that, provided we can get stuff through the border, of course, because we do not know if things are going to get stuck, with refrigeration issues and goodness knows what else.

In manufacturing, we are at that point now where, at the end of the year, we need to know what is going on.

Q252 **Peter Kyle:** Am I correct in thinking that by the end of the year, if you do not have the clarity, you will be implementing contingency operational activity? Contingency plans will be put into operation at the start of the new year. You will be making that decision right at the end of this year regardless of what is happening in the policy environment.

Mike Thompson: Remember, Mark's and Pinder's companies are sole suppliers of the medicines that they produce. They have been working for a long time to make sure they can supply. We are talking about getting all medicines to all patients. There is a whole series of generic medicines where there are multiple suppliers in the market who may not have the same feeling of ownership for their medicines because, if they do not supply, they expect someone else to supply. In that area, it is much more challenging for the Department of Health and Social Care to work out what would be available in the UK. I believe that there is not much more that industry can do. People have built the stocks that they can. They have made the preparations. When I am talking about other things that need to happen, I am talking about Government maybe needing to make some bigger decisions.

Peter Kyle: At some point, however, you will have to change tack. At the moment you are still waiting for clarity and hoping for clarity. Pinder, you were nodding your head a second ago. Clearly, at the end of the year, you will be giving the orders internally to do things differently.

Pinder Sahota: I just want to pick up on the supply piece. As Mike said, we have put in contingency plans since September. We have been building our stocks. If we do not get any further clarity, we will continue with business as usual and we will keep topping up that extra supply. In terms of business as usual, that is what we are aiming for. To your point about whether we will do anything different right now, I do not think we will, but that is only because we have put plans in place already.

Peter Kyle: It will accelerate.

Pinder Sahota: It will just move forward.

Q253 **Chair:** For most of the session today, we have been talking about what you are doing to prepare for scenarios that you do not want to see. Looking further ahead, are there any benefits that you see in either the withdrawal agreement or the political declaration—things that would benefit your industry and the companies that you work for?

Mike Thompson: If you look at the outline political declaration, it is essentially trying to get us back to where we were. As I said earlier, because we work in a completely integrated supply chain within Europe and a completely integrated regulatory system, that makes enormous sense from our perspective.

Q254 **Chair:** Is there anything in the withdrawal agreement or political declaration where you think, "This would be better for my industry than the current arrangements we have with the European Union"?

Peter Kyle: Not all at once.

Mike Thompson: No.

Pinder Sahota: I cannot think of anything.

Mark Hicken: No.

Q255 **Chair:** We have this vote in Parliament, as you know, in 13 days' time. I recognise that you all want to end the uncertainty that you have had to grapple with as businesses over the last couple of years. You say that the withdrawal agreement and the political declaration are not as advantageous as what we have at the moment, but are you keen that the withdrawal agreement is voted through, to end the uncertainty, even though you are moving to a situation that you know is not as good as it is at the moment? Is that your view?

Mike Thompson: You will understand why we try to keep out of political solutions. We think that that is essentially for Members of Parliament to work out. We are looking for a transition period because we think the downsides of the transition period are very significant. That is the key thing that we are looking for. We would like to see something where we have as strong a position in terms of deep regulatory co-operation with Europe and trade that flows as easily as it possibly can.

Pinder Sahota: I would agree with that.

Mark Hicken: I agree. Mike phrased it very well. We are trying to rebuild what we may have taken apart.

Chair: Thank you, all three of you, for coming today. It has been incredibly informative for us as we go through this deliberation over the next couple of weeks. We appreciate as well that you have been brief and to the point with your answers, so that we can get to our vote shortly. Thank you very much for your time today.