HOUSE OF LORDS

Select Committee on the European Union

Environment Sub-Committee

Corrected oral evidence: Future UK-EU relations: energy, environment and health

Wednesday 27 January 2021

9.40 am

Watch the meeting

Members present: Lord Teverson (The Chair); Baroness Bryan of Partick; Lord Cameron of Dillington; Lord Carter of Coles; Lord Cormack; Lord Giddens; Baroness Jolly; Baroness McIntosh of Pickering; The Duke of Montrose; The Earl of Stair; Lord Young of Norwood Green.

Evidence Session No. 3 Virtual Proceeding Questions 17 - 25

Witnesses

I: Kate Ling, Senior European Policy Manager, NHS Confederation; Fiona Loud, Policy Director, Kidney Care UK; Dr Richard Torbett, Chief Executive, Association of the British Pharmaceutical Industry; Emlyn Samuel, Director of Policy, Cancer Research UK.

Examination of witnesses

Kate Ling, Fiona Loud, Dr Richard Torbett and Emlyn Samuel.

Q17 **The Chair:** Welcome to the Environment Sub-Committee of the Select Committee on the European Union. We look at not just environmental issues but public health issues, which are obviously very much tied in with environmental considerations. This week, we have a witness session as part of our report on future UK-EU relations in the energy, environment and health sectors. Today, we are looking particularly at the healthcare sector and consumers—or, as we call them, patients. I am very pleased that we have an excellent team of witnesses with us.

This is a live session and it is being webcast. We are taking a transcript. We will distribute it to our witnesses and, if there is anything you feel is not correct, please let our clerk, Jennifer Mills, know. I ask Members to declare any interests that they may have relevant to this session the first time they speak. I am not aware of any interests that I have in the medical and public health area. I ask Members to indicate who they wish to answer their questions. Witnesses, if you feel you are being left out and have something important to say, please raise your hand, and we will ask you to contribute.

Perhaps I could ask our witnesses briefly to introduce themselves.

Kate Ling: I am here on behalf of the NHS Confederation, which is the umbrella organisation that speaks up for NHS providers and commissioners. Our members are NHS organisations. I am secretary of the Brexit Health Alliance, a consortium that brings together organisations from NHS patient groups, the healthcare industry and medical researchers. We have been campaigning for the last three or four years about the impact of Brexit and the outcomes that we would like to see for the health service. I am involved in the Cavendish Coalition, which I shall mention later. It is a similar consortium of health and social care organisations involved in workforce issues.

Fiona Loud: I am the Policy Director for Kidney Care UK. We are the UK kidney patient support charity. We give emotional, practical and financial support to patients and their families who are affected by kidney disease. Over the last three or four years, we have been campaigning and working hard to represent the needs and concerns of people with kidney disease, to ensure that their health is protected as we go forward into our new arrangements. That particularly affects people on dialysis, about whom I shall be speaking later.

Dr Richard Torbett: I am the Chief Executive of the Association of the British Pharmaceutical Industry. We represent the global research-based pharmaceutical industry here in the UK.

Emlyn Samuel: I am the Director of Policy at Cancer Research UK. Over the last four or five years, we have been working to ensure that cancer patients and the cancer research environment is protected through our EU exit.

Q18 **The Chair:** As this is a health and public health session, we should note the fact that we have passed 100,000 deaths in the COVID-19 crisis. We will not get on to that specifically today, but it would be wrong if we did not note, with sadness, that occasion.

I have a very general question, and I will ask the witnesses, in the same order, to give introductory remarks on the subject of the healthcare sector and the UK-EU Agreement. First, what is your reaction to the Trade and Cooperation Agreement? Are you pleased or disappointed with what has been agreed in general terms?

Kate Ling: I think the best word to describe it is "relieved". We are very pleased that the cliff edge of no deal has been averted and that the uncertainty that has made it so difficult for the NHS to plan ahead has been, to a large extent, removed. On the plus side, we are delighted that arrangements for reciprocal healthcare will continue for patients on both sides of the channel, and on both sides of the Irish Sea. We are pleased about the continuation of participation in EU-funded research programmes and the co-operation on tackling cross-border health threats. That is the plus side.

On the minus side, one disappointment is the lack of mutual recognition for the testing and authorisation of medicines and medicinal products. There are two big things that are not in the deal at all, so I suppose you could say they are the dogs that did not bark. The first thing is that there is only a temporary solution to the question of the flow of data—data transfer and data adequacy. That is still to be resolved, and it is really important. The other thing, which is not part of the deal but is absolutely vital from the point of view of the NHS members I represent, is the whole area of the ending of free movement and the UK's new immigration system. I hope we will be able to get on to that later, particularly the impact on social care. COVID has cruelly exposed the interdependency of the health services and social care.

The Chair: Indeed. Thank you, Kate. That is a very good focus, and I know we will go through a number of those issues further. I find it quite difficult to understand exactly how the future of the EHIC and our global equivalent is supposed to work in practice, so we look forward to that.

Fiona Loud: Like Kate, I suppose relief is one way of describing it. It is a mixed bag. What is good, and we have referred to it briefly already, is that we have an agreement on reciprocal healthcare. We at Kidney Care UK, and many kidney patients, were extremely worried about that, for reasons that I will explain later. That is definitely good.

We are less certain about other things. Where is the Government's strategy for implementing the full deal, for example, for new regulatory systems for medicines? We have new things such as ILAP and our Project Orbis, but how will they be joined up with the work of NICE? The big question is where patients will be in this. How will it benefit patients? The goal is that patients and their treatment can move forward and benefit

from innovation, that they certainly do not go back, and that their voice is heard clearly in the future.

You referred earlier, Chair, to the very sad numbers that were announced yesterday of 100,000 people dying with COVID. That has affected an awful lot of the people we support. Their voices might be quite quiet at the moment because they are living in very difficult circumstances. We all need to look forward to a time when things are a little better, and patients and their families will wish to be involved with those future new developments and new innovations. Finally, or semi finally, we need to monitor and ensure that they work as they should.

I have a couple of points about Northern Ireland. I know we have some temporary arrangements, but we have patients and families in Northern Ireland as well, and we need to protect those who might not be able to benefit as much as others because of the tariff barriers or new procedures that may have to come in that area when different rules apply.

The Chair: In the Northern Ireland situation, we have a temporary get-out-of-jail-free card, but we will come to that later. We obviously need to know what happens there, both from patients and from the industry side.

Dr Richard Torbett: Perhaps I could start with two bits of context to illustrate the two sides of the lens through which we look at the Brexit deal. The industry I represent is obviously very much in the public eye at the moment. My members are very much at the forefront of the COVID effort, and they have thrown their weight behind developing and supplying vaccines.

The most important thing we do generally of course is supplying around 12,000 different types of medicines and vaccines to the NHS. One aspect is whether the deal will allow us to keep that supply going reliably. The second thing is that we are an incredibly important part of the UK economy. We have been the largest investors in research and development consistently over many years, and by some way: over £4.5 billion. As a life science industry, we export around £30 billion. That gives you a bit of context.

How do we view the deal? Echoing very much what both Kate and Fiona have already said, we were hugely relieved to have a deal of any sort. It could have been an awful lot worse. We are a very highly regulated industry. The politics of Brexit aside, as a very highly regulated industry, leaving the European Union has been very complicated for us, and remains so.

There are some real positives. The fact that we will have a tariff-free flow of trade in medicines and active pharmaceutical ingredients, which are important for manufacturing, is very welcome. We were very pleased to see a pharmaceutical annexe to the deal that includes provisions for the mutual recognition of good manufacturing standards and inspections.

There are some gaps. Batch testing of medicines remains a concern for us; I am sure we will get into that later in the conversation today. Northern Ireland has already been mentioned; we still have some uncertainties there that we need to resolve. Then there is the broader picture of how, as a science-based industry, our scientific community is able to work seamlessly together across borders, and continue to develop and research medicines and vaccines for the future. The details of that still need to be worked through. There are lots of issues for us still to work through, but overall great relief.

The Chair: Thank you very much, Richard. You are absolutely right about the importance of the pharmaceutical industry. This committee deals very much with the chemical industry and the REACH process. We sometimes forget how important both those industries are.

Emlyn Samuel: I will say a bit about what we care about as regards the deal and its implications from a Cancer Research UK perspective. There are a few areas where we overlap with others giving evidence today, primarily around the regulation of clinical trials. About a third of the clinical trials that Cancer Research UK funds involve patients from EU Member States. That is primarily in rare and childhood cancers, where we simply do not have the patient numbers in the UK to run the trials ourselves, so we absolutely need to collaborate with our European neighbours on research endeavours to produce new medicines and treatments for those patient groups. It is really important that we do not disrupt our ability to collaborate.

Access to medicines, as Richard and the others have talked about already, is absolutely crucial, whether it is existing medicines or medicines that are being tested in clinical trials. It is about the supply of those across borders and how that works, and how quickly we can continue to access new medicines through licensing procedures.

The last area is the research environment more broadly: our participation in broader EU frameworks such as Horizon Europe, and the impact for researchers of the end of free movement and the new immigration system in the UK. Similar to what the others have set out, we definitely feel relief that we got a deal and avoided no deal. There are some positives that others have mentioned, which I will not repeat, and areas in need of further development.

There are a couple of areas to pull out in addition to what has already been said. To go back to our need to collaborate internationally, there remain barriers to how we run and set up clinical trials. The data adequacy agreement will be crucial, as will mutual recognition of the sponsorship of trials. There are some barriers to how UK sponsors can work with partners in the EU on setting up pan-EU trials in the areas that I mentioned.

Similarly, there remains a big question mark about our future regulatory system for the development of new medicines and access to new medicines. That will be a huge agenda for the UK going forward, including

how the relationship works between the MHRA and the EMA, and with other regulators. Particularly when it comes to clinical trials, we are very interested in seeing that progress over the coming years.

The Chair: Thank you very much, Emlyn. That gives a great foundation for the rest of this session. I agree that data adequacy affects the whole of the UK in all sorts of ways, and it needs to be sorted out fairly soon so that we all know where we are.

May I remind everybody to keep their remarks very sharp for the rest of the session to ensure we can get through and cover all the points in some detail? Baroness McIntosh will start those questions.

Q19 **Baroness McIntosh of Pickering:** I declare my interest as an adviser to the Dispensing Doctors' Association. I am a doctor's daughter, a doctor's sister and a surgeon's niece, but I could not stand the sight of blood so I went into law instead. May I bid you all a warm welcome?

In your remarks, a number of you welcomed the fact that EHIC will continue in its new form of GHIC. That begs this question: what assessment have you made of the arrangements for reciprocal healthcare under the Trade and Cooperation Agreement? What changes do you envisage? As regards its current operation, I have benefited from the EHIC in the past, although I have never had to claim on it. In your experience, have there been issues that you would want the Government to address before we proceed to the GHIC? In particular, I had always understood it was free of charge, so, where charges are made, have you experienced any particular difficulties you would like to see addressed at this stage? Kate, may I start with you from the NHS Confederation?

Kate Ling: We are delighted that UK and EU citizens will continue to benefit from reciprocal healthcare. I think the arrangements have worked pretty well so far, not only from the point of view of patients but in what goes on behind the scenes, where there is a whole mechanism for reimbursement. The deal that has been reached pretty much replicates, albeit on a different legal basis, the existing arrangements with the EHIC and then the GHIC card. I think Fiona will want to chip in on this because there are some important points she will want to make on behalf of patient organisations.

There are some gaps. The deal does not cover the EFTA countries. An agreement has been reached with Norway separately. Switzerland, Iceland and Liechtenstein are not covered, so people travelling to and from those countries will have to take out insurance, and they will be chargeable. Hopefully, there may be some future agreement on an arrangement to sort that out.

There is an important point about implementation and the need to communicate clearly to patients and to the public. There has always been quite a lot of confusion about what people are entitled to, both under the current system and the new system, which will not look very different from the point of view of people on the receiving end. People need

practical advice about implementation, and what they are entitled to, or not.

From the point of view of the NHS, it is a relief for the people who are actually having to deal with reimbursement, and for people on the front line—the staff who are meeting patients from other countries. The deal will make it easier for them to carry on doing that. It would have been a bit of a nightmare, quite honestly, to have to deal with 27 different lots of arrangements for visitors from EU countries.

It is a pretty good deal going forward, but there will inevitably be some hiccups. I will pass over to Fiona to go into more detail. Data adequacy will pop up on absolutely every topic because, obviously, there are questions about transfer of patient data and information. To keep it short, I will stop there.

Fiona Loud: There are about 30,000 people on dialysis in this country; they rely on that treatment every day; the majority of them go into hospital or a unit for their treatment three times a week. It is life-maintaining and it takes about four hours at a time. Of those 30,000 people, about 5,000 are well enough to be on the transplant waiting list. For the majority of them, that is their life, and to keep living well in that situation it is very important to patients and their families to be able to travel from time to time. It is quite difficult for some of them, income-wise, and because of other things; nevertheless, the chance to have a break is very much valued. In fact, as a charity we give people grants so that they can travel from time to time. Of course that has not been able to happen for the last year.

The assurance around EHIC/GHIC gives people some hope. Insurance of course is still needed every time you travel. The cost of dialysis in an EU country, which you need to book, by the way, often months and months in advance to be sure that it is already set up, is somewhere between £250 to £300 a session, but it can cost up to £500 a session. That is three times a week to stay alive. The cost becomes prohibitive if you have to pay for it yourself. As a known pre-existing condition that required treatment, insurance was never going to cover it, and you could not travel without it.

There has been an enormous sense of relief from patients that they will be able, when it is safe, to start to travel again. People are now starting to look into it and think, "Maybe in the autumn we will be able to travel". Naturally, there have been a few teething questions. Kate mentioned communication. A couple of people have been in touch to say such-and-such a unit only wants to receive a GHIC not an EHIC because they think that GHIC is the way forward. There are some things about communication that I think are now being sorted out.

We have been campaigning on this for the last four years to bring out the voice of patients, for whom it means hope. Sadly, some of them passed away over that time, because we do not all have for ever, unfortunately. Nevertheless, people who want to look to the future very much welcome

this measure. We have heard from people who wish to travel to EFTA countries, and we hope that arrangements can be made there. People are planning for their niece's wedding in August—that is the kind of thing people look forward to doing.

We need to make sure that the system is successfully implemented as regards data adequacy, because detailed patient data has to be exchanged between the person in the UK and the unit or facility that will be giving treatment in an EU country. All sorts of details about blood groups and medicines and things need to be shared for the re-charge, and for the treatment. That needs to be as easy as possible.

There was a further question about up-front costs. What we hope will not happen—with EHIC it did not happen, so it should not—is that people are asked to pay up front. In some countries, you have to do something called co-pay. People will be directed to public units, which are units available to members of the public in that country, and that means they should be able to receive their dialysis free of charge or at the cost that a citizen of that country pays. Sometimes people will have to pay a top-up fee as well. People understand that. People are familiar with that. We hope that sort of situation will continue. I have no reason to think that it will not, but we will not see how it works fully until later in the year when people start travelling again. I hope that confirms some of the information and details about what it means to people going forward.

Baroness McIntosh of Pickering: Emlyn, do you expect patients undergoing chemotherapy to experience any potential teething problems?

The Chair: Emlyn, could you be brief in your answer so that we can get on to the trade issues?

Emlyn Samuel: I do not have much to add, I am afraid. It is not something we have been looking into. We are listening to our patient communities to understand whether there are any issues, and we are not hearing anything at the moment. That is as much as I can add.

Baroness McIntosh of Pickering: To put it on the record, Richard, medicines are not covered. Is that generally understood by patients? I got a bit of a shock when I was asked to pay for my medicines.

Dr Richard Torbett: I do not know whether that is generally understood. We would be happy to look into it, but I would have to come back to the committee with a clearer view.

Fiona Loud: Very briefly, the medicines that are given on dialysis are usually covered, but additional medicines are not. We can come back to you with more detail subsequently.

The Chair: We will move on to some of the trade issues and the Earl of Stair.

Q20 **The Earl of Stair:** Turning to the trade of medicines and medical products between the UK and the EU, historically we had a mutual

arrangement for regulation and recognition of standards, batch testing, rules of origin and general working, which will not work in quite the same way in the future. What are the implications of the new limited mutual recognition provisions? How will the new rules of origin requirements affect current supply chains? We should probably start with Richard and Kate, the industry representatives.

Dr Richard Torbett: That is a very important part of the Agreement for us. As I said before, it is a mixed picture. The mutual recognition of good manufacturing practice has been agreed. A huge benefit of that is that the inspections that have to be undertaken to ensure those good manufacturing practices will be mutually recognised on both sides, so we will not see duplicative inspections of sites. We have seen a commitment to regulatory co-operation in future, which is a very good signal. We do not know exactly what it will look like yet, but the principle is very welcome.

You mentioned batch testing, which is a big source of concern. Every batch of every medicine and every vaccine has to be tested, which means that a certain number of doses are taken out of the supply chain and put through laboratory processes of various sorts to test purity, toxicity, et cetera. It is a costly and difficult process; it takes time and resource, and it takes chemicals. If you think about the scale of that, we have 12,000 types of medicines going to the NHS, and we have multiple batches per year for each of those 12,000.

We very much wanted mutual recognition at the start of the process. I have to put on record that we have really appreciated the support of both officials and UK Ministers. I think they understood the needs of the industry in the debate. However, it is unfortunate that we do not have mutual recognition of batch testing, and we are now left with a two-year period when the UK has agreed unilaterally to recognise any batch testing coming in from the EU, but after that the implication is that we would have to duplicate all those processes. That is a big source of concern for us. We would very strongly urge the Government to reconsider that position. It would lead to a huge amount of cost, complexity and, ultimately, delay in the supply chain, which nobody wants. It is of no benefit, it is entirely duplicative, and those resources could otherwise be spent in other areas.

Finally, you asked a question on rules of origin. It is very complicated. We have had the Agreement for just over a month and we do not yet know. To understand the implications of the rules of origin, they have to be worked through on a product-by-product basis across many thousands of different products and SKUs. As we go forward, companies are learning about it, and I would be very happy to come back to the committee on it later. Essentially, it is good that we have a rules of origin framework that we think will work, but it will take time to prove that is true.

Kate Ling: Richard has covered the regulatory aspects. From the point of view of my members, we are the end-users, the NHS. I echo what Richard said. We are concerned about the fact that there is no mutual

recognition of batch testing. There are a couple of years during which the UK will recognise testing, but we are not sure what will happen after that.

From the point of view of NHS supplies of medicines, so far so good, I think. I am speaking about the current situation. A huge amount of work, which Richard alluded to, has gone on for a long time between the Government, the industry and the NHS. An enormous amount of effort has been put in to make sure that supplies of medicines and medical devices can continue unhindered to the health service. There has been a massive amount of work to maintain continuity of supply, which I think is bearing fruit at the moment.

So far, we have not heard about a lot of problems or, at least, no disasters. There are supply problems from time to time that are wholly unrelated to Brexit. They have always happened. We are aware of problems. We have heard, for example, from a couple of research institutes that it has been touch and go for some of their temperature-sensitive deliveries, things such as ingredients for cell cultures that have to be delivered on dry ice. That is the example we were given. We have not been aware of any deliveries that have not arrived satisfactorily.

We are concerned not only with sorting out the regulatory environment going forward but with things such as extra costs. We are aware that some research organisations are incurring extra costs because they have been paying couriers, for example, to guarantee speedy delivery of medicines or ingredients or equipment. That is a concern for the health service. The important thing for the longer term is what Richard said, which is to sort things out so that there will not be massive problems further down the line, particularly in a couple of years' time.

The Chair: Richard, may I come back on one thing? When we looked at REACH, which is even more of a duplication of databases and systems and testing, one issue that came out was the risk of having to redo a lot of animal testing. Is it the case potentially that we risk, if we move into a double regime, having the same problem of duplication of animal testing?

Dr Richard Torbett: It is quite right that there is a risk to a certain extent. For medicines that would be considered sterile, there are certain tests that would at times involve animals or animal products. We need to do some work to understand the scale of that. It is certainly not the case for every medicine and every process that goes through batch testing, but it is fair to say that any resource that is spent in a duplicative way—whether it is animal testing, whether it is the environmental impact of using solvents, which are certainly widely used in batch testing, or whether it is the people, resources and infrastructure required—it is all resource that could, frankly, be put to better use and some sort of benefit. If it is duplicative, it is not benefiting anybody. We would much rather put that resource into ensuring supply chains and have those people thinking about COVID in the short term.

The Earl of Stair: Will any specific medical products or fields of medical supplies be affected more than others?

Dr Richard Torbett: I must be clear that what we are talking about is what happens after the two-year period. After the two-year period, every medicine would have to be tested. The problems, or the challenges, would escalate rapidly the rarer the condition. For example, if you were testing a certain number of batches for a cholesterol treatment that involved treating potentially hundreds of thousands, even millions, of people, the stock involved would be a drop in the ocean. If you were treating a very rare disease where there might be only a small number of thousand vials produced globally, any vial that had to be pulled out of that process and tested in a duplicative way is a vial that would not be treating a patient. The rarer the condition, the worse the problem, but all medicines, fundamentally, would be affected by the current situation.

The Duke of Montrose: You said that the two-year relaxation will apply to imports. Does it apply to exports as well? Would we have any option to extend it on our side if we had the chance?

Dr Richard Torbett: Unfortunately, no, it does not apply to exports. I think the British Government made it very clear that they wanted mutual recognition so that exports were not going into a duplicative process as they went into the EU. For one reason or another, the EU did not agree with that, so there is a duplicative issue with the EU that is a problem. That is a matter for the EU.

Lord Cormack: Two years of time have been bought. Are you confident that you will be able to get a more long-lasting agreement?

Dr Richard Torbett: The Government would need to answer that. I am very much making a strong case that it is in nobody's interests to have the processes duplicated. We can put that resource to better use to grow the life sciences industry in a productive way in this country. I hope the Government will listen and consider that carefully as we go forward. I know that Ministers are listening and that they are considering this at the moment, so I have high hopes.

Emlyn Samuel: I support everything that Richard and Kate have set out. It also applies to the supply of medicinal products that are tested in clinical trials. Some of those trials are working across the EU at the moment and, while the UK is accepting batch testing from EU Member States, as Richard said, it is not happening the other way round. If medicinal products from the UK have to be tested in EU clinical trials, that again puts up a bit of a barrier. All these things build up and absolutely need to be rectified to avoid duplication. It is one of a number of things that adds to the set of barriers to collaborating internationally in some trials.

The Chair: We need to move on. We will go to the complex area of Northern Ireland.

Q21 **Lord Carter of Coles:** I declare my interests. I am a director of NHSI and I have interests in testing, social care, and international healthcare insurance.

As the Chair said, this is about Northern Ireland. We would like to know if the Government have clarified the rules for the supply of prescription and over-the-counter medicines to Northern Ireland after the one-year period. Could you highlight the uncertainties? Could you give us a bit of insight as to where the vaccine might sit if there is some sort of stand-off between the European Union and the UK? Will Northern Ireland be in the European Union or in the UK for these purposes? Perhaps Richard would like to start. I think Fiona commented on Northern Ireland earlier, so perhaps we could go to Emlyn for a patient view, then to Kate and finally to Fiona.

Dr Richard Torbett: Northern Ireland has been the most complicated area for us to think through. We have reached agreement on quite a pragmatic approach for the next 12 months. We have gone from talking about a 12-month grace period for batch testing and we are now, in Northern Ireland, talking about a 12-month period when certain rules and regulations will be phased in.

That is a huge relief to the industry because, historically, medicines supplied to the Northern Irish market typically came through GB; often their supply route was from the EU into GB and into Northern Ireland. That led to a number of questions about the regulatory processes that those medicines would have to go through, such as being checked in and out of the falsified medicines database with the EU, the import rules they would have to go through, et cetera. Some of that has become clearer. I think we are now much clearer on how the falsified medicines directive will work. The 12-month period will have to be used to good effect by companies to re-engineer their supply chains so that they will be able to comply. Often that will mean companies redirecting supply away from GB so that it goes only through the European Union and into Northern Ireland through the Republic of Ireland.

When it comes to some other aspects of the rules around the licensing of medicines, there is ongoing uncertainty about the interpretation of rules by the European Commission and the EMA versus their interpretation by the UK. That involves rules around the location of marketing authorisation holders, and certain other key individuals, where it is important to be compliant with the regulators. My strong message would be that it is great that we have the 12-month phase-in period, but we should use it effectively, to plan and adjust for what happens after the phase-in period is up. We need to get clarity as soon as possible on the regulatory rules.

You asked a question about vaccines. I restrict my comments at the moment to saying that I very much hope that there will not be a political stand-off on vaccines. That is in nobody's interests. The companies concerned, which I am in very regular contact with, have moved heaven and earth to develop something that works within a year of sequencing the virus, which is extraordinary. They have set up manufacturing zones around the world to supply different parts of the world with COVID vaccines as soon as possible. To put it bluntly, we are talking about billions of people. It is on a scale that we have never seen before.

Different countries have taken different regulatory decisions at different times and have struck different agreements with companies on the supply of COVID vaccines, so scale-up will be at a slightly different pace in different parts of the world. It would be unfortunate if we fell into a situation where politicians anywhere in the world fell into slightly emotional rhetoric and policies that interfered with supply chains. Apologies for the long answer.

Lord Carter of Coles: Thank you for that.

Emlyn Samuel: From a patient perspective, clearly the one-year grace period is good to try to minimise any disruption that may otherwise have occurred in patients' treatment. I support Richard's call for clarity as quickly as possible on how it will all work in the future.

As regards the research elements, we have heard concerns from our research community that the uncertainty may discourage researchers from working in Northern Ireland to set up new trials. We do not want that to happen. We want the trials to happen where it is best for them to happen, and Northern Ireland is a key part of that. Clarity as quickly as possible about how the arrangements will work in the future is really important.

Kate Ling: I agree with everything that the other speakers have said. The NHS Confederation has a member in Northern Ireland: the Northern Ireland Confederation for Health and Social Care. It is concerned of course about what impact this will have on its patients. The Agreement that has been reached between the UK and the EU set up a mechanism. There is a medicinal product working group and the Northern Ireland Protocol implementation committee, which I guess will be working very hard over the next 12 months. I echo what other people have said about the importance of using every means at the Government's disposal. The working groups will include people from industry and all the relevant players, to try to reach a solution as soon as possible, because there is no time to be lost.

Fiona Loud: We have talked about clarity. We need communication as well so that patients and their families can understand that these things are being looked into, how they can participate in any relevant consultations, and so forth. Finally, in echo of something Richard said earlier, it is not just medicines but medical devices and other medical products that suppliers will potentially have to re-route. Where they may have taken something from the Republic of Ireland through Northern Ireland, or through GB, they may have to go round and come back in again through a different route. We need time for that, too.

The Duke of Montrose: I declare an interest as a farmer and associate of the BVA.

Presumably, the pharmaceutical industry deals with veterinary medicines as well. Does exactly the same thing apply to veterinary medicines as you have been describing for human medicines? The requirement to

decommission arriving medicines presumably only starts after the first year, and that is when we have to get into batch testing and QP certification.

The Chair: Richard, may I ask you to come in on the veterinary medicine side?

Dr Richard Torbett: I am not an expert on veterinary medicines or regulation, but I would be happy to take that away and come back to you.

The Duke of Montrose: Thank you.

The Chair: That would be very useful. Let us move on to an area that the committee has been concerned about in many ways, which is biosecurity generally.

Q22 **Baroness Jolly:** Do the provisions on health security co-operation allow for effective joint working to address cross-border health risks? If there are any challenges still remaining, what steps can the Government take to address them? Kate, would you start?

Kate Ling: There are some good things in the Agreement. Although the UK will no longer be a member of the ECDC, the EU organisation that oversees health security and co-operation, the Agreement has a provision for the UK to request access to the early warning response system, which is the system used to exchange intelligence to tackle serious health threats. Coronavirus would be a pretty good example of a serious health threat. That collaboration will be able to continue. Clearly, it will be mutually beneficial. The UK has always played a big part in health security and has given a lot more notifications and information than a lot of Member States have in the past. It is really good that the collaboration will continue.

Although we will not be a member of the ECDC, the agreement envisages a memorandum of understanding between the UK and the EU, to allow continuing mutual co-operation on health security. The main message I would want to get across is about what the Government can do to ensure effective joint working in the future. The most obvious thing would be to secure a good, comprehensive, wide-ranging memorandum of understanding that preserves as many as possible of the elements of the former joint working that the EU and the UK found valuable. That would be the most practical thing that could be done. The second thing, which I think will pop up on absolutely every answer, is securing data adequacy, to allow speedy and uncomplicated transfer of data, without having to resort to alternatives to keep information flowing.

Dr Richard Torbett: I do not have a great deal to add. Ultimately, on some aspects, companies will be looking for further guidance from the MHRA as our regulator. The context for that is that the MHRA has had a phenomenal amount to do, not just in adjusting to Brexit but with what it has had to do on COVID. It is understandable that it is later than ideally we would like it to be, but we probably need a bit more guidance.

Fiona Loud: I agree with Richard about the MHRA. It has a fabulous opportunity to do that, because we all know far more about what it does because of its fantastic work on COVID. It is incredibly busy at the moment.

The key points go back to the monitoring of how it will work. We need to look out for unexpected consequences as we go through, because we do not quite yet know how it will work out. We need to communicate as clearly as possible with people about how they can get involved in the work. We should remember that we have some fabulous real-world data that is really useful, for example, for people with rare diseases. We will never have enough people from a single country to be able to address those issues, to do the trials and collect information on them. I would like the committee to bear in mind the opportunity to keep improving care for people with rare diseases by using the data we already have, as well as collecting new data.

Baroness Jolly: Emlyn?

Emlyn Samuel: I have nothing further to add on this one.

The Chair: It is good to see an area where pragmatism and the good of the human race has perhaps trumped some of the theology that both sides have around Brexit. Let us hope that progress continues. We will move on to the research side.

Q23 **Lord Giddens:** Thank you, witnesses, for your answers so far, which I have learned a lot from. A great deal of medical research these days, as has been said, is collaborative across borders. How far are conditions in place to allow UK and EU researchers to co-operate on clinical trials and other research? Emlyn, would you start?

Emlyn Samuel: I will break it down into immediate short-term barriers and long-term considerations. In the short term, the UK is obviously now a third country, but we are working to the same set of regulations, because those regulations have not fundamentally changed yet.

Clinical trial leads in the UK, particularly those who are running trials that cross the EU, have put in place the right mechanisms to try to ensure that there is minimal disruption to the trials that are running now. That includes amending their contracts to ensure that data can continue to flow, hence the importance of the data adequacy agreement. They have had to set up legal representation in EU Member States to ensure that they abide by the regulations from the EU's perspective. There are all the mitigations we have talked about already as regards the supply chain for products being tested in those trials. Ultimately, it has all led to a considerably increased administrative burden on trial leads and researchers. Those things have been put in place. A lot of guidance came out to ensure that there was minimal disruption, and we are monitoring the situation very closely.

When it comes to setting up new trials, there are now more short-term barriers. One of those in particular comes back to the point about

recognition of sponsors. If you have a trial that is led from the UK but needs to recruit patients across the EU, at the moment the UK sponsor will have to set up legal representation in the EU. The way it works is that, if there is an EU-led trial that the UK is part of, we do not require that process. There is an additional barrier for UK researchers in setting up such trials and there is an associated cost. That will particularly impact on academically led trials. Universities that hold those sponsorships have to invest money to set up processes to ensure that they can continue to collaborate.

I will not labour the data point, but it is absolutely crucial that a data adequacy agreement is put in place to ensure that the data flows for clinical trials can continue. As regards the sponsorship issue, we would really like to see mutual recognition. We would like that taken forward as quickly as possible, through the working group, because we see that as a barrier to appetite and perception of the UK as a collaborative partner.

In the long term, the UK, as I said, is outside the EMA's regulatory processes for clinical trials. A new clinical trial regulation is coming into force, I think in 2022, so relatively soon. The UK played a key role in the development of that regulation. We think it is very beneficial. It will streamline processes of approval, and, essentially, make it easier to collaborate across Europe on clinical trial set-up and delivery. Unfortunately, we are now going to be on the outside of that regulatory system.

As the UK sets its course for its new regulatory framework, we encourage the Government to consider carefully how we can co-operate closely with the EMA on the new regulatory process. There is a balance to strike in our regulation for the development of new medicines. We need to promote domestic innovation within the UK and balance that with our ability and need to collaborate internationally, where we need to, particularly on areas of rare disease and childhood conditions, where we simply do not have the number of patients. That will be high on our agenda going forward.

The last element, which we might come on to, is about the mobility of researchers to collaborate. The Agreement provides for a 90-day visa-free waiver, including for research purposes. That is good because it will support short-term collaborations on clinical trials, for example. However, many researchers who come to the UK are originally from the EU and, now that they will have to go through an immigration system that is relatively costly in comparison with other countries, we are concerned about perception of the UK as a destination for international talent. That will also be high on the agenda of our research community in the coming months.

Lord Giddens: Very briefly, are there any specific problems that face university-based research as regards personnel? I am talking about academic medical research.

Emlyn Samuel: Could you repeat that?

Lord Giddens: Are there any specific problems facing academic medical research that you could single out very quickly, as contrasted to more practical research?

Emlyn Samuel: The issue of sponsorship is potentially more impactful for the academic sector. It is likely that larger companies will have sites in the EU already and will be able to transfer their legal status, whereas academic sponsors in the UK have not had that previously. There is a new process and new expense for them to set those things up. That is one area where the agreement disproportionately impacts on the academic setting.

Fiona Loud: I absolutely agree with all the detail that Emlyn has just given. We look to the Government to support research in this country so that patients are able to move forwards rather than backwards without any of the barriers Emlyn has just talked about. We have seen how we can do that with COVID. We need to look forward as well, appreciating what we can do to overcome the barriers, and to ensure that patients in the UK continue to benefit.

Dr Richard Torbett: Emlyn has given you such a brilliant answer that I do not have a huge amount to add, but I would like to emphasise one thing that he said. On the regulatory side of things, the UK and the EU are starting from a very close place. There is a fine line to tread on where we go from here. There are clearly very healthy ambitions for the MHRA to compete and be as attractive as possible for the UK. The trick will be whether we can pull that off in a way that keeps to international standards and leads to other regulators following us. If we diverge for the sake of it and go it completely alone, that will not be helpful. We want constructive competition that enhances collaboration, not destructive competition.

Kate Ling: The only thing I want to add is about the workforce. The point was just made about additional barriers for the academic workforce with the new immigration system. Academic researchers will not benefit, for example, from the exemption from the immigration health surcharge that health and social care workers will benefit from.

The Chair: Sorry, Kate, may I intervene? We will come on to workforce in the next question, so perhaps you could keep your powder dry until then, rather than mix them up. Is that okay with you?

Kate Ling: I was just going to make one particular positive suggestion.

The Chair: Please do.

Kate Ling: The Government could help by reviewing the cost of the immigration system, which is higher than for a lot of other leading scientific nations. That is a positive point I wanted to get in as something practical that the Government could do to address that.

Lord Giddens: I would like to follow up, but we are a bit short of time.

The Chair: I am sorry I interrupted you, Kate. Thank you for making that final point. Let us move on to workforce issues.

Q24 **Baroness Bryan of Partick:** My question is directed specifically to Kate, but if others want to add to her answer we would be pleased to hear it. Kate, in your first response, you raised your relief and concerns over the mutual recognition of healthcare qualifications, and you mentioned your concerns about the impact on social care of the new points-based immigration system. What is the combined impact on healthcare in the UK of the loss of mutual recognition of professional qualifications and the UK's new points-based immigration system?

Kate Ling: I will keep it very short on the question of qualifications because that is not such a big problem. The UK healthcare regulators will continue to recognise qualifications obtained in the EEA for two years from 1 January, so there will be no significant impact on incoming healthcare professionals for the immediate future. As far as inwards migration is concerned, recognition of qualifications is not really an issue.

There are issues for outgoing professionals who have UK qualifications, because the Agreement does not contain a provision for reciprocity. It contains provisions for a possible framework for mutual recognition, but there is nothing concrete. It will therefore be up to each EEA country to decide how they process applicants from UK-qualified professions to join their register. I am aware of the shortness of time, so I think I can follow that up in the written submission we will send. There are certain groups of people who will be specifically affected, but I do not think recognition of professional qualifications will be a big issue, certainly not from the point of incomers in the short term.

The thing we are really concerned about, and the point I would very much like to get over today, is the new UK points-based immigration system, which particularly affects social care. I made a point right at the start about the interdependency of health and social care. The fragility of the social care system has a knock-on effect on the NHS, and that has been brutally demonstrated during COVID. You can build field hospitals more or less overnight, but you cannot magic up the staff to fill them.

As far as existing employees are concerned, in the health, social care or any other sector, for EU citizens who were already in the UK before 1 January this year, including those working in health and social care, there is no change in employment status. They are protected by the Withdrawal Agreement between the UK and the EU. They and their family members will enjoy the same rights as before. There is no problem as far as existing staff are concerned.

The only difference, as you will be aware, is that they have until 30 June this year to apply for settled or pre-settled status for the right to stay in the EU. The Government have publicised the scheme widely. NHS employers, trade unions and professional bodies have done everything that we can to support the messaging and to ensure that all eligible staff apply. The feedback has been good. There are bound to be a few blips,

and there will be some people who get caught out, but, by and large, we are pretty okay with that.

The health and social care sector in the UK suffers from an enormous shortage, and unless there is significant additional recruitment and retention the situation is pretty alarming. As you know, the Government announced a target of recruiting an additional 50,000 nurses in England over the next five years. A very substantial proportion of that target would rely on inward migration. Clearly, the COVID situation and the restrictions on international travel will not help that.

As far as NHS staff and the new immigration system are concerned, although freedom of movement between the UK and the EU has ended, nearly all professional healthcare workers will meet the points-based entry criteria for a visa. They will be able to get a visa and, as healthcare workers, they will benefit from fast-track entry, reduced fees and exemption from the immigration health surcharge. COVID apart, the immigration system should not, we hope, dramatically impede the supply of international healthcare professionals to the NHS.

It is a different story with social care. Front-line care workers do not qualify under the new points-based immigration system. They do not qualify for visas to enter the UK because they do not earn enough and they do not have high enough qualifications. There is severe concern about the impact of the new system and the knock-on pressures on the NHS. The figures are pretty stark. The Migration Advisory Committee highlighted them in its recent report. The NHS Confederation was part of the Cavendish Coalition, which gave evidence to the Migration Advisory Committee. The estimate was that there is a gap of about 112,000 care staff. That is pretty alarming. There is no difference whether people come from the EEA or wider afield. Either way, they would be very unlikely to qualify for a visa under the new system. The only way to make up that shortfall is from the domestic workforce.

Baroness Bryan of Partick: I would love to come back, but in view of the time thank you very much. I will leave it there, Chair, to give a chance for last question.

The Chair: Kate, thank you very much for making very clear the divide between social care and the NHS. That is an important point that the committee will take forward. I hand over finally to Lord Cameron.

Q25 **Lord Cameron of Dillington:** Mine is a sweep-up sort of question. We have the Minister coming to see us in a few minutes. Apart from all the issues you have told us about already, and I have made extensive notes, is there anything else you want us to tell him or ask him in relation to this? My second question is perhaps easier to answer. What is the one issue concerning the Agreement that you want him to focus on over the next three or four months?

The Chair: Bullet point answers, please.

Lord Cameron of Dillington: You are only allowed one issue.

Kate Ling: My one issue is obviously the workforce and what the Government can practically do. The Government have said that they will review the impact of ending freedom of movement on the social care sector. I urge them not only to review the situation but to have the boldness and the wisdom, or perhaps we should say the flexibility and pragmatism, to come forward with solutions. That could involve flexibility and discretion and possibly making changes to the immigration system.

Fiona Loud: Of the many issues I could mention, the one I shall go for is resilience of supply lines. Patients have spoken to us about that consistently over time. We know they can be fragile. We have seen some of that happening with COVID as well, so it is not just a Brexit issue. We need to look out for all the barriers that we have discussed in so much detail around mutual recognition, batch testing, and getting things to Northern Ireland. These things need to be monitored now and over the next couple of years so that patients do not miss out.

Dr Richard Torbett: Clarity on Northern Ireland and batch testing. I know it is two.

Emlyn Samuel: To cover off something else, I would wrap up a review of the collective barriers that have been created to our ability to collaborate on research with our EU partners and address those.

Lord Cameron of Dillington: Very good answers and very quick, thank you.

The Chair: That brings our session to an end. I thank our panel members, Kate, Fiona, Richard and Emlyn, for such an informative session. I found it really interesting, and I certainly found out a great deal more both on detail and on major issues. Thank you for arming us for our session with the Minister and his senior civil servants. It is greatly appreciated. Please send any further information you wish to our clerk, Jennifer Mills.