HOUSE OF COMMONS

Health Committee

Oral evidence: Brexit – medicines, medical devices and substances of human origin, HC 392

Tuesday 23 January 2018

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Watch the meeting

Members present: Dr Sarah Wollaston (Chair); Mr Ben Bradshaw; Dr Lisa Cameron; Diana Johnson; Johnny Mercer; Andrew Selous; and Dr Paul Williams.

Questions 336 - 442

Witnesses

I: Rt Hon Jeremy Hunt, Secretary of State for Health and Social Care; Lord O'Shaughnessy, Parliamentary Under-Secretary of State at the Department of Health and Social Care; Dr Ian Hudson, Chief Executive, Medicines and Healthcare products Regulatory Agency.

Written evidence from witnesses:

- Department of Health and Social Care

Examination of witnesses

Witnesses: Rt Hon Jeremy Hunt, Lord O'Shaughnessy and Dr Ian Hudson.

Q336 **Chair:** Thank you very much for coming to this final session on our inquiry into Brexit—medicines, medical devices and substances of human origin. Unfortunately, we are again expecting some votes this afternoon. Lord O'Shaughnessy, I apologise, because this was the experience last time that you came before this panel, so I hope we will not be holding you up again. I am also keen that at the end of the session we should have quarter of an hour—thank you very much, Secretary of State—to ask you some other questions. Before we start, for those following from outside the room, would you mind introducing yourselves, starting with you, Lord O'Shaughnessy?

Lord O'Shaughnessy: Yes. I am James O'Shaughnessy, Parliamentary Under-Secretary for Health in the House of Lords.

Jeremy Hunt: I am Jeremy Hunt, the Health and Social Care Secretary.

Chair: That is what we are going to ask you about later.

Dr Hudson: I am Ian Hudson, the chief executive of the Medicines and Healthcare products Regulatory Agency.

Q337 **Chair:** Thank you very much. Could I start by asking you a key question for patients, and that is, after Brexit, how are we going to ensure that there are not disruptions in the supply chain?

Lord O'Shaughnessy: The main way we are intending to do it, of course, is to negotiate a deep and close working relationship with the European Medicines Agency to replicate the arrangements that we have now, albeit, obviously, on a different legal basis. That is what we have clearly set out that we want to achieve, not least Jeremy setting it out about six months ago. It is the message we have taken into our negotiations, both with the Commission and in bilaterals with the other 27 European countries. The second part is obviously around customs arrangements and making sure that, whatever our future trading arrangements, we have very swift and frictionless customs arrangements so that there is not that kind of friction at the border.

Q338 **Chair:** We would all hope that that will be the case. The difficulty will come if we have a disruptive Brexit and, particularly, if at a late stage all the negotiations break down. Of great interest to this Committee is, what is happening about contingency planning in the event of a disruptive Brexit?

Lord O'Shaughnessy: Yes, you are quite right. We have to prepare for all eventualities, including the one that we do not want as well as the one that we do want. I would re-emphasise that we are very clear about the one we do want. Indeed, in those conversations with our partners in Europe, there is a strong recognition of what the UK brings to the patient

safety agenda across the EU; and Ian can talk more about that than I can. In terms of a no-deal scenario, I think two things are true. Clearly, we have to make sure, whatever happens, first, that patients are not disadvantaged in their access to medicines, devices and other things, and, secondly, that there are no additional burdens and barriers to industry, so that they are happy to bring their products to the United Kingdom. There is work going on with our agencies across Government to work out what that looks like, but I am not at a point where that is something that we are able to share.

Q339 **Chair:** At what point are we likely to be able to see these plans?

Lord O'Shaughnessy: We want to give that transparency as soon as we can, because there is a degree of uncertainty—particularly felt by industry, but not just industry—about what that will look like. We want to bring that forward, but that has to be allied to the overall progress of negotiations, and that is going to be something that reflects an overall Government position about when we need to go public with those contingency plans.

Q340 **Chair:** The reality is that we have heard some very stark warnings during our sessions about what could happen to the supply chain, and that could translate into people turning up at their pharmacy and not just everyday but essential medicines or supplies not being available because of the complexity of the supply chains. Is that something you are actively investigating?

Lord O'Shaughnessy: Yes. We have commissioned an external analysis of the supply chain from an external consultancy, and they will be speaking to companies to get the information and their insights about what their concerns are. We are undertaking that work as we speak, or, indeed, it is about to start.

Q341 **Chair:** Are you doing that also for devices, because we have heard that this is not something that just affects medicines but potentially things as essential as dialysis tubing, of which there are no manufacturers in the UK?

Lord O'Shaughnessy: It is primarily about medicines, medical radioisotopes and vaccines. I do not think it is particularly looking at devices, but I can go back and check on the brief for them for that.

Q342 **Chair:** When are you anticipating that this Committee might have further details of what exactly is being put in place in the event of a disruptive Brexit?

Lord O'Shaughnessy: I am not able to give a date, I am afraid, at this point. As I say, there are a number of issues that are going to drive what date that is. The first is when we have to start, if we have to start, enacting any of these contingency plans. The second is as to what is the state of the overall negotiations, because we do not want to do anything that is going to prejudice our negotiations, and that is the view of

Parliament. The third is at what point the Government as a whole are going public, as it were, with their contingency planning, because lots of these things are interrelated. Our issues are heavily influenced by the customs and trade position being driven by the Department for International Trade and so on.

Q343 **Chair:** We would also like to explore this with you. While everyone accepts that we want to see what we want to see and there is a great deal of good will on both sides of the channel, we are also hearing a message that there are no sector-by-sector deals. So, if something should collapse in another part of the negotiations, with the best will in the world, all this might fall apart. Is that something that you are concerned about?

Lord O'Shaughnessy: I do not know if I am concerned about it. I think we need to be prepared for it. Obviously, we are not in a position to affect directly negotiations that are being driven by other Departments, but from our point of view we clearly need to be ready so that, whatever happens, those principles about no delay for patients, no extra barriers for business, and the third principle that the Secretary of State set out, which is making sure that the UK always plays a leading role in global health, are informing whatever regulatory position we put in place.

Chair: Thank you. Ben wants to follow up.

Q344 **Mr Bradshaw:** The pharmaceutical and medical supply industries were quite clear to us about their contingency planning, which includes moving operations abroad; they have already done it. GlaxoSmithKline is investing £70 million already in contingency planning, yet you do not seem to be able to tell us anything about your contingency planning. Can you give us a broad-brush or broad-principles approach as to how you hope to achieve the ends that the Chair has just outlined to you of a seamless, ongoing supply of vital medicines and medical equipment in the event of either a hard Brexit or no deal?

Lord O'Shaughnessy: First, we do recognise that industry is having to make those arrangements, and indeed the European Medicines Agency has set out some instructions, if you like, for what they should do. We have a close dialogue with industry to make sure, first, that we understand what that looks like and, secondly, that we do what we can to mitigate it, because that money being spent is money we do not want to be spent and they do not want to be spent either.

As to what the actual contingency plans look like, to make sure that we do not prejudice negotiations and make sure that we are in lockstep with the rest of Government, I am not in a position to give more detail at this point. We have commissioned this very detailed piece of work from Ernst & Young to look at supply chain issues. That is going to collect commercially confidential information, so you will understand that publication of that would be restricted, but it may be that we are able to provide a summary of that, which I think might give the Committee—

Q345 **Mr Bradshaw:** That would be very helpful, because the longer the uncertainty goes on, the more that these medicines companies are having to spend on contingency. That £70 million being spent by one single medicines company is now not being spent on research, so I think the sooner we have some idea about what you are planning in the event of things going wrong, the better. Can you at least tell us how much money you are spending on contingency planning?

Lord O'Shaughnessy: I am not in a position to say how much money we are actually spending.

Q346 **Mr Bradshaw:** It would be helpful if you could write to us. Didn't the Chancellor allocate some money in the last budget for contingency planning?

Lord O'Shaughnessy: He allocated an overall amount of £3 billion, I think it was.

Q347 **Mr Bradshaw:** It would be helpful to know exactly what is being spent on this particular area. Can I ask you about Euratom? What is the Government's current position on our membership of Euratom?

Lord O'Shaughnessy: We have said that we will be leaving Euratom as we withdraw from the European Union because the legal arrangements of the two are so intertwined. It is very important to point out, because I know there has been a lot of concern about the trade in medical radioisotopes, that there is nothing in the Euratom treaty that prevents EU member states trading with countries outside the EU regarding medical radioisotopes. It is a very important point. Indeed, that trade is not subject to the approval of the Euratom Supply Agency. Therefore, it is not an issue about whether we can trade with Europe. We can trade with Europe. The question is on what basis.

Again, to re-state, our desire is to have as free and frictionless trade with the European Union as possible through our free trade agreement. What that means, critically, from our end is making sure that, whatever situation pertains, whatever deal there is, we have customs arrangements that can process these materials very quickly, because they often have very short half-lives and need to be transported and moved quickly. On that basis, it is worth pointing out that 96% of imports outside the EU were cleared by HMRC within seconds, and there is a two-hour clearance commitment for urgent goods. So, those customs arrangements are already in place and working for goods outside the EU. Clearly, we would need and want them to apply for goods coming from the EU if we did not have that free trade agreement.

Q348 **Mr Bradshaw:** Can I put to you the comments of John Buscombe, who is the president-elect of the British Nuclear Medicine Society, back in November, who said: "We do not know what the situation will be [after Brexit]. We all hoped we would have an answer by now and we do not," and, "We need more detail than just being told it will not be a problem"? Are we any further down the road than we were back in November?

Lord O'Shaughnessy: I think we are further down the road because the Department has had discussions with many of the relevant UK bodies, not least the British Nuclear Medicine Society itself, the Royal College of Radiologists, and the Society and College of Radiographers, to identify the risks and to reassure them that some of the popular perceptions about what the Euratom treaty means for medical radioisotopes may not be accurate: that trade is possible and that we do have customs arrangements that are capable of dealing with it. Therefore, we are engaging in the dialogue so that we can reassure them, find out what they are worried about and deal with them. That is quite a significant change. I believe that meeting took place in December, after the comments that you are referring to.

Q349 **Mr Bradshaw:** As to our future relationship both with Euratom and the European Medicines Agency, of which we will not be members, apparently, but with which we will have a close relationship, that will involve, will it not, some level of jurisdiction for the European Court?

Lord O'Shaughnessy: I do not think that that necessarily follows. What would be the arbitration body for any involvement is a matter for the future negotiations.

Q350 **Mr Bradshaw:** Haven't our European partners, including President Macron in the last 48 hours, made it absolutely clear that any sort of relationship like the one we currently enjoy, delivering the same benefits we currently enjoy with any European institute or organisation, is going to require oversight by the ECJ of some kind?

Lord O'Shaughnessy: I think that is probably a question for colleagues in the DExEU rather than for me. Whatever arrangement we negotiate in the future for the phase II negotiations about the future relationship will involve some kind of court of arbitration, as all free trade agreements do. What that looks like is a matter for discussion.

Q351 **Mr Bradshaw:** The Government have already acknowledged that that will be necessary during the transition, which was a previous red line.

Lord O'Shaughnessy: Again, the discussions about the transition are taking place now about what exactly that will include. Again, I do not think we are in a position to say what precisely that will include.

Q352 **Andrew Selous:** Carrying on with that theme, we have heard about GlaxoSmithKline and the £70 million it is spending now, £70 million that is not going into research, which is obviously concerning. Looking at the transitional agreement that is going to be needed, what is your assessment of when we need that agreement to make sure that more companies do not have to do what GlaxoSmithKline has already done in terms of timescale?

Jeremy Hunt: Maybe I could answer that. We are very encouraged that we have secured the agreement to have a transitional agreement, and the hope is that it could be concluded potentially as soon as the end of

March, but it may take a little bit longer than that. That is subject to the ongoing negotiations, but there was a very important breakthrough in December that said there should be a transitional agreement on both sides. Combined with the potential difference with this sector, which is that it is uniquely damaging to both parties if we do not come to an agreement—it is not just us who want to continue getting cancer drugs that are manufactured in Europe; it is Europeans who will not want any interruption to their supply chain for drugs that are manufactured in this country—that gives me a lot of confidence that we will be able to agree ultimately what needs to be agreed, but, in particular, that we should be able to agree what we need to on a transition deal.

Q353 **Andrew Selous:** My memory from our last evidence session from the trade associations was that a number of businesses were saying that even in January—this month—they would have to be taking decisions. I am encouraged you say that the end of March may be possible, but weeks are critical at the moment.

Following on from that, what assurance can you give us that the specific needs of the health-related products sector are really being factored into the negotiations at the highest level on the UK side because of the critical matters you have just referred to, Secretary of State?

Jeremy Hunt: All I can say is that we are involving them in all the industry discussions that we have. We know it is a critically important sector. It is not just the pharmaceutical sector. It is incredibly important.

To add a point to what James has said, the real confidence that we have is that we have the transition deal and we have the reciprocity of need to get the deal that we need. That gives us confidence, but the reason why it is difficult to be more specific about the no-deal preparations is not because we do not want to be open with the Committee, the public and industry; it is just that in the middle of a negotiation, if you reveal precisely what you would do, if the negotiation goes nowhere, you give your negotiating counterpart a huge advantage.

To negotiate the best deal—and we all want to get the very best deal for the UK—there has to be some element of strategic ambiguity about what the no-deal outcome might be as far as your counterpart is concerned, but it does not mean to say that you do not make incredibly extensive preparations for that eventuality.

Q354 **Andrew Selous:** We respect the confidentiality of the negotiations. Finally, I want to ask how responsive you have found the UK negotiating team to the specific needs of health, which are extremely urgent?

Lord O'Shaughnessy: First, we have a group called the UK EU life sciences steering group—admittedly, not the most natty name in the world—that was set up in the wake of the referendum result to have that direct engagement between the public sector and the private sector to raise issues of concern and then deal with them. We have a very productive relationship there and also complete agreement that the right

outcome for the UK and for the EU is continued collaboration. Indeed, that message is coming not just from the UK but from the EU-headquartered companies, regulators and others because of the incredible contribution that the MHRA, among others, makes to patient safety across the continent. That message is being funnelled through the Department to DExEU, to the negotiating team—I have to say that they have been extremely receptive to it—as well as through other channels in EU member states and the Commission. Therefore, as I said, there really is a confluence of interest here, because the consequences of putting up barriers are not merely inconvenience but patient harm, and that is the point.

Q355 **Andrew Selous:** They are potentially life-saving issues.

Lord O'Shaughnessy: Absolutely.

Q356 **Mr Bradshaw:** If you are giving this the priority that you say you are, why in your recently published departmental plan is there nothing about Brexit, although, as a Department, you have the third highest number of Brexit-related workstreams to deal with?

Jeremy Hunt: I think it is covered totally in what we are doing. It is a crucial part, and it takes a significant proportion of both mine and James's time. Let me get back to you, if you like, on why it appears not to be mentioned in the plan. I must admit that I would be surprised if it is not in there somewhere.

Lord O'Shaughnessy: It is definitely part of our work.

Chair: It is down there, but it is quite far down.

Q357 **Dr Cameron:** My questions are about long-term considerations and the attractiveness of the UK life science sector. If the UK is unable to negotiate its preferred relationship with the EU, what action would be needed to enhance the UK trade in life sciences going forward?

Jeremy Hunt: Shall I take that one? The best way to answer that question is to recognise that, while trade and access to markets are very important, I do not think, even in a no-deal scenario, we are talking about zero access. In the end, the most important thing to the success of any industry is making the products or doing the services that people want to buy. We have the biggest and most important life science industry in Europe. So, our long-term future, if you are looking at a sort of 10 or 20-year horizon, will depend on our ability to produce the medicines and the medical devices that save lives across the world and make waves with their innovation and cures.

The most important thing in the long run is our science base and the quality of our universities—the fact that, according to *The Times* league table, we have four of the world's top-10 medical research universities in this country. Those are things that are more within our control. We support the investment that happens in our university sector. We have

made it clear that we will make sure that universities are able to continue to attract the brightest and best from all over the world.

I do not want to minimise the importance of having the best possible access to the largest single market in the world, which is right on our doorstep—all that, of course, matters—but there are very fundamental things that have given strength to our science and medical innovation sectors over centuries that we must make sure continue.

Q358 **Dr Cameron:** We have been leading the way, which has been very important for prestige going forward, but we have also heard evidence that there could be a brain drain, that people might go elsewhere, some of the brightest and the best, and that they also want to be able to undertake clinical trials within the EU. It is a much bigger marketplace for clinical trials and reach. What new action would be needed once we leave the EU to achieve the life science industrial strategy?

Jeremy Hunt: Perhaps I could bring in Dr Hudson because he could talk about the clinical trials aspects, and we could put your mind at rest that we would be confident that we could continue to participate in European-wide clinical trials.

Dr Hudson: Companies will do the bare development work where they feel that they will get high-quality data and data relevant to the global development plans that they are developing and run to international standards. The UK is an attractive place for development work and will continue to be so.

As to clinical trials, even in a hard-Brexit scenario—not the one that is the preferred outcome—you will still be able to have the same protocol that is submitted for approval in the UK and the clinical trial run in the UK, and that data combined with data from the study done anywhere else. In terms of orphan diseases, the UK could be part of a multi-centre trial just as it is now. That is not going to change. The great investment and great things that have been happening in the clinical trials network in the UK, for example, all continue, so the UK can be very much part of the global development programme. Now, companies developing products and medicines will do clinical trials in countries all over the world, and as long as that data is relevant to the jurisdiction that is adjudicating it, and as long as the standards are the same, that data is perfectly useful, so that does not change.

Q359 **Dr Cameron:** But we have heard that we have been leading in this field for years and want to continue. Taking part in something is different from leading on it. Is there not a risk that we will no longer be leading on it?

Dr Hudson: The UK is a great place to do clinical research for all the arguments that we have heard. The universities are strong. We have a lot of expertise; the clinical trial networks have grown over the years to really be a fundamentally very attractive part of the UK eco-structure. There is a lot of investment going on in the UK. None of that changes,

whatever the outcome of Brexit, so I think the UK remains an attractive place. We need to make sure on regulation that we follow international standards and ensure that the studies that are done are done to international standards such that the data generated can be used throughout the world.

Q360 **Dr Cameron:** Finally, of the different existing models for trade within the EU, which do you see as being closest to what the UK should be seeking as the most beneficial model of trade for patients?

Jeremy Hunt: We have made it clear that we want the closest possible relationship with the EU, in many ways a continuation of the arrangements that we currently have but with different legal structures underpinning them, because we think patients benefit from the highest possible levels of integration between the UK and European pharmaceutical industry. That is the case that we will be making to the EU in the negotiations. Obviously, it takes two to tango in these discussions, but that would be our preferred outcome.

Q361 **Chair:** Ian, could I return to a point you just made? We heard from previous witnesses to this inquiry that they had concern about access to European-based clinical trials. Are you saying that those concerns are baseless?

Dr Hudson: I do not know if your witnesses were companies or whoever—

Chair: This is not just from companies.

Dr Hudson: If you want to do a clinical trial, you need to have a protocol and then go through various approval processes and so on. The point I was trying to make is that, regardless of the outcome of the negotiations, you could still be able to run a multinational clinical trial involving the UK; so, that does not change. What will change in a hard-Brexit scenario is that an application would have to go to the UK as well as to the European Union, but the point of being able to have a multinational trial does not change.

Q362 **Chair:** We heard from a number of sources that they were concerned that they would not be able to take part in multi-centre clinical trials, particularly those who are representing orphan diseases where it is essential that these take place. Everybody hopes that it will continue, but we heard some concerns expressed that Britain would find it more difficult to be part of these multi-centre clinical trials.

Jeremy Hunt: Perhaps I could just make a point on that. The concern that people might have is that, if a fully sovereign UK were to set up different clinical trial protocols from those that were being used in the EU market, people might say, "In that case, we do not want to do our trials in the UK because there is going to be extra bureaucracy, and it is 60 million, not 500 million people," but the choice of whether we continue to follow the same protocols as the Europeans is ours.

Q363 **Chair:** Of course. Regulatory alignment is something they all want to see, but there was still some concern that people might have difficulties accessing these European databases. Are you saying, Ian, that that has now been resolved?

Dr Hudson: We are talking about a number of different issues here. What I am saying is that the ability to run a multinational trial including the UK does not change, just as now you can run a multinational trial including Australia, Switzerland and Europe. That does not change. The mechanisms for the approval may change in a situation where you are in a hard Brexit and the preferred outcome has not been achieved, but the ability to do it does not change.

Q364 **Chair:** Right. We did hear some concerns. Would it be possible for us to correspond later about some of the concerns that were expressed to us?

Dr Hudson: Yes.

Q365 **Diana Johnson:** I want to ask a very simple question. As I understand it, there are new clinical trials regulations that are due to come into force post March 2019. Is it the Government's expectation that you will accept those new regulations? Is that what is planned, because you are saying it is going to be easy to carry on? Are you saying that you will just accept those?

Lord O'Shaughnessy: It is not the only issue, because we also have the medical devices regulations. As we have said, our desire is to have that continued close relationship, which would mean participating in those kinds of programmes. It is our desire to do that. It is contingent on that being the negotiated outcome, but our desire is to continue to play a full part in the regulatory co-operation that we do now.

Chair: Ben, did you have any follow-up points on that?

Mr Bradshaw: Not until we get to regulatory alignment.

Q366 **Dr Williams:** Are we going to accept the medical devices regulations? Has a decision been made about that yet?

Lord O'Shaughnessy: The point I was trying to make is that those are regulations that have been passed but are in the process of being implemented.

Q367 **Dr Williams:** Witnesses have been asking about them.

Lord O'Shaughnessy: Indeed, and their implementation spans different timeframes depending on what the piece of legislation is. That will be affected by two things. The first issue is the length of any implementation period, what becomes active during that period, however long that period is, and what the nature of that period is in terms of accepting the EU regulation. The second issue, of course, is what kind of relationship we have post-implementation period, and, clearly, as we were saying, we want that close relationship. It is important to point out that the UK has

driven a lot of these reforms itself, particularly on medical devices with Ian and his team, but also in clinical trials. We think they are in a good place and we want to play a part in them, but that is not something that we can guarantee, because that is the subject of a negotiation.

Q368 **Dr Williams:** I think what I have heard is that businesses are likely to get some certainty over the transition or implementation phase hopefully by the end of March. Is that right?

Lord O'Shaughnessy: Yes. That is the next phase of the talks. March has been mooted. It may be later—I don't know—but the first stage is to describe what the implementation period looks likes like, how long it is, and then to move on to the future trading arrangements.

Q369 **Dr Williams:** You can obviously understand that, with regard to the supply chains and the complexity of some of these products, businesses want certainty as quickly as possible.

Lord O'Shaughnessy: Absolutely. I completely agree. We want to be able to provide it. We also do not want to provide false comfort where that is not something that we can do with confidence. That is why we are having that ongoing dialogue—and it really is deep and frank—to make sure that we understand what their fears are and also that they tell us what they are planning to say. GSK is a good example. We knew because it had told us what it told you, and so we have encouraged it to be straightforward and honest about it because that is the reality. We want to be in a position where we can defer or even dismiss those kinds of spending commitments because of guarantees we can give about the future relationship, but we are not there yet.

Q370 **Dr Williams:** We have particularly heard that some of these companies need to make decisions now in order to be able to carry on providing their medicines or products to patients after we leave the EU. What advice would you give to them about preparing for a no-deal scenario—what contingencies?

Lord O'Shaughnessy: The advice we do give them, and indeed the MHRA has published quite recently some advice on its own website, is that they, like us, should prepare for all scenarios. We want to know what they are doing so that we can understand the risks involved and, as soon as we are able to, give them more certainty so that they can, hopefully, defer or even cancel that kind of spending.

Q371 **Dr Williams:** In the event that there are some companies that do not prepare for a no-deal scenario, do the Government have some contingency so that there can be alternative ways of providing the services to patients?

Lord O'Shaughnessy: It is important to point out in these relationships that we are not just talking to individual companies but the trade organisations as well. If you look at medical devices, the vast majority of these companies are SMEs. The ABHI is a critical partner in this exercise,

because it is speaking for thousands of small companies who need to prepare, so that is part of the plans.

Q372 **Dr Williams:** Some of them really feel under threat by this process at the moment and are asking for that certainty as soon as possible.

Lord O'Shaughnessy: Indeed, and we want to provide certainty when we can, of course.

Q373 **Dr Williams:** May I ask about the EMA? Currently, the EMA is located in London and it is moving to Amsterdam. Have Governments been working with the EMA to ensure that that is a smooth transition?

Jeremy Hunt: I will hand over to Ian for some of the details, but I have spoken to the Dutch Health Minister, and I have said that I think it is in both our interests to make the transition as smooth as possible. We want to help the EMA make a success of its new home. We think that is in our interests as well as the EU's interests, but Ian might want to talk about some of the details.

Dr Hudson: I work closely with Guido Rasi, who is the executive director of the EMA, and also my counterparts across the European countries, and we have offered every assistance that we can to make the process as smooth as possible. As you know, we have had a significant role in the work of the EMA, and clearly we are involved in a number of committees and so on. So, we will do our utmost to work with the EMA to help that transition to Amsterdam go as smoothly as possible.

Q374 **Dr Williams:** The EMA is advising businesses that its transition ends at the end of March 2019. Do you agree with that?

Dr Hudson: We have already discussed that there is a transition period negotiation that is going to happen in this first quarter, and I think there will be clarity at the end of this period in terms of what the transition period is and what can be done or does not need to be done during this period.

Q375 **Dr Williams:** The working assumption at the moment is that the EMA will have been fully transferred to Amsterdam by the end of March 2019.

Dr Hudson: That is my understanding from the EMA. I am sorry, I thought you were talking in general about companies' preparation. It is my understanding that the EMA will move to Amsterdam, perhaps not to its definitive home but to a temporary home, and then its definitive home by March 2019.

Q376 **Dr Williams:** I guess the next question should be for Lord O'Shaughnessy or the Secretary of State. There are British firms that are relocating to Europe in order that they can be EU 27 compliant. In the event of no deal or in the event of our deep and close relationship with the EMA that we are hoping for not transpiring, what impact might that have on patients?

Jeremy Hunt: This is really just to echo what James has said, but all companies have to prepare for all eventualities. There may be eventualities where having a small European office helps them secure rapid approval for the European market, but when you talk about patients, I think we are really talking about British patients, who are our primary responsibility, so we need to make sure that there is continuity for supply chains. That would be part of the different scenarios that we plan for, but we absolutely are making sure that we do everything we need to do to ensure that patient safety is not compromised.

Lord O'Shaughnessy: Can I take one point there, because I think it is true that companies are looking at that, and indeed the EMA has been clear about the worst-case scenario and planning for that? We hope to be able to say relatively soon that that is not going to happen and that will involve deferral of those kinds of changes. It is also important to point out—and it relates as well to a question that came earlier about the life science industrial strategy—the number of investments that are still taking place here. There is an ebb and flow, inevitably, with any global market, and the sector deal that we launched at the end of last year showed that big companies and small companies are prepared to make major investments here: MSD, Johnson & Johnson, Seqirus and others.

The UK is still seen as one of the top three global centres for life sciences. Clearly, those companies who are here are having to make preparations for all scenarios, but I do not think it would be fair to characterise that as a sort of one-way street—a drain, if you like.

Q377 **Mr Bradshaw:** Secretary of State, you sounded a little uncertain a few moments ago as to whether you thought there would be a transitional deal by March, and yet we have heard from all of our witnesses that we need one now. You could sign up to one now, could you not, and probably Lord O'Shaughnessy and the Business Secretary could, based on the status quo or as close to it as we can possibly be, so what is holding it up? Is it the hard Brexiteer colleagues in the Cabinet, like Mr Johnson, who is out on manoeuvres again today?

Jeremy Hunt: No. The reality is that these things have to be negotiated.

Q378 **Mr Bradshaw:** Within the Cabinet.

Jeremy Hunt: No. These things have to be negotiated with the EU and the—

Q379 **Mr Bradshaw:** But you and the EU could agree now on a transitional deal, could you not, quite happily?

Jeremy Hunt: That is a question you have to address to David Davis, but the truth is that we have made it very clear that we want a transition deal. That was agreed with the EU in December in, I think, a pretty important moment in the negotiations. It was also said as we move on to discussions of the future relationship that there are going to be some "i"s that need to be dotted and "t"s that need to be crossed in terms of how

that transition deal would work, but there was broad agreement that there would be a transition agreement, as far as the sector is concerned, along the lines that we would all welcome.

I am very confident that we are going to have that transition deal, and, as I say, there are a few final stages. But, as far as the UK is concerned, we have made it very clear that we want to agree to specify how that transition deal will work as quickly as possible, because the value of a transition deal shrinks the closer you get to March 2019. I do not think there is any lack of speed from the UK Government's point of view, but there are two parties in the negotiation.

Q380 **Mr Bradshaw:** All the witnesses that we had, from the industry, from patients' groups and from charities representing certain specific disease interests, said that they would rather we stayed in the single market and the customs union. That is their solution to all the uncertainty we have been talking about, and they could start planning now. They would have some certainty now. The Government are not going to do that. You have set your face against staying in the customs union and the single market, foolishly in the view of many of us, but they also said that the next best thing would be full and permanent regulatory alignment. Is that something that you would like to aim for as well?

Jeremy Hunt: Let me answer both those points, if I may. The reason that we are not staying in the single market and the customs union is because we do not think that, ultimately, that would be compatible with what the British people voted for. I know there is a debate to be had and people take different views on that, but that is our view. Being subject to the ECJ rulings, which is what being part of the single market would mean, but not being able to influence those rules, so being a rule taker and not a rule maker, is something that many people of the 52% who voted for Brexit would find completely unacceptable. We have made that decision based on our interpretation of what the referendum result meant. I appreciate that people can have different views on that, but in terms of the regulatory alignment I think the situation is this.

There is not, I do not think, any intellectual problem or incompatibility with totally close regulatory alignment and the UK agreeing to do that on an ongoing basis. Obviously, Parliaments cannot bind future Parliaments, saying this is what we intend to happen forever. I think the issue is the legal underpinnings for that. If that regulatory alignment is agreed between two sovereign powers—the EU and the UK—with international arbitration, or an agreed arbitration mechanism if one party thinks the other party is breaching that agreement, that is completely acceptable and is the kind of relationship that could work very well, not just in pharmaceuticals and life sciences but also in financial services as well.

What would be difficult to square with my view of what people voted for would be an arrangement where we were obliged to change our regulations in response to a unilateral change in regulations made by the

EU going forward, because I do not think that would be compatible with having control over our own destiny.

Q381 **Mr Bradshaw:** You keep referring to your interpretation of what people voted for, but the latest polling shows that the majority of leave voters and the majority of Conservative voters think we should stay in the single market and the customs union. If you really want full regulatory alignment permanently, as this sector does, isn't that your simplest solution?

Jeremy Hunt: I am basically saying that I think we can get close regulatory alignment but still be outside the single market. I think it is entirely possible to achieve that.

Q382 **Mr Bradshaw:** It sounds like having your cake and eating it all over again, doesn't it?

Jeremy Hunt: I do not think it is, because by leaving the single market we are going to have to do a lot of things where we are not going to be able to eat our cake. We are going to have to have completely different arrangements over immigration and all sorts of other areas. So, we are clear that there will be some—

Q383 **Mr Bradshaw:** Costings.

Jeremy Hunt: There will be some costs, if you like, some things that happen differently when we are not in the single market, but that is our duty—to implement what people have said.

Q384 **Chair:** Following up that point, why would the EU, though, agree to have a totally different system for arbitrating disputes just to align with us? Surely, their view would be, "You can actually align with us and abide by our rules." Are we at risk of having too much optimism about how they will view this—how it looks from the other side of the channel?

Jeremy Hunt: I am regularly accused of having too much optimism, but the answer to that is that that is exactly the arrangement they have in every other trade deal that they do. That would be the arrangement that happens in the Canada trade deal; it would be the arrangement if you had an EU-US trade deal.

Q385 **Chair:** Indeed, for trade, but we are talking about regulatory alignment here, which is something different.

Jeremy Hunt: We will let James come in on this.

Lord O'Shaughnessy: There is a really critical thing to understand here, if we just focus on regulation of medicine and medical devices. It is just the contribution that the MHRA makes to patient safety across the European Union. It is worth emphasising, I think, that it is a quarter of the centralised marketing authorisation procedures, about 40% of the decentralised procedures and 40% of safety referrals. It goes way beyond any other member state. Our regulatory system is seen as a gold

standard across Europe and it is keeping European patients safe. Because of that reciprocal arrangement, which is benefiting everyone at the moment—which is recognised universally as benefiting everyone—we think, realistically, perhaps as well as optimistically, that that is something that we can achieve, because it is so clearly in the interests of patients.

Q386 **Chair:** I completely agree that it is in everybody's interests for us to have close regulatory alignment and a deal in the way that you all set out. However, it has been put to us that, given a choice between that and actually breaking away from some really important principles to the EU around the single market and the role of the ECJ, they might be minded to choose that rather than, even if it is in the best interests of everyone on both sides of the channel, to do otherwise. Does that concern you?

Lord O'Shaughnessy: I come back to this point about safety. When we are talking about health issues—not exclusively health issues because safety issues are there in the aviation industry, in chemicals and other things—if you put up barriers of any kind, you are not just talking about the inconvenience of a slightly more expensive car or a slightly lower spec iPad, or whatever it is. You are talking about treatments not getting through to patients.

The only reason I stress this is because I think there is a case that we are making, internally and externally, which, as I say, is echoed by all parties, that these kinds of issues are different and, therefore, they need to be accounted for in that way. Critically, this is not just a sort of selfishness from us. The UK has a huge amount to offer to patient safety in this field, and in other fields, it has to be said—professional regulation and other things too.

Q387 **Chair:** I completely agree, but the question here is whether we are planning sufficiently if that all breaks down because there is no sector-by sector deal. That is what we keep hearing.

Lord O'Shaughnessy: Of course. As I said, we are obviously contingency planning.

Chair: Paul has a follow-up point on this.

Q388 **Dr Williams:** Yes. I need to understand this a bit better. If a company wants to bring a new product or a new medicine to the market in order to benefit British patients, will there be mutual recognition? Is that what you are hoping for? Will they have to go through a process of getting approval in the EU 27 and a separate process in the UK, or are you hoping for mutual recognition?

Lord O'Shaughnessy: The scenario that we are after—the deal scenario—is that the UK will continue to be involved in the EMA processes in some way. That "some way" is to be determined, because there are various forms that that could take, so that the kinds of activities that happen at the moment—marketing authorisations and licences—can

happen at the EMA level and they can happen locally, and are continued. I think, Ian, there are four routes currently across which a licence can be recognised. It would be a continuation, albeit on a different legal basis, of that kind of system.

Q389 **Dr Williams:** If we do diverge in the future, if there are stricter regulations that come into force in Europe or if a future Government in this Government wanted to deregulate, then we may get to a point where there would not be mutual recognition. To get a product to the market, a company would have to go through a separate process for the EU 27, which represents, in terms of the global pharmaceutical market, 23%, and a separate process for the UK market, which represents 3% if we diverged. That could happen.

Lord O'Shaughnessy: If we diverged, if you want to use that language, then clearly there would be separate arrangements. I would just come back to the point that our intention as a Government is to continue that collaboration because it is in everyone's interest. If a future Government, or indeed the EU, wanted to do that, then that would be a decision for them. Clearly, as Jeremy said, that would be arbitrated through some agreed process.

Q390 **Chair:** The related point is around pharmacovigilance and qualified persons. We heard serious concerns expressed about the shortage of qualified persons and that many of them are now already relocating to the EU. Perhaps this is a question for you, Ian. Are you satisfied that we are going to have enough qualified persons? Do you think it is likely that we are going to need to have one here as well as in the EU for all our manufacturers?

Dr Hudson: As we have discussed, the Government's preferred position is for ongoing collaboration such that the processes that we have been talking about continue effectively. Clearly, we are having to plan for contingencies and to look at different scenarios, and we will ensure that we put in place appropriate mechanisms for patient protection, that products can be brought into the market and that those putting products on the market can be held to account if something goes wrong and we can take action. These are all priorities as part of contingency planning to make sure that we have these arrangements in place in the event of a no deal, but that does not take away from the fact that the preferred option is that continued collaboration.

Q391 **Chair:** Is there contingency planning going on now around training qualified persons in the event that this does not happen? We all accept that we want close regulatory alignment around all these issues, but it takes time to train a qualified person. Who is leading on that process of planning for a no-deal scenario?

Dr Hudson: Within the agency, we are working together with the Department of Health, DExEU and the Office for Life Sciences. We are certainly planning for what the scenarios will look like and what

arrangements we would need to put in place for a no-deal scenario. Specifically on qualified persons in pharmacovigilance, there are anyway ongoing programmes, all the time, to train as new people come into industry. That has not been saying, "Oh, we must put in place a new programme for pharmacovigilance," because there already are programmes out there for people being trained in pharmacovigilance.

Q392 **Chair:** Do you accept the concerns from industry that there is already a shortage of qualified persons?

Dr Hudson: Yes.

Q393 **Chair:** Therefore, should there suddenly be a walk-away, no-deal scenario, we would be left with a critical shortfall in this country because many of them will already be relocating to Europe.

Dr Hudson: Certainly, our intention is to put in place arrangements that protect patients and we can hold people to account. We have not discussed publicly yet the exact details of what they will look like, but there must be an arrangement that protects patients and enables us to hold companies to account.

Lord O'Shaughnessy: Can I add something? I think the MHRA does about a fifth of the EMA's pharmacovigilance work, so, from a domestic capacity point of view, we do have domestic capacity.

Q394 **Chair:** We do now, but we heard that many of these individuals are relocating or making plans to relocate to the EU already. That is what we heard. In other words, if there were no deal and we did need to have additional QPs, we heard serious concerns that they would not be available. The question to you is: what are you doing to address that and to make contingency plans for it?

Lord O'Shaughnessy: We are planning for what that would look like and obviously we do not want to have to action that, which is why the implementation period in the future trading agreements is important, because timing is crucial with that, but we are planning for what that might look like.

Q395 **Chair:** Would you accept there is a challenge that, with the best will in the world, we all want the same thing, from what you have been describing this afternoon, but, given that nothing is agreed until everything is agreed, if this should all collapse at the last minute, there does still need to be planning about what would happen in that case?

Lord O'Shaughnessy: Of course, yes.

Q396 **Chair:** That is happening. That is what we want to know.

Lord O'Shaughnessy: There absolutely needs to be planning, yes. I totally agree that of course there needs to be planning. All I was trying to reassure the Committee of was that we start from a position of strength because of the MHRA's capacity and reputation as a leading global

authority, but that does not negate the necessity of making sure that, if such a scenario did happen, we have everything in place to provide that level of security for patients that we do now.

Q397 **Andrew Selous:** We heard from a number of witnesses from different trade associations concerns that British patients would receive new medicines more slowly than they do at the moment. That, obviously, can be critical for patients' treatment. How are we going to deal with that issue after Brexit?

Jeremy Hunt: The first point to make is that we think that British patients currently receive new medicines too slowly and there are a number of reasons for that, one of which is the NHS budgeting processes. Part of the catalytic effect of Brexit has been for us to look much harder at some of the issues that the life sciences industry raised with us. One of those is the fact that, when they develop new drugs in the UK, they find it takes too long to get those drugs to be taken up by the NHS. That is a significant negative as far as they are concerned. We are looking at that issue more broadly.

I would also say from a patient safety point of view that it is an absolute priority to make sure that things do not slow down as a result of Brexit. We are, I think, confident that we can avoid that, because, when it comes to importing drugs from overseas, we are the customer. So, it is up to us whether the processes that are put in place for the importing of medicines are bureaucratic or smooth and streamlined. I think medicine is one of those areas where it would be patently against our national interest to make it harder to import life-saving drugs. I am pretty confident that we would not see a scenario under any of the different Brexit scenarios where that actually happened.

Q398 **Andrew Selous:** That is encouraging to hear. What is the position as far as withdrawal from the European Union in relation to the accelerated access review is concerned?

Jeremy Hunt: I do not think it affects it. We are absolutely committed to proceeding with what we are talking about. James, do you want to add anything?

Lord O'Shaughnessy: Yes. Effectively, the collaborative, which is the body that is putting into action this new accelerated access pathway, is going to meet next week for the first time, and the first set of products will be identified from April. That has not been changed by any of this.

Q399 **Andrew Selous:** In terms of drawing up a new licensing framework by March 2019 to take account of the needs of the UK life sciences sector, is that something that we are capable of doing as well within that timeframe?

Lord O'Shaughnessy: Yes.

Q400 **Andrew Selous:** I was pleased to hear you say earlier, Secretary of

State, that you added a priority for the Department, if I wrote it down correctly, that the UK should always play a leading position in global health. I know you went to China recently, partly in relation to that. Could you say a little more generally about how you see the UK's role going forward? Currently, we have America, Japan and the European Union, as I understand it, as the three major global licensing authorities, with China perhaps coming up the tracks quite quickly, with their huge 1.3 billion market. What is your future vision of where the United Kingdom is going to be positioned within the global life sciences sector post Brexit?

Jeremy Hunt: When you talk to people in the industry, they generally say that there are three major centres of innovation across the world, or three pre-eminent centres, which are California, Silicon Valley and Boston, London, Oxford and Cambridge, with Edinburgh as an honourable part of that triangle as well. Our absolute priority, if you are talking about our economic interest, is to preserve the UK as hosting one of the three big international centres for innovation. We have every chance to do that, but it will be our decision, and decisions that this Government and future Governments make, that will secure us as a centre for innovation. That will be to do with investment in our science base, how easy we make it for the brightest and best to come from all over the world to do their inventions here, and tackling some long-standing problems that we have, such as the commercialisation of great British inventions, as to which we have always had a weak spot in sorting out the financing of small companies. Although we are the leading global centre of finance, British finances have traditionally been more risk averse than US finances, which makes it harder for small companies to get off the ground.

There are plenty of obstacles that we need to tackle to secure our position, but you were talking, I think, about access to the biggest markets across the world. You are absolutely right that the EU, China and the US are all incredibly important, and we need to make sure that we negotiate that access. Consistent with what James was just saying, scientific innovation is an area where, typically, you will have the fewest barriers to entry in markets around the world. People generally want their citizens to be able to access the latest medical innovations as quickly as possible. That is a healthy and positive thing, but we have a great tradition of free trade in this country and we will continue to champion that.

Q401 **Diana Johnson:** I would like to talk to you about data protection and recognising how important that is, particularly around clinical trials. Does the Department of Health have a view about whether non-alignment with the EU data protection regulations would be a beneficial point?

Lord O'Shaughnessy: Data and technology is part of my policy brief, and the big moment coming in here is the GDPR implementation in May—the general data protection regulation. We, like the rest of Government, are preparing to implement that. It is critical anyway in terms of citizens' rights, safety and so on, but it is particularly important in healthcare

because of the way the NHS is. As a single payer, universal and comprehensive healthcare system, the NHS has the capability to corral patient data, for the benefit of patients themselves in terms of direct care, but also for research and the development of new treatments.

We also know that the public are rightly concerned about how safe and secure their data is when it is held by public and other bodies, and the GDPR is a critical part of reassuring the public that the Government, albeit the health bit of it, is capable of looking after their data properly so that they are happy for it to be accessed by research organisations that are trying to develop those cures. We want those cures to be developed here. We want them to be trialled here and we want British patients to be getting them first. That is a critical part of it. Aligning ourselves with that is very important.

Q402 **Diana Johnson:** So, you are not looking at non-alignment.

Lord O'Shaughnessy: This is happening now. This does not even get you into implementation period time. This is happening in May this year.

Q403 **Diana Johnson:** But post 2019, is the Department considering whether there should be non-alignment to give you more flexibility and perhaps do things in a different way? Is that on the cards? Some of the evidence we have had, I think from industry, seemed to indicate that that might present some opportunities that are being restricted at the moment. What you are saying to me is you are not looking at that. You are just doing alignment.

Lord O'Shaughnessy: At the moment, as a member of the European Union, we are looking to make sure that we are part of that. Data is an emotive issue, and it definitely elicits different responses from different countries and cultures. We have quite a pragmatic approach in this country. That is, in essence, what the GDPR represents. We feel that that is a pragmatic solution.

Q404 **Diana Johnson:** Can I ask you about loss of EU funding and collaboration? Particularly, we are a net beneficiary of European funding in the university sector, as I understand it, and guarantees have been given around Horizon 2020. But what about the next programme that the EU will put forward— the framework programme 9? What involvement do we have at the moment with that being established, and what do you think the involvement of this country will be in the future? Will we have a role to play in that?

Jeremy Hunt: There are two answers to that. The first is that the Prime Minister has been very clear on a number of occasions that we may well choose to continue to be part of European programmes, and I think she has even used the example of research programmes as one thing that we might choose to be part of. So, we would look at that very carefully because we can see some significant benefits in doing that.

While we are a net beneficiary of that particular programme, if you look at EU funding overall, we are a net contributor of between £9 billion and £10 billion a year. Were we not to be part of that programme, we would have the ability to make up for any funding shortfalls, but that would be a decision for the Government and debated by Parliament as to what one might do in that situation. But you do have some flexibility once you have control of funding that would have otherwise gone to the EU budget.

Q405 **Diana Johnson:** Are we having any discussions about this framework programme 9? Are we involved in those discussions?

Lord O'Shaughnessy: As continuing members of the European Union, we would be doing so. That would be organised by BEIS, so I think we would need to get a view from them.

Q406 **Diana Johnson:** Obviously, you would want to be involved in that, would you not, because, as I understand it, clinical medicine and the biosciences are number one and number two in terms of the money that we get through the Horizon 2020, so I imagine that within framework programme 9 they would be pretty high up there? So, you, obviously, as Ministers would be very interested in protecting that.

Jeremy Hunt: We will obviously be interested in those programmes, but there is a limited amount that we can do at this stage while we are in the middle of these negotiations because it is not clear what our options are going to be, but the Europeans have told us that they expect these negotiations to be completed this calendar year, so we ought to have clarity fairly soon.

Q407 **Diana Johnson:** I also want to ask you about what the Department is saying at the moment in terms of making sure that the researchers that we have in this country, who are part of many of these collaborations, are going to be able to stay in the UK post 2019. I know there is a proposal around, and I think it is Universities UK that is talking about saying to these researchers that they would be protected for two academic cycles after March 2019. Have you been making representations as to what is going to be in the immigration Bill around that, protecting against that brain drain post March 2019?

Jeremy Hunt: Absolutely is the answer to that question.

Q408 **Diana Johnson:** You would support that—at least a two-year cycle to protect those.

Jeremy Hunt: We absolutely are committed to making sure that our university research sector is not affected by any brain drain. Obviously, people are free to come and go as they choose—well, they are free to go—but we want to make sure that they can continue to come because we recognise that it is essential to the success of that sector that we attract talented people from all over the world.

Lord O'Shaughnessy: It is worth pointing out that I think it is the case that the tier 1 visa numbers are being doubled, which incorporates some of the postgraduate researchers as well. So, there are things happening now to demonstrate that we do want to continue to welcome those kinds of people to the country—and indeed more of them.

Q409 **Mr Bradshaw:** How much are we prepared to pay to stay in these programmes that you have just been talking to Diana about?

Jeremy Hunt: That is a case-by-case thing that we cannot answer now, not least because part of those things may well be negotiated in the discussions that we have.

Q410 **Mr Bradshaw:** We might pay also to maintain the kind of alignment you want to maintain with the EMA and Euratom on top of that, might we not?

Jeremy Hunt: There is a question about which things should be paid for and which things are just part of the negotiation of an ongoing close partnership, but the Prime Minister has been very clear that we will reserve the right to continue making payments to the EU on an ongoing basis if there are particular programmes that we wish to continue to be part of.

Q411 **Mr Bradshaw:** Are these payments we are discussing here included in the figure that has been agreed as part of the divorce agreement, or are they on top of that?

Jeremy Hunt: No, they will be on top of that.

Q412 **Mr Bradshaw:** On top of that going forward, but you cannot give us any idea. So, the ultimate amount that the British people are going to have to pay to leave the European Union is likely to be considerably more than the figure that we have already been given by the Government.

Jeremy Hunt: That depends on how you interpret the negotiation. We have agreed the parameters of what you call the divorce Bill, but if there are ongoing programmes that we would benefit from by being part of, and so there is a benefit coming back, then the Prime Minister has said absolutely we would reserve the right to be part of those programmes.

Q413 **Mr Bradshaw:** These are going to be replicated across all Government Departments. Are we not looking at a great deal more money that we are still going to have to pay for the cost of Brexit?

Jeremy Hunt: It is hardly money that we are not paying now.

Q414 **Mr Bradshaw:** To quote something back at you that you said earlier, we are still going to be aligned to these programmes, we are going to be paying for them, but we are not going to have any say in them.

Jeremy Hunt: That will depend on the terms on which we are part of them. We may well say we want to be part of a programme as an equal

partner, and I think those are the considerations that you make before you decide whether you want to continue being part of them.

Lord O'Shaughnessy: Some of these programmes also already have countries outside the EU as part of them. It is not exactly an unprecedented thing and it is clearly a choice that we as a country would need to make.

Mr Bradshaw: But staying in the single market and the customs union is a choice.

Chair: Could we now come to questions that follow up from our predecessor's Committee's report that looked at people and the workforce and process? Johnny is going to lead on this.

Q415 **Johnny Mercer:** This is a question to the Secretary of State. How are health and social care issues effectively being talked about within the Brexit negotiations? Is it an opportunity? Interestingly, you said in the House of Commons the other day that we need to start thinking about a 10-year plan: what do we want from health and social care? Are you comfortable that these defining challenges really are being represented within these Brexit negotiations?

Jeremy Hunt: I am, and I think, interestingly, Brexit has been a catalyst for thinking much more strategically about the health and social care workforce anyway. The reason for that is that, whatever one's views about Brexit, when we were going to be staying in the EU we took false comfort from the fact that, if we did not train enough doctors and nurses, we would always be able to import them from another European country. That was never going to be a sustainable position, whether or not we remained in the EU, because we are not the only country in Europe to have an ageing population. The Spanish and Portuguese are recruiting many more nurses than they were five years ago because their economies are now doing better and they are expanding their own workforces. The World Health Organisation says that there is a 9 million shortage of nurses and midwives across the world and a 1.6 million shortage of doctors.

The truth is that, with all these pressures that we face, it is never going to be sustainable to do anything other than to train the number of people you need. Therefore, we are being much more strategic about that.

Q416 **Johnny Mercer:** Do you think it represents an opportunity for a more generational discussion about what this country wants from its healthcare service, about what it expects, and, similarly, what is within the art of the possible? The thing that has always struck me is the expectation and the expectation management of the British people. Does it really represent an opportunity to have a mature conversation about precisely what that is and what the health service looks like in 10 or 15 years' time?

Jeremy Hunt: We need to have that mature conversation, but for me it has never been a conversation that has been about reducing the scope,

availability or the access to the superb services offered by the NHS and the need to continue to offer high-quality services through the social care system going forward. We are going to have to recognise that in a decade's time we will have a million more over-75s, and that is going to require substantial additional investment if we are going to make sure that every older person is treated with dignity and respect. Obviously, those are decisions for future spending reviews.

The reason I use the 10-year period is very simple. It takes seven years to train a doctor. It seems to me that, just as in other parts of Government— for example, HS2—we have realised that, to have a strategic approach to our infrastructure, you have to find a way of thinking beyond the boundaries imposed by one parliamentary term or one spending review term. I think the same applies to health and social care. It does not really work to think four or five years ahead when, in terms of the simple issue of training doctors and nurses, you will never be able to be strategic.

Q417 **Johnny Mercer:** What are you and the Department tangibly doing? What are the options on the table that people can start thinking about now so that people like me, when we get to the age of 70 or 80—if I ever get there, which I doubt—have a health and social care system that we know is going to provide a service to look after us? What sort of things are on the table?

Jeremy Hunt: There are a number of things. First, for a long period of time we have been under-training the number of doctors and nurses that we need. In the last two years, we have seen a 25% increase in medical school training and nurse training, which is the biggest increase in clinical training in the history of the NHS. It is a big step, although it takes time for people to come through the pipeline, so the impact of that is not immediate. That is a very significant long-term change.

We also recognised that it is not just doctors and nurses; it is also care workers in care homes and healthcare assistants in hospitals. We may well need to continue to allow immigration for those kinds of workers, if you think about care homes in the south-east and the south-west, but we also need to think about what it is that will make doing those roles attractive to Brits. That is why we have introduced nurse associate and nurse apprenticeship routes so that you can become a nurse in four years as a healthcare assistant or a care worker.

Q418 **Chair:** Could we stick to the Brexit implication just for now, because we are going to return to hear more about your wider role later on at a point when we can perhaps let Lord O'Shaughnessy and Dr Hudson leave, because I know they have other things they probably need to do? Is it all right if we focus on this bit for now?

Jeremy Hunt: Sure.

Q419 **Johnny Mercer:** What reassurances can the Government give that the

rights of workers will be considered in the Brexit negotiations, but also their families coming over here? You alluded to it there in how important they are in the workforce. What sort of assurances can the Government give them on that?

Jeremy Hunt: I will bring in James, but in the agreement that the Prime Minister reached in December it was very significant in that respect because we made it clear that people can bring over close family members, not just immediate family, but grandchildren, dependent parents and so on will be able to be brought in. That is the rights of the 150,000 EU nationals currently working in the health and social care system. The rights of future Europeans coming over here is subject to the next set of negotiations, but that has given significant reassurance. Indeed, the number of EU nationals working in the NHS has gone up by around 3,000 since the Brexit vote. I think that that is an indication that people are confident that they will be able to continue to stay.

Q420 **Johnny Mercer:** There will be a provision for them. You hear talk about specific provisions for City workers and so on. Are the life sciences workers considered as important as that within the forthcoming immigration Bill and things like that?

Lord O'Shaughnessy: First, absolutely. Secondly, the mutual recognition of professional qualifications agreement as part of the agreement on 8 December is very important, because it means that those who have already been registered with a technical skill will be able to continue not just living here but practising here, which is critical. That is for the stock of people who are here. Obviously, there is a discussion to be had about future flows, but that is part of the future negotiation.

I do think that is a very important moment. As well as the reassurance about family life, also you can have a professional life here. That is why I think the statistic is really meaningful about the increase in the number of EU nationals working in the NHS because we really do value them and they are critical to the success of it and the social care.

Q421 **Johnny Mercer:** So the 3,000 more—

Lord O'Shaughnessy: I cannot remember what the exact figure is, but, if you look year on year, June to June 2016-17, it went up, which is very encouraging, because we do want to continue to keep those people who are making that contribution.

Johnny Mercer: Thank you very much.

Q422 **Mr Bradshaw:** I am afraid you will have to look at those figures again because they are out of date and our Committee has heard repeatedly now in another inquiry that we are doing on workforce that the number of EU nationals working in the NHS has fallen by 89%.

Lord O'Shaughnessy: No, that is not right.

Q423 **Mr Bradshaw:** Can I ask that you go back and check the official figures

that we have been given by the NHS itself?

Lord O'Shaughnessy: I think that was about flows in—flows of new EU nationals joining. If you look at the total stock of EU nationals working in the NHS from June 2016 to June 2017, it actually went up.

Q424 **Mr Bradshaw:** But June 2017 is almost a year ago, and we are not just talking about flows in. We are also talking about EU nationals leaving the NHS. Can I ask you to go away and have another look at those figures?

Jeremy Hunt: I will, but I just want to get down that the latest figures that I have seen say 3,300 up until September 2017.

Lord O'Shaughnessy: Right, so there we go.

Chair: It would be good to have some clarity on that. We have a few more questions on this section, but we would be very happy for both Lord O'Shaughnessy and Dr Hudson, if you wanted, to leave rather than have you come back and then wait as you had to last week. Would you be happy with that? Then, as I say, we have a few questions about your role, but I know you have to leave by 5 pm, so we will suspend the session now and we will be back after the vote. Thank you.

Sitting suspended for a Division in the House.

On resuming—

Chair: Johnny has finished his questioning on the workforce, but I know Ben has a supplementary question before we move on to Lisa.

Q425 **Mr Bradshaw:** Regardless of our differences of opinion about the figures on EU nationals, how sensible do you think it is, given the staffing pressures that the NHS faces now and in the future, for the Government to stick to their net immigration target of tens of thousands?

Jeremy Hunt: That is a Government objective and we think that that was one of the big messages behind the Brexit vote. People were concerned that the political establishment had not taken the concerns that many people felt about immigration seriously enough, but Brexit also throws up a number of other considerations. I do not want to talk about how this would feed into the overall numbers, but I reassure the Committee that I am totally confident that the Home Office will be very sympathetic to any proposals made by the Department of Health and Social Care about what we will need in terms of immigration for the health and social care system. I know they see this as—

Q426 **Mr Bradshaw:** That is very interesting. You seem to be implying that Brexit means the Government are in effect going to have to abandon their target of tens of thousands for net immigration if the health and social care system is going to survive.

Jeremy Hunt: I think I said exactly the opposite to that. I said that I think—

Q427 **Mr Bradshaw:** You said the Home Office would be sympathetic.

Jeremy Hunt: I said that I think the Government are committed to that target because that was one of the key messages from the referendum. I said that I do not feel able to comment on how the numbers will add up overall, but I do know that when it comes to this sector the Home Office will listen very sympathetically.

Q428 **Mr Bradshaw:** You say "this sector," but everybody is making the same argument for their own sectors. The agricultural industry is making the same argument, and so are the food producers and the hospitality industry. They all need migrant labourers. It is not going to stack up to tens of thousands, is it?

Jeremy Hunt: Well, let's see.

Q429 **Mr Bradshaw:** Have you done an assessment of how meeting the net migration target would impact on the NHS at least? Have you done that assessment so that we know what kind of numbers the NHS and social care are going to need?

Jeremy Hunt: We are currently doing a lot of work on that very area, and that is the process that we are going through with the workforce strategy, of which we published a draft version in December, and we are intending to publish the final version of this year. One of the main purposes of that draft workforce strategy is to be able to nail down exactly what we think the immigration requirements will be.

Q430 **Mr Bradshaw:** You say the Home Office is going to be sympathetic. It has been the main driver for this target over the years, including when Theresa May was Home Secretary. If it is going to be sympathetic, the implication of what you say is that it is going to be sympathetic to your arguments to relax it because of Brexit. What do you mean by sympathetic?

Jeremy Hunt: I think it is very sympathetic to the needs of the health and social care sector, and all the conversations that I have had with the Home Secretary suggest that she totally understands that there are particular pressures that we face in this sector. How that matches up with the requirements of other sectors is obviously a matter for her and for the Prime Minister.

Mr Bradshaw: It sounds as if the target is going, Chair, which would be very good news.

Chair: I am going to come on to Lisa.

Q431 **Dr Cameron:** Just before I go on to the main questions that I have, I want to pick up on something. I am aware that the Secretary of State is absent from the Cabinet Committee for European Union Exit and Trade. I wonder how you feel you can effectively represent health and social care issues given that you are not on that Committee. If you ask the public, a critical component of making Brexit work is that it works for the NHS. So,

should you not be lobbying Government to be on that Committee, giving health a voice?

Jeremy Hunt: As a matter of fact, I do attend that Committee when issues that directly relate to the health and social care system are discussed. I went to one of those committee meetings quite recently. It is a slightly more flexible arrangement than perhaps your information suggested.

Q432 **Dr Cameron:** So you dip in and out of it. What I am saying is that the public feel that health is crucial.

Jeremy Hunt: I agree.

Q433 **Dr Cameron:** Perhaps it merits having a voice at that table.

Jeremy Hunt: I absolutely agree.

Q434 **Dr Cameron:** Which aspects of the mutual recognition of professional qualifications that Government are seeking to agree with the EU are to be continued from the current system and which aspects do you think might be dropped?

Jeremy Hunt: As you know, we have already agreed—as part of the agreement made in December—that we will continue to recognise the European professional qualifications of all the EU citizens who are currently in the UK. That was a key part of the transition agreement. What happens on mutual recognition of qualifications for new arrivals from the EU is part of the broader Brexit discussions, and I am afraid we do not have an answer to that because it is one of the things that are being negotiated. There is a lot of work going on as to what the optimal outcome for the UK is. We are talking, for example, to the GMC and the NMC about that. They have some frustrations with the current European system that we are part of, but then there is also the balancing issue of the fact that we want to continue to be able to attract doctors, nurses and other clinicians from the rest of the EU. We are looking at all these issues very carefully, but the paramount policy objective from the UK Government's point of view is that we should be able to continue to attract high-quality clinicians from other countries who want to come and work in the UK.

Q435 **Dr Cameron:** There has to be perhaps some flexibility around this issue, but are the Government looking at allowing the GMC to assess competence of doctors from other countries in the future?

Jeremy Hunt: That is a discussion that, first, we have to have as a country, and we have to decide—and we are doing the work now to decide—what our policy objective is, but it is also part of the negotiations, because this links into the future work rights of EU citizens who come to work in the UK in a range of areas, not just health and social care. So, it is not something that we can do independently.

Q436 **Dr Cameron:** How are you going to marry the two together looking at

ensuring, perhaps, a common assessment of competency in the future as a potential option and making sure that we are still able to recruit to vacant posts? How will you square the circle?

Jeremy Hunt: It is worth pointing out that we do a lot of recruitment from outside the EU, and the GMC is highly professional at looking at the qualifications that people get in countries such as Australia and the Philippines, and all over the world. We have a pretty well-oiled system for allowing people to come in from non-EU countries when we need them in health and care. I do not think we are in a position where we do not have a good fall-back position, but it is also worth seeing how the negotiations work and keeping an open mind.

Q437 **Dr Cameron:** That is something that you will be discussing with the GMC.

Jeremy Hunt: Indeed—ongoing discussions.

Q438 **Dr Williams:** I am going to move on to reciprocal healthcare arrangements. If one of my constituents is lucky enough to go on holiday to Spain in either 2019 or later and they get ill, will they be able to get healthcare?

Lord O'Shaughnessy: First, the agreement of the phase I part of the talks that was announced on 8 December reached a good position on reciprocal healthcare arrangements for the stock of people who are or will be in the European Union until exit day. It dealt with that group of people.

What does that mean in practice? It means that pensioners abroad who have paid their tax or contributions in one country and retired abroad will continue to get their healthcare covered. It means that those people who have an EHIC card that is active on the day, if they are away—that is, they are using it actively on exit day—will be able to get their treatment covered, and those people who are in the middle of planned treatments, because, of course, some people go abroad for treatments, will be able to continue with them. That is a good arrangement that deals with what we know, which was what was basically in scope for the first phase of the talks.

Clearly, we now need to move on to a second discussion, which is what happens from that point forward. Again, the Secretary of State has set out our desire to continue these kinds of arrangements. It is really important to point out that reciprocal healthcare deals have existed prior to the European Union. We have had deals with Spain, Ireland and other countries that pre-exist our membership of the European Community and the European Union, and those countries, and we have them with other countries such as Australia now, as do other European member states. There is a good history of these things existing outside the EU structures. Again, clearly it is in the interests of both sets of parties to continue that, but that is a subject of negotiation in phase II.

Q439 **Dr Williams:** What is the Government's ambition?

Lord O'Shaughnessy: Continuity—to continue to have these reciprocal healthcare rights. I am saying there is no reason to think that we should not have them, because they are not unique to the EU.

Q440 **Dr Williams:** They were not mentioned in the report at the end of the phase I negotiations. Is that because there is any dispute or just because they were not discussed?

Lord O'Shaughnessy: No. If you look at the reporting out of phase I, because obviously each month in negotiations they are reporting the outcomes, they are clearly reporting those outcomes about the stock of people up to the end of March 2019. Clearly, dealing with the flow of future people is a matter for future negotiation, but they absolutely are covered explicitly in phase I.

Q441 **Dr Williams:** I am sorry, but I meant the future.

Lord O'Shaughnessy: I have to say that we were keen to include them. The Commission's mandate was very tightly drawn.

Dr Williams: That explains it, yes.

Q442 **Chair:** Thank you. That brings to a close this session on Brexit, so thank you both, Lord O'Shaughnessy and Dr Hudson, for coming today, but, if you are able to do so, Secretary of State, we would really like you to stay on a bit longer.

Jeremy Hunt: It is my pleasure, Chair.