HOUSE OF COMMONS

# Health Committee

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

Tuesday 5 December 2017

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Watch the meeting

Members present: Dr Sarah Wollaston (Chair); Luciana Berger; Mr Ben Bradshaw; Dr Lisa Cameron; Rosie Cooper; Diana Johnson; Johnny Mercer; Andrew Selous; Maggie Throup; Dr Paul Williams.

Questions 1 -113

### Witnesses

I: Dr Andrew Grainger, Assistant Professor in Logistics and Supply Chain Management, University of Nottingham; Richard Freudenberg, Secretary-General of the British Association of European Pharmaceutical Distributors; Martin Sawer, Executive Director of the Healthcare Distribution Association; and Dr Jeanette Dickson, Vice-President of the Faculty of Clinical Oncology, Royal College of Radiologists.

II: Professor Jean McHale, Professor of Healthcare Law and Director of the Centre for Health Law, Science and Policy, University of Birmingham; Ian Bateman, Director of Quality at NHS Blood and Transplant; Fiona Loud, Policy Director, Kidney Care UK; and Liz Carroll, Chief Executive, The Haemophilia Society.

Written evidence from witnesses:

- Richard Freudenberg
- Martin Sawer
- Dr Jeanette Dickson
- Ian Bateman
- Fiona Loud

# Examination of witnesses

Witnesses: Dr Andrew Grainger, Richard Freudenberg, Martin Sawer and Dr Jeanette Dickson.

Q1 **Chair:** Good afternoon and welcome to the Health Committee for our first session on medicines, medical devices and substances of human origin. There is another Committee—the BEIS Committee—meeting as well for their pharmaceuticals inquiry into Brexit and the implications for UK business. We are not seeking to duplicate these inquiries, so our focus, as the Health Committee, is on the implications for patients. I want to make clear from the outset that that will be our key focus for this inquiry.

For those following outside this room, could the panel introduce themselves and say for whom they are speaking, starting with you, Mr Sawer?

***Martin Sawer:*** I am Martin Sawer, executive director of the Healthcare Distribution Association. Thank you very much for inviting us because this is an issue we have wanted to get on the agenda for a while.

We represent the major distributors of medicines in the UK, distributing about 90% of medicines that the NHS use, about 225,000 deliveries a week to all hospitals, pharmacies and doctors across the UK. That is distribution from 50 warehouses, which depend very much, on a just-in-time basis, on deliveries twice a day on average, 11 times a week.

***Dr Dickson:*** I am Jeanette Dickson. I am the vice-president for clinical oncology at the Royal College of Radiologists and I am here today to represent both faculties. I happen to be a consultant clinical oncologist, so I will be able to talk about the impact of a disrupted supply chain on treatment and diagnosis of malignancy—cancer—and the impact that that would have on patients, but also for the radiology and diagnostic workforce, which is also part of the major use of medical radioisotopes.

***Dr Grainger:*** I am Dr Andrew Grainger. I am an academic currently at the University of Nottingham, with a background in trade and customs procedures.

***Richard Freudenberg:*** I am Richard Freudenberg from the British Association of European Pharmaceutical Distributors—a long title. We represent the parallel importers of medicines into the UK, about 25 million packs each ear, about £1 billion-worth of sales.

Q2 **Chair:** Thank you. Reminding you that the focus of this inquiry is on the impact on patients, may I ask each of you as an opening question to set out what a realistic worst-case scenario could look like after Brexit. Martin?

***Martin Sawer:*** I suppose a worst-case scenario from our perspective is that as businesses—we are all private sector businesses in the association—we do not have any guidelines or rules against which we can

operate. If there is no common regulation with either the EU or other countries that at the moment exists because of the EU, then medicines will become less safe, I would suggest, for UK patients in the long run. We have, on average, about four or five months' stock of most medicines in the UK, but the beauty of the EU system and the single market is that the 28 countries all operate in the same way, with the same wholesaler dealers' authorisation that my members have, so product can be moved around, but there is also a central database against which you can check the origin of those medicines as a wholesaler. That type of patient safety issue is very important to us and guarantees that we are handling proper medicines—kosher medicines, should I say.

The other issue is tariffs. Obviously, at the moment there are no tariffs on medicines between us and the other 27 member states, but nor are there for those from India and China, where a good half of the medicines originate, whether that is on an API basis—where they come in as raw pharmaceuticals—or in finished products. Therefore, in a worst-case scenario, if there is no trade agreement, that will produce a great challenge for trade to be organised properly and systematically following 2019. If it is not sorted out in a few months, we will have great problems importing medicines. Ninety per cent of the medicines in the UK are imported from the EU or third countries—45% from the EU—whether finished or unfinished product. We do not manufacture that much in the UK. Those would be our big concerns in supply and trying to get them safely to patients.

Q3 **Chair:** So it is supply and getting them there safely.

***Martin Sawer:*** Yes; so we would argue for a transition period, clearly.

Q4 **Chair:** Thank you. We are going to explore some of those issues in more detail. Jeanette?

***Dr Dickson:*** If we start off with the medical radioisotopes, the worst-case Brexit scenario covers a number of issues. First off is diagnostics. We import about 80% of the medical radioisotopes used in diagnostics. There are about a million procedures, both diagnostic and therapeutic, a year, and we import about 700,000 of those.

The facility to manufacture them in the UK does not exist at the present time. For the other 20% you can do some substitution, but the capacity there to increase the amount of radioisotope is limited, and the cost of those radioisotopes is much more than the ones we import. You are talking of a significant proportion of patients with cancer, heart disease, bone disease or thyroid disorders, for example, not having rapid access to diagnostic imaging, not having an assured diagnostic pathway and not being able to know, for example, whether they have had an improvement in their cancer or whether it has spread.

Can we use other tests? Yes, we can, but the workforce that provides the medical radioisotope tests and the workforce that provides the other tests

are not the same. They are not cross-trained, so there is a lack of nimbleness there to transfer across.

If we talk then about the treatment of cancer, which is done by what we call unsealed sources—medical radioisotopes that you either ingest, that is, take in by mouth, or we inject into you—these cure patients with predominantly thyroid cancers. If we do not have an assured supply of those, again there would be a reduction in the rate of cure and more people are going to die of their thyroid cancers. We probably treat about 2,000 people a year in the UK for thyroid cancer.

If we talk about the unsealed sources that are used for specific types of radiation therapy called brachytherapy, which is not treating cancer from the outside but into the specific organ, the major use of that is iridium, which is used in cervical cancer. There are about 3,600 ladies diagnosed with cervical cancer in the UK per annum, and brachytherapy is an essential part of their treatment. Despite advances in technology, we still rely on that for a cure rate in about 500 cases per year. We have to deliver the treatment as a combination of external beam and afterloading of brachytherapy. The external beam takes 42 days. If we do not deliver the whole treatment within 56 days, there is a reduction in cure. If you do not have sustained assured pathways, you cannot be sure that those patients will receive the best form of therapy that they could.

In terms of medical devices, that is not so much an area of expertise, although our interventional radiology colleagues use them a lot to prevent surgery; so, again, there are capacity issues. If you are going to take away a medical device and as a result surgery is required, you need to expand your surgical capacity. That also holds true, for example, for treatment of benign thyroid disease, such as an overactive thyroid. If you cannot use radioactive iodine, which is used very commonly, you may have to increase your surgical capacity, and it is very difficult to be nimble to shift that in the short term.

For research, we are also very worried about a lack of supply, partly because we are a net beneficiary from research investment in the UK and about 15% of the academic workforce comes from the UK. The worst-case scenario is that patients in the UK no longer have access to innovative trials as easily. If in the UK we diverge in a regulatory fashion from European trial protocols, then we may suffer a significant disadvantage in our patients being accepted for clinical trials.

Q5 **Chair:** Thank you. Andrew?

***Dr Grainger:*** Probably one of the worst-case scenarios imaginable is that we are not ready and there will be significant disruptions to supply chains, and—pardon the pun—people might not be clear on how to clear goods, with the result that ports might be clogged up. So, even legitimate trade might be behind in the queue compared with other people; systems might not be ready, with all the implications for how companies could be compliant, with follow-on impacts on logistics operations, which might be

delay, but it might also relate to non-regulatory issues with questions such as where to find staff and warehousing or trucking and the like, where we rely on EU member state labour.

***Richard Freudenberg:*** Many of my members' concerns are common with Martin's and indeed with Andrew's, but, uniquely, what our members do is subject to the rules of the single market. We depend on free movement of goods within the European market in order to import into the UK. That is brought about, as you will have read from our written submission, by the exhaustion of rights principle that applies within the single market. Without that, we cannot continue to provide the competitive effects on pricing in medicines in the UK that we currently do. Indeed, our members can be much more reactive than originator manufacturers in bringing medicines to the market when there are shortages in the UK.

Q6 **Chair:** So, for you, it is not only supply, but it is about the increasing costs of medicines.

***Richard Freudenberg:*** Yes.

Q7 **Chair:** Before I move on to other areas to look in more detail, as a broad brush, what are your thoughts about what absolutely has to be done to improve resilience?

***Martin Sawer:*** From our perspective, it would be on 30 March to carry on as we are for medicines supply, because, as far as our members are concerned, they are businesses and cannot plan for uncertainty. Uncertainty is where we are at the moment. Come 30 March, when we have left the EU, then we would be able to work on how the arrangements are going to work post being in the EU. I would suggest that a transition phase of at least two years is needed. We have certainly been talking to the MHRA and the Department of Health about these issues in very much the same way I am talking to you now, so they are fully aware of it. The MHRA is a very good regulator and has worldwide distinction, but without a political guideline—and with the best will in the world—it cannot work out what the post-EU world is going to be like. For us, it is to carry on immediately after leaving the EU as now, but then work on what the new arrangements are going to be.

***Dr Dickson:*** I would echo that. Whatever happens, we need to be able to assure the supply as quickly and efficiently, with no disruption, as we do now. Without that, there will be an implication on patient care and on diagnostics. Patients will be diagnosed and treated as if there will be an uninterrupted supply up to that date, and if there is not a supply at that time those individual patients would be disadvantaged.

***Dr Grainger:*** It is almost a question of what resilience is. One of the tenets of preparing organisations to be resilient is to understand how procedures currently work. Given that trade logistics is incredibly complex, with many different parties involved, it is an exercise that

probably no one ever needed to do so far. Working out what the baseline is so that you can prepare for an event that requires resilience, be it Brexit or anything else, requires preparation. My sense is that in many areas this is the first time we have had to engage with questions such as this. Certainly, when you speak with companies—understanding when to take action, understanding the relationships up and down the supply chain, and the contractual arrangements—these are complex systems. Therefore, it is very difficult, even for the people right at the heart of it, to predict what might happen. There is uncertainty but also there are many unknown unknowns.

Q8 **Chair:** Do you think people have put all their eggs in the transition basket? Do you sense that your colleagues are active—that people are actively preparing for there not even being a transition?

***Dr Grainger:*** I am aware that some organisations are beginning to think about it, but it is very practical things. I am in academia; I know, for example, that in the United Kingdom not many organisations provide something very basic such as training. Other member states in the European Union are much better prepared. They have, for example, a profession of customs professionals. My sense in the United Kingdom is that, if you work in trade and customs, it is something you stumble upon by accident, and it is a very small community; in other member states there might be thousands at hand. I have spoken to some freight forwarders and logistics service providers who have struggled to find expertise in this country and, almost jokingly, have suggested, "But I do know I can find them in Poland or Serbia, and places like that."

***Richard Freudenberg:*** For us, too, resilience is hard to plan for because, essentially, this is a black-and-white—an existential—issue for us, as in a certain set of circumstances my members' business would cease to exist altogether. It is very difficult to make investment plans for the future in this and in other areas of legislation and regulation such as the falsified medicines directive.

Q9 **Maggie Throup:** I want to explore the supply chain aspect in a bit more detail. We do not know what the deal is going to be—whether it is going to be transition or, at the other end, we crash out and burn, or anything in between. We have touched on supply chains, but can we talk in a bit more depth about what risk Brexit poses for supply chains of medicines, medical products and devices? What would this mean for patient access to these products?

***Martin Sawer:*** I will kick off and I am sure others will want to comment. On the access to products, our perspective is that there will be a varied impact of no deal. For example, a manufacturer may make some products in an EU country and not supply them to the UK until, let us say, a few weeks before they are required. Our members typically hold about 10 days' worth of stock, but, behind that, for a lot of manufacturers there are massive pre-wholesalers where they store, say, four months' stock. Some manufacturers in some products—I cannot identify any

particularly—will manufacture a product but send it to the UK maybe only a few weeks or a few days before we get it, so they have their own storage arrangements, maybe centrally, for the whole of the EU.

Once you get a licence in the EU, access to patients is about 28 countries being able to get it equally. Three of my wholesalers have operations in other European countries, so product can move around. With our members working with Richard's members, we will import products when perhaps they are in short supply to make sure we can top up provision in the UK. We can import them from other areas of the single market, which we would be unable to do if we had a so-called hard Brexit.

It is very varied, and it is very difficult to generalise about what the impact will be. It might mean that fewer products are available for UK patients if there is no deal because we would not be able to get some products quickly.

Q10 **Maggie Throup:** That is the end product. What about the supply chain? There are different parts of the manufacturing process.

***Martin Sawer:*** When you are talking about getting products on to the market, do you mean new medicines particularly?

Q11 **Maggie Throup:** No. Sometimes different parts of the product are sourced from different countries. One part may be made in the UK, and then go to another country and back again.

***Martin Sawer:*** Indeed, and I imagine that without a deal that would become much more complicated. I know, for example, that different parts for inhalers for those with asthma are made in different EU countries. The UK would suffer from not having an arrangement with other EU countries, and some of those products may not even be able to be released in Europe if the UK made a certain part of that. I do understand that, yes. The manufacturing organisations are probably better placed to answer that question.

***Dr Grainger:*** On general principles, supply chains are inherently complex and evolve, and no two supply chains are alike. Every part has parts. Manufactured goods or parts might cross borders many times and might be just within the chain of producing things, but sometimes it is just about where you keep spare parts. You might have the manufacturing chain but have a spare parts depot somewhere else. You might send things off to testing, and each supply chain is probably quite unique. Every time there is a disruption it will reconfigure, but there will be an adjustment period. Some organisations might be quite responsive, whereas others might have leaner, cost-focused economies of scale-type operations, which might be less flexible, and that will differ from sector to sector.

**Dr Dickson:** On supply chain issues, medical radioisotopes, for example, decay at a certain rate—their activity reduces. If you buy, say, the equivalent of 100 doses and you have the uninterrupted supply chain that

we currently have, you get 100 doses delivered to your various hospitals so that you can treat 100 people. If you delay that at customs or through border issues, you have paid for 100 but you get 50 doses. You therefore cannot treat the patients adequately. You have no way of predicting that until the shipment arrives, and you are incurring a massive cost for the NHS. In this country, we do not manufacture iridium, but we do import and process it into radioactive iodine seeds, which are then exported. There is a risk to that manufactory and those jobs if the supply chain is disrupted in that way.

Q12 **Maggie Throup:** An individual patient may either get access to radioisotopes or not.

***Dr Dickson:*** Yes. Patients' diagnostic pathways will be interrupted. As I have said, you can shift many tests. You can always substitute something else, but that comes with a cost to the taxpayer. The radioisotopes, for example, which look at bone disease, generally cost £10 or £20. The radioisotopes we would use, for example, for a PET-CT cost £120.

We produce those in cyclotrons in the UK. Actually, that is about a fifth of what we do. Do we have an extra four or five times the capacity at the right point in time, even if we had the cash to pay for it? I am not sure about that.

If you do not go for the radioisotope use, most of those would be done by radiology departments. You would be going for MRI tests, which again are more expensive. We do not have a huge number of MRI scanners in the UK per million of the population compared with other European countries, so they are at virtual capacity anyway. You are talking about a longer test, which not every patient can have because of medical reasons, which is then pushed over to a diagnostic workforce—not the same diagnostic workforce—which currently has a 10% vacancy rate and almost 10% of EU graduates as well. You are talking about a diagnostic workforce that is under stress, so those patients will be waiting longer for the outcome of the tests. Yes, you could prioritise cancer if you chose to, but in diagnostic tests you do not know what the diagnosis is until you have got there.

Q13 **Maggie Throup:** At that stage it is just a name, yes. Richard, do you want to add anything from a patient's point of view?

***Richard Freudenberg:*** I have one thought, and it is about the loss of the authority of the European Medicines Agency after Brexit. I guess that the medicines that we are used to receiving that are authorised, in the sense of an authorised process, will have to be re-authorised by the MHRA in the UK between now and March 2019. With only 15 months or so to go, I am not sure that there is time for that whole process to be completed and whether it will have an impact on patients. It is hard to judge.

Q14 **Maggie Throup:** What should the Government seek to secure in a future

trade deal to prevent disruption to the supply chains and minimise impact on patients?

***Martin Sawer:*** To minimise the impact on patients, the future trade deal needs to mirror and replicate, for example, a lot of the EU regulations, which for the last 20 years have spent a long time being developed to benefit patient safety. That is not to say that in the longer term the MHRA may have more variability of how those rules are implemented on the ground, but the broad structure that business can then respond to needs to be very similar, because tablets and drugs cross boundaries, as you have seen, and are made in many different countries, in part or in whole. If we had something that was at odds with that, it would put a lot of cost into the system and indeed produce supply shocks, which would be to patient detriment.

At the moment the EU is one of the largest markets for medicines. It is perhaps unique. We are quite unique as a sector. A product can be put into the market and be available in 28 countries once the licence is established and the batches are released for particular countries. Indeed, the UK has already adopted EU legislation—the falsified medicines directive—which is barcoding every group of medicines. Ironically, that is due to be implemented in February 2019. At that point, one would hope that the medicines within the EU are going to be much safer than they are today. We think it certainly makes sense to carry on with that.

The medical devices directive is again providing unique numbers for all devices. That arose out of the breast implant scandal, as you are probably aware.

Those are two pieces of legislation that are just coming into the UK. We would hope that they are going to be implemented in full. Some of the regulations are zero tariffs on medicines, as exist now; otherwise, again, the cost, which the NHS is largely paying for, would go up quite considerably.

Q15 **Maggie Throup:** Andrew, do you want to come in on that?

***Dr Grainger:*** Yes. As a better regulation principle, the mutual recognition of controls and procedures, if that can be achieved, has the benefit of cutting out duplication. One country's export is another country's import. If a shared responsibility can be achieved for that, you reduce the regulatory burden by half.

Q16 **Luciana Berger:** Dr Dickson, you have set out some of the problems that Brexit could pose if there is any shortage or delay in the supply of medical radioisotopes. For the benefit of the Committee—and, forgive me, I did not quite hear you—will you repeat the figure on how many diagnostic or therapeutic procedures use medical radioisotopes in our country?

***Dr Dickson:*** Approximately a million use medical radioisotopes, of which about 700,000 depend on Technetium, which is one that we have to import because we do not have a source of manufactory for that.

Q17 **Luciana Berger:** Of those 700,000, how many patients is that? Presumably, some patients will have multiple exposure.

***Dr Dickson:*** It is difficult to be precise. It is pretty close to 700,000, because most of those are diagnostic tests. There are relatively few therapeutic treatments, and not many are duplicated. A number are duplicated, but not many, so you are certainly close to that as the absolute number of patients affected.

Q18 **Luciana Berger:** We previously experienced shortages and delays in the supply of medical radioisotopes following the channel tunnel fire in 2008 and industrial action in Calais in 2015. Will you share with the Committee what the impact was for patients and the supply of medical radioisotopes at that time?

***Dr Dickson:*** With the 2008 tunnel fire, that was a short period of time with a definite view that things would get back to business as normal within a defined time. So, patients were re-prioritised; some patients were pushed towards other therapies or other diagnostic tests, as I have said before; and for some patients treatment was deferred where, clinically, that could be done. For some patients, what access was used was prioritising the clinical patients there at the time, but because of the relatively temporary nature of the disruption that could be done for a period of time. The concern that we have going forward is that, if it is an unknown period of time and the supply chain does not work as efficiently and effectively as it is doing, the guarantee of supply will not be there and what comes out at the end will not be what, essentially, we have paid for.

Q19 **Luciana Berger:** Would members of the panel like to add anything about concerns you might have that Brexit would pose for the supply of medical radioisotopes and its impact on patients, which you have not raised already?

***Dr Dickson:*** We import 80%-plus of our radioisotopes from Europe. As I have said, the drugs are time limited, so the longer they take to get to the UK, the less activity is delivered and the fewer patients you can treat for the same amount of radioisotopes. You can import from other places—you can import from South Africa—but you lose more activity and therefore reduce the number of patients you can treat.

As Andrew alluded to with customs, I understand there are concerns about increasing the number coming in by air. Most of the medical radioisotopes currently come through Coventry airport, and there is a good bulk of expertise there on how to manage them efficiently and effectively. Does it have the capacity if we increase the amount coming in by air? We do not think so.

Q20 **Johnny Mercer:** I have a great little company in Plymouth—well, a not so little company—called Becton Dickinson, which is involved in the manufacturing and is the largest supplier of needles and tubes for blood collection in the NHS. Its products are manufactured in Plymouth; it has just undergone a huge £172 million expansion. They then go to Belgium. What impact is Brexit going to have on that sort of operation?

***Dr Grainger:*** It is tricky. I would not be able to comment on a specific company, but, yes, I could imagine—

Q21 **Johnny Mercer:** With that sort of operation, where we are manufacturing things here and they are going abroad, and then potentially coming back to the UK—the company is the biggest supplier into the NHS—how is Brexit going to affect that supply chain for patients? Is it going to make it harder for them to get tests and results?

***Dr Grainger:*** Under current customs legislation, there are all sorts of procedures in place, such as outward processing relief, where you start the manufacturing process in one country, you take it to somewhere else and you take advantage of skills or expertise that might exist somewhere else. That might cross borders a few times, each of which might have certain customs control implications.

With the UK being separate from the European Union and the other member states becoming de facto outside, companies such as the one you are referring to might have to start considering this rather complicated customs regime, such as outward processing relief, coupled with inward processing relief, which would require sophisticated IT systems that would need to be able to track each and every part in their inventory, in their manufacturing process. These are sophisticated, complex operations that do require expertise, which brings me back to one of my earlier points as to whether that expertise would be readily available. I am not sure, because even the number of consultants is quite limited. You are dealing with uncertainty.

Q22 **Johnny Mercer:** Richard, do you have anything to add to that?

***Richard Freudenberg:*** It is not my area of expertise.

Q23 **Johnny Mercer:** Does anyone else have a comment? It seems that there is no pleasant answer to that question.

***Martin Sawer:*** It certainly does not sound like it. One could imagine that, if it becomes more challenging for businesses generally, if they are small businesses that is going to be a big cost problem, and if they are larger businesses they might move. Our members respond to lots of regulation and laws, and you would understand that. With medicines, it is very important to get everything right for the patient, and there are so many legal challenges here. All the licences, as Richard mentioned, that the MHRA has issued—2,500 wholesaler licences—would have to be rewritten. All the marketing authorisation holders—there are 1,200 of

those—would have to be rewritten and reapplied for. The logistics of trying to make this legal in one year's time is almost impossible.

***Dr Dickson:*** One other thing I would add is that all the products you are talking about are sterilised. They are generally now sterilised using a medical radioisotope. So, again, it depends where that would be done, and the importation of that might be threatened as well.

Q24 **Johnny Mercer:** What customs arrangements could be adapted to support the import of time-sensitive medicines such as radioisotopes? You mentioned a couple there, but, to be honest, I did not really understand what you said. What sort of things for the layman could be done to make this work?

***Dr Grainger:*** In essence, these are control regimes where customs acknowledge that certain manufacturing processes probably are best done outside the customs territory. When you reimport it, you do not want to pay the full customs duties on the value added that has taken place abroad and you take advantage of that. That is the principle.

Q25 **Dr Cameron:** What could the impact be if the UK diverges from the EU regulations covering manufacturing, batch testing and distribution, both for the industry and for patient care?

***Martin Sawer:*** I can talk about distribution. It would put up the cost of distribution, because at the moment there is a template to follow that has been well established and proven. If we were to start diverging in regulations and producing new types of licences or being inspected in a different way, the standard training for our members' staff would have to change and the type of responsible QPs or RPs would have to be retrained. The costs can only go up, which would impact on the cost of medicines because we get paid, basically, by the NHS to distribute medicines. That is how it works. The costs, I think, would definitely go up on regulation.

Q26 **Dr Cameron:** When you say the costs would go up, is this a minimal amount or quite a significant increase? Can that be estimated?

***Martin Sawer:*** The volumes are huge. We distribute 2 billion packs of medicines every year, so the volumes are very large, and, as you know, the medicines bill is very large. We get paid on a margin within that, which is agreed, and therefore you can imagine that the amount of money could be quite large because of the turnover of the sector. We are talking about billions, really.

Q27 **Dr Cameron:** Does anyone else want to comment on patient care?

***Richard Freudenberg:*** There is a small part of what Martin was referring to, and you will be aware, Dr Cameron, that batch release is done by a QP—a qualified person—which is a European qualification. If we are not part of that process in future, and we already suffer from a

shortage of QPs in the UK as it is, in that particular area alone it is going to increase costs and have an impact on availability.

Q28 **Dr Cameron:** What should the Government be doing to prevent the loss of expertise from qualified persons?

***Richard Freudenberg:*** The expertise will have to change. If we do not follow the existing EU rules in the future, we will have to change and retrain our existing specialists.

Q29 **Dr Cameron:** How long would that take? How long does it take to train a qualified person?

***Richard Freudenberg:*** It takes a long time. Is it three or four years, Martin?

***Martin Sawer:*** Yes.

Q30 **Dr Cameron:** It cannot be done in time.

***Richard Freudenberg:*** Not in a very quick way, no.

Q31 **Dr Cameron:** How would that impact on patient care?

***Richard Freudenberg:*** It is going to have an impact on availability as well as cost.

Q32 **Dr Cameron:** If we do not have these qualified people—

***Richard Freudenberg:*** You need to start planning now.

Q33 **Dr Cameron:** Yes, and you say three to four years.

***Richard Freudenberg:*** Absolutely. The question is a theoretical one at the moment. We hope it will continue as it is, but at the present time the UK is having to bring in qualified persons from other European member states to fulfil the demand in this country as it is today, never mind post Brexit.

Q34 **Dr Cameron:** How much will it cost to train or retrain the additional qualified people?

***Richard Freudenberg:*** It is supply and demand, but I think these are not cheap individuals. A typical salary for a qualified person is £100,000 a year.

Q35 **Dr Cameron:** It sounds as though we are not ready.

***Richard Freudenberg:*** I do not think we are ready, unless Martin would like to add to that, but I do not think we are ready.

***Martin Sawer:*** No, we are not. Again, it boils down to my point that businesses will only budget and plan when they have something certain to plan for. They have their shareholders to be answerable to. They are not going to try to put something in the budget line that they are not sure about, and I have already been told by a couple of members that 8

January next year is their cut-off time for budgeting through Brexit; so, it is just not feasible unless there is a transition period.

Q36 **Dr Cameron:** What should the Government be doing now or what can the Government do?

***Martin Sawer:*** To be fair, we are engaged with the Government on their own Brexit working parties, so there are operations within the respective Departments that we have been engaged with where we have been talking to them about this. The Government have a political negotiation, and for businesses the sooner that is set in place the better, whatever that is, so that we can plan for the future. I cannot really answer your question specifically, and certainly I am not aware of planning going on. As Richard said, it is almost academic or theoretical, and we cannot work on that basis.

Q37 **Dr Cameron:** My concern is that if we do not have these qualified persons in place who are able to apply the current regulatory framework or a new one, given that potential circumstance, what does that mean for the consumer? What does that mean for patients?

***Martin Sawer:*** To be pragmatic, if that was the situation, business would be sensible and carry on with the rules as they are and wait to be challenged by the authorities. They would have to use existing rules until they were challenged. I would hope that the MHRA would not challenge that because there is nothing against which they can challenge us for or even be ready for. Other regulations get delayed because industry is not ready. There are other precedents for that, so I think that would be the case this time as well.

***Richard Freudenberg:*** A longer transition period would help.

Q38 **Dr Cameron:** It sounds as though the Government have to act extremely urgently on this issue.

***Richard Freudenberg:*** I know that the MHRA is busy on this issue at the present time, yes.

Q39 **Chair:** To be clear, as I understand it, qualified persons have been told already that they have to relocate to the EU after we leave, so we could end up with almost none.

***Richard Freudenberg:*** I do not think so. The question was whether the qualifications or the methodology will change after Brexit, so it is not so much about the location of the QP. If that were to change, if we applied different standards in the UK than are currently practised across all of Europe, we would have a problem.

Q40 **Chair:** But, as far as you are aware, they have not been told that they have to relocate to the European Union.

***Richard Freudenberg:*** No, far from it.

**Chair:** Thank you for clarifying that.

Q41 **Andrew Selous:** What would the impact on the UK be if on 29 March 2019 the UK went on to World Trade Organisation rules? What would be the impact on the trade in life sciences for the United Kingdom?

***Richard Freudenberg:*** Martin has painted a rather broader picture, but specifically for my sector it would be quite difficult. There is trade in European products from within the EEA in both directions in the UK at the moment, so we both import into the UK and export from the UK to the rest of Europe. In the circumstances you describe, my understanding is that certainly exports from the UK would cease. My learned friend will correct me if I have got that the wrong way around, but in certain circumstances imports could continue with agreement. This is the question, as I mentioned earlier, of exhaustion of rights. At the moment, we operate under what is called a regional exhaustion within the single market. If the UK were to go towards a more international model of exhaustion, that would be a completely different criterion. It would mean, technically, from a trademark and legal point of view, we would be able to trade with the rest of the world, but medicines regulations would not be in place to bring those in line with the trade rules.

Q42 **Andrew Selous:** Martin, do you want to add to that?

***Martin Sawer:*** I do not think so, only to say that, as I understand it, under WTO rules—there was a quote from the WTO head last week, I think—most medicine products are quite low tariff, 2% to 3%. If we were able to move product appropriately, clearly the cost would go up, as would all the bureaucracy associated with trying to deal with WTO rules. That is all I would add.

Q43 **Andrew Selous:** Have you looked at comparable jurisdictions outside the European Union—reasonably wealthy countries with advanced health services—to see how they cope on a WTO basis? Have you done any of that preliminary work of scenario planning just in case we do go to WTO rules?

***Martin Sawer:*** No, we have not done that. There has been talk about whether the regulator—the MHRA—should or should not think about partnering with Australia, Canada or other countries for common regulations. We are mainly concerned with UK distribution. Export is not a major part of our operations. Sourcing medicines and getting them into the country is usually a manufacturer's operation, because once they are in the country we distribute them. If you like, we are one step removed from trying to understand what might happen with WTO rules or otherwise, but clearly there are other options.

For example, if we were to strike some sort of open trade agreement with America, which has been mooted—they do not allow parallel imports into the USA at the moment, but if that were to happen—I would probably vouch that a lot of medicines would start leaving the UK. These things are not necessarily attractive, because in America the same medicine would probably cost 50% more at least, so there would be a very big export

trade from the UK. We are a very low-price market. The NHS has done a great job in negotiating prices in this country. We are only worth 2.5% of the world's pharmaceutical business, and, therefore, we have to be careful about doing trade deals with other quite—as you say—well-off countries because it could start sucking medicines out.

Q44 **Andrew Selous:** That is helpful and it leads me on to my next question. What would happen if the United Kingdom were to lose access to parallel trade after Brexit, and what would the impact of that be on patients and the NHS? The Committee has been given some figures. Parallel trade is estimated to have saved the NHS €986 million between 2004 and 2009, which backs up the point you were making, Martin. Richard, I think this is your particular area of expertise, is it not?

***Richard Freudenberg:*** Those figures were from a period when sterling was particularly strong. We were importing a lot of products—more than we do today—in that period. Sterling is particularly weak now. I think it is also in our submission that we measure imports at about £1 billion a year, which saves the NHS about £100 million a year, based on the clawback that operates in pharmacy reimbursement. It is a much lower figure these days than it was in the past, but even that figure would be lost in certain circumstances were parallel trade not possible within the EEA in the future.

Q45 **Rosie Cooper:** Notwithstanding the comments you have already made, how would the Government look to ensure a smooth transition for the life sciences sector?

***Martin Sawer:*** The best thing from our perspective is that on 29 March we have everything as it is now and then work probably for two years, I would suggest—I know Astra Zeneca have suggested three—with the regulators, industry and obviously the EU, because then we know on what basis Brexit is being negotiated, to establish mutual recognition and how broad it is. It is really the Irish border situation writ large, if you like. We are going to have to see how it is going to work, because it has to work. Patient safety is at stake here, so it has to work. I think that is the only way.

I know there is a life sciences strategy, which is very well developed, and the distribution of medicines would flow from that, because the life sciences strategy is more about releasing new medicines and being able to cross borders because they are manufactured in lots of different countries. Our type of regulation for distribution of medicine must flow from that. It is building on the work that has started, but it is not going to be able to be completed until there is a political settlement and the structure is understood about how we relate to the EU after March 2019, I am afraid.

Q46 **Rosie Cooper:** I understand how difficult all this is. You mentioned Astra Zeneca talking about three years for a transitional period. We have had evidence that would suggest that lots of people have different views of

that, from two years to five years, and whether you are a large company or an SME would shape your view of how you would get to that. Is two years, which is the minimum period I have heard talked about, long enough for the science sector to absorb the necessary changes it would have to make?

***Martin Sawer:*** Distribution-wise, again, which is what I represent, two years would be time in which we could adapt. Given the fact that we are going to have to work with the regulator on all the new procedures, the mutual recognition and the licensing issues, it would be down to how quickly the regulator could work and what its resources are. I cannot speak for the life sciences sector because that is about getting a licence and a patent, and batch-releasing different products and all that type of thing, but certainly for distribution two years could be realistic, yes.

***Dr Dickson:*** What we are concerned about predominantly is that life sciences is not just about the drugs or the medical radioisotopes. It is about the workforce. As I say, the diagnostic workforce is at least 10% primary EU qualification, and for cancer treatment it is about 5%. We have a significant vacancy rate in radiology for diagnostics. The research component is very concerning for us. Yes, the Government have underwritten the Horizon 2020 funding, but we have been a net beneficiary of EU research funding.

Again, it is not just about specific drugs and radioisotopes. It is about the whole of life sciences in terms of academia, making the UK attractive to bright things, making it easy for people who have those skills that we need still to immigrate into the country.

We are looking at significant retirements in certain sectors. The cervical cancer retirement rate is about 20% in the next five years, so we know we have a gap. Can we attract people to the UK? It is about the whole of the transition period trying to do the whole of the sector. Certainly, with radioisotopes, partly it is a drug, partly it is radioactive, partly there are time constraints and partly it is about customs. There is not one unified place to go to talk about that for Government. You talk about health, transport and customs; they are all different things. To get a unified voice is quite a difficult thing.

Q47 **Rosie Cooper:** It is always a difficult thing before you add the complexity of the direction we are taking now. Do you think we can square that circle in the time we have?

***Dr Dickson:*** That would be very difficult.

Q48 **Rosie Cooper:** My last two questions are more business focused. What do the business end need to transition smoothly, and what clarification, almost, of the arrangements, if there was a transition period, would you need?

***Martin Sawer:*** Close working with the regulator would have to be a given, because we need to understand what the new world might look

like. Then, as I say, investment plans can follow from that. That would be a strong message that we would want to put out. Part of that is consultation—for them to consult about how things might affect business and supply chains. That would be important for patient safety, I am sure, as a consequence. We need to be working together on it.

Q49 **Rosie Cooper:** Is there a timetable beyond which you need the clarification? What is the drop-dead date almost, if there is such a thing?

***Martin Sawer:*** As I say, we are probably not going to make a move until we hear what some of the structures are going to be like. If the negotiations on Brexit continue up to 28 March, we won't know until 29 March, will we? That is the trouble. We cannot react against something whose structure we don't know. We cannot invest behind something that is theoretical. That is the main challenge for us.

**Rosie Cooper:** It is a very difficult period.

**Chair:** Thank you.

Q50 **Mr Bradshaw:** You all seem pretty clear that what we need, to coin a topical phrase of the last 24 hours, is continued regulatory alignment. Would I be right in thinking that that is something we need? Yes, you are all nodding. We need continued regulatory alignment, a bit like Northern Ireland, and a bit like every other sector of our economy that has expressed a view on this. That is very helpful. How about staying in the single market and the customs union?

***Martin Sawer:*** Certainly, from our perspective, we would appreciate that. Richard's businesses obviously depend on that, but, for supply to UK patients, being able to bring in medicines that have a licence already in the EU can ensure resilience and flexibility in the supply chain, perhaps in the short term, because there may be a forecast by a manufacturer for what the UK needs that is not completely accurate because a disease has taken hold in a certain part of the country and we need more medicines for it. Being able to do that is important for patient safety. It also saves the NHS money.

Q51 **Mr Bradshaw:** What about the rest of you?

***Dr Grainger:*** The benefit of being in a single market is that there are no barriers.

Q52 **Mr Bradshaw:** Again, there is unanimity on that too. Are you saying this publicly to the Government?

***Martin Sawer:*** Yes.

***Dr Grainger:*** Yes.

Q53 **Mr Bradshaw:** You are saying it loudly and clearly.

***Richard Freudenberg:*** To anybody who will listen, yes.

***Martin Sawer:*** Yes.

**Mr Bradshaw:** That is encouraging, because my worry is that we are hearing from lots of sectors all the time and lots of groups with interests in the health and social care sector, but also in other parts of our economy, who believe it but for some reason think it is not achievable. Let me commend to you the Hansard report of the urgent question in the House of Commons an hour or so before this hearing where there was overwhelming support from the Back Benches on both sides of the House for staying in the single market and customs union. It is achievable. Please keep fighting for it. Thank you, Chair.

Q54 **Dr Williams:** Following on from Ben's question, could there be a situation where the needs of UK patients are different from the needs of other patients in the EU? However, as members of the single market and customs union, we have to accept the EU rules, but we do not have any influence to make sure that they take into account UK patients' needs. Can you think of any scenario where that might happen?

***Dr Dickson:*** It is very difficult. There are different cancer instances, disease instances, across the EU, but not massively so. We are culturally quite a close population. For example, there is certainly more lung cancer in the former eastern European countries than there is in the UK, but there is still lung cancer as our patients get older. Cancer is a disease of the elderly and you still have the same things. The divergence is not as significant as you imply.

Q55 **Dr Williams:** I guess I am asking because, of course, the consequence of staying in the single market and customs union but not being members of the EU is that we cannot influence the rules. I guess I am asking you whether the organisations you represent would be comfortable with not being able to influence the rules. There would be no Member of the European Parliament. We would not have a seat at the table if we were members of the customs union and the single market but not members of the EU.

***Richard Freudenberg:*** The Norway model.

Q56 **Dr Williams:** Yes. You would be comfortable with that.

***Richard Freudenberg:*** It would be better than the worst-case scenario, certainly.

***Martin Sawer:*** I think my members would be comfortable with it, and, indeed, that would probably imply that the MHRA, at least, had some mutual agreement; and they are certainly well respected within Europe at the moment. Working through the MHRA would give our members a degree of comfort.

Q57 **Mr Bradshaw:** If we get to a deal, there is also a consensus among you four that we need a transition deal of between two and five years.

***Martin Sawer:*** Yes.

Q58 **Mr Bradshaw:** We need to know, I think you said by 8 January, that we are going to get one.

***Martin Sawer:*** I have had feedback from certainly a couple of my member companies that they are making investment plans by 8 January for 2019.

Q59 **Mr Bradshaw:** They will move jobs elsewhere if they do not know by 8 January.

***Martin Sawer:*** What I mean is that they will not be budgeting for changes because they do not know what the changes are.

**Mr Bradshaw:** Thank you.

Q60 **Chair:** Does anyone have any more questions? I know, Dr Grainger, you have to leave to catch a flight, but are there any points that any of you, perhaps starting with you, Andrew, feel you would like to make to this Committee before you leave today?

***Dr Grainger:*** I would reiterate the complexity of the thing and that, although we are focusing on health sciences here, of course you would rely on logistics service providers to support the supply chain. Therefore, there are other industries that are tied into this that need to be considered; so there is overlap, I am sure—or I would imagine—with many other inquiries. But you would probably need to be prepared for the unexpected, especially as we are interfering with the regulatory landscape. I could imagine that there are scenarios that people have not thought of yet, and the Government might want to be ready for that.

As an anecdote, a few years back a volcano broke out in Iceland. The UK Government had to repatriate two million tourists back into the UK and the ships that carried them over needed a derogation for lifejackets, otherwise they would not have been able to take people back into the country. That required, I believe, a Minister to take action. These things cannot be foreseeable—just so much happens. Government, I would imagine, would want to be prepared for things like this.

Q61 **Chair:** Did you want to make a point, Martin, Jeanette or Richard?

***Dr Dickson:*** It is partly the fact that there is the patient there. The patients appear; they come all the time. We are treating them as they appear and we are treating them as they are diagnosed. We are imagining that things will be the same, and, if they are not, the nimbleness to change is very difficult. If you want to increase your oncologist capacity, that is nine years postgraduation from medical school, and for radiology it is seven years postgraduation. As I said, there are significant vacancies and there is a high proportion of EU primary medical qualification folk working in the UK at the moment. It is about the patient because it is the direct impact on the patient of not having the treatment that they should have, but it is also about the workforce to

deliver that and the resilience of that workforce to deliver the treatment as and when it is needed.

***Martin Sawer:*** I would make one final point. Quite rightly, we take the supply chain for granted. A doctor writes a prescription; the patient might go into a pharmacy in the morning and the pharmacy says, "Come back in the afternoon and the medicine will be there." We are invisible, and we should be, but I think it is important to recognise that that supply chain is there and operating all the time. A jolt to it like this could throw a lot of cogs out of a very complicated machine.

Q62 **Chair:** It already causes severe problems on a very occasional basis when there is a disruption in the supply chain. What kind of extent of disruption are we talking about if we do not end up with a deal?

***Martin Sawer:*** I would hope that common sense is going to prevail because patient safety is too important. Business would carry on until we are challenged. We have contacts, obviously, all around the EU. All the wholesalers around the EU—and I know because I go to meetings—operate with the same principles: we have an obligation continuously to supply medicine. I do think it would carry on for as long as it could. WTO rules or some customs problems would be where we would start running out of medicines, and that would be a challenge—after some months, I would suggest.

***Dr Grainger:*** I could imagine that there are scenarios where the logistics sector might be overwhelmed, and even with the best good will challenges will present themselves just through lack of capacity.

***Richard Freudenberg:*** If Martin's members are invisible or less visible, we are even less visible than Martin's members are. Although we are a small part of the market, as I have said earlier, we bring competition to the market that would not exist without us. We are the only price competition that the original manufacturers have in the market here, so we deliver savings to pharmacy and to the Government. We provide competition to keep lids on medicine prices in the UK. Without us, that would disappear. We are also very reactive. We can deal with the shortage issues, and in a small way we are also delivering medicines to patients that are unavailable through any route other than through imports.

**Chair:** Thank you very much for coming this afternoon.

## Examination of witnesses

Witnesses: Professor Jean McHale, Ian Bateman, Fiona Loud and Liz Carroll.

Q63 **Chair:** Thank you very much to our second panel. As I mentioned to the previous panel, there is a parallel inquiry going on with the BEIS Committee looking at the impacts for industry. Our focus within this Committee is primarily on the impacts for patients and healthcare. With

that in mind, could I ask you to introduce yourselves to those who are following this from outside the room and also say a little bit about your role, starting with you, Mr Bateman?

***Mr Bateman:*** I am Ian Bateman. I am director of quality at NHS Blood and Transplant. I am responsible for ensuring our regulatory compliance across blood, tissues, organs and medicines that we manufacture as well. I am the responsible person under the blood safety and quality regulations and the designated individual under the tissue regulations, and, therefore, legally responsible for maintaining our quality management systems and compliance with the regulations.

***Fiona Loud:*** My name is Fiona Loud. I am policy director for Kidney Care UK. We are the national kidney patient support charity. We are here to push for or to promote the interests of kidney patients and perhaps the way in which they may be adversely affected, because kidney disease is something that affects the whole life. We have about 60,000 people in this country with kidney failure and it is incredibly demanding. I use the evidence from all the work we do day by day with kidney patients to bring to bear that knowledge and to try to avoid unintended consequences of the range of policies for which we are specifically here—Brexit.

***Liz Carroll:*** I am Liz Carroll. I am chief executive at the Haemophilia Society. Our community was devastated by blood-borne viruses in the past, so, obviously, the safety of plasma and blood products is incredibly important to our community today as well as what has happened in the past. Also, as a rare disease, access to medicine and research across Europe is incredibly important because there just aren't enough people in the UK alone to be able to gather the data together to ensure we get access to the right medicines. All those things have an impact as well as access to plasma products and product safety. In fact, some of our patients also need transplants because they received hep C from their NHS treatment. Those who failed their treatment are now needing liver transplants. Our work covers a huge range of issues that we are talking about today.

***Professor McHale:*** I am Jean McHale. I am professor of healthcare law at the University of Birmingham. I am also funded under the ESRC, The UK in a Changing Europe initiative, along with my colleagues Professor Tamara Hervey and Dr Mark Flear at Queen's University Belfast. We are looking at questions around Brexit and health.

**Chair:** Thank you very much. Paul is going to open the questions.

Q64 **Dr Williams:** My question is about substances of human origin. We do not know what the regulatory regime is going to look like after the end of March 2019. What would be the impact for UK patients if the UK diverges from EU regulations covering the safety of blood, tissue, cells and organs?

***Mr Bateman:*** First, we have a very strong framework of regulation across Europe and in the UK. The aim, as far as I am aware at the moment, is to transpose the regulations through the withdrawal Bill on a like-for-like basis to the extent that they can be. It is really important that we maintain the strength of that regulatory framework as we transition across.

The potential effects of divergence come for us around the sharing of information, the reporting of events, and so on, through the current networks that we have available. In terms of the operational aspects, I do not see those as having a huge impact at the moment as long as we transition across, as I understand it, but I think there are some elements that perhaps Jean will touch on later about the regulations and how we interface with the EU that would perhaps cause some bigger issues.

***Fiona Loud:*** For us, many of the patients we support have been able to have their lives transformed by a kidney transplant. Current regulations allow for organs that are donated in this country for which there is no match for them in this country to be taken to an EU or an EEA country and be given to a patient there, and likewise an organ donated there can come back here. The reason for doing that is to get the best possible match, and everybody I hope will understand that a transplant will last longer if you have the best possible match. While it is not a huge number, to every single person who benefits from that transplant it is an amazing and fantastic gift. That is well regulated at the moment for the benefit of patients.

We have rules for patient safety, and Ian already referred to traceability and public health information there. We also have those rules in place to prevent organ trafficking, which I am sure people know is something that does not happen in Europe because we have good regulation there.

To add specifically to that, there are about 29,000 people on dialysis at the moment in the UK. Just 5,000 of them are well enough to be on the organ donor waiting list, waiting for a transplant. There are about 50 or so organs that are donated from this country and have been over the last three years, and we have received, I think, about 70 or 74 organs back again; so, we are net beneficiaries of those rules. Some of the rules regarding harmonisation also apply to living kidney donation as well, and I can talk about that in a little more detail anon.

For us, it is very much about maintaining an arrangement that has been put there for very good reason and benefits absolutely everybody. If you like, it is a humanitarian and incredibly positive thing to do, because as families and living donors it is an amazing thing to achieve. Those are probably the key issues I would like to raise with the Committee today, but I would like to mention consumables for dialysis equipment, about which there is a particular vulnerability. Perhaps I will come back to that later.

***Liz Carroll:*** For us, the biggest issue is safety. The EMA holds a plasma master file, which means that you can trace every single donation of plasma from the donor to the recipient. That helps when we are looking at viruses—particularly emerging viruses. We know that when viruses emerge around the world it takes time to work out what they mean. If we lose that connection with the EMA plasma file, we lose the ability to trace what has happened, and that is absolutely fundamental to safety and preventing happening what has happened in the past. That is really important.

The other thing that is important is that we have the ability to go to different areas of the world to receive plasma. We currently cannot use UK plasma for our health needs because of variant CJD. We use plasma from abroad; we do not use any UK plasma. We need to be able to access from around the world plasma that is safe. If a new virus emerges—for example, the Zika virus, which we thought was going to be a big issue in America, and a lot of our plasma comes from America—we would need to have the opportunity to say that we can no longer take plasma from this part of the world because this is happening at this point, and we need to be able to access it somewhere else quickly.

We need to have all those processes in place; there isn't time to wait. Equally, if something had happened in Europe, we would need to be able to switch to another part of the world. We have that at the moment and we cannot risk losing it—because we cannot produce our own. If we do not have those systems and safety mechanisms in place, there is no way that we can step up and put something in place quickly.

Q65 **Dr Williams:** Do we have that as a result of our membership of the EU?

***Liz Carroll:*** It very much came out of that. My understanding is that we have helped drive a lot of those safety standards now, but there are risks coming forward. Currently, there are a few EU member states that are increasing their safety profile and screening, which could well come into EU law in the next year or two—for example, screening for hepatitis E. Some countries are beginning to do that. The UK has said we cannot afford to start screening for that; it is not part of the legislation and we will not do it. However, if it becomes EU legislation in the next year or so, and we follow what has been said today, which is that we cannot afford to do it, our plasma will not be as safe going forward. So, it is really important that we do not allow that to happen, because that is what happened in the past and we ended up with 6,000 people with blood-borne viruses.

Q66 **Dr Williams:** On day one, in your understanding, the plan is that we have regulatory alignment; we transpose all the existing EU regulations into our retained EU law; but the EU may change going forward.

***Liz Carroll:*** Absolutely.

Q67 **Dr Williams:** That could mean that other EU countries may be protected

against currently unknown emerging viruses but we would not be.

***Liz Carroll:*** Yes—or even known viruses.

***Mr Bateman:*** That was the point made about the sharing of information through Public Health England, and the networks that are global rather than European. The Zika virus and the West Nile virus are examples of cases recently where we have had to make adjustments either to the way we handle blood and defer people who have travelled to certain areas of the world or to test things slightly differently.

Q68 **Dr Williams:** That sharing of information takes place through the EMA.

***Mr Bateman:*** It does not take place through the EMA because we are not talking about medicines now; we are talking about blood. However, there are networks through Public Health England into Europe, through the ECDC and so on, where these things are shared.

***Fiona Loud:*** Could I add to that? Kidney patients, particularly those with transplants, have their immune system suppressed in order not to reject the transplant, which makes them peculiarly vulnerable to all those viruses. Our population receives an awful lot of blood as well in support of the conditions. So, there are strong vulnerabilities there that mean we absolutely need this to be continued.

Q69 **Dr Williams:** Jean, what are the implications of regulatory divergence?

***Professor McHale:*** Regulatory equivalence and regulatory alignment, and how those are defined in the future, are quite critical. Taking Ian's point, if we had at least initial continuity, and which the withdrawal Bill would allow us to have in relation to the existing regulations, we would be aligned for the time being. At the moment the EU is looking at blood, tissue and cells, and the directives in relation to that, so it is certainly conceivable that in the future those areas themselves will be reformed as well as in light of some of the issues that are raised here.

There are also those questions, though, of when and how we relate on a reciprocal basis. You will come across these issues in relation to pharma and medical devices in other parts of your inquiry. It relates in terms of blood, because we are dealing here with questions of safety, as has been indicated. The idea of passing on information across Europe where there are health risks is something that is very much common EU regulatory strategy and this is utilised very much in relation to blood and tissue safety. For example, there is a rapid alert system in relation to tissue in cells, a web-based system, which enables information to be passed on from the competent body through to other competent bodies of the member state very quickly.

The question will come—and the regulators will be in a better position to advise as to where they are on this—as to where we will be able to sit in the future in relation to mutual systems operating alongside that.

There are other things, too. We have standards that at the moment we will have to comply with. The Single European Code has come on stream in relation to labelling the tissue in cells. In terms of third countries, if we ended up being in that situation, products that come from the UK to the EU would have to be labelled at that point. There is a database again as to labelling for the actual code itself, which I understand is a public one. We would be able to access a certain amount of information from that, but my understanding is that we would be cut off unless we had access to it. But I am not sure—

***Mr Bateman:*** At the moment we are treating the new regulation as if it is going to come into implementation. We have done all the work to introduce the coding and import directives that are coming through, and also the medical device directive that came into force in April this year. We are working through those on the basis that we will have continuity of regulation. But you are right: things could change later on, but that is speculation and we just do not know at the moment.

From an assurance point of view, we have fed all the information that we feel is useful to the Department to be able to redraft the regulations so that we get through the withdrawal Bill and they put us in the best place, hopefully, to not have divergence. However, it depends on our EU colleagues as to the sharing of information and so on.

Q70 **Mr Bradshaw:** I am sorry, Mr Bateman, you just said that you are assuming that there will be continued regulatory alignment, but that would not happen in the event of no deal, and it would not happen in the event of the hardest of Brexits, would it?

***Mr Bateman:*** No, I am sorry. If it was a no deal, I am not sure how that would unfold, but in terms of the ongoing planning arrangements at the moment, the withdrawal Bill and all the information going into that, then—

Q71 **Mr Bradshaw:** Do you not have a contingency for a no deal?

***Mr Bateman:*** We are looking at a no-deal situation at the moment and what that might mean. That planning process is ongoing, yes.

Q72 **Maggie Throup:** Liz, I might have missed it, but you said that a lot of plasma comes from across the world and not just the EU. What is the split between EU plasma and the rest of the world?

***Liz Carroll:*** I do not know exactly, but the majority of the plasma used in the UK, I understand, comes from the US, but the EU market is growing. Other people may know more than me, but there is a real split at the moment.

**Chair:** Andrew has a point and I have a follow-up.

Q73 **Andrew Selous:** That is quite a significant point: the majority of the plasma coming into the UK is from the US.

***Liz Carroll:*** I think so.

Q74 **Andrew Selous:** I am interested in the standards in the United States. I am also interested in the global network that you were talking about, Ian, just now; how you would see the United Kingdom's place in that global network; and what that would mean post Brexit. Could you say a little bit about the non-EU plasma?

***Liz Carroll:*** It still comes into the EU, so it has to follow the EU standards.

***Mr Bateman:*** It does, yes.

***Liz Carroll:*** The plasma that comes from America has to follow EU standards.

Q75 **Andrew Selous:** That was not quite my question. How high are plasma standards in the United States? Are they more demanding than the EU? Are they to a higher standard?

***Mr Bateman:*** NHS Blood and Transplant does not import plasma for the products that Liz is talking about. We only import fresh frozen plasma from the EU for treatment of young adults and children born after the year 1996 as a safety measure in the UK because of the potential transfer of vCJD. The plasma being imported for factor VIII products and so on, which comes from America, is not dealt with by NHS Blood and Transplant. We only deal with a very small quantity—around 27,000 units out of the 1.5 million units that are sent out each year. They come just for a particular cohort of individuals on the basis of a safety requirement that came from the Committee on the Safety of Blood, Tissues and Organs. It is a different supply chain that you are talking about there.

***Liz Carroll:*** We are not experts in this at all because we are a patient organisation, but our research suggested that the EU regulation is much higher than most of the world and is seen as something to aspire to rather than anything else. We would definitely want it to remain at least at EU standards.

Q76 **Andrew Selous:** Would it be possible to have a note perhaps from you, Ian, on the US standards within this area, because we heard from our advisers earlier that there are some areas where US regulatory standards are higher than the European Union. I am not saying that is the case in this particular example, but it would be of help to the Committee to have an understanding of how global standards work in this area.

***Mr Bateman:*** I am sure I can get something for you, but, as I say, NHS Blood and Transplant does not import, and is not responsible for the importation of, plasma from the US. Certainly, from our point of view, the fresh frozen plasma would all comply with the European standards from the blood safety and quality regulations.

Q77 **Chair:** Could I check something?

***Mr Bateman:*** I am sure, to be helpful, we can try to do that, yes.

Q78 **Maggie Throup:** Also, if you are able to access the information about the split between the rest of the world and the EU, that would be useful.

***Liz Carroll:*** Yes.

Q79 **Chair:** Can I ask for a clarification from you, Jean? We have heard the clear case for ongoing regulatory alignment in the interests of safety, not just for people in the UK but in the EU, but we have also heard that there can be no sector-by-sector deals—special deals. If all this falls down because of an issue in another sector, we could find ourselves thrown into a cliff-edge, chaotic Brexit. How satisfied are you, Jean, that there is some contingency planning going on for that? In other words, would there be mechanisms to bypass this so that information sharing could keep happening, because it is clearly in everybody's best interests?

***Professor McHale:*** First, I have no back-door access to information on what is happening at the moment. I would anticipate one would need specific agreements to address various issues, such as access to things like databases—whether we would be able, in effect, to buy into those. You have the analogies of those you will be coming on to when you look at medicines regulation later on and how that sectorial question will work. Specific agreements in relation to that, I think, would have to be addressed.

There are questions in relation, again, to transplant issues that would need to be addressed. As to the cliff edge, the other issue of material passing over the Northern Ireland-Ireland border would also need to be addressed. I understand with organs, for example, that organs are passed across, and we will come back to that in a second. Those sorts of questions would have to be addressed as well and, presumably, fairly rapidly.

**Chair:** Thank you. Paul has a final question.

Q80 **Dr Williams:** Ian, you mentioned the ECDC—the European Centre for Disease Prevention and Control. Presumably, we will be leaving the ECDC. We have heard quite a lot about us leaving Euratom and the EMA, but we have not particularly focused on the ECDC. It is a focal point for global level surveillance of blood-borne viruses, is it not? How are we going to continue that global surveillance if we are not members of the ECDC?

***Mr Bateman:*** The answer is that at the moment we are still trying to work out what avenues we can use going forward if that is not available. We are members of the Alliance of Blood Operators, for example, in America. We have very strong links with Australia, New Zealand and so on. We are in the process at the moment of looking at what options we will have and talking to the Department to try to make sure that we maintain collaborations where we can, going forward.

Q81 **Dr Williams:** We might have to align ourselves with an Australian surveillance organisation instead of a European one.

***Mr Bateman:*** That is speculation at the moment, but we are going through all the potential options that there are so that we are ready when that comes about.

Q82 **Luciana Berger:** This is an extension of Paul's question to you all. If the UK does become a third country, how do you believe this would affect the import and export of blood, tissues and organs from within the EEA—particularly what do you believe the risks are to patients—and do you think there are any opportunities that would be available as well that have not come forward so far?

***Mr Bateman:*** There is importation of tissues; there is importation of just the fresh frozen plasma, which I have talked about; and there are a small number of organs that do exchange, as Fiona has mentioned. As to blood supply, we are generally self-sufficient in the UK so that would not be an issue. As to the organs, which would be the main ones we would be concerned about, we would want to maintain a collaborative or mutual arrangement to allow us to continue. Three people die every day because we do not have enough organs, so we must improve our rate of organ donation, and any arrangements that we have must continue that, as Fiona said. The information we have fed into the Department of Health asked it to seek out collaborations and arrangements to allow that to continue.

Q83 **Luciana Berger:** Have you received any assurances or feedback from the Department about that?

***Mr Bateman:*** That is an ongoing process at the moment.

***Fiona Loud:*** Could I add to that as well? Obviously, that is incredibly important to the population that we support, but I also want to mention time. The arrangements we have at the moment allow for rapid and seamless transportation of organs between countries. You may well be aware that, if an organ is donated, it needs to be treated and packed in ice so that it can be safely transported. I am talking about kidneys, but as well as kidneys other organs can be moved between countries. I believe hearts last for about four hours, and kidneys can last nowadays perhaps for up to 48 hours. But you can see there is a definite period of time and the shorter the better. We would absolutely not want to have arrangements with every single one of the other 27 member states where you have to do something different depending on how the organ is being moved through Europe, which could endanger the ability of that transplant to take place.

Specifically talking about Ireland as well, there are some very particular arrangements with Ireland. As to paediatric transplants, my colleagues at the Irish Kidney Association have let me know that the paediatric patients from Ireland will come to England to receive their transplants. This is

something you can probably comment on a little more, but I would say this anyway.

For people with liver failure, the UK and Ireland also share livers. There is an awful lot of movement, some of which I believe pre-dates EU arrangements because it is a practical arrangement. However, we absolutely need to be aware that it is not just patient safety and the rules and regulations in terms of that, and traceability, but it is also speed. It is timeliness, and that really is of the essence here. Any arrangement that goes forward should not and cannot be subject to additional time being taken with the burden of other regulations. If we think about it, our transplant surgeons and our hospitals are working very hard to do things within a finite period of time, and we need to make sure we are able to continue to do what we are doing now because that works for a range of good reasons.

***Liz Carroll:*** For the community that we work with, the drugs that come under drug regulation that are plasma based could be a real issue. In terms of licensing, for some of the bleeding disorders, the only treatments available are plasma based. There is no manufactured treatment available, particularly for the very rare bleeding disorders. We do not produce it in the UK. It comes in as a drug from Europe. If we are an additional licensing authority for those drugs outside the EMA, there is the potential that, because the market is so tiny, we may not get access to those drugs. That is a real fear, particularly for the very rare diseases where you might only have a handful of people for whom there is no other choice. I think there is a risk about that, which is a real concern.

***Professor McHale:*** Coming back to your point on imports again, and to pick up Ian's earlier point on the question of equivalence, certainly in terms of exporting to a third country, the same rules apply to us at the present time. We would be expected to align ourselves with EU law in relation to that as well. If we want to play ball in that way and engage with it, we will still have to adhere to those standards for import purposes, essentially, but on a third-country basis.

For example, with tissue, my understanding is that there will be a slight difference again because, with the competent authority, there would be a need for a tissue establishment licence. There is extra regulation over and above that in relation to if we were a third party with a third-party-type relationship. I am not sure how effectively those operate at the present time for other countries—whether they tend to slow things down, for example. That might be a consideration as one of the practical problems.

Q84 **Maggie Throup:** We have already touched on this, but I want to go into more detail on what the risks are for patients if the UK does not have access to European safety mechanisms. We have already touched on it, but could you delve a bit further into it?

***Mr Bateman:*** Can you repeat the question?

Q85 **Maggie Throup:** If we do not have access to European safety mechanisms, what are the risks for patients?

***Mr Bateman:*** We are trying to make sure that that does not come to fruition—that is the starting point—but if there was a situation where, for example, a safety alert came across and we were not aware of it, then we would not be able to act on it and that would not be effectively dealt with in this country. Likewise, if we did not have information on an infectious disease that was becoming prevalent in a European country, again we would not be able to take the safety measures in the UK that that would necessitate. However, that is not the intent. The intent is to maintain the safety frameworks that we have and to try to get the right collaborations in place so that we cannot be in that position.

Q86 **Maggie Throup:** I suppose it is to everyone's advantage, is it not? It works both ways.

***Mr Bateman:*** Absolutely. It goes both ways as well; absolutely, it does, yes.

***Fiona Loud:*** There are standards for transmission of information at the moment with regard to transplantation, things like suspected serious adverse events or reactions, so having—

Q87 **Maggie Throup:** How would it affect the patient?

***Fiona Loud:*** Do you mean the patient who was receiving a transplant?

Q88 **Maggie Throup:** Yes, so I can see a picture of what is—

***Fiona Loud:*** We know it has already happened in the past. I was speaking to someone just the other day to whom we were giving support. An individual who received blood as part of his transplant a long time ago now was infected with hepatitis C and is still now having to have treatment with a new drug that has come in, which is perhaps better than some of the older drugs, to help him to deal with the impact on him, and now on his liver. Being immunosuppressed for all those years can also have an impact on the liver. Now, 30 years later, he is still having to go through a whole new regime of drugs, which are causing him exhaustion; he can only work three days a week; he is tired all the time. He is quite a young man because he had his transplant as a child. He is now also involved in a fight for compensation, which he is finding extremely challenging as well.

Q89 **Maggie Throup:** So, if there had been alert mechanisms in place 30 years ago—

***Fiona Loud:*** Yes, back in the day, we believe that would have been avoided. That is probably a key reason why this kind of thing has been put into place. It is, day to day, affecting people's ability to work, affecting their income and their overall quality of life. That is happening right now, if that helps.

***Liz Carroll:*** Following on from that, our community is one of those most affected by what happened, but it seems that the decisions that were made—and we will find out from the public inquiry that is about to start—about safety and cost of delivering what had been promised were not delivered. Basically, it was that it cost too much so we did not do it.

Q90 **Maggie Throup:** But if regulations had been different and in place—

***Liz Carroll:*** If the regulations that the UK Government had said they would put in place had been put in place, it is highly likely that many of those—

Q91 **Maggie Throup:** Are the regulations that we have today in collaboration with the other EU states going to stop that?

***Liz Carroll:*** The regulations we have today absolutely would prevent that happening, but if we are going to learn from the past we need to learn that, if we are making our own decisions without other people feeding in and maybe being looked at from the outside, there is a risk that cost will come into it once again, and that cannot ever happen. Six thousand people—

Q92 **Maggie Throup:** I was working in hospital labs at the time that happened, so I know. I was at risk from stab injuries and things.

***Liz Carroll:*** Yes, absolutely, you will understand. The standards that are currently in place are some of the highest in the world. We cannot let ourselves have the opportunity to drop back, because people forget over time. Yes, in the next five or 10 years or so people might not forget, but if we are a whole generation apart there is the potential that it can be forgotten. It is really important that we do not set a process in place that can allow things to just drop slightly, because each little step could have catastrophic consequences.

Q93 **Maggie Throup:** Thank you. Jean, do you want to add to that?

***Professor McHale:*** Just to add to that, the blood regulation originally in the EU was triggered by the reaction to the blood contamination scandals. This whole area is very much seen as a question of public health, the jurisdictional basis of it being under article 168. The patient is seen as part of a community. Those regulations are there for that purpose. Because of the need for the continuity of that and to enable disease—which is no respecter of borders—information to transfer across, it is particularly critical to ensure that those mechanisms remain.

***Fiona Loud:*** When we are talking about the importance of regulations and a good transition, we also need to bear in mind the continued harmonisation of these things, because on day one doubtless it will be fine, but what is going to happen in five or 10 years' time? It is that continued harmonisation and the continued ability to work together with whatever arrangement we are able to come up with that we must have

for the interests of patients, because it is the vulnerable population who will suffer if it is not looked after appropriately.

Q94 **Maggie Throup:** We also need the safety mechanisms in place with any country that we trade with, for want of a better word, for blood products.

***Liz Carroll:*** Yes.

***Fiona Loud:*** Yes.

***Liz Carroll:*** It is the shared learning, I think, and the shared information that enable us to maintain those standards, and that is at risk.

Q95 **Andrew Selous:** Professor McHale, you have pointed out very helpfully that the European Union has legislation to prevent the commodification of human material. I want to find out the extent to which organs are currently trafficked within the European Union. I think this is something that Kidney Care has also spoken about perhaps, starting with you, Jean.

***Professor McHale:*** All the blood, organ and tissue directives are predicated on the idea of voluntariness in terms of donation itself being seen as fundamentally important, going back to the early work with Richard Titmuss, and this being seen as a gift relationship. Although expenses are allowed, payment is not. The EEU itself has not, though, enacted a convention specifically in the area as such totally regulating organs. There is reference to the question of commodification in article 3 of the charter of fundamental rights and freedoms. The EU is also drawing upon the work of the Council of Europe and the convention on human rights and biomedicine there. These are indeed important questions in ensuring both long-term safety of material and engaging with ethical questions, because the concern internationally around organ trafficking is a major issue.

Q96 **Andrew Selous:** I am sorry to interrupt you, and that is very helpful and I am grateful to you, but my question was specifically about the extent to which organs are currently trafficked in the EU notwithstanding the provisions of article 3.

***Professor McHale:*** Absolutely. I am not aware they are as such, and that is the point. Ian will be in a much better position to know precise numbers.

***Mr Bateman:*** I am sorry, I do not have any numbers to verify that.

***Professor McHale:*** Our own domestic regulation in this area was also triggered by organ trafficking, but that was from outside the EU a few years ago.

***Fiona Loud:*** We have robust ethical standards in this country that were also introduced in the EU under some of those directives, as you said, precisely to prevent that happening.

Q97 **Andrew Selous:** The question that then arises, when we leave the

European Union, is whether new risks are opened up because we are not subject to article 3 in relation to the trafficking of organs. Does that become a risk?

***Fiona Loud:*** I would say that is unlikely because of the laws we have.

***Mr Bateman:*** I think that is extremely unlikely and we do work very closely with—

Q98 **Andrew Selous:** Which UK laws currently prevent that?

***Fiona Loud:*** It is the Human Tissue Act.

***Mr Bateman:*** Yes.

***Fiona Loud:*** That is enacted by the Human Tissue Authority.

***Mr Bateman:*** We work closely with the Human Tissue Authority in this area. It is prevention really.

Q99 **Andrew Selous:** That is very helpful; thank you very much. Turning to another area, the Wellcome Trust has called on the Government to create an environment after Brexit that uses regulation to support emerging technologies and innovative interventions. What opportunities might arise from regulatory divergence for the UK life sciences sector? You have been quite negative, but are there any things we would be able to do or that we might like to do that we currently cannot do? That is at the heart of my question.

***Mr Bateman:*** I am not aware of anything that we cannot do at the moment. One thing would be around funding to support research that we would need to continue, which is something that a number of people are concerned about at the moment. We are again making links with academic organisations and so on to try to maintain that funding and therefore carry on the research.

Q100 **Andrew Selous:** The example that the Wellcome Trust used, which they praised in particular, was the UK's track record in using IVF techniques to prevent mitochondrial disease. I do not know if that was something that was enabled to happen because of specific actions the UK Government took, or did that just happen here?

***Mr Bateman:*** I am sorry, I cannot comment on that.

***Fiona Loud:*** I could comment on the rare disease issues, but more in an urgent way to keep that going. About 12% of kidney patients will have a rare disease, and, as Liz has said previously, there will be only handfuls in different nations. So, it is about being able to work across the world, but across Europe, because geographically that is easier, in terms of the researchers, scientists and the transplant surgeons as well, on the other side of this. There is a great deal of co-operation at the moment, much of which is not done through regulation but through practicality. As an organisation, we are reaching out to and working closely with any of our

European kidney health or kidney patient forums that we can to ensure that, where possible, that kind of thing can continue, but we do not want to lose the opportunity of being a part of those larger things and that funding opportunity.

Q101 **Andrew Selous:** What do you see as being the risks of regulatory divergence for the future of the UK life sciences sector?

***Mr Bateman:*** I think we have covered it in terms of our particular—

**Andrew Selous:** You have nothing extra to add. We have had quite a negative session, I suppose, on that. That is fine, thank you.

Q102 **Mr Bradshaw:** Let me get my head around this. You are saying that Brexit could affect the supply and safety of blood, tissue and organs—life-saving things like that—to British people if it goes wrong, if we do not have continued regulatory alignment.

***Fiona Loud:*** Yes.

***Liz Carroll:*** Yes.

Q103 **Mr Bradshaw:** I am going to ask the question I asked the previous panel, and this is maybe fairer to Liz and Fiona because you represent charities and the other two have to be independent, or I imagine that you have to be independent as the regulator and as an academic. Does that mean you think we should just stay in the single market and the customs union, and that will be the simple solution?

***Fiona Loud:*** The easiest thing would be to continue as we are. Whether that pertains to a single market or to retaining those regulations and that harmonisation—

Q104 **Mr Bradshaw:** Are you campaigning on this? Are you making your views plain, including to all your supporters, and getting them to write to their MPs?

***Fiona Loud:*** We are doing what we can.

***Liz Carroll:*** We have not to date, because we have been quite busy with some other stuff that is going on, but it is certainly something we have highlighted in coming here and are starting to talk to members about because it is important.

***Fiona Loud:*** May I make a couple of points there? One is around dialysis consumables, and I can come back to that in a minute, but the other would be a separate effect of Brexit, which is reciprocal healthcare, which I know is not quite in scope here, but through the EHIC card, with which you will all be familiar—

**Mr Bradshaw:** Huge.

***Fiona Loud:*** People who are on dialysis and who depend on that three times a week to give them only 10% of their kidney function are

presently covered by the EHIC card, free when it is given, at the same rate as it is given in this country, which is free of charge. Those patients will no longer be able to travel unless they can afford the additional £1,000 or £2,000 a week to pay for their treatment or we can have an arrangement there as well. That is something we have been campaigning on, we have written to Ministers about, and we have also given evidence about to the Lords Committee on reciprocal healthcare.

Q105 **Mr Bradshaw:** Given that we are at such a critical juncture of this whole issue with what has happened in the last 24 hours, anything is possible, and it would be incredibly helpful for those who are arguing for the softest or preferably no Brexit at all to galvanise their supporters to contact their MPs. It does make a difference.

***Fiona Loud:*** Certainly that is what we have done with reciprocal healthcare for that very reason.

Q106 **Mr Bradshaw:** That is particularly because a lot of our colleagues in Parliament are focusing on the economic side. They do not realise that this has such a huge impact across the whole of our lives, including health and social care, so please do that if you feel able to.

***Fiona Loud:*** That is our concern. It is the unintended consequences.

Q107 **Chair:** Fiona, you mentioned at the beginning that you had other concerns about devices that were accessed by your patients.

***Fiona Loud:*** Thank you, yes. From the dialysis industry, and from kidney doctors as well as from patients, our understanding is that there is no dialysis equipment that is manufactured in this country, although there is possibly something that is being developed at the moment. None of the dialysis consumables is made in this country. They are imported from the EU, and many of them are made in EU plants; all that material travels free of tariff and it travels freely. As we have already mentioned, it is critical to keep supply of those materials going. We have a very tight tariff by which hospitals are paid to give their treatments to—in this case—their dialysis patients. If there were to be some kind of tariff introduced on those life-maintaining materials, it would immediately be of great concern.

If I might use an anecdote from a few years back, there is one form of dialysis that uses a lot of fluid, so it is different from the type that takes place in hospital, but still we have 15% of patients using that. There was an infection in one of the EU plants, which meant that manufacture had to move, while that plant was out of action for a while, to Turkey, I think, and then another plant was brought in in Poland. Although Turkey is not in the EU, that manufacturer was able to bring the fluid in through that third country very quickly so that people could maintain their supplies of dialysis fluid in order to keep having that kind of treatment.

Thinking back to that, five or six years ago, I realise that we are quite vulnerable in terms of supply and tariff. We want to make sure that there

are robust arrangements continuing, as well as keeping a stockpile here in this country, which already is there, which is my understanding from some of those manufacturers, so that we are also able to continue with a reliable supply of those kinds of materials; otherwise, patients will be at real risk, as you will understand.

Q108 **Chair:** There are really critical issues around the supply chain that you want to see the Government addressing as they prepare for a contingency plan in the event of not having a deal.

***Fiona Loud:*** Yes—contingency and cost.

Q109 **Chair:** Yes. Contingency, cost and safety are very key concerns. Jean, are there any issues around access to other pan-European systems that have not been covered today that you think the Committee should be aware of?

***Professor McHale:*** There is the Eurotransplant network and the links, again, around sharing organs across Europe. Some of those were also funded and supported by the EU. Again, what happens to those sorts of networks and links across? The other thing, too, is with funding going into European reference networks and groups of clinicians being able to work together. What will impact precisely on those? You would want chapter and verse from the clinicians on the ground as to precisely how they have been benefiting more recently from it, but those sorts of organisations, off the top of my head, would be the best starting point.

Q110 **Chair:** Finally from me, there are some international networks—for example, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals; they do not make it easy sometimes with these long names. I gather it would take two years for us to become a full member. Do you feel there is sufficient attention being given to these kinds of issues?

***Professor McHale:*** There certainly does not appear to be very much high visibility in engagement with it. Again, I am not privy to where, for example, the Department of Health is at this particular point on this. All these issues may very well have been addressed behind the scenes or they may be in those impact case studies, but I am certainly not personally aware as to whether or not they are.

Q111 **Chair:** Thank you. Are there any other points that any of you feel you have not been asked that you wanted to make today?

***Liz Carroll:*** I have one point I wanted to make, which probably fitted in slightly with the last session you had around research and access to research, particularly in rare diseases. Most of the research in rare diseases takes place across Europe and a lot of it is European funded. We are a huge contributor to a lot of the research that is done by the pharmaceutical industry, partly because we are part of the EMA. The hope is that we will have access to those drugs as we go forward. There

will be a huge cost burden, never mind the burden on patients who may or may not have access to those drugs in the future.

For haemophilia treatment, I asked some of our clinicians what they thought the cost might be. We have about 2% of people with haemophilia A on clinical trial products in the UK at the moment, which is about 50 patients. I asked them to give me an idea of what the standard treatment for those people would cost, because they are getting free treatment that we are not paying for. This is for children. Haemophilia treatment is based on your weight. These are children aged 3 to 10, so they are tiny. Per patient, one clinical trial product is saving between £250,000 and £1.5 million per patient, who is a child. If an adult were on that trial product, the product we would be paying for from our NHS budget could cost up to that. So, they are the expensive patients of our population.

There is a real risk, if we are not part of the research networks and the future of new drugs coming forward, that patients will not have access to them. This particular drug is life changing. It takes you from extreme pain, bleeding into your joints several times a month, leaving you with terrible long-term damage, inability to work or go to school and all those things, having to inject three or four times a day intravenously, to once a week, subcut and no bleeds. This type of treatment is life changing, and yet we may in the future not have access to all of that. We would have to pay for it, but the patients would not get that potential life-changing treatment if people have to go through a different regulatory authority. There is a real concern across rare diseases as a whole that access to research, the research funding and then the drugs afterwards could reduce dramatically.

Q112 **Chair:** Then, as we have heard, there would be slower access to those products once they are licensed.

***Liz Carroll:*** Absolutely—slower or none, because the market is not big enough in the UK for them to bother to go through the regulatory access as a third country. We are just not big enough because the numbers of patients are so tiny.

***Fiona Loud:*** I am sure it is the same with you, but the EMA will come to us from time to time to ask for expert patients—which it did just this week—who will go in and give their view on this life-changing treatment. They often come to the UK patient forums, as we have some quite developed and good expert patients who are willing to go out and speak on that. That is something we can give; we can offer that expertise and that help, but of course we receive back absolutely in the way that Liz just described. I know of patients who are receiving treatment on a trial basis in different parts of Europe at the moment and are gaining enormously as a result of that.

Q113 **Chair:** Thank you. Does anyone have any further questions? No. Did you have another point you wanted to make?

***Fiona Loud:*** No. It is probably fine; thank you very much. It was on reciprocal healthcare.

**Chair:** Thank you to all of you for coming this afternoon.