UK TRADE & BUSINESS COMMISSION

Closed Session & Live Evidence Session: Regulatory Approaches: Pharmaceuticals, Medicines & Chemicals

Thursday 2nd December 2021

09:45am - 12:00pm

Chaired by Dr Philippa Whitford MP

CLOSED Session 9.45am-10.00am [15 MINS] - Commissioners Only

1. Approval of Minutes and Transcript from the session on Services: The Lion's Share of the Economy (including People, Talent & Skills)
2. AOB

PUBLIC Evidence Session (Two Panels), Commissioners and Witnesses

Panel 1: 10.00am-11.00am [60 MINS]
The challenges for pharmaceutical research: from benchwork through to patients

Witnesses:

Emily Crossley, Co-founder and CEO, Duchenne UK
Mark Dayan, Brexit Programme Lead and Head of Public Affairs, Nuffield Trust
Laura Williams, Europe & Global Affairs Manager, Cancer Research UK

Panel 2: 11.00am - 12.00pm [60 MINS]
What is regulation, and what does the future hold for it going forwards?

Witnesses:
Anton Spisak, Tony Blair Institute for Global Change
Kate Ling, Senior European Policy Manager, NHS Confederation
Michael Warhust, Executive Director, CHEM Trust

Philippa Whitford MP

So, we're looking in detail at the impact of leaving the EU both on medical research but also on the regulation and licensing of pharmaceuticals and chemicals. We will have one session for the next hour and then we will change to a different panel. So, to this panel if I could ask our three witnesses to just introduce themselves and the organisations that they represent. If I could remind everyone to remain on mute when you're not speaking and if I could ask Commissioners to target their question to the first witness and ask our other witnesses to please contribute as briefly as possible additional information rather than that we spend too much time agreeing with each other. So, if I could start asking you Emily to go first.

Emily Crossley

Thank you, my name is Emily Crossley and I'm the Co-Founder and CEO of Duchenne UK. I am here today as a mother whose son was diagnosed with a terminal chronic disease, Duchenne muscular dystrophy, when he was just three and a half. The doctors told me he would be in a wheelchair by the age of eight, he'd be completely paralysed in his mid-teens in what should be the prime years of his life and that he would be dead by his early 20s. But in that moment, I did have a choice to be defined by Duchenne muscular dystrophy or be defined by my response to it. And my response and my instinct as a mother was to fight, so I set up Duchenne UK with my Co-Founder Alex Johnson, and in 14 years, in ten years sorry we've spent more than £14 million. We fund clinical trials in the UK and abroad, we won an award for international collaboration from Eurordis, and we have seeded and funded trials that have then benefited from Horizon Europe funding, so I thank you for inviting me today to give evidence.

Philippa Whitford MP

You're very welcome. If we come to you next Mark.

Mark Dayan

Sorry I was on mute there. Hello everyone, I'm Mark, I am Head of the Brexit and Trade Programme of the Nuffield Trust which is an impartial thinktank that studies health and social care. I've been leading our various research projects on the effect of Brexit on different things that impact mostly the NHS and to some extent social care for the last five years. I'd like to apologise if my voice is a little bit raspy today, I've got some sort of cold, I've been tested and it's not Covid but my apologies in advance if I start cracking up a bit.

Philippa Whitford MP

OK thanks very much. And to yourself Laura.

Laura Williams

Hi, I'm Laura Williams, I'm Europe and Global Affairs Manager in the Policy Department at Cancer Research UK. CRUK is the world's largest cancer charity dedicated to saving lives through research. Last year we committed £388 million towards cancer research projects that will run up to five years. Our ambition in the UK is to see three and four people survive cancer for ten years or more by 2034. We have a thriving research network at around 90 labs and institutions in more than 40 towns and cities across the UK. We support the work of other 4,000 scientists, doctors, and nurses.

Philippa Whitford MP

OK thank you all very much. If we just, I'm going to start with the first question, I'm going to start with yourselves Mark and then Emily and Laura can add into that. Obviously, we've seen the UK's involvement in Horizon Europe, delayed because of wider disagreements let's just say between the UK and the EU and we've also seen the overseas aid funding to UK research and innovation halved in the recent ODA cuts. Can you just describe to us from your own points of view how you see it impacting on research funding for projects, but also on collaboration both with EU colleagues and the wider international research fields. Starting with yourself Mark.

Mark Dayan

Thank you. So, I should start by saying I don't feel I'm greatly across the implications of the ODA cuts for this area, I can speak more of the Horizon Europe delay and the effects that has. I mean I think it's important to see this primarily just as you say as a problem for collaboration and inclusion of UK science rather than funding. While the UK could I think replicate that level of funding internally the issue is non-inclusion in the projects in Horizon Europe and a greatly diminished capacity to lead them and I think that is a problem because quite a lot of the flagship life sciences projects that we've seen in the past decade happened under Horizon Europe's predecessor, many of the most significant ones are aspiring to get funding from Horizon Europe and if the UK isn't included in that then that's a pretty serious problem I think in terms of our ability to play a role in what you might see as some of the most promising, or I don't want to say something like top tier but certainly some of the biggest impact and the most widely watched life science initiatives.

I think it's also worth saying that there is pretty good evidence that the uncertainty per se has shifted decisions around funding and inclusion. So if you look at even the last few years of Horizon 2020 which is the old EU sciences funding programme, there was quite a drop off in UK inclusion post the actual EU referendum vote in about 2016, even though nothing had technically changed I think it's probably fair to infer that that reflects concerns around the UK's future status and possibly to some extent concerns around the ability of professionals to move across borders as well. So yes, I think it's a significant problem.

Philippa Whitford MP

Well certainly obviously my background is breast cancer and involved in breast cancer research and I certainly am aware of colleagues who were asked to no longer be the principal investigator, even of projects that they had instigated and as you say a lot of the very top-level research if you like is international, it does involve collaboration. If I can come to yourself next Emily, what have you found or observed in your sphere?

Emily Crossley

Well to start with the comment that rare diseases really require cross-border collaboration because of the very nature of them there are only small patient numbers in each country, and I think that's why the UK has been so engaged in Duchenne research, both globally and in the UK. I welcome the fact that the Government will cover the first waves [ph 0:07:00.8] of Horizon calls but really this short-term measure does nothing to give certainty and in the world of drug development certainty is king and nervousness and delays do not create the dynamic environment that we need for drug development. I would say the effects of leaving the EU were, some were immediately ending of freedom of movement but …

Philippa Whitford MP

Emily if I can just cut in on you, we will, there are questions on all those threads to come so rather than we cover all of them, I mean this is just this change if you like in the framework that we were part of that involved both funding and the ability to collaborate very easily, so particularly picking up Mark's comment about collaboration is obviously your issue about recruiting the numbers.

Emily Crossley

Yes, and there has definitely been a cultural shift within the rare disease space about the UK not being central to Europe now. Covid has obviously slightly muddied the waters, but I think it's this uncertainty that is creating real tension and concern about collaboration going forward which is devastating for a rare disease like Duchenne muscular dystrophy.

Philippa Whitford MP

OK and coming to yourself Laura obviously cancer research of course the kind of sphere that I was more involved in myself, what have you seen already or what are your concerns going forward?

Laura Williams

Yes, so 32% of CRUK funded clinical trials involve an EU member state, so yes, we're interested in the kind of European policy air space as you might call it, but actually the UK's relationship with the EU is very much core business for us in terms of our clinical trials portfolio. So, we're running about 145 trials at the moment, so right now around 45 to 50 CRUK funded trials involve at least one EU member state. I don't pretend that our only research partnerships are with EU countries,

we do work across the globe, and we've got huge projects, grand challenges and so on but we are starting to hear about increased bureaucracy around clinical trials and we just feel really strongly we've got to try and reduce that as much as possible. This is why the UK was so involved in harmonising those research regulations that led to the EU clinical trial regulation. We're just always so conscious that people affected by cancer at the heart of what we do, and we surveyed them, obviously they felt that cross-border trials should operate as easily as they had done before, 99% of them of course they said that. I think what we really need to see are some long-term agreements to ensure the smoothest possible access to medicines and medical devices including those used in clinical trials. So quite often we'll be in conversations about standard access to medicines which is absolutely crucial but of course we always have to say and trials as well. It is more expensive and bureaucratic to run trials with an EU based sponsor now, so that obviously is of concern, we want to get some of these longer-term agreements in place to make it easier and less bureaucratic. And I echo the calls around Horizon as well and I don't need to labour that point, I would just say that the EU at the moment has this very welcome particular focus on cancer at the moment, it's got this huge pot with the EU cancer mission, it's got its first ever EU cancer plan so you know, given that the UK tends to excel in these pan-European initiatives and generally you'll hear UK voices at every kind of EU cancer related event, yeah I won't labour the point but collaboration, yeah.

Philippa Whitford MP

Just to come back to yourself Mark and to give you a heads up to unmute, obviously part of if we are either not in Horizon Europe or if it takes a long time, I mean we're even seeing Switzerland not expecting to get back into Horizon Europe for two years, so even that kind of delay as Emily talks about creates uncertainty, but how big a problem would it be if we do get involvement but we are not able to drive what the themes are, because obviously that is something that is agreed within the EU. Laura was talking about the cancer strategy and a cancer focus; how big an issue is it for UK researchers that we won't get to say this is the next thing we're looking at?

Mark Dayan

That's a good question. I mean at the moment that almost feels like a bit of a luxury to be asking because as you say we are so caught up in the question of participation or not. And I think it's good that you point to the example of Switzerland because I think that demonstrates that the EU does have quite a track record of using access to these programmes in their various guises as a kind of lever in negotiations with countries as different types of agreements with. And so, my concern would be that at least to some extent the uncertainty will be a fairly permanent feature. I mean in terms of the UK's decisions about where Horizon Europe focuses, I think in an ideal world it would be good to have more of an input on that, but there is perhaps also a sense in which areas that are de-emphasised by Horizon Europe, we could I think and should be looking at other options which we could maybe discuss for international collaborations to look at some of those, in a sense …

Philippa Whitford MP

What would be your suggestions?

Mark Dayan

I think Cancer Research UK among others have suggested the UK could look at seeing up other forms of internationally collaborative science funding. I think it is fair to say as well that the sheer size of Horizon Europe means that it is present in a very large range of areas, I wouldn't say that the priorities as I understand them are necessarily particularly contrary to UK priorities, though other people may differ on that. It probably will be a reality that the direction will tend to be somewhat less well aligned to particular research strengths that the UK has, than if we were within it.

Philippa Whitford MP

OK. Thank you very much to all three of you. If we move now to Hilary Benn with his questions, thank you.

Hilary Benn MP

Philippa thanks very much indeed. The Government has just opened a consultation process on medical devices which is very interesting, I suppose the question I wanted to ask is what does that tell us about what the Government is trying to achieve and I suppose in putting that question if I could start with you Mark, is it that the existing EU regulatory system that we have been part of is regarded as being too slow, too cautious, preventing new devices from being developed, because it would be hard to say it's been an issue of controversy amongst the general public but maybe in the medical devices world it has, and I'd be really interested in how you read this. Mark.

Mark Dayan

That's a great question. So, I'll give you a slightly longer answer here but I think it's worth going back to the old EU regulatory system which the EU had until last, well until May of this year. That I think it's fair to say was not generally regarded to be a system which was slow and non-responsive, it was usually quite the opposite, it was regarded to be a system that was very fast, quite closely aligned with the interests of companies and occasionally threw up some pretty serious safety concerns. The EU has reformed that system in May of this year under its new medical devices regulation and that will expand to other types of devices next May. Now, this means that essentially the UK has been left running the old version of EU regulations because the change happened after we left the single market, so a system which I think probably the clearest area of difference is it doesn't involve as much surveillance of medical devices after the point at which they're sold, as other regulatory systems do. So, if you like the UK's starting position was that it had a regulatory system which in theory wasn't that demanding compared to some others but left some things to be desired in terms of safety. The consultation signals by and large an intention I think it's fair to say to realign the UK with the European Union, so to mimic the EU's increased emphasis on post-market surveillance, that is to say manufacturers doing regular

updates on what's been happening with their devices, putting a unique identifier on each one so that it could be traced, other procedures like that.

A couple of things to be aware of there I think are that just because we align with the EU doesn't mean that it restores mutual recognition with the EU, so there'll still be that degree of a barrier specially to shifting a medical device from the UK to the EU because it won't recognise the UK system even if it's highly similar. In the interim as well the UK has actually been recognising European conformity assessments, so the CE marks that you get on various products including medical devices, the UK has been accepting the EU's ones of those and the proposals also indicate that it may continue to have a sort of fast-tracked process to recognise what other countries do. So that I would say is sort of 80% of the story which is that the consultation in very broad-brush terms signals the UK trying to sort of move up in terms of at least issues like safety to realign itself with the EU has moved too.

There is also a bit in the consultation which is not very fleshed out about what it calls new routes to market and the implication here is that for certain products for rare diseases or highly innovative products the UK would introduce a new route where you can actually put it on the market without having a UK CA mark which is the approval stamp that would be our equivalent to the CE mark and monitor it closely to essentially see how it went. I think the intention there my guess would be is to give the UK still some kind of reason to encourage a company to launch their product early here, which otherwise they don't really have because why would you introduce it first in the EU and rely on our accelerated approvals to get it approved in the UK.

Hilary Benn MP

That is a really helpful and interesting answer Mark because I think it's the first example we've had on the Commission where the Government's intention appears to be to align more with the current EU regulation rather than moving away. Now, you've said that we are in effect saying yeah, we'll recognise the CE marks so devices from Germany and France can come in here and can be used, but you referred to difficulties involved in getting devices developed in the UK being recognised by the EU. Is there anything more that needs to be done to facilitate that or is it a question of going through a regulatory approval, I don't know what the testing arrangements are for the product, do you have to have a branch in the EU, because we've come across this in lots of other areas. What is needed to make it easier for stuff developed here to be sold and used in the European Union?

Mark Dayan

That's a really good point and I think I may have over-simplified there because it's not necessarily that it's harder for a UK firm to get their product approved in Europe, it's just that if they get it approved in the UK first that won't really help. So, if they do want to sell it in both the UK and Europe, once we stop recognising CE marks automatically because at the moment, they can just get it approved in Europe, it's all they need, they really don't need to worry about the UK side. But the policy is that at some point the UK will start requiring its own mark instead of just accepting the EU one. Even then I think because it has accelerated approval for things approved elsewhere suggests in this consultation, the incentive will still be very strong to get your product approved

first in the EU. And that, you know, there are probably down sides to that in terms of there will be a temptation to invest to some extent where you get your approvals done, possibly a bigger issue is it implies that the EU will typically get it first.

It is worth saying actually that that to some extent has already been the experience between the USA and the EU, so until the change that the EU brought in quite recently, the USA had a more demanding system for medical devices regulation with somewhat fewer requirements at least for new and innovative products and so many American companies would actually launch their product first in the EU taking advantage of it being faster and probably more likely to say yes if we're totally honest.

Hilary Benn MP

That is really interesting. I just wondered whether Emily or Laura you wanted to add anything on this subject of medical devices and then I've got a question we'll come onto about other research opportunities outside of the EU, but would either of you like to say something on this?

Emily Crossley

I think Mark's been very comprehensive.

Hilary Benn MP

He certainly has, OK well let's, that is really helpful Mark. Can I move on then to my second question I wanted to ask? We've touched on in answer to Philippa's opening question what the impact of all of this is going to be on international research collaboration, does Brexit give the Government more opportunities for research cooperation outside of the EU, bearing in mind as you've all said research is a very international activity already. I don't know, could I come to you Emily on that, particularly on you know rare diseases that you've got a very close interest in.

Emily Crossley

Well, yes there are frameworks for research globally outside the EU, but I just want to make the point from the patient perspective that all of this causes delays, where before we had a frictionless environment that was conducive to innovation and collaboration, we now have a situation where we have to start from scratch or start from a different position. For the patient this is devastating because a delay can mean life and death, you know for my son a delay to a clinical trial can mean him never walking again and being able to walk for the next ten years. So, I just want us to remember that when we talk about delays this is actually meaningful potentially life or death situations for patients which is why having to relook at the environment and recreate new agreements and collaborations is challenging because what we had before was working.

Hilary Benn MP

OK, thank you. Laura.

Laura Williams

Yeah, so I think our scientists yeah I mean they continue to work with partners beyond Europe and every time I speak to one of our scientists I do play Devil's Advocate a little bit and ask them OK so why not [inaudible 0:23:10.4] further afield, so yesterday I spoke to somebody leading a radiotherapy trial and that's got partners in the US, Australia, Hong Kong and she just described the process of sorting out a trial including France and Germany and the arrangement of that depended hugely on the goodwill of our European partners. She was originally supposed to include eight to ten European partners but the sheer cost, the amount of work her legal team are having to do meant that they in the end they had to focus on France and Germany where it would be the most straightforward. I posed the question and she just said look maybe of course we're looking globally and of course that's important, and she said but what a shame, what a shame to have that as a solution because we need Europe and the Rest of the World and that's the point is we need both. And someone else I spoke to yesterday again in radiotherapy and other trials, she talked about the more that we understand different cancer types and as we look in more detail at molecular subtypes, of course the fewer people there are in any one country with that subtype of cancer, you know thankfully, but of course that means more international trials, so a number of studies in stereotactic radiotherapy being discussed at the moment, they've got to be multi-national to recruit enough patients. So yes, beyond our EU friends but as she said look, you know we've got UK research leaders in all these European groups, she just said why reinvent the wheel, you know why start again, they want both.

And something I think I would want to point to as well is that while we're sort of thinking broadly we've also got to consider the impact too on Northern Ireland, it's so, so vital that people in Northern Ireland have the same access to opportunities for trials and medicines as people in Great Britain and they are feeling the ill-effect to be honest on trials in Northern Ireland, but we're monitoring that.

Hilary Benn MP

Yeah, well we're going to come onto that later. Just finally and very quickly, what are the lessons, thinking about the speed at which new devices, new medicines can be brought to patients who may benefit from, what are the lessons to learn from the speed with which the Covid vaccines were developed? Because I mean I've heard it argued well a lot of money was put in and clearly a huge amount was, but also there was an ability to not to cut any corners on the safety testing at all, but to make it all happen much faster than happens with lots of other drug development. And is there anything that we can do in the way we run things in future to make those things quicker or is Covid so global and so unique and has had so much money and attention put in it that that is in practice unlikely to happen for other medical trials. I don't know, Mark does you want to just come in on that? Just quickly before I run out of time.

Mark Dayan

Yes, so that's a really good question, I think you're right to say that we probably can't treat Covid vaccines as a kind of good example in the sense of what it would be like for all medicines because there was so much money and so much regulatory kind of attention committed to them. But the model on the sort of regulatory end, the model that was used to approve them both sort of fastest of all within Europe in the UK, but also by the European Medicines Agency was a rolling review where essentially you don't necessarily do the usual approach of having the structure of a clinical trial as traditionally proposed and waiting for the data at the end, you sort of update it as you go along. I think I'm right in describing that, Laura may well know more than me. And there is interest in that I think and other models of getting approvals done faster basically by not using the traditionally structured process in the hope that the higher level of information that's generated throughout the testing and use of a product now can enable you to take those decisions sooner. I think it does tend to be something that's set aside for a minority of high impact products where you can spend the amount of regulatory time on them to make sure this can happen safely, but there's probably a connection between that and the intended new route for medical devices which is in some ways analogous in terms of being about a faster version of the existing process relying on more intensive scrutiny of data that sort of comes out as you got along, although the regulatory systems are quite different.

Hilary Benn MP

That is really helpful, thank you so much. Back to you Philippa.

Philippa Whitford MP

Thanks very much Hilary. And we're now coming to Andrew Ballheimer for his questions.

Andrew Ballheimer

Thank you very much and thank you to each of the panellists as well, it's clearly important stuff here. As we look ahead you know how important is it that the UK follows the key EU regulations in areas like the clinical trials and data protection, also interested in terms of the impact of being outside of the EMA's clinical trials regulation and information system. And how likely is it that the UK is able to obtain a data adequacy agreement to help in terms of the collaboration on trials. Emily.

Emily Crossley

I think it's fundamental. We're hearing of companies looking at new impact measures and going to the EMA for advice rather than the MHRA as they're yet to have confidence in coming to the UK without the EU. The UK is a small market and companies need to look at the FDA and the EMA and significant inconsistencies won't help. In rare diseases trials tend to be global so a single trial

design for instance needs to be approvable in multiple countries. Just to touch on the Northern Ireland agreement, we're concerned that this means that the UK regulators will be restricted in licensing approval and new medicines in any form other than to rubber stamp approvals done at the EMA because no such regulatory changes exist to make it more streamlined. And I think we need to go faster and build on expert clinical centres with informed and involved patient organisations and faster decision making to enable the UK to be one of the first countries to open sites in a trial. And just one final point, access to treatments after trials is a huge consideration for companies, I know NICE are undergoing a methods review now but I think we need to not forget the reimbursement aspect of this in making sure that the UK continues to be an attractive place for innovation to thrive and for clinical trials to be conducted.

Andrew Ballheimer

Thank you very much, Laura also interested on your thoughts and also insights into how open are the EMA to our access?

Laura Williams

Yeah, thank you. So CRUK was very involved with the EU clinical trials legislation before it passed 2014, I think. Harmonising research of course does bring many benefits. I think now it's about ensuring the regulations are compatible enough, so we don't end up with hugely increased bureaucracy over and above what we're already seeing with the existing trade and cooperation agreement framework. Certainly data adequacy, that was really important to us and the whole health research community because being able to share data in an appropriate way with patient consent, it's at the heart of the research progress that we all want to see, so we've got to make sure that these future regulatory frameworks are compatible enough to ensure that health data can flow between research partners, so we are focusing at the moment on the UK's new clinical trial regulations, you'd expect. In terms of the [inaudible 0:31:07.8], the trials information system to be honest we don't know what impact that's going to have at the moment, so I asked a senior leader recently and she just said to be honest I've been so busy setting up Covid trials as well as cancer trials I just haven't had time to think about it. Yes, it probably will have an impact, until they're actually living the difference in practice, she didn't really want to predict the impact, but to be honest I think it's a good question to ask again in about 12 months' time I think we'll have a lot more evidence.

One more thing if I may is just it's also about making sure, and I mean Dr Whitford knows far more than I do about this, is that the NHS is a really great environment for doing clinical research, we brought out a report recently called 'Creating Time For Research' which looked at the barriers and the opportunities but if we can make sure that the NHS is as well set up as possible you know that will do good things.

Andrew Ballheimer

And Mark.

Mark Dayan

Nothing to add to those which were all great points. All I would say and I think this mainly applies to regulatory steps a bit further down the chain of getting a medicines laboratory for patients, is that I do sometimes think we almost put too much faith in alignment, we need to recognise that when we're not in the single market, you know there's a limited amount you can achieve by having rules that are exactly the same as the EU's because your regulatory outcomes will still not be accepted by the EU, so without that mutual recognition there's always going to be friction even if alignment is almost perfect. Data is quite a different case because the adequacy system does exist for the EU to accept that other countries have aligned regulations and treat them in that way. But for other areas on its own alignment will help create fewer barriers but it doesn't eliminate them because they are still two systems being applied in two territories that you have to go through twice even if they're the same.

Andrew Ballheimer

Are there pressures emanating from the researchers, in the EU and over here for that sort of alignment or acceptance if nothing else, or is it just in the hands of the authorities/the politicians?

Mark Dayan

I wouldn't know that well on the research side. I think in terms of the supply and medicines and devices at the moment the NHS appears to have been largely shielded from the worst of it, partly because the UK has simply continued to recognise such a wide range of EU regulatory approvals that getting things in remains quite straightforward, but that won't I think last forever.

Andrew Ballheimer

OK thank you. Moving on, sort of linked to my other question, how are the clinicians and the patients over here able to take part in research the treatment through the EMA's referenced network for rare diseases? Emily.

Emily Crossley

Well, this is a source of huge frustration to us because the European referenced network for neuromuscular disease, the ERN Euro NMD was actually established by experts in the UK who we work very closely with at the John Walton Muscular Dystrophy Research Centre in Newcastle University. The ERN has now been moved to Paris where we believe staff have been made redundant and you know the tragedy is that UK clinicians, many of whom are PIs on global trials and researchers can no longer take part. It's a huge disappointing blow [ph 0:34:42.3] for our research community because we can't effectively benefit now from something that we set up.

Andrew Ballheimer

Ironic if it wasn't awfully sad right? Laura.

Laura Williams

Yeah, I keep asking people about the European reference networks and the paediatric research community do want to make sure that they can still have the relationships, but they're sort of thinking that they'll have them outside of those very specific frameworks because they have those relationships anyway. Others not so much, I think it's quite discipline specific if that makes sense. But I'd be happy to come back to you once I've got a bit more evidence about how it's going in practice.

Andrew Ballheimer

OK thank you. Mark.

Mark Dayan

Not much really to add to that. I did find the lack of the ability to stay in European reference networks was quite a disappointing aspect of the trade and cooperation agreement. It really, I think would have been quite a, there would have been few downsides to allowing it to continue I think, but probably got caught up in wider paradigms about the sorts of things that they UK would continue to do.

Andrew Ballheimer

Thank you. Back to you Chair.

Philippa Whitford MP

OK, thanks very much Andrew. Over to you Paul Blomfield.

Paul Blomfield MP

Thank you, many thanks Philippa. I wonder if I could move to look at the sort of impact this actually has on those most directly affected, patients, and Emily you began to talk about that earlier and I wonder if you could say a little bit more about what difference patients are going to see, you talked about delays but in quicker, slower access to drugs, and how quickly those effects are going to emerge.

Emily Crossley

Well thank you for the question and I just want to start with a quick reality check that you know the EU27 represents around a quarter of global pharmaceutical sales and the UK represents under 3%, so we really need to focus our minds on making the UK the best place in the world to access trial and innovative new therapies and our concern as patients is that we are going to be put to the back of the queue, because the UK population is relatively small and the rare disease population is even smaller and so making the commercial incentive to pay for additional fees, additional regulatory review, by having to go to the MHRA outside of the EU and questionable reimbursement decisions from NICE NHS England means that it's highly unlikely for pharma to come here until other large markets have been secured. So, we really do have great concerns that there will be delays and that the UK will be at the back of the queue for clinical trials and for marketing authorisation.

I think divergence from the EMA or the FDA will only help if it makes things simpler or quicker, you know my worry is that otherwise it will just be an additional burden to companies who will prioritise the larger markets and you know as we all know drug development is incredibly complex and any additional burdens that are placed on already challenging and complex timelines are worrying for patients.

Paul Blomfield MP

Thanks very much. I think Mark has made a point very strikingly in our discussions about irrespective of alignment and a lack of divergence the absence of mutual recognition is going to cause difficulties anyway. But I wonder Laura if I could bring you in to share your perspective on the sort of patient impact?

Laura Williams

Yeah, sure. There's a few different angles actually, so in terms of access to trials you know we're starting to hear more about importing the drugs that are used in trials, so we heard from our paediatric research community about the significantly increased costs of importing and unlicensed investigational medicine that's used in the UK arm of one of our funded trials that's got a sponsor in the EU. And this is a trial for children, teenagers, young adults whose treatment stopped working or their cancer has come back. They need to have access to trials like this but the trouble is the predicated cost is significantly more for the UK arm compared to other arms of the trials in EU countries, so the sponsor wants to keep the UK in the trial, we've got expertise, you know we want to continue, it's world-leading stuff, we might have to find some more money and of course if this keeps happening then of course ultimately our clinical trials budget won't stretch as far and fewer people with cancer can take part in trials. So, we'll just have to see how it goes.

On a more positive note, in terms of getting treatment to patients more quickly, we're very interested in the impact of Project Orbis, so this is a US-led programme, at the moment it involves Australia, Canada, Great Britain, Singapore, Switzerland and Brazil, so this reviews and approves promising cancer treatments, so we are looking forward to seeing how that goes. And you know

just seeing also more broadly I suppose where the MHRA goes and I've got colleagues who obviously are feeding in and my counterpart at the Dutch Cancer Society said he's really excited to see what the MHRA does, hoping he can get a few ideas you know for getting some treatments to people more quickly. But again, you know we've got to make sure there's a solution in place for regulation so that patients in Northern Ireland can benefit from the same fast track routes to drug approval as other parts of the UK so, you know especially when promising new candidates are emerging from trials. Sorry, that's quite a lot, various angles there.

Paul Blomfield MP

No, that's extremely helpful. I'll bring you back in in a minute Emily, but I was just wondering if I could push Mark on that point you made about the MHRA, I mean obviously in the previous world that we were part of the EMA was here and centred in the UK and the MHRA played a central role in its work. What does the future look like for the MHRA now, centrally produced funding …?

Mark Dayan

Well that's a very good question and I imagine you've probably seen the reports in the Financial Times about reduction in workforce and funding at MHRA which reflects I think in part what I was talking about earlier in terms of the UK's decision to keep accepting a lot of EU regulatory steps and there's a bit of a difficult dilemma here between the kinds of things that Laura was speaking about, so the MHRA kind of innovating and looking for new and attractive ways to bring things to market, many of which require a lot of regulatory time and expertise and then there's [inaudible 0:41:47.5] of the most innovative products but for many other things just accepting the approvals of other countries might be the fastest way to get it here rather than asking companies to go through a whole separate UK process. And so that does create a bit of a difficult future for the MHRA really where it's kind of simultaneously asked to become a rubber-stamping agency and the world's most innovative regulator. But I do think there's a reason they're trying to go in that direction because it is to some extent the logical answer to that dilemma which is we try to be innovative and fast for the innovative and fast drugs, for the rest we simply minimise the barriers.

I just want to add as well, it might be that we'll cover this in later questions, we are talking here about things that are sort of nearer to the lab approval end of the spectrum of getting a product to a patient than they are to the product actually gets handed to the patient end. And so far I think it's fair to say the biggest problems we've had have been at that gets to the patient end, and so we have seen very big shortages of blood tubes in this country over the summer, they are certainly not what we'd describe as an innovative product and there is certainly no problem with them being regulatorily approved, but it does seem that the barriers at the UK border probably contributed to the UK getting the worst of a global shortage which has emerged, as shortages do in various medical products from time to time. And so I think while one end of this is about medicines regulation and clinical trials regulation, there is also a wider effect that's essentially from the general pattern of how easy it is to get things in and out of the UK that will have a significant impact as well, even if it's not primarily driven by things that we might think of as being within this sector.

Paul Blomfield MP

And it's interesting you mention that as delays on things coming in because at this stage, we haven't actually put the barriers up for inward movement of goods.

Mark Dayan

Well, we haven't in terms of medicine and devices specific regulation, but we have for at least many wider customs related checks that happen at the border for everything, not specifically for medical devices. And of course, we have for people as well, I think the HGV driver situation, which is probably in a bit of a feedback loop with the difficulty of getting in and out of the UK played an important role there.

Paul Blomfield MP

I'm going to come back to some different sorts of people issues in a minute, but I think Emily you had your hand up and wanted to come in on that point.

Emily Crossley

Just to say that I agree with Mark about that tension within the MHRA of being a world leader but also you know rubber stamping. I sit on the steering group for a pilot they're running called the ILAP, the Innovative Licensing Adaptive Pathway and that has had some good uptake, but to bring it back to a case study from the field of Duchenne, we funded a phase one clinical trial of Vamorolone which is a synthetic steroid and the trial was run from the UK with the PI based in the UK and it then subsequently went on to win Horizon 2020 funding. The phase two data from that trial was very promising and you know it looks like it could be a potential treatment for Duchenne patients, but they're moving further trials to Canada unfortunately because they say they've too small and lack the resources to develop a whole new data submission for marketing authorisation for the UK now that we're no longer part of the EMA. So, I do think being outside of these regulatory structures is a barrier and you know British patients are losing out because we managed to fund that phase one study through donations from our supporters, many of whom are families with Duchenne, and now we're seeing potentially being back of the queue to access these treatments and you know it's devastating.

Paul Blomfield MP

Well thanks for that and it's a very striking point Emily. Could I just move on to look at an aspect of the people issue which is the strength of our research base here, obviously built on an international academic community, medical research community, so I just wondered what thoughts you might have on if we're not part of the European research network, what impact is that going to have on recruitment of researchers from the EU to work in the UK, what are we seeing so far and what do you anticipate? Perhaps I could start with Mark.

Mark Dayan

It's a good question, I can't claim to have actively studied that, our focus is more on the NHS itself. I mean I would imagine that it's not going to be a positive impact because one of the things that we have looked at is the trends in EU migration of doctors and nurses, both of which remain categories where it is actually very easy still to get a visa to come to the UK from the EU, but it's still a much more expensive and burdensome process than it was pre-Brexit and there has been decline even in those groups who probably can get permission if they try. So, I would suspect that there is certainly a headwind there. Exactly how severe it is I don't feel that I have the data to be sure.

Paul Blomfield MP

I mean if you've been looking at it in that wider context do you have any thoughts about what the impact of new immigration rules are going to be on recruiting young researchers?

Mark Dayan

Again, it's not my area of expertise, I would have thought that …

Paul Blomfield MP

I just wondered if there are lessons you could draw from where you had been looking in the NHS context.

Mark Dayan

Yes, so I think probably they are to some extent analogous with doctors in terms of being groups who certainly can cross the threshold to migrate to the UK under the new points-based system, but equally who are in quite a lot of global demand and could go elsewhere. And if you are a European researcher or a doctor the other places you can go there's just very little in the way of legal barriers and you also get your qualifications mutually recognised. So I would imagine there'll be a bit of a headwind but you know not to the point where it certainly hasn't stopped migration of EU doctors, I guess partly because for many English is the second language that they are most at home with and so from that perspective it may still for some at least be a viable option to move to the UK over another European country with a national language they can't use professionally. But it's certainly slowed down the rate, so I suspect that is the case for many sectors of the economy.

Paul Blomfield MP

OK thanks very much, Laura I don't know whether you can share any reflections on what impact there's been on our research base and particularly you know if we're not part of that European research network.

Laura Williams

Yeah, so I asked one of our senior scientists quite recently whether she'd seen much change this year and she said actually she hadn't, she'd seen quite a bit after the referendum result but she hadn't, she just wondered if Covid was actually a bigger factor at the moment, so I think it's a really good question to ask in about 12 months' time, we will have had you know more chance to kind of survey the community, they're so busy getting their trials up and running again after the Covid pause, but what I would say is that if we've got the best possible research environment in the UK for world class researchers at every stage of their career that will obviously do good things. We did, we co-funded a study in 2017 on the impact of collaboration and that was with other UK medical research funders and charities and that looked at kind of the value of UK medical research to EU science and health and they looked quite a lot at the research base and it showed that the UK had made a really key contribution in training early career researchers from across the EU, so in terms of people developing their skills and launching their research careers the UK was seen and known to have really high quality training experiences and have a real positive impact on people's progression, it was a really attractive destination for early career researchers. So, you know clearly, we still want to make sure we can attract the best talent and you know as I say so far, we're not hearing that lots of people have moved on in the last year, but yeah, we'll see.

Paul Blomfield MP

I mean you're clearly right in terms of the strength of the UK's research position and I guess that's why we were always such a huge net beneficiary of Horizon programmes. Emily, do you have any reflections on this?

Emily Crossley

Well I do, because we, Duchenne UK, my co-founder and I several years ago were trying to get our sons onto a clinical trial and we found out that the UK was actually turning away those trials because of a lack of capacity, so we set up a network of clinical trial sites called the DMD Hub and we've invested over £4 million now and we now have 11 sites delivering clinical trials across the UK and the number of boys on clinical trials has increased by 300 and you know we were able to weather the Covid storm and the DMD Hub played a role in this so that clinical trials for Duchenne did continue during Covid which was excellent. I do think Covid is slightly blurring the picture here, but I think it is safe to say that because of the changes in immigration rules the ability of researchers and clinicians to come to the UK is severely limited, but we know there's a shortage of research nurses and doctors, it's hard enough for them to get to the UK but from 2022 our

understanding is they'll need to do a test of competence, so that's more red tape, more barriers, more costs. Currently if we're trying to recruit doctors from the EU they need to be registered with GMC and pay fees before they even know if they have the job, and it can take three months to register and it's an expensive process for a specialist. And we have heard of the problem of people coming to the borders for interviews and being told that they need a work visa, but they can't get a work visa until they've had the interview, so I think there needs to be much more attention focused on creating clarity, because we really need doctors and nurses to run these clinical trials.

If I look at Great Ormond Street and the neuromuscular clinic where my son is seen, more than half of the consultants there come from the EU, from Italy and from other countries in the EU, and we need to keep being an attractive location for these researchers to come, because when the good people come the pharmaceutical companies come and the trials come, so I do think this is a really challenging area and I agree with the other panellists that we need to give it more time to see it through, but anecdotally we are hearing that this is a big problem.

Paul Blomfield MP

Thanks very much indeed and on that point, I'll hand back to you Philippa.

Philippa Whitford MP

Thanks very much Paul. If I could come to Aodhán thank you.

Aodhán Connolly

Good morning witnesses, thank you very much for being here. I want to, as you'll guess by the accent, ask about Northern Ireland and in particular the sort of double-edged on as far as firstly are there benefits as far as Northern Ireland is concerned about supplying GB and Europe given the dual market access and the emphasis that there is in Northern Ireland in the life sciences and medicines area, I'm thinking people like [inaudible 0:53:54.0], but on the other side as far as Laura mentioned about clinical trials, is Northern Ireland and specifically Northern Ireland patients at a disadvantage at the moment or going forward because of the status of the Northern Ireland protocol. So, I'll start with Laura if you don't mind and then Mark, please.

Laura Williams

So yes, it's something that concerns us to make sure that people do have the same opportunities in Northern Ireland, certainly we want to see agreement, we want to see long-term agreement. Talking to people yesterday in Belfast they're still trying to understand how it actually is on the ground, so I'm a bit loathed to say anything very specific because I'm not sure that we have enough evidence yet, but you know later on I'd be happy to come back and talk in a bit more detail.

I'm sorry I know that's a terribly vague answer, but I think we just want to be sure that we genuinely do have the evidence. I mean look, we've got to be hopeful and there is huge appetite to make this work is all I would say, you know. Yeah.

Aodhán Connolly

Thank you. Mark.

Mark Dayan

Yeah, it's a really good question and quite complex to answer because you have your sort of four different dimensions through which Northern Ireland can send and receive medicines and medical devices. So in a UK to Northern Ireland direction it's become harder and I think not to Northern Ireland's advantage and that's because the European Union under the Northern Ireland protocol won't allow medicines to have certain regulatory steps done in the UK for movement to Northern Ireland which is what had been happening for many, quite possibly most medicines before we left the single market. Now that's obviously the subject of pretty intensive negotiations right now, where the EU has been offering to let more of those regulatory steps happen in the UK for medicines that flow through it to Northern Ireland, which would help but probably not completely address the situation because you'd still have to follow parallel rules for those products as they went through the UK. So, in a UK to Northern Ireland importing direction not much to the advantage of Northern Ireland.

For exports from Northern Ireland there are some possible benefits actually, certainly relative to the rest of the UK, although perhaps not as many as I think some people had hoped for. So, under the UK's internal market act, products on sale in Northern Ireland can be sold elsewhere in the UK but at the same time they're actually following essentially EU rules, can be put there under EU processes which means there's no extra barrier to then export them to the rest of the … well to export them to the European Union proper either. So, there is maybe some advantage from that point of view although it's not, perhaps people might have hoped it could be because there are certain regulatory processes that you can't do in Northern Ireland and expect them to be good for the whole of the European Union as well.

In the Northern Ireland importing from the EU direction basically not much has really changed which is an advantage relative to the rest of the UK where new barriers exist. So, it's a bit of a mixed bag. I think yes in theory there are advantages compared to the rest of the UK, the problem is that actually historically Northern Ireland has been very reliant on medicines coming through, well through Great Britain essentially and that's possibly the dimension which has been worst affected by this.

Aodhán Connolly

I think that's very much where, I'm part of the Northern Ireland Business Brexit working group, that's very much where we're pushing on even that sort of can we get it from the Republic of Ireland, the Republic Ireland is the seventh most expensive place on the planet for generic medicines, six times more expensive for Brufen and Paracetamol, so yeah the talks that are

ongoing at the moment is mostly about the removal of that GB to NI friction. Emily is there anything that you want to add to any of that?

Emily Crossley

I don't have any direct information to hand but I'm happy to write to the panel afterwards with some details.

Aodhán Connolly

Thank you very much, back to you Philippa.

Philippa Whitford MP

Thanks very much. I'd like to thank our witnesses but just to wind up very quickly because we're about to run out of time, if you could give one short recommendation each to the UK Government that would help this situation that you're in. If I can start with you Mark, then Laura, then Emily. Just one.

Mark Dayan

I think looking for opportunities for regulatory and funding cooperation with other countries outside the EU should be much more of a priority.

Philippa Whitford MP

And yourself Laura.

Laura Williams

We would like to see a mutual recognition agreement with the EU so that medicines batches tested in either area will be recognised in the other and that will reduce costs and bureaucracy.

Philippa Whitford MP

Absolutely and Emily yourself.

Emily Crossley

Swift clarity on Horizon Europe funding.

Philippa Whitford MP

OK and if I can thank all three of you for coming as witnesses and for giving us such useful information for our reports and our inquiry, thanks to you all.

Laura Williams

Thanks for having us.

Philippa Whitford MP

OK and now we come to our second session, do we have our three witnesses? I'm just watching my Zoom channel changing all the time in front of me. Have we got everyone? If I can again then ask our speakers, our witnesses to this panel to remain muted when you're not speaking and if I can come to you starting with Anton and ask you all just to introduce yourselves and the organisation that you represent briefly before we kick off with questions.

Anton Spisak

Good morning, thank you very much for this kind invitation. I'm delighted to be here today with you. My name is Anton Spisak, I'm a Trade Policy Lead at the Tony Blair Institute and the primary UK Government official working on Brexit.

Philippa Whitford MP

Thank you very much, and to Kate Ling.

Kate Ling

Hello, I'm Kate Ling, I work for the NHS Confederation which is the member organisation that represents providers of NHS services in England, Wales and Northern Ireland. So, our members are primarily the NHS Trusts and I also coordinate the Brexit Health Alliance, which is if you like a cross sector, well it's across the health sector bringing together the NHS industry research organisation, patient groups, etc to look at the impact of Brexit and going forward the opportunities from trade deals with other countries.

Philippa Whitford MP

Thanks very much, and yourself Michael.

Michael Warhurst

So, my name is Michael Warhurst, I'm the Executive Director of CHEM Trust, we are a charity that works on environment and health issues around chemicals and chemicals regulation, we work a lot at EU level as well as UK level, so we are active at both levels, and we have a partner organisation in Germany as well.

Philippa Whitford MP

OK, thank you very much. If I can kick off then with the first question in this session, obviously there was a lot of discussion when after the referendum during legislation in Parliament, during the negotiations, about the impact of non-tariff barriers and obviously tariffs, so if I could start with yourself Anton, in this situation what would you say is more important from the point of view of impact on the pharmaceuticals industry, is it the potential for tariffs particularly under rules of origin, or is it the impact of what we've been talking about so far, kind of regulatory alignment and indeed recognition?

Anton Spisak

Thank you very much, I mean that is a really interesting and important question and one which I'm afraid doesn't have a very clear answer, but I'll try my best to answer it as much as I can. In terms of trades and the impact of regulation clearly regulatory compliance and regulatory requirements are one of the biggest barriers to trade, both in terms of cost but also, and this is very important, in terms of market access. But at the same time regulations and having clear regulations, clear rules of the game, can be really helpful in terms of [inaudible 1:03:01.3] trade. In the area of highly regulated goods like pharmaceuticals, chemicals, medical devices, regulatory standards are often new to the very strict market access and often to the extent that those products can demonstrate they need certain regulatory standards, they can be accepted in the importing country. So, the shape of the regulatory system is really quite crucial to trade.

In terms of your question about tariffs and non-tariff barriers which regulations would fall under, I would personally argue that as far as market access is concerned regulations are a little bit more important than tariffs because they can really facilitate access to the markets or restrict it. But in terms of cost and this really depends on very specific products that we are talking about, it is clear that non-tariff barriers can be more expensive than tariffs in many cases. If you ask me for a figure it would be very difficult to actually find one, but I can try and I've looked at some research that has tried to quantify what non-tariff barriers and regulations mean in terms of tariff equivalence, there was a piece of research done during the peak of negotiations that tried to do that, for pharmaceuticals they haven't done this but they did this for chemicals and they found out that non-tariff barriers for EU imports were equivalent to 9.1% tariff compared to 2.3% tariff which is the MFN [ph 1:04:45.2] equivalent. So, it means that you know there is a big difference potentially in terms of regulatory cost and the cost of compliance and in many cases that cost is actually higher than the tariff.

Philippa Whitford MP

OK thank you very much. If we can come to yourself Michael, then for you comment from the chemicals industry point of view.

Michael Warhurst

I think from a chemicals industry point of view, I mean I'm not an expert on chemical tariffs, obviously within the EU the UK chemical industry had no tariffs within the EU anyway, so but I think the regulations are massively important because you know we're dealing with tens of thousands of chemicals which then end up in many millions of products and to put it most simply if you produce a chemical which you want to sell in Europe you have to register it in the EU REACH database and what's happened with Brexit is you now also have to register it in the UK REACH database. So now if a company in the UK just registered in the UK REACH database it would not be able to export to the EU, so that would obviously be a significant barrier for that company.

So, I think that the point that anything that is exported to the EU must follow the EU regulations will be, will mean that companies have no choice really and it's worth saying obviously in this case the EU includes Northern Ireland, so it's only Great Britain that has a separate regulatory system.

Philippa Whitford MP

Thanks very much, and to yourself Kate.

Kate Ling

Yes, from an NHS perspective then clearly regulation is about safety, it's about protecting patients and the public, but also picking up on the point that Anton made, that it can also be a tool to, you know it can be used commercially or politically to protect or exclude products and people and to secure a commercial or political advantage. So, I think from the point of view of if you like the end user, the NHS, I would agree that yes, I think regulatory barriers are more important than tariffs to us, at least they are a bigger barrier. Medicinal products tend to be tariff free anyway, although there are still issues, I think Anton also mentioned rules of origin, but it's generally regulatory requirements that facilitate or hinder trades in those products and the sort of things I'm thinking of in this arena are things like inspection of manufacturing premises and processes, batch testing and certification of conformity with relevant standards. And the only one of those issues which was where mutual recognition was agreed in the trade and cooperation agreement was the mutual inspection of manufacturing premises, the good manufacturing practice and not having mutual recognition of batch testing is a really big issue for us.

Philippa Whitford MP

OK, thank you very much. Moving onto the next question if I can come to Stephen Farry.

Stephen Farry MP

Thanks Chair and good morning to all of our witnesses. Just building on the last question, can I maybe ask all three of you just to say a little bit more in terms of some of the costs that may arise from diversions from the European Union in terms of regulation and building on that then what sort of procedures do you think the Government should have in place to manage that divergence. And then finally could you also comment on the potential implications from the change from the CE mark to the UK CA mark for medical devices, so basically just wrap those three questions together and potentially start with Kate then Michael and then Anton.

Kate Ling

Thanks Stephen, that's actually three really big questions all wrapped up in one. I think the main risks of divergence in whatever sort of area are the, well the creation of additional regulatory barriers and for which normally, which often means duplication to be honest, so the biggest risks, I'm thinking always of course from the NHS angle, there are risks in terms of cost and there's both financial cost and human cost, and also availability of the products, medicines and medical devices. So from the point of view of cost there's the extra barriers and paperwork involved, regulation and customs which you know these costs are likely to be passed onto the end user, i.e. the NHS ultimately, and I was listening to the previous session where Mark Dayan for example mentioned things that are not specific to the health sector but things like the cost of transport and hauliers and customs checks and all of these sort of things that didn't happen basically before we left the EU. And from the point of view of human cost we're concerned about availability because suppliers simply may not want to bother, if the hassle and costs are disproportionate to their profit margin, they may just not want to bother continuing to supply certain routes and I know we're going to get onto Northern Ireland later.

So, the other thing I wanted to put in because it's not specific in any of the questions is the question of divergence when it comes to data that we're very concerned about data equivalence and divergence from EU data regulatory norms that could cause big headaches in future. We're hoping this won't happen of course. I think one of the previous witnesses in the previous session mentioned data equivalence as well, and that's very important of course across all sorts of sectors of the economy but it's also very important in health. Things like use of health research data for example.

So, from the point of view of mitigations, the really obvious one is simply not to diverge too much, or not until other supply chains are in place which will take a bit of time. There's the also obvious one about keeping extending status quo for example with Northern Ireland but that's if you like a kicking the can down the road sort of solution, but it's a pretty useful one. But the longer-term solutions, people have already mentioned a lot about particularly about mutual recognition as much as possible and particularly of batch testing of medicines. There's a mechanism in the trade and cooperation agreement, there's a medicinal products working group that has been set up, I don't think it's actually met yet but the job of that working group is to look at if you like reducing these barriers and ensuring the operation of, you know ensuring that medicinal products can continue to flow basically.

I think that's most of the most important things. I mean the other longer-term thing really is to seek as much global harmonisation as possible so that the UK's regulatory system is recognised by competent authorities internationally and not just the EU, but that's a sort of longer-term bigger thing.

Stephen Farry MP

Just on that last point Kate, to what extent is the EU likely to be the global trendsetter in terms of the norm setter for a global recognition system or to what extent can the UK be a player in that regard?

Kate Ling

I'm not sure whether either is the answer to be honest. I think that all parties recognise that, it's not really in anybody's interests to be honest to have a lot of different regulatory regimes all over the world, I wouldn't know, clearly the EU is bigger, you know in terms of the size of the market it's much bigger than the UK but then also you could say that for other major markets there's an international medical devices regulator's forum for example which brings together all the major markets including the EU, USA and China, so I think there is a trend towards if you like global convergence and that would certainly be very helpful. And previous witnesses have referred to the tension if you like between the MHRA wanting to be an innovative sort of world leading regulator, doing new and quicker and different things and at the same time wanting to, well I think the expression was rubber stamp, but needing to harmonise as much as possible with the EU just to make life easier really and to let things carry on a bit more as normal.

So, I think there was a third question, I know it was a very big one, it was about, was this about the changing …

Philippa Whitford MP

You're muted Stephen. If you're trying to speak, you're on mute.

Kate Ling

Yes, sorry, was there a third question about changing from the CE to the UK CA mark for medical devices? I should say something specific about that. Yes, there are practical issues for industry and the practical issues within the UK are about businesses wanting to have clear guidance to achieve compliance about having as long a transition period as possible, so that they've got the time to change things and to implement the guidance. And there's also a concern about the testing and certification capacity to allow companies to meet those timelines, so in other words having enough people [inaudible 1:14:24.5] bodies that can do the job because certification has to be done by third organisations. So, it's increasing the number of certificating bodies in the UK I think to meet the demand and then the other issue of course is duplication which is of course

having to meet one lot of standards for the UK market and another one for the EU market. But I'm conscious I've taken an awful lot of time and the other witnesses need to get a word in edgeways.

Stephen Farry MP

That was very comprehensive thank you very much Kate and over to Michael and then to Anton.

Michael Warhurst

Thank you. I think on the chemical regulation the point to understand really is that effective chemical regulation is very demanding, you need to gather information on tens of thousands of chemicals, you need to have an idea about uses and really nowhere in the world has yet done the job fully, but the EU system is acknowledged as the leading one in the world and it's now examining how it can improve various studies over the past few years and new proposals coming out. So you have that EU system, it has a lot of information in it and what the UK decided to do on Brexit was rather than look at what the outcomes of that system were, the conclusions on how you classify a chemical as a carcinogen or control it, the UK decide to duplicate the process, so this means that companies in the UK or Great Britain must re-register their chemicals in a UK system, you have lots of UK civil servants now mainly in the HSE but also in Environment Agency then trying to work out which ones need action and you have lots and lots of consultation process, so a huge bureaucratic monster has been created. And what happens is because this is a process that constantly moves forward as more is understood about individual chemicals, the UK taking this process approach means that it's already diverging from the EU because the EU is moving forward and controlling chemicals and the UK is much slower. And in the UK, there's more opportunity for companies to come in and say well we don't agree with that and just general it's a much slower process.

And so, the passive divergence is happening even before you might actively diverge. And this is causing obviously all these processes require people spending time, there were issues around access to data, data that's used in the EU system may not be accessible to companies using the UK system and it's important to note that the UK does not have full access to the EU's chemical database, it just has the same access that anyone else around the world would have. The industry had hoped that there'd be more access in the deal and that did not happen. So you have this divergence and the bureaucratic monster really and industry are quite unhappy about that, we're unhappy about that because we think that we should be in a converge situation, and so the alternative model is you say at the most extreme you have fully aligned where you actually just say well let's just do what the EU does, they have the data, the EU consultation process allow companies from outside the EU to input on these processes, why don't we just fully align and that's essentially what the Swiss do, because they've got a reasonable chemical industry, they're obviously surrounded by the EU.

A compromise position is you could say well we'll take the outcomes of the EU system and we will routinely apply them, we will have some sort of semi-automated process to apply them, but if we want to diverge, if a company says well we really think that's wrong, we want to carry on using that chemical then you have a process, a transparent process. So rather than copying the entire

process, you essentially copy the outcomes and then create a smaller process to diverge and that's certainly where we think that there is a possibility to make a much more effective system.

And I think when you get onto the issue of the global level, the EU is the dominant system and it's generating much more data, so you do have things like the globally harmonised system for classification and labelling of chemicals, but a lot of the data going into that is coming from the EU anyway and the EU has plans on how they wish to improve that system. So I think that the EU is very dominant in chemicals and the complexity of chemicals and the fact that they're in all these supply chains, essentially just about any product has industrial chemicals in it from a sofa to some paint and so the system now is really, because of this copying process is really, really ineffective and it does mean that there's reduced protection in the UK, by restrictions not coming in, and there's also much higher costs for industry.

Stephen Farry MP

Great, thank you very much for that answer on the chemicals end of things. Appreciate I'm very close to the end of my time slot here so Anton any sort of final comments on this section that our two previous witnesses haven't really touched on so far?

Anton Spisak

I thought I would just build on what Michael was saying very briefly and talk about how divergence actually might happen and he spoke about active and passive divergence and I think this is very, very important because we often think of divergence as the UK Government proactively deciding to change EU derived rules that are already on the statute book, but actually you know that is only one type of divergence which is the active divergence where either the Government or the regulators or actually UK Courts decide to change the approach that is already on the statute or in the case law.

But actually divergence, in my view divergence that is more costly in the long term and that becomes a drag on the UK economy is the passive divergence and that is the EU developing its rule book continuously the UK diverging from that globally whilst Northern Ireland remaining aligned in many aspects of that and that is creating a lot of the cost, a lot of the barriers to trades that are really hard to track without a proper process. And I think you asked about the process of how can we mitigate some of those impacts. At the moment the Government strategy really is to let divergence drift, it doesn't really have a consistent coherent process of how it does manage that kind of passive divergence, how it would look at what the EU is doing in some kind of very comprehensive way and identify the areas in which it is actually in the UK's interest to unilaterally copy paste things that the EU is doing because they're creating extra cost. And in addition to that, as other witnesses have said, we don't really have a lot of the process in the trade and cooperation agreement and therefore the divergence is kind of just happening passively and gradually.

So I think that's a really kind of important piece of process that's missing on the UK's Government side, they need to think about as they try to think of some kind of post-Brexit regulatory strategy because in many areas such as chemicals which are hugely reliant on exporting to the EU, I don't

have the exact figure, Michael might know, but in those areas those costs of passive divergence just builds up over time so you need to have some kind of process in place to manage those.

Stephen Farry MP

That's very useful, thanks Anton. Back to you Chair.

Philippa Whitford MP

Thanks very much Stephen and we now come to Claire Hanna.

Claire Hanna MP

Thank you very much Philippa and thanks very much to the witnesses. I want to talk about the UK's regulatory choices and the extent to which you're being consulted as they think them through. We've touched on this a little bit throughout, but I wanted just to go to each of you in turn just to get your thoughts on how you're being consulted and what your priorities are around regulations. Kate, can I go to you first from a health system perspective?

Kate Ling

Yeah, I mean obviously we're not a business, so, well we are a business actually, the NHS is a very big business but yeah, I mean we have, I mean the NHS Confederation as I said we represent all of the, or nearly all of the NHS Trusts basically in England, Wales and Northern Ireland. We engage very, very extensively, we have very close relationships with our counterparts in the Department of Health and Social Care and in NHS England of course. So yeah, we have very close relationships with them. For example, on the implications in a practical sense of what's happening politically, so for example the supply chain and whether or not NHS organisations are actually experiencing problems and I'm pleased to say up until now, no not really. So yes, so we have these sorts of conversations all the time. We've also recently responded to the Cabinet Office have been asking for organisations to join the Domestic Advisory Group and the Civil Society Forum which they're setting up as part of the trade and cooperation agreement, so we'll be also we hope participating in that. And of the various public consultations that have been taking place.

I think it's worth saying, as I said I can't speak for the health industry because I'm not from the health industry, but I did mention that we convened the Brexit Health Alliance which includes people from the pharmaceutical and medical devices and life sciences industries and I know that they do have very close cooperation and sort of dealings with their counterparts in NHS England and Wales and the Northern Ireland health departments, now whether that involvement results in if you like the practical action that they want to see I couldn't say, I couldn't speak on their behalf about that. I think that's probably, I think that's probably enough from me really about the public consultation.

Claire Hanna MP

Thanks. Michael, could you pick up maybe from environmental protection perspective about your priorities and the extent to which you're being consulted and engaged with?

Michael Warhurst

Yes, so I think maybe it's worth going slightly further back to the actual Brexit process as well because I think it's important to note that we at CHEM Trust, we actually did joint statements with both the UK chemical industry association and the EU one SEFIC [ph 1:24:56.2] calling for the UK to remain aligned and as close as possible to the EU system and at that point Michael Gove was Secretary of State for the Environment under Theresa May and he did actually accept that argument, he accepted that the UK should try and stay in REACH. That obviously changed down the line. So we're now in this parallel duplicative process and what you see and hear essentially is that there are lots of consultation processes set up but there's a lot of things that in the EU level would be discussed between representatives of 27 member states in an open meeting where people like ourselves can contribute, but those discussions are not happening in the same way in the UK. So you've got a lot of consultation processes, but they're all about you know which individual chemical shall we prioritise, so they are consultation processes but are of quite limited use, but they can absorb an awful lot of your time and energy, and ultimately we're trying to get a situation where you do not have chemicals like the PFAS [ph 1:26:01.4] these ploflorinated [ph 1:26:02.5] forever chemicals that are contaminating our waterways and into our bodies or brominated [ph 1:26:08.3] flame retardants in furniture or phalates [ph 1:26:11.4] or bistrinols [ph 1:26:12.2], there's so many chemical problems out there we need to address and you know even the EU finds it hard work to do these and then in the UK we are ending up in some ways having long complicated meetings on things of very little relevance, because really the UK does not, because it's so much about duplication it doesn't, it's not prioritising the important issues at all.

Claire Hanna MP

Thanks very much, Anton have you thoughts on this as well?

Anton Spisak

Again, just to add to what has been already said, so there has been quite a lot of consultation on post-Brexit regulatory initiatives from Government. If I was to comment on the kind of overall approach that the Government has taken for this it has been very, very ad hoc, so things just crop up as any regulatory change is thought about in a Whitehall department but there hasn't been a consistent approach across the Government identifying across different sectors and sub-sectors of the economy to see how you want to approach this and that has been the case in [inaudible 1:27:18.1]. So, I think what's really missing in this one landscape of regulation post-Brexit is quite

a comprehensive and systematic audit of where the regulations stand post-Brexit and what are the choices that the UK wants to make going forward. And this is really important because if we don't, the Government doesn't really determine those choices and we don't have a public discussion about the level of risk that is being acceptable to the public and the kind of trade off that arrives in the context of divergence for the UK internal market, for trade, for level of public safety and so on then the risk really is letting that divergence drift and not really having a very coherent regulatory policy. So, I think that's what I see as the biggest risk is that yes there is a lot of consultation going on in individual files but actually on the really crucial questions of what is the direction of UK regulatory state post-Brexit and how that's placed in different files, those are missing any kind of active engagement from the Government.

Claire Hanna MP

Thank you very much, thank you. Back to you Chair.

Philippa Whitford MP

Thanks very much Claire, and over to you Tamara.

Tamara Cincik

Thank you Chair, so my question is what are the opportunities of diverging from EU regulations, can the UK pharmaceutical industry and regulators be more nimble as is often suggested, and I'll start with you please Kate.

Kate Ling

Well there are certainly very big markets outside the EU that the UK can tap into and we do have a really big plus, the UK's reputation as a centre of excellence for medical and scientific innovation and I think some of the previous witnesses in the previous session mentioned that basically people are still coming to the UK and they still want to, they still want to research because of that very, very strong position. So, I think we are in a strong position to sell both our goods and services abroad. But we do have to try and reduce the tariffs and regulatory barriers particularly the regulatory barriers as much as possible. So I think about being nimble, I think yes, I mean also referring actually to the previous session that I think we've proved during Covid, during the last year, 18 months, how much we can do very quickly, not just the UK of course but we have been sort of remarkably good because of our existing very strong infrastructure, our very strong science industry and also the size of our population and research base and we can develop and trial new products very quickly. And we also have an autonomous regulator now who can license and move very quickly, there's been reference to the innovative licensing and approval pathway, the ILAP, with the MHRA and we have this incubator for new technologies. All these acronyms, you know ARIA etc. So, I know that MHRA's ambition is to be the go-to regulator that gets new treatments approved and devices on the market very quickly and I think that is an advantage that we can seize. Nevertheless, as I said there are issues obviously to do with if we go too far too fast,

to what extent are we going to be not aligning so much with other markets, but yes, I think there are opportunities.

Tamara Cincik

Thank you. Anton, if I could ask the same question of you.

Anton Spisak

I think in theory there are several reasons why the UK may want to diverge and the opportunities that come with it. The most basic reason is simply the fact that UK economy and [inaudible 1:31:18.3] might have different interests and different domestics needs than some of the EU member states and this is opportune when it comes to the EU level discussions, this is an opportune discussion about how do we reconcile those two things. Then there is another rationale for divergence is to enhance competitiveness in specific areas for specific strategic issues of different sectors. Then you may want to diverge because you want to open up the policy space for other international agreements for new trade deals, again you know that is a very legitimate reason why you may want to diverge. And finally, and I think this is the most attractive reason why divergence actually should be thought about is to enable some kind of regulatory innovation which we will enable other regulators to choose the premise of achieving broadly similar objectives because they may have good reasons for doing so.

So all those reasons broadly you know [inaudible 1:32:18.1] rationales, but on the other hand we have some of the costs of divergence that you need to weigh against those things and those are the economic costs of doing trades, those are political costs of damaging internal markets, if different devolved governments choose different approaches in some areas and if Northern Ireland specifically stays aligned. And then you have the kind of international dimension of what happens if you diverge, what does it mean to your international standing in the regulatory landscape. So, all of these things have to be considered in the round and you know often we just kind of make decisions or you know the Government proposes decisions about diverging in specific [inaudible 1:33:03.2] without really taking a comprehensive view of how those different things measure up. So you know if I was to propose one thing it would be to set up some kind of process that actually evaluates those decisions of divergence in a more systematic way against a set of criteria that are usually considered in these things which would be around the lines that I've just outlined, because otherwise you just risk creating inflated costs for no very good rationale. But it really comes down to very specific files and very specific rules and obviously it will be very different for different sectors.

Tamara Cincik

So, it's about innovation rather than red tape essentially is what you're talking about having a vision and being able to really step up as a global leader.

Anton Spisak

What I would say is that there can be good reasons to diverge if you really want to empower your regulators to do things differently with good reasons and we see that with MHRA in the last 12 months or so. But there needs to be a clear idea of what this is for and what are the trade-offs on the other side, so that would be my kind of headline message.

Tamara Cincik

Thank you very much. And Michael.

Michael Warhurst

I think this is a really interesting point because I think it's interesting based on the idea that if you have fewer people involved in a process then you make decisions better and faster and I think the evidence for that is very limited. I suppose one classic example is you look at existing, where does the UK have full competence at the moment and so you could look at regulations around building fire safety and you look, has the UK made good decisions on building fire safety, no it hasn't. That was nothing to do with the EU, that was a UK owned system and so I would really question that. And the nimbleness, I don't work on pharmaceuticals and vaccination, but I think it's really interesting that the European Medicines Agency approved the Pfizer vaccine for 5–11-year-olds last week, last Thursday, and the MHRA says it will do it hopefully by Christmas. That doesn't suggest a more nimble system.

And I think this key thing about how you make a good decision, you know fewer people doesn't always mean you can make a faster decision, doesn't mean it's better. And one key thing with chemicals which is slightly different in some ways to other areas of innovation, most of what happens with chemicals is about existing chemicals that are on the market, in products and debating whether they should stay on the market. You do have new chemicals coming in and there can be debates about them, but it's not the same as say pharmaceuticals where your main debate is new chemicals coming in. And one of the problems with a process that has fewer people in it is less open as it's more open to influence by interests. And so, there was coverage in the last few weeks of a Minister who apparently directly lobbied on a decision about allowing continued use of leaded fuels in aviation, small aircraft, so that's an example of something that's much easier to do in the UK system. In the EU system, it's more difficult because if you have 27 people around the table in some ways the interests become more obvious which is actually quite useful and you also get a more diverse group, so I think we need to be very, very careful about this idea and I think your best way of doing it is to say well let's look at the last ten years of UK only regulation and see if we see excellent UK only regulation or not, because that's the best test. Because in some ways the rest is just rhetoric and whether you claim that it's somehow going to be better because the UK believes in sound science or other items.

Tamara Cincik

So, it's about detail, not narrative in this instance isn't it. It's about being sure that it's an erudite system rather than being a top line story.

Michael Warhurst

Yes, and it's about, you achieve a lot of these things through the openness. Fortunately the EU chemical system is particularly open, it's had a very long history of openness, which means that there are these meetings where things are discussed openly, there are stakeholders there, industry and NGOs and they can make points, they obviously don't get a vote but you, and by having 27 countries you know you know that Sweden is not necessarily going to stay in the same position as Germany on something, but that's actually good to have in the discussion rather than saying it's better to just keep the discussion to the people who agree with us.

Tamara Cincik

Thank you very much, I'm now going to hand back to the Chair. Thank you.

Philippa Whitford MP

Thanks Tamara and we come now to Hilary Benn.

Hilary Benn MP

Philippa thanks very much indeed. I want to ask about the Northern Ireland protocol and the supply of medicines in Northern Ireland. Now there is a grace period at the moment and the first question I just wanted to check with you Kate is are the medicines arriving and getting to patients in the way they need to currently?

Kate Ling

Yes.

Hilary Benn MP

They are, right.

Kate Ling

Yes, that's the shortest answer I've given so far.

Hilary Benn MP

There we are, no, no well that is reassuring. Can I turn now then to the proposals that Maros Sefcovic has put forward because this is obviously one of the issues that are being debated,

negotiated, between the EU and the UK at the moment, what do you make of what he has proposed in respect of medicines and their supply in Northern Ireland?

Kate Ling

To be honest on a practical level, they seem pretty sensible. It's a political question obviously because well I don't have to explain. The, it seems hard to believe, at least I want to believe, that it would be possible to craft some sort of agreement for medicines if not perhaps for all other aspects of the protocol because it's simply unacceptable and unthinkable that patients in Northern Ireland would not be able to access the same range of medicines after the 1st of January that they can now, and the NHS Confederation together with many other health organisations, we've made very strong statements and public representations and obviously politically, you know to this effect. The important thing is that medical products really from the rest of the UK, from GB, can circulate freely in Northern Ireland because I don't need to quote the figures to you because I'm sure you've seen them but you know the sort of huge majority of medicines supplied into Northern Ireland do come through Great Britain and I think one of the previous commission members mentioned that supplying them from the Republic of Ireland doesn't really help very much from the point of view of cost because yes, that's a possible supply route but the cost implications for the NHS would be very big. So, at the moment people are getting all the medicines they need, we're concerned about the number of companies who have said that they may not be able to continue to supply those medicines in future. The Sefcovic proposals, yes, they seem quite sensible but they're suggesting that products that are licensed in Great Britain could be supplied to Northern Ireland basically, which sounds sensible. The UK as you know wants ideally to exclude medical products from the scope of the protocol but is suggesting as an alternative that these goods could circulate freely but they would be backed up by strong enforcement from the point of view of goods at risk of going on into the Republic. I mean that's also a sensible suggestion actually, but as you know it's got tied up with the arguments about who enforces compliance and of course who'll be ultimately the jurisdiction.

Hilary Benn MP

Right, as I understand it the makers of generic drugs in the UK are not entirely happy with the proposals that Mr Sefcovic has put forward, could you shed any light on that?

Kate Ling

To be honest I don't know the exact reasons why they're not happy with those. I think really, they just want the absolute sort of minimum of barriers because they will still need to be checked basically, the UK licensed products could be supplied in Northern Ireland, but I don't know exactly what their objections are or what the problems are, I would have to check with those companies.

Hilary Benn MP

OK fine. No that is really helpful and finally before I invite the other two witnesses to comment if they'd like to Kate, do you think the EU's understanding of the issue when it comes to medicine supply in Northern Ireland and the NHS, do you think it has changed over the course of the to and fro, or was it obvious to them from the start that the UK has a National Health Service and you really can't be in a situation where the National Health Service cannot provide medicines to patients, NHS patients, who are living in Northern Ireland.

Kate Ling

Well, obviously I can't really speak for the EU or what's inside the negotiators' heads. It does seem obvious yes, it does seem absolutely obvious. I guess it wasn't always the case, you know in all the negotiations that led up to the trade and cooperation agreement it wasn't always the case that we were necessarily envisaging this effectively you know flight barrier in the Irish Sea when it comes to east/west products, that wasn't perhaps always envisaged, but yeah I mean it does seem obvious.

Hilary Benn MP

OK, thank you very much that's been really helpful. Michael, do you want to add anything on this subject or Anton?

Michael Warhurst

I could quickly say something more about, I mean it's the chemical angle rather than the pharmaceutical angle, but I think, ultimately it was the UK decided to put the border in the sea and that is always going to cause problems. And obviously in the case of chemicals it's quite a strange situation that Northern Ireland is actually also enforcing REACH and are sort of part of REACH, of EU REACH, but I think the key is always going to be how far diverged the UK is, because if the UK was aligned with the EU then everything that was going across that sea border would be aligned anyway and it's worth saying if we look more widely on the nations, you know both Scotland and Wales are far more key on alignment and it's the UK Government, at the moment it's the UK Government. You know Northern Ireland has to align, Scotland and Wales would like to align, and the UK Government doesn't want to align and that's essentially the situation at the moment.

And I think we don't really know quite how that's all going to work out on that border, but it does, because it just becomes part of the work that UK based companies have to do.

Hilary Benn MP

Yeah, thank you and Anton briefly have you got anything you'd like to say?

Anton Spisak

Just to add very briefly, so I think you know the EU's approach has clearly shifted in a big more fundamental way than actually has been commented on in the press, because initially they had a very rules based approach saying these are the rules that should apply for Northern Ireland, you the rest of the UK don't comply with these rules, hence here is the border. What they have done now is they've adopted a more risk-based approach where they say to the extent that you comply with certain minimum standards and that you're licensed in GB but actually that licensing process is recognised by us and our regulators and is robust enough we recognise those drugs to be acceptable for sale in the NI market. That's a big shift. Is it enough, I don't think it is actually because it doesn't provide a fully comprehensive solution to the full scale of pharmaceutical products and medical devices that actually fall under the checks in between GB and NI. So, I think they do need to also defer them.

But I think just to comment briefly on the politics really because this really is what they are proposing is a form of mutual recognition, they are saying we would recognise GB drugs as being [inaudible 1:45:58.5] to the EU for the purposes of NI trade. Obviously they can't say that publicly because mutual recognition as a term has become very politicised, but I think this really is the kind of arrangement that makes … this is where mutual recognition makes complete sense because to the extent that those products are placed on the NI market they are [inaudible 1:46:18.8] adequately by regulators and there is some kind of risk of their disrupted supply having some material impacts on the Northern Irish society and economy, I think there is a very legitimate case to be made that the EU should mutually recognise those goods and I've just written a paper about that.

Hilary Benn MP

That is really helpful, thank you so much. Philippa back to you.

Philippa Whitford MP

Thanks very much Hilary and now to Geoff Mackey, thanks very much.

Geoff Mackey

Thank you very much Chair. We've heard about some of the implications for pharmaceuticals and medical devices, if I could just go back to the practicalities, it was mentioned earlier on of UK REACH and where that fitted into various things. I just wondered would the witnesses like to comment on any practical impacts in losing if you like our connection to the EU REACH and starting to have UK REACH. Michael, would you like to start on a few practicalities?

Michael Warhurst

I think the key thing is that the UK lost the connection to EU REACH from the moment of full Brexit as it were at the end of last year, so we now have no access to that database. And so, the

UK has this duplicative process set up and I think it's worth saying that there might have been a scenario where we could have had access to that database, but it would have required an awful lot of commitment to alignment, legal commitment to alignment, I think. We don't know exactly what we'd need to do but it would be around that time.

But it does mean now that in some ways the UK regulators are a bit blind because they've only got the information that's publicly available and obviously they're now trying to get industry to deliver new information, so industry has had to be working on getting together its data packages and working out its access to safety data, whether it needs to do any new tests forming groups of companies and putting in data, so it's created an awful lot of administrative burden. And those administrative burdens continue, companies have had to be doing initial registrations, that will continue over the following years, so there's lots and lots of extra work done and meanwhile those companies who are exporting will have to continue to do that and it's worth saying that the EU is now in the process of reviewing its legislation and will amend REACH over the next two or three years, this will be potentially could generate issues around the rebalancing provision in the trade and cooperation agreement, where if the EU moves ahead or indeed the UK moves ahead you could have measures on rebalancing, so that could also come into the debate over where the UK in some ways is pushed to go by the EU.

Geoff Mackey

Thank you very much, really, really interesting. Anton the practicalities of the UK REACH is one thing, just to extend the question slightly further, do you think the UK should retain any opportunity it can to be linked to the EU regulatory agencies, should we take every opportunity even though it's outside of the market?

Anton Spisak

I think, trade and cooperation agreement doesn't go very far in terms of cooperation with the EU chemicals agency and some of the infrastructure on the EU and very clearly much more can be done on a practical level to facilitate data exchange and information exchange and Michael has hinted at some of those practical arms that are missing at the moment. But I think, if we look at the annexe of chemicals in the trade and cooperation agreement it is [inaudible 1:50:15.3] annexe and it only talks about the very necessary things that need to be in place, but it doesn't really go very far. So, what I would suggest is that when the next opportunity for the review of the TCA comes up which will be I think in 2025, there should be a discussion about trying to come closer to some of those practical arrangements because it is clearly in the interest of the UK and the chemicals industry to be much more plugged into the whole EU infrastructure.

Geoff Mackey

Thank you. So, looking for opportunities to keep EU regulation and the alignment how does that sit with you and your thinking?

Kate Ling

Sorry, I didn't hear the question very well there's a bit of distortion.

Geoff Mackey

Sorry, the whole question of trying to keep EU regulatory alignment where we can, how does that fit with you?

Kate Ling

I think as obviously I couldn't comment, I don't know anything about REACH or chemicals but I think the issues that everyone has been talking about are essentially the same across sectors, which is about not necessarily alignment, we don't have to have the same standards as the EU for everything, whether it's medicines or chemicals or you know medical devices, but it's about having if you like processes, a system for recognising each other's standards and I think the more of that we can have the better, so that you know for example with data which I mentioned earlier, which underpins all sectors, that we don't have to have the exactly same data protection standards as the EU, but they have to be sufficiently similar that we can recognise that they're if you like equivalent, if not identical, and I think that's really important particularly for obviously medicines which are, well life-saving.

Geoff Mackey

Just again to pick up this theme and you must excuse my optimistic look at the world, could I just take one comment from each of the witnesses about what your hope is for the future of regulation going forwards? Michael could you just pick up, literally just one sentence.

Michael Warhurst

I think my one point would be for the UK to realise, the UK Government to realise that what it should be doing is aligning by default and then having a process to discuss where they wish to diverge.

Geoff Mackey

Thanks. Anton.

Anton Spisak

What I would say is I think what has happened with leaving the single market is really the biggest kind of earthquake to the UK's regulatory model in the last few decades and a lot of these choices

that were made were not made very transparently and there is a lot of choices that are being made right now that are not being very transparent. So I think what the Government should do is to do a proper audit of the UK's regulatory system after Brexit trying to understand how the interests of devolved governments [inaudible 1:53:32.9], what are the future barriers that might come into play with devolved governments taking a different approach, to some of the aspects of regulation, and what are its interests with respect to other countries and the EU but not only the EU but also other spheres of influence, the United States and you know what's happening in Asia. So, I think it really needs a proper comprehensive review of the UK's regulatory model is and what are the objectives that the UK as a country decides should guide that evolution of the model in the years to come.

Geoff Mackey

Kate, one hope.

Kate Ling

I think my hope for regulation going forward really would be for greater and greater if you like convergence, harmonisation, less protectionism globally, especially in a market that's so beneficial to human health worldwide that patients need to access and benefit from new treatments as soon as possible and that's a worldwide issue, it's not just for the UK or not just for the EU, so I would like to see greater convergence.

Geoff Mackey

Thank you. Thank you Chair.

Philippa Whitford MP

Thanks very much Geoff and now finally to Sir Roger Gale.

Roger Gale MP

Thank you very much indeed, I've listened to everything this morning with very great interest and most of the issues that I wanted to have covered have been covered. It does seem to me that there is still a significant tension, two significant tensions, one between the European Union and what is happening in the effect upon Northern Ireland specifically and then more generally the apparent deleterious effect upon cooperation that I find unnecessary. There are going to be differences of opinion clearly, but it seems to me and this is what I'd really like you in turn to comment upon and I'm going to leave it at that, it seems to me that there is a almost a

bloody-mindedness that's getting in the way of necessary if not vital research and cooperation and I'd just like each of you to comment on that please. One of you, take the floor.

Michael Warhurst

I'm fine to go first if that's easiest?

Roger Gale MP

Michael, if you would.

Michael Warhurst

I think one of the problems we have, ignoring the NI which I do less on, I think that the, I suppose there are two issues, one is that the UK system in general has been designed on this duplicative process that's the general approach of the entire legislative process over the last few years was to copy across the EU processes and that wasn't really if you look at it now, as a pragmatic approach that's not really how you would do it. I think in general you might want to modify some things, but I think the aligned but then have options to not align is more rational than the copy across. So, this is a general approach the UK has taken, maybe it was easier in a legislative sense, but it causes a lot of problems.

And then on, I know people have mentioned the Horizon programme and things like this, I think we need to be aware that the EU if you look at what's happened in Switzerland, the EU both has what's written into treaties as methods of trying to keep its partners in line, let's put it like that, and then it has things that aren't in the treaty that the EU can decide to give you or not, and Horizon fits in that category and so you know the EU has a tool over Switzerland and indeed over the UK as to whether it wishes to let us in or not and there's very little we can actually do about that apart from negotiating in a positive way which gives the EU something they want in return for us getting something we want, and I think at the moment the EU play is not in that sort of position in its negotiating.

Roger Gale MP

Thank you very much indeed.

Kate Ling

Sorry, there's strange background noises going on. I absolutely echo what you said about clinicians and researchers, they want to carry on cooperating as much as possible and it was quite sort of heart-breaking really Emily I think from Duchenne in the first session, but the way that the UK is not able to take part now in the European reference networks. I would like to mention that our organisation together with a lot of other European organisations, there's a European health stakeholder group which brings together patient groups and all sorts of organisations including

industry, medical research charities from across the whole of Europe, we are planning to issue a statement next week saying how important it is to continue collaborating for the UK to associate to Horizon Europe and to continue as much collaboration as possible because whilst we really welcome the money and the investments that the UK Government is putting into research and development, that as previous witnesses, particularly the previous session said, it doesn't, it can't make up I think for this human interaction and collaboration which is so important and clinicians and researchers, they really, really want to carry on doing this and cooperating for the sake of patients and I think we really mustn't forget the patients in all of this. It's become so politicised that I think sometimes people forget who the end users are and who it matters to.

Roger Gale MP

Thank you very much indeed. And final word from Anton please.

Anton Spisak

Thank you. All I would really add is to say that there is a lot of ideas and solutions that could really help here and we've just talked about ideas around mutual recognition and specificities, the big and I think this is the most fundamental problem in all of this is, and it sounds a little bit trivial but this is lack of mutual trust because for all this you need to be able to trust the other side that they will do what they say and they will enforce the rules even if those rules are not exactly the same on the paper. And if you have that trust embedded in your relationship, in your trading or regulatory relationship then you can really overcome all of these problems. What we have seen in the last couple of years is a complete breakdown of that trust in the political relationship between the UK and the EU. And the result of it plays out in those very specific practical and operational arrangements that witnesses have just talked about. So, my plea really would be to try to depoliticise regulation and make it boring again so that we don't have to see how the high politics and lack of trust really plays out in how regulations affect end users.

Roger Gale MP

Thank you all very much indeed.

Philippa Whitford MP

Thanks very much Roger and that brings us to the end, remarkably on time for such a complex session and I would again just like to thank our three witnesses from this session and the three from the earlier session and to all Commissioners for asking interesting questions and sticking remarkably to time. So, thank you all and to those who have been watching us this morning.


UK TRADE & BUSINESS
COMMISSION