Understanding Brexit and its Impact on Patients

January 17, 2019

Featuring: *Darshan Kulkarni, Vice President, Regulatory Strategy and Policy; and Nirpal Virdee, Director, Client Services and Technology*

Transcript

Intro: This is Synchrocast brought to you by Synchrogenix regulatory and communications strategy, science and solutions.

Darshan Kulkarni: Hey, this is Darshan. I am excited to have Nirpal Virdee on the line. We're going to be talking about Brexit. We've all heard about it. It sounds like a delicious chocolate. But I'm curious about what the impact is of Brexit on patients, whether we're talking about in the European Union, in the UK, or even in the U.S. So Nirpal, do you want to say hello?

Nirpal Virdee: Yes, hello. Darshan, nice to be doing another podcast with you. I really enjoyed your last one. So I jumped at the opportunity to do another double act with you. And I think this is very timely, right? Because I think this is sort of a segue into a lot of the things that you've already spoken about around the U.S. closure. So it's going to be a great topic to go through. And looking at it from a patient perspective is going to be interesting. So I'm looking forward to the discussion.

Darshan: Great. So, so let's start with the basics. What exactly is Brexit?

Nirpal: So Brexit is a term that has been put together based on the UK's intention to leave. So if we recall, there was a public referendum that was put to the United Kingdom's citizens, on whether they wanted to leave the European Union. It was a binary, "Do you want to leave or stay?" There was no other nuances to it.

So on the 23rd of June in 2016, the UK surprisingly for many, decided to vote to leave. It was very marginal, but it was enough for this to become a binding decision from a UK perspective. And we've obviously seen the outcomes from that. There's been a lot of turmoil from a government perspective. We had a new prime minister, we've had this government call a snap election in which they lost more majority. And it's really been trying to work through and negotiate over protracted two years on what this potential split with the European Union would look like.

Darshan: Which I think, I kind of still want to discuss with you this weird idea of just doing a binary discussion and sort of binary option. I know we've spoken offline and one of the things you talked about was, it's a bad idea to even have it be binary. What were the other options out there, Nirpal?

Nirpal: Yeah. It was a very simple question that was put out to the public and I'm sure we'll cover some of this, but some of the rationale and the issues that were being brought up were really centered around immigration. So that really was striking at the heart of a lot of citizens in the UK. And that became sort of the leading decision to opt out, but that was it. There was no other option to potentially stay and renegotiate certain aspects with Europe around concerns on immigration or any particular economic policy or any particular human rights type of policies. The public were just not given that opportunity to voice that, "Hey, I'm not happy with the way the EU relationship is, but I would like to stay and see it change." That just was not on the table. So I think that was unfortunate oversight by that present government to not allow folks who were on the fence to have some other way to voice what they were feeling about their membership of the European Union.

Darshan: So that really brings us to the basic question. What actually caused the referendum to go the way it did? What were the factors that affected it?

Nirpal: You talk to different people and you'll get a different perspective on this. The key thing that's been going on in British politics for many years is the infighting within one of the leading parties, the Conservative Party. They've had a split in their membership and key figures in their government that either were pro-European and supported the continued relationship with Europe. And you had the more right-wing elements of the party that have for a very long time opposed being part of Europe and all of the constraints that they have and also the diminishing accountability of parliament in the UK and the justice system to make its own decisions.

So that's always been a big riding conflict within that party. And there was also the UKIP party that was a single topic party if you like, that were put together just on the principle of leaving the UK. And they were at that point starting to get a lot of traction, if still on the peripherals of mainstream politics.

So that was some of the rationale I suppose of that government to look at ways in which they could just put that to bed once and for all. And to just call this referendum, it was sort call the bluff, let's get the people to vote. They are going to vote to stay. This will stop this element of the party from continuing to badger more of the central and the majority of the party. So I think that's where it came from.

But there was also other factors outside of politics. You've had additional countries joining Europe. From the Eastern European block. And there has been what would be considered a high level of immigration and I think that was causing strains on public services, but just the perception of the public, the impact that was having. So I think there was a few factors that drove that potential, that thought process, if you like, on whether to call a referendum.

Darshan: Obviously when we talk on this podcast, Nirpal, one of our big goals is how does this affect the pharma industry, or the medical device industry? So what has been the impact of that? Why should we care is really the question to ask.

Nirpal: It's such a big deal in our sector, right? There is obviously a big impact generally to the UK. We have access to $11.9 billion of exports, with the EU. So it's a big deal in terms of the overall trade. But particularly in our industry, we contribute a turnover of $41.8 billion to the pharmaceutical sector. So from that perspective it is huge.

We were talking offline of course, preparing for this around the angle that we always take, right, which is what's the impact to the patients. It is really access to medicine and access to information. There's been big drives to coordinate the activities.

You could argue that EMA is one of the most refined and efficient regulatory authority in the world. It is governed in a way in which there are two member states, and the UK is the primary, that manage a lot of the scientific analysis of drugs that come in for approval within the EMA. And there's then a secondary, which is generally Holland or Germany.

So UK has had a big presence on actually working through that process. So from a patient perspective, if UK is out of that process, these other countries will then have to carry that scientific burden. At this point the other member states are just signatories. Do they need to have more active role?

All this leads to impact to the patients because it's going to slow down. There is going to be a slowdown. At this point regulators already struggle with the amount of drug applications that they have to manage. And when you take a large chunk of the process out or your experts out, it's going to impact getting drugs to patients.

Darshan: But Nirpal, do you think that that's more of a long-term impact than a short-term impact? Short term, do you think that there might be a little bit of a problem, but eventually there'll be more access of drugs to patients because the EU now can operate without the big brother behavior of the UK. Or do you think that it's actually the other way around? In which the EU is slightly more handicapped?

Nirpal: Yeah, that's interesting. I mean time will probably tell. There is going to be a short to medium term impact just because physically EMA is moving out of London to Holland. So that in itself is going to cause an impact when they do move to Amsterdam. Just on sort of resourcing and getting that level of expertise.

Now, the concept of big brother, I'm not quite sure. I think UK has naturally taken that position and was selected in the nineties to be the headquarters of EMA because they had the expertise. A lot of big pharma are based out in the UK. Your GSKs, your

AstraZenecas, your Pfizers have had traditionally a large footprint in the UK with a lot of scientific expertise. So I'm not quite sure if I buy into the big brother analogy of this.

Nirpal: But yeah, I think it's going to be an impact both ways. I think it's going to be an impact to EMA just to try and fill that void. Whether it means they can take a different perspective on things without the UK, again, it's difficult to tell. I have not read anywhere that there's ever been contention with the analysis that's been done from the UK or the MHRA on behalf of the UK into EMA.

Darshan: But isn't that also because no one's actually been able to even challenge that, right? Because in a certain way, if someone else is handling the finances, I don't typically go in and go, "Let me look at what you're doing and I think you have a problem." I trust you to do it because you've done it, and you've done it well. But now if you're forced to take on a different role, might there be a difference of what actually happens?

And more importantly, I think, do you think, and again, one of the big reason, and we should probably state the obvious here, but one of the big reasons we're interviewing Nirpal for this topic is you are in the UK as we speak. You live there and you're seeing this happen right now around you. So the big question here is, do you think patients will be impacted, and what kind of impact do you see?

Nirpal: Yeah, I think the first thing is really the access to medicine. And two pronged. One is the MHRA will have a couple of scenarios. Whatever the scenario, whether it's soft Brexit or hard Brexit, they will have—

Darshan: Nirpal, before you continue, what exactly is soft Brexit and hard Brexit? I've heard the terms, never quite understood what that means.

Nirpal: Again, I'm probably not an expert around the particular political terminology around this. But I'll have a go. The soft Brexit is probably what's been campaigned by the moderate folks within society and within the parliament structures. And it's really looking at maintaining a relationship and collaboration with the EU, even potentially looking at maintaining single market access and those sort of beneficial parts of the relationship. Those come with its typical constraints with the EU. It's, can I have a divorce, but can I still live with you sort of scenario. That's been the topic of a lot of debate and I think this is what you're seeing in all of the fascinating events you're seeing in Parliament at the moment in which a sort of a hybrid type of an agreement with EU—

Darshan: I loved your analogy. Can I get a divorce, but can I still stay with you?

Nirpal: Absolutely. The hard Brexit is, I want a divorce and I'm leaving. So the hard is really, look—

Darshan: Can I still look through the window and see what you're doing though, right? Or do they not want to look through the window?

Nirpal: No, I want to put a wall up.

Darshan: Oh really? I thought they'd still look at the EMA and go, "Yeah, okay, you guys approved this, we'll still approve it as well."

Nirpal: Well, the thing is with the hard Brexit, really it's, "We can't come to an agreement between ourselves, we're walking." So it's, "I'm not paying my divorce bill, I'm not splitting anything with you. I'm walking. And I'm taking everything I had with me and I'm going to have a relationship with someone else." So that's basically what is driving that. It could be catastrophic for the UK, but I think a significant impact to the EMA, not establishing any deals.

And it's beyond just our pharma space that we're both very passionate about. I mean, goods and services, availability, goods being able to move across borders and ports, collaboration on a traffic control and those types systems. Immigration…

Darshan: One of the most favorite things I heard, and favorite is probably the inappropriate word to use. Please feel free to substitute it with a much better word. But they are literally stockpiling medications right now.

Nirpal: Yes. That was the second part I was going to get to, which is the physical challenge. At the border, because we know that pharmaceutical product is temperamental, right? There is temperature sensitive products in there as well. And it means that you need to have a very slick way of moving product between the different territories.

And we also know that there's a larger amount of pharmaceutical product that is developed in the EU. So just moving those things between them... I don't know if you've been hearing the news in the U.S., but they've been trying to work through a hard Brexit deal, if you like, or no Brexit deal, we're leaving and simulating what might happen at the ports. With big delays, not being able to process these lorries and products to actually move as freely as they do now.

That could be absolutely catastrophic for our industry just because of the nature of the products that we have. And that inevitably means the contingency has got to be to stockpile, but how long will that stockpile last and what going to take place? We really don't know. What's the alternative? If this whole deal collapses in the next week or so, what happens? Does it trigger another negotiation? Does it trigger a collapse in the government, and a general election where there might be another stance. Is there another referendum? All of these things are up in the air.

Nirpal: But yeah, physically trying to move those products and the impact is going to have to daily folks in the UK and our patients could be catastrophic in the short and medium term.

Darshan: One of the things I think about, and again, you tend to be more EU, and you've obviously understood a lot of stuff around the EU because you live there. I think about it more from the U.S. perspective because I live here. And I think about the fact that as an industry we're moving towards this patient centric viewpoint. We're trying to make sure that patients are aware, they get access to information and drugs and everything else that is appropriate.

And what I think would be fascinating is the fact that in this specific instance, the lay summaries in which the EU is the leader are probably going to get delayed, the release of results which patients can benefit from is probably going to get delayed. This has a direct impact on patients and on patient care.

And as you start moving towards this whole empowered patient movement, it's not like these patients are just looking in their local library to find information. They're googling, they're going, I don't care where this information is, if it's trustworthy and I can see what the information is, if it's validated in some way either by, I guess by a government in this specific instance, it's worth at least considering because the government will hopefully take action if the information is biased or inappropriate.

So patients all over the world look to the EMA to guide therapy and to understand what's going to be right for them. And I think something like Brexit is at the very least delaying, but may actually change how patients will access information about the drugs that they take, and therefore change the therapy that they get, and may actually directly impact patient care.

Nirpal: Yeah, I absolutely agree. And you're probably already seeing the impacts now. We're obviously very close to transparency. We support and help a lot of sponsors through that journey. The things that are very important obviously to our organization is not only supporting, but what it means from a patient centricity perspective. The impact we're already seeing is that policies like the EMA policy 70, which was aimed at getting a lot more of the study information back out to healthcare practitioners, even back to patients if they wanted it, has been curtailed. We know that that's all been put on pause. So we're already feeling the effect.

If we can't get access to that data, academia we're relying on getting access to that to continue their analysis that could lead to new indications or a new insight using that data on even those existing therapies. And you're also getting patients who felt they were getting more informed about their particular conditions and the research that's going around that, not being able to now access anything for the next 12 to 18 months.

Nirpal: So it's not saying that whatever was published is going to be taken away. That's obviously still there. But there was obviously a big drive to get through all the retrospective submissions, get all of the current submissions that are ongoing, and getting access to their data. And that's been withheld now for the foreseeable future.

And who's to say what that's gonna look like. If we continue to be in this, we don't know where this is going, we don't know the decisions that the UK are trying to make here, that could continue to go on and impact access to all of this type of information. Getting access to the lays language elements that is really useful for patients. All this has a trickling effect.

And I know pharma still going to try and do the right thing. We've seen that trend, haven't we, together as we're working with our sponsors that more and more sponsors feel it's right thing. We want to start it. We want to start it now.

But where there was a movement from a regulation perspective to really drive us, they're trying to get a lot of that information back out there. Data has been stifled and that's not just an impact to, as you mentioned, the EU or UK, that is an impact to the U.S. too because just the fact that the data is being generated here in the UK or Europe doesn't mean that it's not digestible from folks learning more in the U.S. as well.

Darshan: Which really raises an interesting question to me, and it's not something anyone's discussing primarily because there are much bigger concerns out there. But it could result in some interesting bedfellows. And what I mean by that is imagine if the MHRA goes out and goes, you know what, we have one of the world's most sophisticated pricing systems in the world. We have NICE. We understand how drugs are made. Because we were, as I referred to it earlier, 'Big brother,' we understand drug approvals better than most countries maybe outside the U.S., but maybe including the U.S. And we without much argument with NICE, understand pricing of drugs. And as you know, pricing of drugs is a huge issue in the U.S. It may result in an interesting bedfellow where MHRA says, "We'd like to coordinate more with the U.S. now and actually help drop the cost of drugs."

I mean, today's news I think was California is saying that they want to bid on drug costs instead of using... One of the laws in the U.S. prevents governments from bidding on bulk quantities of drugs. And California saying that they want to buck that trend. And if that's true, the UK would be a great model to follow. And the UK might reach out and start building those relationships.

Everyone talks about the huge fallout and the huge problem that Brexit's going to be, and it probably will be at least in the short term. But it may result in some really interesting connections that probably didn't exist before, that the UK can go, we didn't have the freedom to do that because we still had to coordinate with all the other member states. But now we do.

Nirpal: Yeah, I see where you're going with that, Darshan. Absolutely. You always have the foresight to go in those types of directions. But the reality is that is absolutely going to be long-term. If you think about the fact that the EU represents 44 percent of the UK pharmaceutical exports and 73 percent of imports. Trying to replace it with other relationships, just doesn't bear with the numbers around the impact of our current model and our current relationship.

Of course there are, if we think above the financial relationships that you potentially can have, the ability for an organization like the MHRA to be able to scale to offer that level of expertise is really questionable whether they have the capacity to do that. Because if you think about the collective system of Europe and the fact that they are very slick at evaluating drugs for approval and they still find it challenging to get through all of the applications that they have, can you imagine the impact that the UK will have?

And also, if you are some of the bigger countries or if you're, I suppose, the pharmaceutical companies of this world, you're going to go to U.S. first as a regulator, you're going to go to Japan, you're going to go to Europe. UK is really going to be a sideline because it's just not going to matter as much. And the influence of the UK is really going to go down.

Those are some of the realities that, checks and balances with some of this, I wouldn't say fanciful, but there is this thought process that "Hey, new relationships are going to come up and hey, all of this great stuff that the UK is very good at is going to be so much more valuable to all of these other regions, it's going to lead to all these new opportunities." Yeah. But at what scale? And at what pace?

Darshan: Right. The short term is definitely difficult in almost any scenario.

We usually do these podcasts for only about 10 to 15 minutes. We're already at 27 minutes, so—

Nirpal: It's been so much fun. There's so much to talk about.

Darshan: We can easily keep going for a few more hours, but we're going to cut it here. Nirpal, this was awesome having you on. Thank you so much. And let's stay connected. Let's keep talking and I'm sure we'll do an update on this again.

Nirpal: Yeah, always a pleasure speaking with you, Darshan. Always a lot of fun and the topics are always fascinating. Sort of looking at the dimension of a patient that we always try and do, I think makes this really useful for a wider audience. And look, things are going to really start to heat up even further with Brexit in the next few weeks and maybe we can come back and talk about the impact of any sort of vote or direction that the UK Parliament takes.

Darshan: That sounds excellent. Let's talk soon then. Thanks again, Nirpal.

Nirpal: Thank you so much.

Closing: Thanks for listening. For more information, visit us at synchrogenix.com.